

United Nations Conference on Trade and Development

**The Convention on Biological Diversity
and the Nagoya Protocol:
Intellectual Property Implications**

A Handbook on the Interface between Global Access and Benefit
Sharing Rules and Intellectual Property

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The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property

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Note

This publication has been developed as a handbook aimed at better understanding the intellectual property implications of the 1992 Convention on Biological Diversity and the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. When used as a textbook, it can be adapted to courses of various formats, including lectures, distance learning and blended learning.

The German Federal Ministry for Economic Cooperation and Development (BMZ) commissioned the United Nations Conference on Trade and Development (UNCTAD) to develop this handbook in cooperation with German International Cooperation (GIZ). UNCTAD is mandated to undertake research and analysis on trade and development aspects of intellectual property, including on the protection of traditional knowledge, genetic resources and folklore and fair and equitable sharing (paragraph 105 of the Accra Accord (2008) and paragraph 65(j) of the Doha Mandate (2012)). UNCTAD's work is carried out through intergovernmental deliberations, research and analyses, technical assistance activities, seminars, workshops and conferences.

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Table of Abbreviations

ABS	Access and benefit sharing
ACP countries	African, Caribbean and Pacific countries
AIDS	Acquired immune deficiency syndrome
ASEAN	Association of Southeast Asian Nations
BRDR	Biodiversity-related disclosure requirements
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties
EIA	Environmental Impact Assessment
EC	European Community
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization
GB	Governing body of a geographical indication
GIs	Geographical indications
HIV	Human immunodeficiency virus
ICTSD	International Centre for Trade and Sustainable Development
IGC	Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore
ILCs	Indigenous and local communities),
INDECOPI	National Institute for the Defense of Competition and Protection of Intellectual Property of Peru
IP	Intellectual property
IPRs	Intellectual property rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for the Conservation of Nature
LDC	Least Developed Country
LMO	Living modified organism
MAT	Mutually agreed terms
MTA	Material transfer agreement
NCAB	National Commission against Biopiracy of Peru
NGO	Non-Governmental organizations
PBR	Plant breeders' rights
PCT	Patent Cooperation Treaty
PDO	Protected denominations of origin
PGI	Protected geographical indications
PIC	Prior informed consent
R&D	Research and development
SMTA	Standard material transfer agreement
TCE	Traditional cultural expressions
TK	Traditional knowledge
TRIPS Agreement	The Agreement on Trade-related Aspects of Intellectual Property Rights
UK	United Kingdom
UNCCD	United Nations Convention to Combat Desertification
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
UNDRIP	United Nations Declaration on the Rights of Indigenous People

UNU-IAS	United Nations University Institute for Advanced Studies
UPOV	International Union for the Protection of New Varieties of Plants
US	United States of America
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Introduction

The conservation of biological diversity (hereafter biodiversity)¹ and the ability to continue to use biological resources sustainably are amongst the most pressing issues that the world currently faces. Balancing the protection of ecosystems, which involve a plethora of animal, plant and microbial species, with sustainable development objectives demands a systematic response at the international, regional, national and sub-national levels by a myriad of actors. The effective preservation of biodiversity cannot be met through environmental protection laws alone. A critical problem is one of incoherence – i.e., the situation where laws, policies and regulations designed to protect biodiversity and to encourage its sustainable use and development are not established in a consistent and mutually supportive manner with laws, policies and regulations in other domains, such as industrial policy or intellectual property (IP), that have an impact on biodiversity.

In order to address the linkage between biodiversity conservation and its sustainable use, the Convention on Biological Diversity (CBD) introduced as one of its three objectives the fair and equitable sharing of the benefits arising out of the utilization of genetic resources with those providing such resources. The inclusion of access and benefit sharing (ABS) as an objective of the CBD was based on the premise that biodiversity has been used by public institutions and private entities to produce new knowledge and products that brought various benefits to its new users, but not necessarily for its original owners or custodians. It is the ABS aspect that entails the greatest interface between IP rights and biodiversity issues.

Clear, fair and equitable rules on ABS are critical to prevent the misappropriation of genetic resources and associated traditional knowledge (TK), a situation also sometimes referred to as ‘biopiracy’. Narrowly defined, misappropriation refers to access to and use of genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and applicable international rules on access and benefit sharing.² One means by which genetic resources can be misappropriated utilizing the IP system is when, for example, a company sources biological resources from a country without consent, utilizes that resource in R&D to develop an invention, and then attempts to patent that invention utilizing the resource without any benefits to the provider, or without mentioning where the resource was obtained. Civil society organizations have cited as an example of misappropriation the attempted patenting of products by a Swiss company that contained rooibos and honeybush, as described in the box below.

