Chapter 3
Disclosure of Origin/Source and Legal Provenance

I. Introduction

Developing countries had been pushing in various intergovernmental forums to make it mandatory to disclose in patent applications the source and/or country of origin of biological resources, of associated traditional knowledge and of legal acquisition of such resources, if such resources and/or traditional knowledge (TK) are contained in an invention over which an applicant is seeking patent rights. Disclosure of origin (and its variations) is seen as a key means to ensure that the IP system supports the access and benefit sharing (ABS) objectives of the CBD.[65]

The negotiations at Nagoya had opened up the possibility for the intergovernmental machinery to address proposals for such a mandatory disclosure requirement, while this issue remains contentious to this day at both the World Trade Organization (WTO) and at the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC). Ultimately, delegates at Nagoya were also unable to resolve whether such a requirement should or should not be included in the final treaty text, and the Nagoya Protocol therefore contains no mandatory disclosure obligation, leaving it up to the Parties to decide whether or not they wished to incorporate such a requirement in their national laws.

For purposes of this handbook, a disclosure of origin/source requirement will mean a requirement that is incorporated through national patent law, rather than through an ABS law.[66] For pedagogical purposes, it will be used, unless otherwise noted, as shorthand for a range of biodiversity-related disclosure requirements (hereafter BRDR), including requiring proof of legal provenance to be submitted along with a patent application. From the perspective of the patent office, the objective of a disclosure requirement is to enable examiners to better assess whether a claimed invention meets the patentability criteria of novelty, inventive step and industrial application, and helps to clarify standing to apply for a patent. Disclosure of origin/source can also be made mandatory for plant variety protection/plant breeders' rights (PBR) applications as well, and this issue will be discussed in the text where appropriate.

Of course, disclosure itself is nothing new – it is an integral part of the patent application process. Disclosure is considered part of the social contract underlying patents: the right to exclude others from using an invention for a limited period of time, except under license, is granted in return for making information about the claimed invention available to the public. As a matter of international law, Article 29(1) of the TRIPS Agreement establishes for WTO Members the minimum standard for disclosure to be contained in national patent legislation.

> "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying

[65] See Vivas-Eugui and Muller, in Chouchena-Rojas (ed.) (2005), et.al., p. 24.
[66] Disclosure of origin requirements can also be contained in ABS laws.

> out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of application."

Some national patent laws further require patent applicants to disclose prior art known to the applicant.[67] Prior art is discussed in detail later in this chapter.

Disclosure functions to help ensure that inventions that meet the criteria of novelty, inventive step and industrial application are granted exclusive rights, and to exclude from patentability those that do not meet these criteria, as well as to make technical information available to the public so others are able to recreate the invention and improve upon it.[68] From the perspective of ABS law, by requiring inventors to include and make public relevant information about important inputs obtained from provider countries, disclosure can act as a check against misappropriation, and help in determining the scope of benefit sharing due to provider countries and indigenous groups.

A disclosure of origin/source requirement builds on this basic obligation and specifies that when applying for a patent over an invention, applicants must include a description of the invention and how to work it, while specifying the origin and/or source of any genetic resources and/or related TK used in that invention. Many countries have adopted some form of disclosure of origin requirement, notwithstanding an absence of obligation to do so under international law.[69] The authors of this handbook take the view that even in the absence of an international obligation, many countries have recognized the potential of disclosure requirements in patent law as a natural complement to ABS legislation, and that with the coming into force of the Nagoya Protocol establishing the minimum standards for ABS worldwide, the trend will be for both provider and user countries to introduce such disclosure if they have not already done so.

The way in which countries have implemented a disclosure requirement varies, and references to various texts are contained throughout this chapter where appropriate. Countries making choices with respect to introducing or revising existing legislation need to be aware of how disclosure affects the patent system, and how this requirement can aid in preventing the patent system from becoming an instrument of misappropriation and 'biopiracy'. This chapter examines these choices in detail.

Key Points

⇒ The Nagoya Protocol contains no requirement for countries to adopt mandatory disclosure of origin or legal provenance. Ongoing discussions at other intergovernmental forums touching upon the possibility of mandatory disclosure may take some time.

⇒ By requiring inventors to include and make public relevant information about important inputs obtained from provider countries, disclosure can act as a check

[67] Rule 56 of the United States Rules of Practice in Patent Cases (37 CFR §1.56) includes a duty to disclose all information known to that individual to be material to patentability. Japanese practice also provides a similar duty. See Japan's *Examination Guidelines for Patent and Utility Model*, Japan Examination Standards Office, December 2011.
[68] UNCTAD-ICTSD Resource Book, p. 448.
[69] See Henninger's "Disclosure Requirements in Patent Law and Related Measures: Overview of Existing National and Regional Legislation on Intellectual Property and Biodiversity" in GTZ (2010), pp. 311-21.

against misappropriation, and help in determining the scope of benefit sharing due to provider countries and indigenous groups.

⇒ Countries are free to introduce disclosure requirements, and many have done so to date.

⇒ Disclosure requirements build on the minimum standard for general disclosure in a patent application stipulated in Article 29(1) of the TRIPS Agreement.

II. The Relationship between Disclosure and Prior Art

Prior art refers to any information available to the public before a specified date that may be relevant to a claim of patentability. At the international level, while there is no strict definition of the term, Rule 5.1(a)(ii) of the Regulations of the Patent Cooperation Treaty (PCT) refers to such art in describing what must be contained in disclosure: the Rule provides that the description of the claimed invention should contain "the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, preferably, cite the documents reflecting such art." Prior art is particularly relevant to two of the three patentability criteria: namely, *novelty* and *inventive step*. This section reviews these criteria and then explains their relationship with disclosure and prior art.

Novelty is one of the three criteria for patentability. Patent examiners must assess, *inter alia*, whether a claimed invention is new in light of the applicable standard for examining novelty in their patent law. Generally, the burden of proof is on the applicant to show to the patent examiner that, in the light of prior art, the claimed invention represents something that is truly new. This does not, however, exclude the possibility of patent examiners relying on sources external to the patent application to determine the state of the art.

Each country has flexibility in determining the applicable standard for examining novelty, and a number of variations exist. According to Abbott, the criterion of novelty may be construed at one end so that only a later claim exactly the same as the prior art is considered to lack novelty, while at the other end of the spectrum, novelty may be construed so that subject matter implicit or inherent in the prior art is considered to defeat novelty.[70] Prior disclosures of the invention to the public anywhere in the world may result in rejection of the novelty of a technology described in a patent application (worldwide novelty), or this may be limited to disclosures of the invention within a country (domestic novelty[71]). Depending upon the practice of the country, the prior disclosure of the invention may be oral, contained in a single document or could be derived from a combination of publications.[72]

A second criterion for patentability is *inventive step*. Generally, an invention is considered to have met the inventive step criterion if, taking into account prior art, it would not have been

[70] See Abbott (2005).
[71] It should be noted that domestic novelty is hardly used any more. Of the OECD countries, New Zealand abandoned domestic novelty in favor of absolute (i.e., worldwide) novelty in 2008. In the United States, oral prior art only destroys novelty if it occurs within the United States (See 35 USC § 102(b): "A person shall be entitled to a patent unless - [] (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.").
[72] UNCTAD (2011b), p. 67.

obvious to a person skilled in the art on the date of filing. The purpose of this requirement is to prevent the granting of exclusive patent rights for trivial inventions. While novelty is met through a 'quantitative' assessment of the claimed invention at issue and relevant prior art, the inventive step test requires the new invention to qualitatively exceed what a 'typical person skilled in the art' could produce. This is done by first, identifying the prior art; and second, by assessing the extent to which the invention embodied in the claim would have been obvious to a person skilled in the art who had (or should have had) knowledge of the relevant prior art.[73] The relationship between prior art and inventive step can therefore be summarized as follows: the more prior art is taken into account, the greater the chance that the invention would be treated as obvious, and increase the possibility that it would fail the inventive step test.

Taking aside consideration of *industrial application* (the third criterion of patentability, which has less connection with prior art), countries differ in the extent to which they apply an expansive or restrictive criterion for novelty and combine it with a more or less expansive criterion of inventive step. The two criteria usually function, however, to assess whether there is a difference between the claimed invention and prior art, and if such a gap exists, to examine whether the claimed invention would have been obvious to a person skilled in the art, given publicly available knowledge.[74] In this regard, what can be considered prior art for purposes of novelty differs from the prior art for assessing inventive step. The prior art is more narrow in the case of inventive step, and is limited to publicly available knowledge that an average expert skilled in the art would reasonably consider pertinent in a particular case.