¹ According to Article 2 of the CBD, ‘Biodiversity/Biological Diversity’ consists of the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic systems and the ecological complexes of which they are part; this includes diversity within species (genetic), between species and ecosystems. Biodiversity is a term describing variability, whereas ‘ecosystem’ describes a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

² This view is based on the definition proposed by Switzerland for WG-ABS 9 on 18 February 2010 regarding the need for definitions in the lead up to COP 10 at Nagoya, Japan.

Box 1

Patent Applications on Rooibos Products

Nestlé, the world's largest food company, [faced] allegations of biopiracy after it applied for patents involving two plants found in South Africa without having negotiated permission to use them with the South African government.

In what they have dubbed the “rooibos robbery,” the Berne Declaration, a Swiss advocacy organisation, and Natural Justice, a South African environmental group, [accused] Nestlé of having violated South African law and the Convention of Biological Diversity (CBD).

At issue are two plants found in South Africa, rooibos and honeybush, both of which are commonly used to make herbal teas. Nestec, a Nestlé subsidiary, filed four international patent applications for using the plants or extracts from them to treat hair and skin conditions such as acne, wrinkles, and hair loss. A fifth application sought patent protection for using rooibos as an anti-inflammatory. It is seeking patent protection in a large number of countries around the world, including South Africa.

Benefit-sharing a key issue

According to Natural Justice and the Berne Declaration, the South African Biodiversity Act — the country's implementing legislation for the CBD - requires companies to get a permit from the government if they intend to use South African genetic resources for research or patenting. These permits can only be obtained with a benefit-sharing agreement.

In a press release, Natural Justice and the Berne Declaration said that South Africa's department of environmental affairs told them that Nestlé never received permits to use rooibos and honeybush.

“Based on the information provided,” the groups said, “it is clear the patents of Nestlé and the research on which they are based are in contradiction with South African law and the CBD.”

Although best known for food product brands such as Nescafe, Nespresso, and Gerber, Nestle is active in the cosmetic industry. It owns over a quarter of l'Oréal, the world's largest cosmetics firm; the two companies together own Laboratoires Innéov, a nutritional cosmetics venture.

“Nestlé builds its new business on illegally accessed material, precluding South Africa of their rightful share of benefits. Such illegal behaviour must no longer be supported by the patent system and tolerated by our governments,” said François Meienberg of the Berne Declaration.

Plants not sourced in South Africa, Nestlé says

Nestlé ... rejected the accusations. According to a report in the South African newspaper Business Day, company spokesman Ravi Pillay said that Nestlé had neither sourced the plants in South Africa nor done research on them there. South African suppliers had provided rooibos and honeybush extracts and material to two Nestlé research facilities in Switzerland and France, which then used it for basic research on active ingredients.

Following this research, he said, Nestec filed several patents to protect its research results, which showed potential benefits for consumers.³ “Nestec has not filed any patent relating to the plants themselves, or extracts of the plants. Nestlé has not made any commercial use of these patents, and has no plans to do so in the near future,” he added.

Pillay said that if Nestlé decided to use the patents commercially, it would comply fully with the benefit-sharing provisions in South African law.

However, Johanna von Braun of Natural Justice in Cape Town said that, under South African law, the commercial phase of bioprospecting begins once a patent application has been filed. At this early

³ Note by the authors: these patent applications later failed pre-examination by the World Intellectual Property Organization (WIPO).

phase, a permit - which would include a benefit sharing agreement and a material transfer agreement - has to have been submitted regardless of where the research takes place, she said.

Von Braun said that the companies that supplied the rooibos and honeybush to Nestlé had also not secured permits.

International law unclear on “ex-situ” resources

There is a lacuna in international patent law about who owns genetic resources once they have been removed from their country of origin. The Convention on Biological Diversity clearly specifies that genetic resources are under national sovereignty. But it is less clear about Nestlé’s responsibilities vis-à-vis genetic resources from another continent supplied to it in Europe.

South African law, however, is quite clear: it specifies that all indigenous biological resources are those historically from South Africa.

The terms under which the South African suppliers provided the plants to Nestlé mattered, von Braun explained. “If they’re exporting rooibos to make tea, they don’t need a permit. But if they were going to be used for research, the suppliers would have needed an export permit including a bioprospecting application from Nestlé.”

Since 2002, parties to the Convention on Biological Diversity have been negotiating an international regime on access and benefit sharing. This would create firmer rules about the use of genetic resources, including so-called “ex situ” resources that are no longer in their country of origin.

“The Nestlé case highlights the urgent need of a new protocol that prevents the misappropriation of genetic resources and associated traditional knowledge,” said Kabir Bavikatte from Natural Justice. “Only a strong protocol will protect developing countries from an unlawful exploitation by companies.”

Source: Reproduced with permission from International Centre for Trade and Sustainable Development (ICTSD), originally published in *Bridges Trade Biores*, Vol. 10, No. 10, 31 May 2010.

As misappropriation of genetic resources is not a defined legal term, however, it is possible to define misappropriation of genetic resources and associated TK more broadly. Aside from compliance with ABS legislation, misappropriation through the IP system could also potentially occur when a firm or person in a user country attempts to obtain exclusive rights over proprietary names associated with a genetic resource or related TK to the exclusion of its providers, without his or her consent. The effect of allowing such marks to be registered would be to allow the registrants to take advantage of the goodwill represented by the mark without attribution or compensation to the providers. One example often cited in academic literature are the attempts by coffee bean distributors in developed countries to obtain global trade name rights to various Ethiopian coffees such as *Sidamo*, notwithstanding that those local communities had obtained geographical indication rights to the coffees grown in their respective regions. In this regard, Robinson has suggested a typology of problematic activities, which include patent-based biopiracy and non-patent based biopiracy and misappropriation.⁴

At present, it may not be possible to quantify the extent of misappropriation of genetic resources and associated TK as many of the underlying contracts to transfer genetic resources remain private and confidential. The new ABS regime, discussed herein, whereby information on when resources have been accessed with permission based on mutually agreed terms would be registered nationally and internationally, will hopefully go some way to address this

⁴ Robinson (2010).

information deficiency. Nonetheless, various sources have documented examples of potential misappropriation, and the problem remains one of concern particularly to provider countries.⁵

The contentiousness of the negotiations at Nagoya in the fall of 2010, which set up the treaty laying down international rules on ABS under the CBD (the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, hereafter the Nagoya Protocol) is perhaps a reflection of the difficulty in reaching agreement at the multilateral level in this day and age. Divisive issues were routinely excluded from the final text in search of a wording that is minimally acceptable to all of the negotiating parties. The result is far from satisfactory for most stakeholders. One could possibly conclude that it was a miracle that an agreement was reached that contained at least some definitive rules on ABS of genetic resources and associated TK, even though many important issues were left out of the final text. To be fair, no treaty can be expected to cover all aspects of a topic, and there will always be gaps where additional work is needed to examine how different legal regimes need to be configured to work in synergy, rather than in conflict.

This handbook is thus designed as one means to begin to fill the gap in understanding where the treaty text has chosen to remain silent. *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications* addresses how the global rules on ABS of genetic resources and associated TK should work in tandem with an area that is mentioned minimally in the 2010 Nagoya Protocol, i.e., IP. Specifically, this handbook is designed to show the complexity of relevant IP policies that have an impact on various aspects of the CBD and the Protocol, particularly from the provider country perspective. It is all too easy and simplistic to see IP as a stream of cash rents that derive from certain granted exclusive rights that could potentially be shared as benefits. Our view of IP is necessarily much broader, examining when it is (and when it is not) appropriate to grant such rights, how the application process can generate important information that could assist in the implementation of the ABS rules, when such rights are subject to important exceptions and limitations on policy grounds, and when traditional IP instruments such as patents may not make much sense for protecting certain intellectual or creative endeavors.

Chapter 1 starts with an overview of the ABS system as established by the CBD and the Nagoya Protocol, highlighting the obligations of countries and the international community to put in place national ABS legislation and the administrative machinery to ensure that countries meet their treaty obligations. Because of an absence of clarity in these two treaties on many important issues, however, it is necessary to look to other sources of law to fully understand the relationship between IP and ABS. Chapter 2 therefore follows with a complementary examination of various other treaties and policies that govern and shape the rules on IP and ABS. Particular emphasis is given to an examination of IP treaties such as the TRIPS Agreement, which gives some minimum measure of uniformity among the signatories' respective legislation on IP. As seen in the later chapters, though, the language contained in both the CBD/Nagoya Protocol and the TRIPS Agreement is the result of political negotiations and therefore leaves a good deal of 'policy space' or 'flexibility' for countries to tailor their national legislation so as to support important policy objectives, including when read in conjunction with important international policy statements such as the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).