An examination of patentability criteria is the necessary starting point of this chapter because, ultimately, a disclosure requirement that forces patent applicants to be open and honest about genetic resources of provider countries and/or related TK contained in a claimed invention is most effective when that disclosure (or lack thereof) affects the application in substance, as opposed to *pro forma*. A 2004 WIPO study notes that "[f]ailure to comply in formal terms may not necessarily have serious consequences, provided it is not fraudulent and is remedied in a timely manner. Failure to comply in substantive terms (such as requirement to disclose sufficient material to sustain patent claims) may have major consequences for the fate of a patent application or granted patent."[75]

There is an ongoing debate on whether a disclosure requirement in patent applications amounts to a distinct condition for patentability apart from novelty, inventive step and industrial application (see discussion in the section on Enforcement, below). As noted from the WIPO study above, however, there can be little doubt as to the compatibility of a disclosure requirement with the TRIPS Agreement if the information gleaned from that disclosure affects the assessment by a patent examiner of the claimed invention against the three basic patentability criteria. Not all jurisdictions that have a disclosure requirement in their patent legislation explicitly take such an approach, however. The European Union's Recital 27 of Directive 98/44/EC on the Legal Protection of Biotechnical Inventions states, for example:

> "*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*

[73] Ibid., p. 68. The latter assessment of non-obviousness is complex and involves a combination of various subjective and objective factors too detailed to examine in this text. Those interested are invited to consult this document at pp. 69-72.
[74] The South Centre v. I, p. 49.
[75] WIPO (2004), p. 5.

> *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 patents.*"

This type of text would not confer an obligation to disclose origin if the source were not known to the applicant, and would not affect the substantive examination of the application. At the same time, where disclosure is deemed not to affect the validity of the rights arising from the patent, it is difficult to see why a patent ought to be granted if elements potentially material to the consideration of the three patentability criteria were not disclosed in the patent application. Hence, the authors of this handbook take the view that disclosure of origin need not be considered as introducing a new substantive element for assessing patents, even absent an amendment of Article 29 of the TRIPS Agreement or a new WIPO treaty mandating disclosure of origin/source.

Generally, countries' national patent legislation has incorporated mandatory disclosure of origin or source either as a pre-requisite to or additional condition for submitting patent applications[76]; while this reflects a conservative approach, it should be noted that there has to date been no WTO dispute settlement ruling on this issue. Some examples of such national laws are highlighted in the sections below.

Finally, there is a unique issue with respect to TK and prior art. It would be a mistake to assume that all TK is in the public domain or that it automatically constitutes 'prior art' for patent law purposes. Mgbeoji, for example, cites the examples of native healers who keep their medicinal knowledge largely secret.[77] National TK legislation and customary laws, to the extent they exist in a given jurisdiction, may confer ownership or attribution rights to communities. It is therefore theoretically possible for a patent applicant to submit an application in respect of an invention that is similar to or contains certain TK. The benefit of a disclosure requirement in such cases is that it puts the onus on the applicant to truthfully divulge in a submission to the government whether an application had been based on or used TK.

Key Points

⇒ Disclosure helps to reveal prior art, which can be taken into consideration in assessing the patentability criteria of novelty and inventive step.

⇒ The prior art for novelty is not necessarily the same as the prior art for inventive step.

⇒ While generally disclosure of origin/source is incorporated under national laws as a condition for patent applications, some legislation contains text which implies that disclosure is strictly *pro forma*. Even in such cases, it is difficult to see how a disclosure that is material to one of the patentability criteria ought not to be taken into consideration.

⇒ Requiring disclosure as a condition for submitting patent applications is a relatively conservative approach that is generally seen as procedural, and does not add a separate

[76] Ibid., p. 314. Some jurisdictions have made evidence of prior informed consent a pre-requisite for patentability, such as Peru.

[77] See Mgbeoji in Subramanian and Pisupati (ed.) (2010), *Traditional Knowledge in Policy and Practice: Approaches to Development and Human Well-Being*, p. 140.

substantive element to existing patentability criteria, notwithstanding ongoing debates at WTO and WIPO regarding a mandatory disclosure requirement under international law (see Chapter 2).

⇒ No WTO case to date has challenged the validity of a disclosure requirement under national patent legislation.

⇒ For purposes of assessing patent applications that utilize TK, it would be erroneous to assume that all TK is in the public domain. A disclosure requirement forces the applicant to be honest about when s/he has drawn on TK in an application.

III. Shaping a Disclosure of Origin Requirement

A. Assumptions, Objectives and Limitations of Disclosure of Origin

Countries that are considering putting in place a disclosure requirement in their patent law or otherwise considering revising existing disclosure legislation/regulations should be clear as to why they want a disclosure requirement in the first place, and what they reasonably seek to accomplish through such a requirement. Once these policy objectives are clear, it becomes easier to shape an appropriate requirement. Other details, such as what text should be made part of the patent law and what can be in regulations and/or guidelines, can and should be considered at a later stage.

The rationale for putting in place a disclosure requirement rests on a number of general assumptions. They are as follows:

1. Most provider countries see disclosure requirements as a means of preventing the misappropriation of genetic resources and/or related TK. Disclosure is therefore viewed as primarily a defensive strategy that prevents the granting of erroneous patents, for purposes of the CBD and the Nagoya Protocol.
2. Only a handful of inventions which incorporate genetic resources and related TK from provider countries are the subject of a patent application, and fewer still are commercialized. Such applications are generally filed in developed countries and the larger developing countries.
3. Patent applicants in developing country provider countries are predominantly foreign.
4. Ensuring benefit sharing: joint ownership of patents or other possible arrangements to share royalties/license fees from patents offer one means to share benefits from an invention that incorporates genetic resources and/or related TK from provider countries. The largest monetary benefits will arise from successful marketing of the inventions, even through third parties, and the sharing of these benefits needs to be covered by contractual agreement.
5. Transparency and monitoring: patent offices in developing countries are often under-resourced, and frequently do not have the capacity to undertake comprehensive examination of applications, let alone do independent research to verify claims made in patent applications. Research centres and providers of biological resources in developing countries, such as the ministries of agriculture and the environment, frequently do not have the capacity to identify, trace and monitor the use and

commercialization of the resources they supplied in the absence of a duty on the part of the recipients to disclose the origin of biological resources in patent applications.

6. Most developing countries have or are aiming to have TRIPS-compliant patent legislation.

These points are important in so far as they delineate some of the limitations of what a disclosure requirement will be able to accomplish.

First, incorporating such a requirement into the patent law will only cover a handful of all ABS cases. While the existence of a disclosure requirement may help to justify the designation of an IP office as a checkpoint, it is clearly not a national focal point and competent national authority within the meaning of Article 13 of the Protocol.[78] Further, there is a potential tension between the first and fifth assumptions above. If a provider country is overzealous in rejecting patent applications that contain references to genetic resources and related TK, the country may be foreclosing opportunities to share benefits accruing from that patent, provided the patentability criteria are met.

The second assumption points to the need for a great deal of investigation and research before any attempt is made to commercialize a product based on genetic resources or related TK. This has implications beyond disclosure, i.e., on how to frame an appropriate research exception in the patent law and how R&D is treated in the Protocol (this topic is covered later in this handbook).

While it may be true that in many developing countries patent applications are overwhelmingly submitted by foreigners, domestic actors can and have attempted acts of misappropriation through the filing of patent applications. It therefore would not make sense to carve out separate disclosure requirements targeting foreign applicants. Moreover, the national treatment principle in Article 3 of the TRIPS Agreement obliges Members to accord treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property.

Another major limitation on disclosure requirements established by a provider country in its patent law is that this requirement would not necessarily prevent a so-called 'biopirate' from seeking patent protection in jurisdictions where such a requirement does not exist or is voluntary, or where there are no consequences of a lack of disclosure on the patentability of the claimed invention. Such individuals could simply avoid attempting to obtain a patent in provider jurisdictions. This handbook acknowledges this limitation, but takes the view that: 1) many countries worldwide, including many developed countries, are increasingly adopting some form of disclosure of origin requirement and a critical mass of countries having such a requirement could lead to changes in countries which currently do not make it mandatory[79]; 2) patent applications in user country jurisdictions still find their way to certain provider country

[78] The Nagoya Protocol avoids linking the competent authority with checkpoints. However, a meaningful implementation of the Protocol and how IP relates to its provisions requires a linkage between the competent authority and checkpoints, otherwise it remains unclear for whom and for what purpose the checkpoints are collecting information.