⁵ See Vivas-Eugui (2012), Box 1 for some well-known examples.

An area where there is clearly potential for the IP regime to support the ABS regime is disclosure (Chapter 3). Patent applicants must disclose material information when they seek to obtain exclusive rights over a technology. This could potentially include the country of origin of genetic resources or associated TK contained in an invention, whether the invention is a product or process. The idea behind this is to make transparent and subject to public scrutiny whether ABS obligations have been met and to ease the identification of potential cases of misappropriation at the point of time someone applies for a patent. While disclosure has to date been discussed in the lead up to the Nagoya Protocol negotiations, at the TRIPS Council and at the World Intellectual Property Organization (WIPO), no intergovernmental body has to date mandated disclosure of origin or source when applying for a patent as an international legal obligation, and there has been no dispute settlement case at the World Trade Organization (WTO) that tests the limits of a disclosure requirement. From the perspective of a provider country, the weakness of disclosure of origin/source requirements in the absence of an international requirement to include them in national legislation is that while a provider country could require disclosure, there is no guarantee that user countries would similarly require disclosure.

There are a number of different ways in which disclosure of origin can be woven into a patent law. This could include, for example, requiring proof of legal provenance to simply assuming that disclosure of origin is required under a generic obligation to disclose material information relevant to the patent application, without specific reference to the origin or source of genetic resources and associated TK. A disclosure requirement could similarly be woven into plant variety protection legislation, provided a country is are not under any treaty obligation to refrain from doing so.

Beyond disclosure of origin, chapter 4 examines a wide range of IP tools that could potentially be harnessed to support the CBD/Nagoya rules on ABS. One set of measures are those that can keep certain genetic resources from being patented, i.e., excluding discoveries, gene sequences, pathogens and naturally occurring biochemical compounds from the scope of patentability. Another set of measures deals with protecting certain activities from liability notwithstanding the existence of a patent so as not to impede innovation, or for other good policy reasons as in the research and experimentation exception (and its variant in plant variety protection laws) and the medical treatment exception. A final set of measures include theories to invalidate a wrongly granted IP right, including the judicial doctrine of ‘clean hands’ and violations of public morality and order, among other theories. Chapter 4 makes clear, however, that the law in many of these areas is still very much developing. For example, New Zealand’s proposed approach of treating patent applications that contain Maori TK as presumptively a violation of public morality has yet to be tested and the issue of the patenting of gene sequences was recently considered by the Supreme Court of the United States.⁶

Chapters 5 and 6 of this handbook deal with two aspects of IP law that could potentially support the ABS system in so far as they are designed to create rights for local and indigenous communities in provider countries that use genetic resources in their daily life, and associated TK. A number of countries have passed legislation that gives rights to indigenous and local communities (ILCs) over their TK and traditional cultural expressions (TCEs). Such *sui*

⁶ *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* (Case No. 12-398, slip op, decided by the Supreme Court of the United States on 13 June 2013).

generis legislation is often necessary because Western notions of IP law such as patents and plant variety protection are not always an effective vehicle to provide the local community with proprietary rights. While there are many policy goals that are pursued by such a *sui generis* regime, these laws are designed to be both defensive and offensive from a provider country perspective, i.e., so that the TK/TCE is not misappropriated, but also to give the local and indigenous community a chance to exploit the TK/TCE to secure benefits in the event that the TK/TCE can be commercialized. The scope of such laws can potentially cover practices such as farming techniques and traditional medicine. Chapter 5 highlights that these laws, in particular, need to be interpreted in the context of international human rights instruments that recognize the various customary rights of indigenous peoples. Most of these laws are relatively new, however, and it could very well be said that many countries are still struggling to define the contours of a law that would grant to ILCs a set of enforceable and exploitable rights.

Chapter 6 examines the power that distinctive signs can have to help secure benefits for biodiversity derived products from provider countries and how they can help protect TK. Distinctive signs cover a range of IP instruments including trademarks, collective trademarks, protected geographical indications (PGIs), protected denominations of origin (PDOs) and certification marks (see Table 2, Chapter 6). The broad objective behind these tools is to communicate certain information to a potential buyer of a product to which a distinctive sign is affixed. To the extent that the sign adds value to the product upon which it is affixed, the sign or mark can be used to secure benefits. In the case of PGIs and PDOs, the mark certifies quality and originality linked to a specific location. Certification marks indicate to a consumer that certain procedural and quality standards are met. While trademarks are simple indications of distinctiveness that a trademark holder may affix on a product for which that mark is registered, collective trademarks, which are privately owned by a group of proprietors, are potentially useful when certain practices are not able to be defined by geography as in the case of PGIs and PDOs.

The Chapter also points out the difficulties of managing and maintaining these distinctive marks. Such difficulties include determining the geographical coverage and the standards that must be met in order to be able to use a sign, how to maintain the quality that the sign stands for and how to enforce the signs abroad in order to prevent misappropriation. The rural populations of provider developing countries and ILCs are often ill prepared and under-resourced to be able to effectively manage the systems that govern certain distinctive signs. A final remark on signs from the perspective of the CBD is that to the extent that the signs are promoting the consumption of resources abroad, there is a need to be conscious about how mass consumption may affect sustainable practices.

Finally, Chapter 7 looks at how ABS and IP laws are reflected in private contracts which cover the physical transfer of genetic resources. Such private contracts are referred to in the CBD and Protocol as benefit-sharing agreements, and can take the shape of material transfer agreements (MTAs), collaborative research agreements, bioprospecting agreements and the like. The handbook starts by explaining the difference between MTAs over genetic resources and contracts where physical transfer of a private object confers a complete transfer of ownership. To the extent that genetic resources are subject to the sovereign jurisdiction of the provider country, the agreement is one that merely permits access to the resource and governs the provisions on what the transferee may do with the genetic resource.

In contract negotiations, issues that could potentially be difficult to ascertain are, *inter alia*, who the owners of a genetic resource are when local and indigenous communities are involved, the description of the genetic resource being transferred, what research is permitted with the resource and how to handle IP applications from the fruits of that research, what benefits will be shared, whether third party transfers will be permitted and what happens to the resource after the voluntary or involuntary termination of the agreement. Effective negotiation takes practice and an understanding of the underlying laws and principles. ABS authorities in provider developing countries and local and indigenous groups may be at a disadvantage in effectively negotiating contract terms with the lawyers representing biotechnology, cosmetic and pharmaceutical firms based in developed countries.

If there is an overall message that carries through all seven chapters of this handbook, it is that many, if not most, of these areas are as yet developing areas of law and policy. As such, countries are very much experimenting with various models of IP protection and ABS. For example, Switzerland's disclosure regime differs significantly from disclosure in the Andean countries; many countries are only just beginning to introduce *sui generis* regimes for geographical indications; and judicial interpretation of laws on the patenting of gene sequences in the developed countries has rarely been consistent. The example of *sui generis* laws on TK and TCEs shows that no country has yet come up with an optimum model law that works satisfactorily.

It is therefore far too early to be talking about 'best practices'. The slow pace of progress at intergovernmental negotiation forums discussing the relationship between IP and ABS is perhaps a reflection that the interface has not yet reached a level of maturity where additional global consensus for regulation would be 'ripe'. There is, however, much to learn from each country's experience in implementing IP and ABS legislation, as well as other flanking legislation such as those governing ILCs, in a manner that is mutually supportive. For this reason, the handbook cites as many examples of existing policies as possible. Moreover, the TRIPS Agreement and the CBD/Nagoya Protocol provide ample room for policy makers to experiment and to revise their national legislation as necessary, given each country's unique circumstances.

Chapter 1

The International Framework for Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge

I. Introduction

The focus of this handbook is legislation at the international level (treaties) and how that affects national policymaking and legislation mainly from the perspective of the provider countries. In this regard, treaties are agreements that have been negotiated between States, stipulating the terms, conditions, rights and obligations which the signatories must abide by. They may be bilateral, meaning that the agreement binds two States, or multilateral, meaning that the agreement binds more than two States. Multilateral treaties may cover a region (the European Union (EU)) or a sub-region (the Mekong countries); they may be between regions (EU-African, Caribbean and Pacific (ACP) countries) or global in scope (the Patent Cooperation Treaty, the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement)). A number of formalities may be needed for a treaty to become effective, including, for example, ratification. In many cases, treaty provisions will need to be implemented through national legislation, which may call for either establishing new laws or changing existing ones to fully comply with a treaty. Finally, established treaties may be amended or be further elaborated by means of additional or supplementary treaties such as protocols. This chapter examines the multilateral treaty framework for access and benefit sharing (ABS) of genetic resources and associated traditional knowledge (TK).