[79] The authors have deliberately excluded an analysis of the question of whether a mandatory disclosure of origin requirement should be adopted as a matter of international treaty law. While a critical mass of countries that have such a requirement contained in their patent law certainly creates momentum for intergovernmental consensus, the debate remains controversial at the time of writing. Moreover, there already exists substantial literature on this issue, much of it written in the hopes that such a requirement would be contained in the Nagoya Protocol.

jurisdictions as a result of applications submitted in numerous countries through the PCT or through requests for dossiers on prior art; and 3) patent application disclosures will generally comprise prior art in other jurisdictions to the extent that they have adopted a worldwide standard of novelty, and are increasingly accessible due to advances in information communications technology (hereafter ICT), including through the use of databases.

Moreover, a major advantage of patent disclosure is that it permits the assessment of applications that utilize accessed genetic resources and TK that pre-date the CBD and/or the Nagoya Protocol, making the issue of when genetic resources and associated TK were accessed moot, at least as far as patent applications are concerned. It therefore can serve as a check on misappropriation even where the subject resources and/or TK were not subject to PIC and MAT requirements when they were accessed.

Finally, while not explicit in the assumptions above, one of the greatest tensions is between the economic incentives created by the patent system, and the objective of the CBD which attempts to set up basic rules for conservation and sustainable use of biological resources and ABS worldwide. Patent systems establish an incentive for commercializing and rewarding technological innovation without any particular regard to conservation or sustainable use or ABS. The Nagoya Protocol sets up the basic rules for access and the fair and equitable sharing of benefits arising from the utilization of genetic resources and TK associated with genetic resources. While the pre-amble to the Protocol acknowledges the potential role of ABS to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability, there is no research to date on whether an ABS system which encourages commercialization, such as patenting, may or may not potentially lead to an acceleration of resource depletion. Although the Convention on International Trade in Endangered Species of Wild Fauna and Flora (hereafter CITES) is designed to address the issue of resource depletion to a certain extent[80], there is ample room for future empirical research on the relationship between patents and resource depletion, and it perhaps also reiterates the need for an ABS competent authority to ensure that access is granted in a manner that is overall supportive of CBD objectives. The CBD, for its part, takes up this challenge when connecting the duty of its Parties to create conditions to facilitate access with the requirement that its use needs to be environmentally sound. The worldwide accepted instrument to analyze the environmental implication of certain activities is the Environmental Impact Assessment (hereafter EIA) according to Article 14 of the CBD, implemented as standard operating procedure in most national environmental laws.

This handbook recognizes that the patent system was never set up to address conservation and equitable ABS concerns, and acknowledges that these are in effect two systems set up under different sets of rules. This section points out, however, that setting up a disclosure obligation within the national patent system involves a number of potentially competing objectives and interests. Countries will need to consider how to balance these objectives in shaping the contours of an appropriate disclosure obligation. Additionally, a later chapter on GIs also shows how certain IP instruments can potentially be tailored in a manner that supports sustainable use.

[80] The CITES treaty, established in 1973, regulates imports, exports and re-exports of plants and animals that are endangered. For more information, see http://www.cites.org.

Key Points

⇒ Countries need to be clear about what they seek out of a disclosure of origin requirement before introducing it in their legislation, or revising existing legislation.

⇒ A number of important assumptions and limitations need to be considered when framing appropriate legislation. These include that:

- only ABS cases in certain industries are generally going to be the subject of patent applications;
- national treatment under TRIPS requires that foreigners and nationals be treated alike, notwithstanding that patent applications in many developing countries tend to be overwhelmingly filed by foreigners;
- would-be bio-pirates can always file patent applications in potentially profitable jurisdictions where there is no disclosure requirement; and
- the relationship between commercialization and patenting, and the depletion of resources is to date under-researched.

⇒ Patents and ABS are systems that are set up under two different sets of rules. This can also be advantageous, as, for example, the patent system permits the assessment of applications that utilize genetic resources and TK that pre-date the CBD and the Nagoya Protocol.

B. What Ought to be Disclosed? The Case of Where Patent Offices and National Competent Authorities Function Relatively Independently

The starting point for this analysis is the Nagoya Protocol. For disclosure to be useful to the implementation of the Protocol, it is necessary to examine which provisions of the Protocol such a requirement would support. The Protocol covers three categories of resources – genetic resources owned by the state, genetic resources owned by indigenous and local communities (ILCs), and associated TK owned by ILCs. The key obligations of the Protocol as far as PIC and MAT are concerned are contained in Article 5(1) and 5(5), which state, respectively, that:

> "*In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms"; and*
>
> *"Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.*"

The implementation of these provisions falls under the purview of the national competent authority, as stipulated in Article 13 of the Protocol. This authority is responsible for

"granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms." The national authority therefore achieves the objective stated of ensuring appropriate access and fair and equitable sharing of benefits through the review of PIC and MAT for cases where genetic resources and associated TK are sourced within the country. The authority for the Protocol will often be the same national authority for wider CBD issues.

The national competent authority will generally be separate from the country's IP office. The IP office can, however, be designated as a 'checkpoint' to assist the competent authority in discharging its duties. The rationale of the so-called 'checkpoint' system under the Protocol is that compliance is best served by a separation of these functions. It follows, then, that the patent system needs to be designed in a manner that, for the national competent authority of a provider country, generates information that first, flags to the authority that a genetic resource sourced from the provider country or associated TK of the provider country is being utilized; and second, indicates who is claiming exclusive rights to an application or commercialization of that genetic resource or associated TK.

While the patent system could conceivably generate other useful information for the national competent authority such as evidence of PIC and MAT[81], these are, strictly speaking, not necessarily material as to whether the claim concerns an invention and whether the criteria of novelty, inventive step and industrial applicability have been met. This handbook will return to the question of whether it makes sense to include evidence of PIC and MAT in a patent application later in this chapter. At a minimum, though, the disclosure of origin/source requirement should be structured in a manner that ensures that patent applications, when they are made public by publication in the official gazette, contain the relevant references to both genetic resources sourced from the provider country or associated indigenous group(s) in the case of genetic resources owned by an ILC or associated TK, and clearly indicates who is the applicant. This should enable staff of the national competent authority to monitor patent applications, and to flag potential cases of interest and follow-up.

The patent system, however, provides a potentially more powerful tool than to simply generate information for national competent authorities whose primary duty is to ensure compliance with PIC and MAT. From the perspective of patent law, by generating information through disclosure requirements, examiners may decide whether a proprietary claim over an invention merits the award of exclusive rights, or whether the innovation is not worthy of the award of such rights. Ideally, the exercise of a patent examiner's duties in assessing applications can serve as a means to address misappropriation and 'biopiracy' beyond examination of the existence and contents of certificates of compliance and benefit sharing agreements to be conducted by national competent authorities. As stated earlier, the patent system could also address potential cases of inventions that utilize genetic resources and associated TK that pre-date the CBD and the Nagoya Protocol. In order to do so, however, the system must function to generate the type of information that will allow patent examiners to reach an informed and fair decision about the merits of a patent application.

[81] This could be done by requiring a box be checked indicating whether there is an underlying material transfer agreement, license agreement or similar agreement, for example, and asking the applicant to attach a copy thereof.

Patent systems work on the basis of applications filed by those who seek to obtain a temporary right to exclude others from using a claimed technological innovation in exchange for disclosure of the technology so that others would be able to build on it. An applicant has the burden of proof for showing that the technology over which a patent is sought is an invention (whether product or process, or a combination thereof), and that the requisite criteria of novelty, inventive step and industrial application are met. In so doing, applicants are often under a legal obligation to show, *inter alia*, how the invention represents a significant innovation from existing prior art. At the same time, the economic incentive is to disclose as minimally as possible in order to secure the grant of the exclusive right, given that the applicant will generally seek to preserve as much of a competitive edge for working a technology in the event a patent is not granted, or to exaggerate or misrepresent a claim in a bid to secure exclusive rights. Given that disclosures cannot always be trusted, applications are generally subject to pre-grant opposition, and sometimes post-grant review procedures, which provide opportunities for interested parties to contest a patent.