II. The Global Framework for Access and Benefit Sharing

The starting point for understanding the existing international framework for ABS of genetic resources and associated TK is the Convention on Biological Diversity (CBD). The CBD is one of the multilateral treaties that opened for signature at the 1992 United Nations Conference on Environment and Development in Rio de Janeiro, Brazil (hereafter the Earth Summit or UNCED). To date, the CBD has been ratified by 193 parties, making it nearly universal. Of the major user countries, the United States of America remains a non-party (and consequently not bound by its provisions), despite having signed the treaty in 1993. The treaty entered into force on 29 December 1993, and has three objectives, namely:

1. the conservation of biological diversity;
2. the sustainable use of the components of biological diversity⁷; and
3. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Parties to the CBD have nominated national focal points, which act as the designated person representing a Party on all matters related to the Convention.

⁷ Sustainable use – the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations (Article 2, CBD).

The CBD contains a large number of obligations which its signatories must abide by, including requirements for general conservation measures, *in situ* and *ex situ* conservation, incentives, and a range of other topics.⁸ The substantive provisions agreed to in the CBD with respect to the fair and equitable sharing of benefits arising out of the utilization of genetic resources⁹ is found in Articles 15, 16 and 19 of the treaty, which are reproduced in Box 2 below.

Box 2
CBD Provisions on Access and Equitable Sharing of Benefits

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic

⁸ *In Situ* – conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties (Article 2, CBD). *Ex-situ* – conditions where genetic resources exist outside their natural habitats, such as botanic gardens, zoological garden and gene banks (Article 2, CBD).

⁹ The CBD and other international instruments utilize closely related descriptions of ‘genetic material’, ‘genetic resources’ and ‘biological resources.’ According to the CBD, genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD). With respect to plant genetic material, the term is defined to include any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity (Article 2, The International Treaty on Plant Genetic Resources for Food and Agriculture). As a result, genetic material is a description of the subject matter without reference to human use. ‘Biological resources’ under Article 2 of the CBD are defined as genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems *with actual or potential use or value for humanity*. With this definition, the actual or potential use by humans defines the subject matter. Biological resources include genetic resources and microorganisms. Genetic resources are genetic materials of actual or potential value (Article 2, CBD). The scientific concept of micro-organism refers to a ‘member of one of the following classes: bacteria, fungi, algae, protozoa or viruses’ (UNCTAD-ICTSD (2005), p. 392). Plant genetic resources refer to the economic, scientific or societal value of the heritable materials contained within and among species (FAO, p. 33). From a legal perspective, therefore, the ‘actual or potential value’ differentiates genetic resources, microorganisms and other biological resources from simple genetic material.

resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Source: The Convention on Biological Diversity (1992).

At the national level, the implementation of the ABS provisions, as called for under Articles 15, 16, and 19 of the CBD, have generally been slow since its entry into force in December 1993. The continuing lack of "user measures" that implement the benefit sharing obligations of CBD Parties, as well as support for user compliance with ABS legislation in provider countries and negotiated MAT conditions have been highlighted as persistent problems. Of those countries that have ABS legislation, few contain substantial provisions on "user measures" while practically all address access issues. While several biodiversity-rich countries developed access-oriented policies and legislation, the lack of corresponding benefit-sharing policies and legislation in industrialized countries since the coming into force of the CBD turned into a bone of contention and finally resulted in the call of the 2002 World Summit on Sustainable Development to negotiate an "international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources", providing the mandate to begin the long and arduous process that led to the adoption of the Nagoya Protocol in 2010.¹⁰ There is still much work to be done even on the provider side as well. According to the multi-donor ABS Development Capacity Building Initiative, only 6 of the 54 African countries had developed ABS legislation as of 2011.¹¹

Two protocols have been adopted under the CBD to date, further elaborating the obligations of its signatories on specific issues. As called for under Article 19(3), the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (the Cartagena Protocol) regulates at the international level the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The Protocol was adopted on 29 January 2000 and entered into force on 11 September 2003.

The second protocol adopted under the CBD is the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity* (the Nagoya Protocol). The Nagoya Protocol sets out the rules and mechanisms for access to genetic resources and associated TK, and supports the fair and equitable sharing of benefits arising from their utilization, and, along with the basic provisions of the CBD on ABS, forms the central body of law that defines how the ABS system operates. Many of the provisions of the Nagoya Protocol borrow from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, a set of voluntary non-binding guidelines on access and benefit sharing endorsed by the CBD Conference of the Parties (COP) at its Sixth Session in 2002.¹²

¹⁰ See para. 44(o) of the Plan of Implementation of the World Summit on Sustainable Development, A/Conf.199/20 of 4 September 2002.

¹¹ GIZ (2011). http://www.abs-initiative.info/struct_compedium0.html.