Arguably, the existing patent system already requires disclosure of all relevant information, including disclosure of origin/source, if it is material to the decision of an examiner as to whether or not to grant a patent.[82] Some commentators have even suggested that disclosure of origin and source would therefore have little effect on the patent system as such, and that disclosure of origin existed primarily to check that the MAT providers had negotiated with users of genetic resources and associated TK.[83]

A decision to include disclosure of origin/source above and beyond normal disclosure requirements (what is sometimes called 'enhanced disclosure'[84] or BRDR[85]) has the advantage, however, of removing any uncertainty as to whether or not the use of a genetic resource or associated TK from a provider country is material or not to the patentability of the claimed invention. Users must disclose it in the stipulated cases and let the patent examiner decide him/herself whether the information disclosed is material or not to patentability. While only a country or source may be revealed in the patent application, in effect such a requirement acts as a 'red flag' that some type of local genetic resource or associated TK may be implicated in a patent application, and sends a signal to the examiner that the application may warrant further investigation. Moreover, it ensures that the necessary signal is made to a national competent authority and other stakeholders looking at the gazette of a potential case of interest, and by so doing, helps to ensure that ABS stakeholders are able to provide the patent system with information on the invention that may be relevant to patentability. Finally, it could be argued that while Article 29 of the TRIPS Agreement stipulates a minimum standard for disclosure, this has apparently not been particularly effective in preventing the patent system from being used as an agent of misappropriation and biopiracy.

A great deal of variation already exists in patent laws with respect to disclosure of origin/source including what triggers the requirement and what should be disclosed. Article 49(a) of the Patent Law of Switzerland provides, for example, that "[f]or inventions based on

[82] Tobin et.al. (2008), p. 43.
[83] See comment of Pierre du Plessis at the 19th Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, contained in document WIPO/GRTKF/IC/19/7 of 20 May 2011, para. 78.
[84] See UNEP/CBD/COP/10/INF/44.
[85] Vivas-Eugui (2012), p. 6.

genetic resources or traditional knowledge the patent application must contain information concerning the source:

a) of the genetic resource to which the inventor or the applicant had access, when the invention is based directly on that resource;

b) of the traditional knowledge of indigenous or local communities related to the genetic resources to which the inventor or applicant had access, when the invention is based directly on that knowledge.

If the source is not known to either the inventor or the applicant, the applicant must confirm this in writing." According to the United Nations University Institute of Advanced Studies (UNU-IAS), the European Community (EC) has adopted a similar position on disclosure, perhaps responding to "industry concerns that overly comprehensive disclosure requirements could involve unnecessary costs and efforts."[86]

Mandatory disclosure of source is triggered in the above cases when the invention is *based on* genetic resources (or biological resources in the case of the EU) and associated TK. The requirement is triggered more easily in the existing legislation of a number of other countries. Section 10 of India's Patent Act stipulates, for example, that "[e]very complete specification shall . . . disclose the source and geographical origin of the biological material in the specification, *when used in an invention*" (emphasis added). Section 30(3A) of South Africa's Patent Law (as amended in 2005) provides that "[e]very 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." Act 41 of 2000 amending Denmark's Patent Act provides that "[i]f 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. If the applicant does not know the geographic origin of the material, this shall be indicated in the application" (emphasis added).[87]

The main difference between these approaches is that in the first set of cases, disclosure of origin is required only when the claimed invention is based directly on the resource, while in the second set of cases, disclosure of origin is triggered when the claimed invention is 'based on or derived from' the genetic resource or associated TK. Thus, while the first set of cases would result in minimizing the impact of a mandatory disclosure requirement, the latter texts would expand the scope of required disclosure.

In addition to what triggers the disclosure requirement, another distinction is what ought to be disclosed. The difference is whether the disclosure should include disclosure of both source and origin or one of them only, disclosure of associated TK, or the provision of evidence of prior informed consent or compliance with national ABS laws, certificates of compliance issued by national competent authorities, and/or evidence of a benefit sharing arrangement.

[86] Tobin et.al. (2008), p. 42.

[87] This amendment also provides that lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent. The amendment also does not cover TK.

Some jurisdictions make a reference to disclosure of origin only, while others stipulate disclosure of source (see the Swiss example above) and some require both (see the Indian example above). Yet others, referred to below, require evidence of compliance or legal provenance (see the Costa Rican, South African and Andean Community examples in the section below). The box below outlines the potential implications for these distinctions.

Given the variety in the texts by countries that have adopted disclosure requirements, what is the appropriate level and content of disclosure if patent offices and ABS national competent authorities function relatively independently? A UNU-IAS study suggests that a mandatory disclosure of origin requirement should clearly state the obligation for IP applicants, be unambiguous regarding the information to be provided, not unreasonable and capable of implementation by IP authorities.[88] In this regard, while empirical evidence is as yet scarce, the 2010 study distributed to delegates at the Nagoya Conference of Parties concludes that "[t]here is clear evidence that in countries that have adopted enhanced disclosure measures patent applicants are readily able to include information on the origin and sources of materials concerned within patent applications."[89] This would seem to suggest that even in countries where disclosure is easily triggered, applicants who seek patents over inventions that contain provider country genetic resources and associated TK have been able to cope with the requirement.

Box 8
Origin, Source and Legal Provenance

The terms origin, source and legal provenance are frequently used in the context of establishing an appropriate ABS certification regime, and are not indigenous to the terminology typically used in patent law. These terms were originally discussed in the context of the Nagoya negotiations as proposals to establish a system that would generate, as the case may be, certificates of origin, source, compliance or legal provenance.[90]

In the end, the Nagoya Protocol, in Article 17(2), establishes a system where the publication of a national ABS permit in the ABS Clearing House would constitute an "internationally recognized certificate of compliance" that serves "as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent." It should be noted, however, that the Protocol mandates only that the certificate system foreseen under Article 6(3) of the Protocol applies to genetic resources and not to traditional knowledge associated with genetic resources of ILCs as defined in Article 7. TK may, nonetheless, be included in the certification system through national legislation.

It is worth examining what the transplanting of the terms used to describe certification procedures means in the context of patent disclosure requirements. **Disclosure of origin** generally refers to the obligation to disclose in patent applications the geographical origin, by country, of the genetic material and associated TK.[91] **Disclosure of source** would require the disclosure in patent applications of primary sources of genetic material, such as the contracting party providing genetic resources, and secondary sources, including *ex situ* collections. Source may be defined as any person or entity providing access to genetic resources that relates in any relevant way to the subject matter of IP

[88] Tobin et.al. (2008), p. 41.
[89] See UNEP/CBD/COP/10/INF/44, p. 63.
[90] Tobin et.al. (2008), p. 7.
[91] See Muller (2010), p. 7 and UNCTAD (2006), p. 12.

applications. It may thus include indigenous groups in the case of related TK and where they enjoy rights over certain genetic resources.[92]

Legal provenance is a requirement whereby applicants would need to provide evidence that the process of innovation which is the subject of a patent application was undertaken in compliance with the national ABS system of the country providing PIC before granting the patent right.[93] A permit issued by an ABS national authority and published in the international ABS Clearing House is assumed to provide evidence of compliance/legal provenance[94], though it is noted that this may not be the only way for an applicant to prove adherence to the law.[95]

Patent application disclosure obligations can require the disclosure of origin and/or source, and in addition, may require evidence of compliance or legal provenance. Thus, a disclosure obligation could require disclosure of origin and source, and to provide evidence of PIC and MAT.

Source: compiled by UNCTAD, unless otherwise referenced.

The 2010 study by the UNU-IAS shows that it is possible to obtain information from the patent system to obtain good leads on disclosure of origin and source through the patent system (see Box 9 below for examples). At the very minimum, such disclosures should trigger the national competent authority as to whether the source materials cited had been legally obtained from sources under its jurisdiction.

Box 9
Examples of Disclosure of Origin and Source in Patent Applications: Results of a Patent Search using Context Words such as "From/Origin/Source"

"The invention therefore can provide an excellent agent for treating ulcerative colitis. Best Mode for Carrying Out the Invention: **Peony root (paeniae radix) as an active ingredient in the treatment agent provided by the present invention is obtained by drying the root of a perennial plant of the peony family (paeonia albiflora var. trichocarpa) <CW>grown in <ST>China, Korea, and Japan or a relative plant.** Peony root is used as astringent, emollient, antispasmodic, analgesic, a drug for oversensitive to the cold, and a drug for dermatosis. Further, it is used for abdominal distension, abdominal pain, body pain, diarrhea, purulent tumor, and the like. **Peony root is contained in Chinese medicine formulations** such as Shao-Yao-Gan-Cao-Tang, Dang-Gui-Shao-Yao-San, Shi-Quan-Da-Bu-Tang (Juzen-taiho-to), Xiao-Qing-Long-Tang (Sho-seiryu-to), Da-Chai-Hu-T..." US6586022B2

"...be considered to constitute preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed and still obtain a like or similar result without departing from the scope of the invention. Crude Extract from Vernonia amygdalina Example 1 Aqueous Extraction of

[92] Article 2 of the CBD defines "Country of Origin" as the country that possesses those genetic resources in *in-situ* conditions (CBD, Article 2). Country providing , on the other hand, is defined as the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country (CBD, Article 2). The question of whether a mandatory disclosure requirement in treaty law should be disclosure of origin or source is an important point of debate in international negotiations.

[93] See Vélez (2010), p. 3.

[94] The Protocol provides a mechanism under Article 17(4) by which the information contained in a certificate could be declared confidential, which potentially raises transparency issues.

[95] In this regard, Article 17(4) of the Protocol seems to grant the possibility for international certificates to keep confidential terms related to PIC and MAT, and leaves open the question of the extent to which all certificates can be assumed to be proof of compliance, and what would be needed to establish that fact if certain information does not appear on the certificate.

Vernonia amygdalina Leaves 1. **Fresh Vernonia amygdalina leaves were <CW>collected in Benin City, <ST>Nigeria from pesticide-free plants (it is important to note that the plants investigated in the Kupchan et al. report were collected from east Africa, specifically Ethiopia and thus may represent a Vernonia amygdalina sub-species with properties distinct from employed for use in the instant invention)**. 2. 18 grams of Vernonia amygdalina leaves were washed three times with distilled water. 3. Next the leaves were soaked overnight (12-18 hours) in 36 mL of distilled water....” US6849604B2

“Cosmetic composition containing an extract of Limnocitrus littoralis. The present invention relates to the field of cosmetics. It relates more particularly to novel cosmetic compositions comprising an extract of Limnocitrus littoralis (Miq.) Swingle, hereafter denoted as Limnocitrus littoralis, and to novel uses of this extract in the field of cosmetics. Limnocitrus littoralis is a plant of the Rutaceae family with the basionym Parainignya littora/is Miq. **It <CW>originates from south-east <ST>Asia and, according to our information, is the only species so far indexed in the genus Limnocitrus.** Its habitat is essentially located in hot and dry zones. They are shrubs in the form of bushes that are found essentially, but not uniquely, in Vietnam, which is moreover the origin of those used in the description of the present invention. **Traditional or religious uses of this plant are related in legends and in Vietnamese literature**.... GB2439793A

“The Phlebodium extract contains a plant extract obtained from a plant within the Family Polypodiaceae. The Polypodiaceae family generally includes fems, especially those native to the tropical regions of the world. For example, many of the Polypodiaceae family are **<CW>indigenous to Latin <ST>America, especially those in the Honduran rainforests, to South America especially those in the Brazilian rainforests, Mexico, and to the Caribbean islands**. The Phlebodium extract is typically obtained from the rhizome or root system, and/or the leaves. The Phlebodium extract is a mixture of one or more of various flavonoids, alkaloids, and/or lipids. Within the Family Polypodiaceae, Phlebodium extracts can be obtained from plants within the Genus Polypodium, the Genus Chrysopteris...” US20060246115A1

Source: results of a search conducted by P. Oldham in UNEP/CBD/COP/10/INF/44 (2010), p. 50 (emphasis added for possible disclosure or origin or source). <CW> refers to the context word term and <ST> refers to the country or region. reproduced with permission.

This section assumed that patent offices and national competent authorities under the Protocol function relatively independently, each discharging its respective mandate. Even under this scenario, it is possible to ensure that there are positive synergies from the patent and ABS systems established under national law. The following section will examine the case where the patent offices assume a more activist role in the implementation of Nagoya Protocol.

Key Points

⇒ Patent offices and the national competent authority have different functions, but can complement each other even whilst retaining relatively independent mandates.

⇒ The patent system can be designed in a manner that, for the national competent authority of a provider country, generates information that first, flags to the authority that a genetic resource sourced from the provider country or associated TK of the provider country is being utilized; and second, indicates who is claiming exclusive rights to an application or commercialization of that genetic resource or associated TK.

⇒ Enhanced disclosure (or BRDR) could encompass disclosure of origin, disclosure of source, certificates of compliance or proof of legal provenance.

⇒ Disclosure of origin and/or source can be triggered at different instances, from when the claimed invention is based directly on a genetic resource or associated TK to when such resource or TK is an input to the invention. Variations closer to the former creates a safe harbour for inventions that do not rely directly on the resource or TK, while variations closer to the latter have the effect of leaving the discretion of materiality to the patent examiner.

C. What Ought to be Disclosed? The Case of Where Patent Offices Assume a Greater Role in Nagoya Protocol Functions

In the negotiations leading to the Nagoya Protocol, debate emerged as to whether patent offices should be designated as a so-called 'checkpoint'.[96] Under Article 17(a) of the Protocol, a checkpoint exists to monitor the use of genetic resources, and each Party must designate at least one such checkpoint to:

1) Collect or receive, as appropriate, relevant information related to PIC, to the source of the genetic resources, to the establishment of MAT, and/or to the utilization of genetic resources, as appropriate;
2) Requires users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint, and establish effective and proportionate measures to address non-compliance;
3) Provide such information to national authorities without prejudice to the protection of confidential information, to the Party providing PIC and to the ABS Clearing House, as appropriate;
4) Encourage users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and
5) Encourage the use of cost-effective communication tools and systems.

Generally, these designated checkpoints are not responsible to undertake all of the above functions, but only those for which it would be considered appropriate, given the characteristics of the organization. As of the time of writing, however, in part because the Protocol's ABS Clearing House and its international certification system is only at its trial stage, no country has yet designated a patent office as a checkpoint. A number of countries have, nonetheless, used mandatory disclosure of origin and/or source to undertake some functions that could eventually qualify the patent office to become a checkpoint under the Protocol. These functions and examples are examined below.

One possible role if the patent office were to act as a checkpoint would be to require the submission of evidence of PIC and MAT either as a pre-requisite to or concurrent with the filing of a patent application. Section 30(3B) of South Africa's Patent Law (as amended in 2005) provides that "[t]he registrar shall call upon the applicant to furnish proof in the

[96] See Medaglia and Rukundo (2010), p. 10.

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." Article 26 of the Andean Community's Decision 486 on the Biological and Genetic Heritage and Traditional Knowledge (2000) requires that a copy of the contract for access be filed with the competent authority in the event that a patent application is filed over a product or process obtained or developed from genetic resources or by-products originating in one of the Community's Member Countries.[97]

Where national authorities grant certificates of origin/compliance, this certification is required to be presented along with the patent application. Article 80 of Costa Rica's Biodiversity Law provides:

> "*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. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.*"

As the examples above show, the requirement to submit evidence of PIC and MAT is often contained in the national ABS legislation, as opposed to the national patent legislation.

The main argument in favour of a requirement to submit evidence of fair and equitable benefit sharing or evidence of PIC and MAT (either independently or through certificates of legal provenance) when applying for patents is that "[i]ntellectual property applicants should not be rewarded with rights or privileges that convey commercial benefits, when the subject matter of the applications was obtained or derived from genetic resources or traditional knowledge acquired in violation of CBD prior informed consent requirements and conditions of access for genetic resources. Similarly, intellectual property owners should not retain such commercial benefits in violation of CBD benefit-sharing requirements."[98] Requiring IP applicants to submit evidence that basic PIC and MAT obligations have been complied with in the provider country helps achieve this objective.

The major argument against a requirement to submit evidence of legal provenance as part of a patent application is that "[r]equiring patent authorities to examine ABS agreements in order to ensure compliance with ABS and TK laws of provider countries, adequacy of benefit sharing, and existence of valid PIC and MAT would place" a large burden upon many provider country IP offices, especially since many of the IP offices are located in resource-constrained developing countries.[99] Moreover, staff of IP offices are trained to examine patent applications, and generally not trained in compliance with ABS laws. While one study suggests that certification could help alleviate this burden since it would enable IP offices to confirm legal provenance in an easily recognizable fashion[100], few developing countries have to date established a working system of certification on which the IP offices could rely.

[97] The Andean Community Member Countries are Bolivia, Colombia, Ecuador and Peru.
[98] UNCTAD (2006), p. 5.
[99] Tobin et.al. (2008), p. 43.
[100] Ibid.