¹² Decision VI/24 of COP VI (2002).

The Nagoya Protocol was adopted by the 10th COP to the CBD in Nagoya, Japan on 29 October 2010, and opened for signature for one year from February 2011, finally receiving 92 signatures, amongst them 22 European Union (EU) Member States and the EU. When the period for signatures ended, the Nagoya Protocol had two ratifications.¹³ The treaty has now been ratified by over 50 countries, and will come into effect as from 12 October 2014. For countries that have ratified the CBD and the Nagoya Protocol, domestic ABS legislation will be shaped by the relevant provisions of the CBD and the Nagoya Protocol, as treaty implementation relies to a large extent on national legislation to put the access and benefit sharing provisions into effect. The decision making bodies of the CBD and its Protocols are serviced by the CBD Secretariat, located in Montreal, Canada, which is administratively part of the United Nations Environment Programme (UNEP).

Over the years, the CBD Secretariat has commissioned a number of studies on the relationship between IP and the CBD, including, in particular, the compatibility of disclosure requirements with the TRIPS Agreement (see Chapter 3). Article 16 of the CBD recognizes the impact of intellectual property (IP) on access and benefit sharing. Specifically, it states that “[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.” In order to achieve agreement in 2010 among the governments negotiating the treaty text in Nagoya, however, IP ended up being largely absent in the Nagoya Protocol, with the exception of its mention as a means for possibly securing equitable benefit sharing (see the Annex to the Nagoya Protocol). Despite its importance for the ABS system, the relatively few references to IP in the Protocol means that it is not possible to derive an understanding of the interface between IP and ABS from the CBD and the Protocol alone, and that other sources of law will need to be consulted.

Key Points

- ⇒ The CBD enjoys nearly universal acceptance as the most comprehensive source of international law to date on issues of biological diversity. The CBD established the basic principle that States have sovereign rights over their own biological resources.
- ⇒ The Nagoya Protocol, the text of which was agreed in October 2010, sets out the system to implement those rights and obligations on ABS of genetic resources which on the basis of CBD Article 8(j) also cover traditional knowledge associated with genetic resources. The Nagoya Protocol received 92 signatures and awaits 50 ratifications to enter into force.
- ⇒ National implementation of ABS legislation, while required by the CBD, is slow and generally tends to focus more on access issues and much less on benefit sharing.
- ⇒ Despite its importance, intellectual property is largely absent in the Nagoya Protocol, with the exception of its mention as a means for possibly securing equitable benefit

¹³ As of the 3 September 2014, 52 countries have either ratified or acceded to the Protocol. For an updated list, readers may consult <http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>. COP12 of the CBD, scheduled for October 2014 in Korea, will also be the first meeting of the Parties to the Nagoya Protocol.

sharing. As a result, it becomes important to examine other legal instruments in order to determine how best to shape national IP legislation to further the goals of the CBD.

A. How Does the Global Access and Benefit Sharing System Work?

Underlying the ABS provisions of the Nagoya Protocol and the CBD is the notion, as stated in the Preamble to the CBD, that States have sovereign rights over their own biological resources. Access to genetic resources by users must therefore be based on *prior informed consent* and equitable benefit sharing must occur on *mutually agreed terms* (hereafter PIC and MAT, respectively; Nagoya Protocol, Articles 5 and 6 (see Box 3 below) and CBD, Articles 15, 16 and 19).

Box 3

Nagoya Protocol Provisions on Access and Equitable Sharing of Benefits

Article 5. Fair and Equitable Benefit Sharing

1. 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.
2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.
5. 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.

Article 6. Access to Genetic Resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of 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, unless otherwise determined by that Party.
2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.
3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

- (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
- (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
- (c) Provide information on how to apply for prior informed consent;
- (d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
- (e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
- (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
- (g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:
 - (i) A dispute settlement clause;
 - (ii) Terms on benefit-sharing, including in relation to intellectual property rights;
 - (iii) Terms on subsequent third-party use, if any; and
 - (iv) Terms on changes of intent, where applicable.

Source: The Nagoya Protocol (2010).

National legislation must therefore provide a means of ensuring that those who seek to access genetic resources and associated TK for utilization have the PIC of the country or indigenous peoples and local community (hereafter ILC) concerned. Parties to the Protocol may specify the instances where PIC is required for access, which may include:

- genetic resources from areas under national jurisdiction
- in case they are countries of origin,
- including such genetic resources in *ex-situ* collections.