Moreover, it is conceivable that patent applicants may choose to establish legal provenance by means other than certificates (i.e., to submit the underlying contract, particularly if the contract pre-dated the establishment of a national competent authority for ABS).

The example of the Andean Community provides one possible solution that helps resolve the tensions above: that incident to the filing of a patent application where a genetic resource or associated TK is implicated, a copy of the contract for access to the resource must be filed with the national competent authority by the patent applicant. This would not impose an additional burden on patent offices to collect the contracts and underlying certificates. If this obligation appears in the relevant ABS legislation only, however, prospective patent applicants may not be aware that they need to file the underlying access contract with the national competent authority. Corresponding text should therefore also appear in the patent law. Alternatively, the disclosure requirement may only require the declaration of compliance with PIC and MAT by the patent applicant.

Key Points

⇒ Jurisdictions can require submission of legal provenance or the submission of evidence of PIC and MAT concurrent with disclosure in a patent application.

⇒ Patent offices could go further than simply to ensure that certain information is disclosed which the Nagoya Protocol national competent authority could make use of in discharging its ABS functions. The possibility exists for IP offices to discharge the responsibilities of a checkpoint under the Protocol.

⇒ Some jurisdictions such as those in South Africa and the Andean Community have adopted legislation that bars patent applications from being considered in the event that legal provenance is not established.

⇒ The argument for barring patent applications where legal provenance cannot be established is that applicants should not be rewarded with rights or privileges that convey potential commercial benefits, when the subject matter of the applications was obtained or derived from genetic resources or traditional knowledge acquired in violation of CBD prior informed consent requirements and conditions of access for genetic resources.

⇒ Patent offices in provider countries, especially developing countries, are often under-resourced, are not trained in examining compliance with PIC and MAT, and may not be happy with the prospect of taking on an additional mandate without additional resources.

⇒ One possible solution could be that when filing of a patent application where a genetic resource or associated TK is implicated, a copy of the contract for access to the resource must be filed with the national competent authority, or alternatively, the disclosure requirement could be complied with by a simple ‘declaration’ by a patent applicant that they have complied with applicable ABS laws, where they exist, without the duty to furnish such contracts and certificates to the patent office.

D. Enforcement and Remedies

The analysis above discusses the range of possibilities for disclosure requirements, ranging from where IP offices and ABS national competent authorities act in relative independence, to where IP offices take on so-called 'checkpoint' functions under the Nagoya Protocol. From the perspective of the CBD/Nagoya Protocol, though, the ultimate aim of a BRDR is to ensure that basic PIC and MAT requirements have been complied with. As it may be naïve to assume that applicants will altruistically comply with a voluntary disclosure requirement, the implication is that there must be some sanction for non-compliance with applicable disclosure obligations. Here, too, there are a range of possible variations.

The first is that "[f]or countries that do not require disclosure or that have a voluntary disclosure requirement, there are no particular consequences to patents for lack of fulfilment", leaving any sanctions to be dealt with under ABS laws.[101] However, in countries where there is a duty to disclose in patent applications information material to patentability, failing to disclose information about genetic resources and associated TK could be a breach of duty to truthfully fill out an application submitted to a government office. Such a possibility exists under United States patent law, although there must be clear evidence that what is omitted in the disclosure of prior art is a material element to the patentability of the claim, and that it was reasonably known to the applicant.[102]

Among countries requiring disclosure of origin/source, there are different approaches on the remedy for failure to disclose, or for inadequate/insufficient disclosure. These differences can broadly be divided into remedies within the patent system and remedies outside the patent system with no relationship to the validity of the patent.

The latter is the case in many of the European Union countries. For example, Act 41 of 2000 amending Denmark's Patent Act states that "[l]ack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent." This does not mean, though, that applicants are completely relieved of the obligation to disclose. Even in these countries, there remains a question as to whether an absence of disclosure is material to the three patentability criteria of novelty, inventive step and industrial application. In such cases, it would be important for ABS authorities to monitor patent applications in the pre-grant phase (i.e., when an application is published in the official gazette) and to provide comments to the IP office when appropriate. The national competent authority or other stakeholders contesting a patent application should bear in mind that the basic question is not whether ABS requirements of PIC and MAT have been met, but whether there is any prior art that could have an impact on the respective criteria of novelty and inventive step (see discussion of prior art above).

A second possibility is where disclosure of origin is a pre-condition for examination of patentability. A country that has adopted this approach is, for example, Switzerland. Switzerland basically stays the examination of patentability until the disclosure requirement is

[101] Henninger (2010), p. 300.
[102] For this purpose, the United States advocates the development of a database of genetic resources and associated TK, as an alternative to a disclosure requirement.

fulfilled. If the absence of disclosure is not cured, the patent office is empowered to reject the patent application (see Article 59a(3b) of the Patent Law of Switzerland (2007)).

A third possibility is for the provision of legal provenance (i.e., evidence of PIC and MAT, or other proof that the resources were obtained legally) to be a pre-requisite for the examination and granting of a patent. This type of requirement appears in the text of the biodiversity laws of some Latin American countries. For instance, in the Second Complementary Provision of Peru's Law 27811 on a Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (2002), "[w]here 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."

A fourth possibility is for the disclosure obligations to be enforced by administrative fines, and criminal sanctions in the case of wilful violations. Criminal sanctions can be limited to wrongful disclosure, but also include non-disclosure as a breach of duty. Article 81a of the Swiss Patent Law stipulates, for example, that "[w]hoever wilfully makes a wrongful declaration as referred to in Article 49a, shall be liable to a fine up to 100,000 Swiss Francs. The judge may order the publication of the ruling." Section 8b of Norway's Patent Law states in relevant part that "[b]reach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code Section 166."
Other possible enforcement mechanisms include termination or full or partial transfer of entitlements to apply for or own intellectual property; curable or incurable, temporary or permanent, full or partial unenforceability[103], revocation in the case of granted patents, narrowing of the subject matter; return or transfer of benefits received from intellectual property ownership; and enforcement of existing obligations to provide for equitable benefit-sharing.[104] The ability to impose these remedies may differ depending upon the discretion given to a country's adjudicatory authorities under domestic law.

For countries assessing proposals for an appropriate enforcement regime, there are a number of important points to bear in mind.

First, these variations can be combined – in the case of Switzerland, for instance, the criminal penalty is coupled with a mandatory obligation to disclose, but without prejudice to the examination of the patent on substantive grounds.

Second, while a number of countries, particularly in Latin America, have made disclosure of origin/source or legal provenance a prerequisite for the examination and grant of patent rights, it is arguable that this potentially adds a new condition to patent applications beyond the standard that is required under the TRIPS Agreement, which merely requires a disclosure "sufficiently clear and complete for the invention to be carried out by a person skilled in the art". Some governments have openly questioned whether such a requirement is TRIPS

[103] IP rights can be granted but not enforced. Under Sections 407-408 of the US Copyright Act (1976), for instance, registration of a copyright is required as a condition for lodging an infringement suit, but it does not affect the existence of the copyright as such.
[104] UNCTAD (2006), p. 59.

compliant."[105] While an amendment to the TRIPS Agreement for a universal disclosure of origin requirement could potentially settle the question of the compatibility of such requirements, to date the issue of a possible amendment remains in limbo at the TRIPS Council. It should be noted, however, that WIPO recognizes that disclosed information is potentially material, and the requirement to submit evidence of legal provenance imposed by a number of Latin American countries have not yet been challenged in any WTO dispute settlement panel.

Of note is the case of New Zealand, which practices an interesting and unique way of dealing with the TRIPS compatibility issue. Disclosure is not a substantive patent law criterion, but a claimed invention using Maori TK without PIC is considered to violate public morality under Section 17 of the 1953 Patents Act. The result is that "[i]f disclosure is required as a precondition to processing, then the patent application will suffer, as none of its substantive elements would have the chance to be examined."[106] Under Article 27(2) of the TRIPS Agreement, WTO Members may exclude from patentability inventions necessary to protect public order and morality in their respective jurisdictions.

Third, when designing appropriate enforcement mechanisms, it is important to leave an opportunity to cure defects in patent applications, particularly for inadvertent or non-wilful violations of disclosure obligations. A 2006 study commissioned by UNCTAD notes:

> "*Opportunities should be provided to rectify failures to disclosure required information . . ., in the absence of bad faith or a showing that any required inquiries were not performed. However, opportunities for redress should be more limited following the granting of the intellectual property.*"[107]

In particular, some thought will be needed in considering the appropriate action in the event that the claimant is truly unaware of origin or source when filing the patent application. The underlying assumption in this case is that origin/source issues are brought to the attention of the patent examiner during the application process, either through research by the examiner him/herself, or through comments received incident to publication of the application in the official gazette. The outcome of this situation is potentially different depending on whether or not there is a mandatory requirement to submit evidence of legal provenance. If there is no such requirement, the applicant could simply cure by amending the patent application and to disclose as appropriate (or forfeit the application if s/he does not disclose). If there is such a requirement the application would be 'frozen', and the question could be referred to the national competent authority or back to the patent applicant for obtaining proof of compliance with applicable ABS laws. It may very well be that depending upon the patent and ABS legislation in effect the applicant must negotiate and conclude a benefit sharing agreement in order to continue the patent application process.

Fourth, if a poor quality patent has been mistakenly granted, an interested party should have the opportunity to contest that patent. This makes it imperative that some form of post-grant review procedure be incorporated in the national patent legislation. The burden of proof would lie on the contesting party in such cases, however, as the assumption is that the moving

[105] See the US statement in WTO Document IP/C/W/162 of 29 October 1999.
[106] Henninger (2010), p. 301.
[107] UNCTAD (2006), p. 9.

party would have had the opportunity to raise the objection when the application was initially made public in the official gazette.

Finally, the imposition of criminal sanctions requires some proof of criminal intent, which is usually demonstrated by evidence of wilful fraud/lying on a patent application. Cases involving criminal sanctions will need to be tried by a court of law. The applicable standards for adjudication are usually set out in other laws requiring government filings such as tax returns to be completed honestly. Wilful violations may be difficult to establish, however, as applicants are likely to claim when they are confronted with a situation where s/he should have disclosed but did not, that they simply were unaware of the source and origin of the resources or related TK. On the other hand, if an applicant obtained a resource directly from a provider country under a contract, and the patent office or national competent authority becomes aware of that contract, it would be difficult for an applicant to argue that s/he was not aware of the source or origin of the genetic resource or related TK.

Key Points

⇒ Various means exist to enforce compliance with disclosure of origin rules. These can range from voluntary compliance to criminal sanctions, and may also include consequences when a patent is later found to have been mistakenly granted. These enforcement measures are not mutually exclusive.

⇒ A debate exists as to whether evidence of legal provenance as a pre-condition for filing a patent application is TRIPS-compliant. The issue has not been adjudicated before a WTO dispute resolution panel to date.

⇒ While some countries have made legal provenance a pre-requisite for the granting of a patent thus contributing to better compliance, as noted throughout the text, this is controversial.

⇒ As a matter of due process, enforcement measures need to be balanced. An opportunity to cure ought to be offered for inadvertent or non-wilful omissions that are brought to the attention of a patent examiner during the application process.

⇒ Post-grant opposition procedures need to be incorporated in the patent law in order to address the situation of mistakenly granted patents due to absence or incorrect disclosure.

⇒ Criminal sanctions should only be applied in the case of wilful violations; this may, however, be difficult to establish in the absence of strong, incriminating evidence.

IV. Disclosure and Ownership

Aside from providing a patent examiner with information related to assessing patentability criteria, disclosure requirements can help to determine whether an applicant has the standing to file a patent application. Typically, patent laws are set up to give to an inventor or his/her assignees the right to file an application for a patent over the inventor's claimed invention. If two or more persons have jointly made an invention, then patent laws will provide for the possibility of joint ownership.

One major distinction between IP and ABS laws is that, absent a corresponding clause that prohibits a patent application from being considered without evidence of legal provenance, legal or illegal physical possession of a GR or TK would generally have no effect on an inventor's ability to submit a patent application, since the patent application is addressing only the underlying intellectual endeavour. ABS laws address the issue of the legality of physical possession of the GR or TK. This can result in a dichotomy, however, where an invention, if a patent is granted over the intellectual endeavour, contains or is based on something that arguably is not his/hers and quite possibly used without permission. In such cases where possession of the underlying GR or TK was not legal, it would be for the national competent authority to ensure that some form of benefit sharing arrangement be worked out to comply with ABS legislation in order to remedy the situation.

If disclosure reveals that an invention is no different from the underlying TK, for instance, the application could fail on grounds that: 1) the claimed invention is not new; or 2) the applicant had no right to apply for the patent and was trying to pass off someone else's technology as his or her own. The latter case may also open up the possibility to pursue criminal sanctions, and a functioning law to protect TK and accurate information contained in TK databases will help in establishing this argument. The mere existence of a disclosure of origin/source requirement in the patent law will likely deter these situations, though, and it can be predicted that attempts will generally be made by applicants to show that the claimed invention builds on the TK. In such case, the question for the patent office becomes one of simply assessing novelty and inventive step (i.e., is the claimed invention truly different from the existing TK, and if so, how?).

If evidence of legal provenance is required by national legislation, disclosure may also reveal that the inventor had agreed to share in the ownership of the claimed invention. In such cases, the patent examiner would need to request that the application be amended to reflect joint ownership, if this had not already been done. Proof of legal provenance simply means that ABS requirements have been met, and may not necessarily be relevant to ownership of the invention. Thus, if evidence of legal provenance shows that the inventor must share the benefits of an invention, but makes no mention of joint ownership as such (for example, a proportion of any stream of royalties) the applicant would still be free to proceed with the application as the sole inventor. The Annex to the Nagoya Protocol stipulates numerous ways in which benefits may be shared, so if a valid ABS arrangement does not specifically stipulate joint ownership of inventions arising from the resource or related TK, then it would probably be fair to require any party claiming joint ownership to prove otherwise.

The more difficult case will be where it is not entirely clear whether an applicant is a joint owner. This could happen, for example, where the underlying resource being used by the applicant was received from a party other than the original provider, and there is no corresponding legal text on ownership in the documentation under which the resource was provided to the applicant (but a clause on ownership may exist between the original provider and the first recipient); or where a resource can be claimed as not being within the ambit of ABS legislation, for instance because the transfer of the resource pre-dates the ABS law or the CBD. In these cases, there may be no indication of how ownership is to be treated, and patent offices especially in the developing countries are usually not trained to address such issues. It is suggested that in such cases, the question be referred by the patent office to the ABS national competent authority for advice.

Independent of disclosure, a final scenario in which ownership may be disputed is the case where two or more persons claim to have made the same invention. In such cases, the outcome may differ in jurisdictions following a *first-to-file* approach and for jurisdictions following a *first-to-invent* approach in patent applications. Under a first-to-file approach, the right to apply is conferred upon the person whose application has the earliest filing date or, if priority [108] is claimed, the earliest validly claimed priority date. Under a first-to-invent approach, the right to apply is conferred upon the first person to conceive and diligently reduce to practice an invention. Most countries follow a first-to-file approach, including the United States, which recently changed from a first-to-invent to a first-to-file approach in 2013 with the passage on 16 September 2011 of the Leahy-Smith America Invents Act.

Key Points

⇒ Disclosure of origin requirements may help in clarifying who has the standing to file a patent application.

⇒ ABS agreements may stipulate that any inventions resulting from transferred genetic resources or associated TK be jointly owned. It follows that patent applications ought to reflect this relationship, where stipulated.

⇒ In the absence of a clear indication as to joint ownership, however, it may be difficult to establish that an application should be filed jointly. The Annex to the Nagoya Protocol enumerates a number of ways in which benefits could potentially be shared, other than joint ownership.

⇒ Most jurisdictions follow a first-to-file rule in the event that two or more persons claim to have made the same invention.

V. Temporal Scope of the Protocol and Disclosure

In Chapter 1, the issue of pre-CBD and pre-Nagoya transfers was addressed, where resources in the possession of a user may have been obtained legally, notwithstanding an absence of PIC and MAT, or of benefit sharing. It was mentioned that patent law operates independently of ABS law, so disclosure of origin/source could not only act as a check on patent applications over inventions that utilize genetic resources that are clearly covered by Nagoya-compliant ABS legislation, but it can also help check patent applications for the utilization of genetic resources that are, by virtue of having been pre-Nagoya/pre-CBD, not clearly within the scope of the Protocol. Indeed, it is difficult to see how an ABS law that subjects new applications of pre-Nagoya/pre-CBD acquisitions would function without a commensurate patent law disclosure requirement that necessitates making public the origin of the genetic resource utilized.

While a requirement to apply ABS principles to new applications containing accessed genetic resources that pre-date the Protocol and the CBD (as mentioned in Chapter 1), as well as to require disclosure of origin/source in national patent law are important measures that will help to ensure that benefits are shared with provider countries in the absence of earlier PIC and

[108] A priority right permits an applicant to file subsequent applications in other jurisdictions based on the date of filing the first application.

MAT, it should be kept in mind that these measures will not act as a complete barrier against misappropriation. This is because there is no guarantee that user country legislation will similarly require disclosure of origin and benefit sharing for new applications involving the utilization of genetic resources previously acquired unless Article 29 of the TRIPS Agreement were to be amended to require mandatory disclosure.

Key Points

⇒ ABS legislation can in provider countries stipulate that it should apply to new applications utilizing genetic resources acquired before Nagoya-compliant ABS legislation took effect (i.e., pre-Nagoya/pre-CBD). A mandatory disclosure of origin requirement in the patent law, and in the plant breeder's right law as well, will help to expose those situations where such genetic resources are being used.

⇒ IP law operates independent from ABS law, as there was no intent to ensure coordination between these two regimes under the Protocol. It therefore does not matter that the patent law extends disclosure of origin to new applications using genetic resources transferred pre-Nagoya Protocol or pre-CBD, which are arguably not covered by these treaties.

⇒ Mandatory disclosure and subjecting new uses to ABS requirements is not an absolute check on misappropriation, as not all such uses will be the subject of patent applications, and there is no guarantee that user country legislation will incorporate similar requirements.

VI. Measures to Help Prevent Bio-Piracy Abroad

Up to now, this chapter has dealt with the disclosure function in relation to domestic patent applications, mainly in provider countries. This is because, to a large extent, stakeholders in the provider country will only have direct influence over domestic legislation, and can only wield indirect influence over policy decisions adopted by other countries. Some IP offices have been more pro-active in preventing biopiracy and misappropriation, however. They have been providing information that helps other jurisdictions to determine patentability where there is a question of prior art (whether or not this was part of the disclosure).

Box 10
The Recent Experience of the National Commission against Biopiracy of Peru (NCAB)

The NCAB was created in 2004 as an interagency coordination and technical advisory body that directly reports to the Presidency of the Republic. The Commission is Chaired by INDECOPI (the National Institute for the Defence of Competition and Protection of Intellectual Property) and is composed of several public agencies (e.g. environment, health, agriculture and tourism authorities), domestic research centres and non-governmental organizations (NGOs). The mission of the NCAB is to develop actions to identify, prevent, and avoid potential cases of "biopiracy" with the objective of protecting the interest of the Peruvian State. Among its functions are:

- Creating and maintaining registers on biological resources originated in Peru as well of collective

knowledge of Peruvian indigenous peoples;

- Identifying, assessing and following up on patent applications filed abroad that have utilised Peruvian genetic resources or associated TK;
- Initiating legal actions for the defence of Peruvian genetic patrimony and the TK of indigenous people, including within the IP system;
- Establishing channels of contact and dialogue with IP offices abroad on these matters;
- Undertaking consultations with all relevant stakeholders; and
- Supporting the Peruvian State in multilateral negotiations.

Recently, the NCAB is also focusing on the simplification and review of ABS regulations.

The NCAB has prioritised 35 Peruvian biological resources of significant utility and potential value. It has prepared dossiers on these resources and sent various studies on potential cases of "biopiracy" and prior art to IP relevant offices in third countries. It has also provided contributions on the matter to the IGC. So far the NCAB has contributed to decisions to reject, abandon or withdraw 9 controversial patents utilizing Peruvian GRs and associated TK. Below is the list of controversial patents rejected, retired or abandoned for which the NCAB provided dossiers. In these cases, without the action of the NCAB, these patents would likely have been granted, feeding the list of actual cases of "biopiracy" and potentially "misappropriation".

Resource	**Patent or patent application**	**IP office**	**Status**
Maca	Compositions and methods for their preparation from Lepidium (WO 0051548)	PCT	Rejected
Maca	Functional Food Product Containing Maca (Publicación N° 2004-000171)	Japan	Rejected
Maca	Ameliorant for sleep disturbance (JP2007031371)	Japan	Rejected
Maca	The manufacturing method and composition of a maca extract (Kr20070073663)	Korea	Rejected
Maca	Testosterona increasing composition (jp2005306754)	Japan	Rejected
Sacha inchi	An extract of a plant belonging to the genus Plukenetia volubilis and its cosmetic use. (WO/2006/048158)	PCT	Retired
Sacha inchi	Utilisation d'huile et de protéines extraites de graines de Plukenetia volubilis linneo dans des préparations cosmétiques, dermatologiques et nutraceutiques. (FR 2880278)	France	Retired
Camu camu	Preserves of fruit of Myrciaria dubia (Publicación N° 09 – 215475)	Japan	Abandoned

Pasuchaca	Inhibitor of glycosidase (P2005-200389[a])	Japan	Abandoned

Sources: compiled by David Vivas Eugui (2011). Information taken from NCAB web site, official documents of the NCAB (2011) and interviews with governmental officials.[109] Reproduced with permission.

This is the case in Peru, where the IP office chairs a commission charged with developing dossiers that are made available to patent offices in other countries, to assist them in conducting a thorough examination of patent applications that contain genetic resources and related TK. The activities of Peru's National Commission against biopiracy are summarized in the box above.

It is noteworthy that the Peruvian patent office took the lead in this exercise, since the patent examiners were best situated to compile dossiers that help other IP offices make an assessment of whether a claimed invention is patentable, and because the IP offices usually have the best contacts with other IP offices abroad. The practice of identifying resources of significant utility and creating dossiers is a systematic way of helping user countries comply with due diligence and their own disclosure requirements.

Another example of a pro-active approach to defence is India's database of TK, the contents of which are shared with patent offices in developed countries. Some commentators have pointed out limitations to such a database, however, which may, *inter alia*, actually limit a patent examiner's ability to find out the state of prior art.[110]

Key Points

⇒ Some countries proactively develop strategies to assist user countries in the assessment of patent applications that contain domestically-sourced genetic resources or associated TK.

⇒ The example of Peru shows that the IP office is ideally situated to take the lead in a coordinated effort among local stakeholders to develop dossiers on identified priority biological resources. This could be taken as a best practice example for purposes of this handbook.

VII. Conclusion

[109] Vivas Eugui (2010), pp. 50-51.

[110] See comment of N S Gopalakrishnan at the 19th Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, contained in document WIPO/GRTKF/IC/19/7 of 20 May 2011, para. 8. According to Gopalakrishnan, "*[d]atabases put limitations in finding out the prior art, as understood by the patent system, and for determining inventive step, because of the science involved in TK, on the one side, and the science involved in modern knowledge, on the other side. Typically, a modern patent application was drafted using modern scientific techniques and scientific language, which involved largely the genetic analysis of the components of the GR associated with TK. On the other hand, typical TK documents in the database had not been documented using modern science language, but using the language of the science of TK. If a comparison was made between patent applications and TK, a tremendous difference between those two would be found. That put tremendous limitations on the patent examiner to determine prior art. He would conclude that what had been disclosed was different from what had been disclosed in the patent application form, unless there was an attempt to merge and understand the science of TK and modern scientific principles*".

Disclosure constitutes one of the important pillars of the social contract underlying patents – i.e., that the technology of an invention must be sufficiently disclosed if an inventor or his/her assignees seeks to obtain exclusive rights over that invention for a limited period of time. Depending upon what is required to be disclosed under the national patent law, the disclosure system can potentially help efforts to combat misappropriation and 'biopiracy', by flagging potential cases to the national competent authority when patent applications are published in the official gazette.

Variations exist on the extent of disclosure required. Beyond the TRIPS minimum, which says nothing itself about disclosure of origin/source when genetic resources or associated TK are utilized in an invention, countries may require disclosure of origin and/or source, or they may require applicants to provide evidence of compliance with ABS laws. The Nagoya Protocol neither makes disclosure of origin/source nor proof of legal providence mandatory. Controversy exists whether some formulations of disclosure text add a new substantive element to patentability under the TRIPS Agreement. Disclosure of origin/source may nonetheless be used by patent examiners to assess novelty and inventive step.

The value of information that the disclosure system may generate is vast. While an IP office may be designated as a checkpoint under the Nagoya Protocol, it should be borne in mind that patent offices were never set up to police ABS laws.