On the other hand, the Protocol specifies various procedural requirements, which must be complied with. These include the requirement to formulate fair and non-arbitrary rules and procedures for access, information on how to apply for PIC, the issuance of permits as evidence of PIC, the requirement to provide written decision by the competent national authority within a reasonable period of time and the like. National legislation must also provide a way to ensure that the results of research and development (hereafter R&D) and the benefits arising from the commercial and other utilization of genetic resources are shared in a fair and equitable manner, based on MAT.¹⁴

The Nagoya Protocol establishes a compliance system for ABS. As noted above, Parties need to ensure that genetic resources utilized from the area under national jurisdiction have been

¹⁴ Frein and Meyer (2012).

accessed based on PIC and MAT as required by the provider country. A national competent authority must be established to implement the ABS system, where it will be possible to register ABS agreements and any other documentation that can potentially serve as evidence of PIC and MAT (Nagoya Protocol, Article 13). The competent authority grants a permit for access when it is satisfied that PIC and MAT requirements under national law have been met.

Supportive measures with regard to the utilization of genetic resources include the nomination of one or more effective checkpoints relevant to the entire product chain (Nagoya Protocol, Article 17(1)(a)), designed to provide information to the authority about permit applications and to investigate claims where ABS regulations have not been followed. The competent authority also facilitates the transformation of the national access permit – providing information on PIC, MAT, etc., into an internationally recognized certificate of compliance through publication by the ABS Clearing House (Nagoya Protocol, Article 17(2)), which is designed to facilitate the legitimate movement of resources across borders. This Clearing House has recently been established and is now in its pilot phase.¹⁵ Furthermore, Parties need to support the fulfilment of MAT through the opportunity for legal recourse and access to justice (Nagoya Protocol, Article 18(2) and (3)).

Agreed upon ABS rules for PIC and MAT are thought, *inter alia*, to help combat ‘biopiracy’ or in more legal terminology, the misappropriation and misuse of genetic resources and associated TK. As mentioned above, IP rights, by granting the right to exclude others from the use of an intellectual creation, are one means by which misappropriation can occur. At the same time IP rights are also one means to generate income from the commercialization of a technology that contains a genetic resource and associated TK, from which benefits could potentially be shared.

Key Points

- ⇒ Articles 15, 16 and 19 of the CBD and Articles 5 and 6 of the Nagoya Protocol set out the basic rights and obligations of Parties on ABS of genetic resources. These provisions establish the requirement that access to genetic resources shall be based on prior informed consent (PIC) and mutually agreed terms (MAT). Benefits accruing from the utilization of genetic resources need to be shared on a fair and equitable basis.
- ⇒ While laying down procedural requirements for the grant of PIC, the Protocol leaves leeway to countries to determine the substantive conditions under which PIC is required.
- ⇒ Competent national authorities need to be established to administer the system, which checks whether PIC and MAT have been complied with, and issues access permits when applicable requirements have been met. The national competent authority will also be in charge of ensuring that national permits based on compliance with domestic legislation are converted into an internationally recognized certificate of compliance through the ABS Clearing House. The ABS Clearing House is currently in its pilot phase.

¹⁵ See <http://absch.cbd.int/>.

B. What Does the Global Access and Benefit Sharing System Cover?

The Nagoya Protocol covers the utilization of genetic resources as defined in Article 2 of the CBD, meaning any material of biological origin containing functional hereditary material for use in R&D – i.e., when working on the genetic or biochemical composition of the material, including development of products and processes through biotechnology. The simple sale of a fruit or vegetable across borders for consumption would therefore not be covered under the Protocol. On the other hand, the transfer of sample plants and animals for research purposes, even if not immediately commercialized, would trigger the Protocol. If biological resources are brought across borders for trade or consumption purposes initially, but later used for research, the provisions of the Protocol would still apply. This sometimes creates difficult situations as documents for the mere purchase of commodities do not necessarily have clauses in them that address requirements to obtain PIC and MAT. According to a recent study by Laird and Wynberg published by the CBD Secretariat:

“According to the CBD and the Nagoya Protocol, ABS policies are intended to address research and development on genetic resources and associated traditional knowledge, and biodiscovery, rather than the commodity trade of raw materials that may result from research and development, or local trade and subsistence use. While it is important to ensure that regulatory frameworks address the differences between biotrade and biodiscovery, it also needs to be acknowledged that these distinctions are becoming less clear with increasing research and development focus of commodity-based industries such as food”¹⁶

The following sections describe some of the key controversies surrounding the scope of coverage of the ABS system as established by the CBD and the Protocol.

Key Points

- ⇒ The Protocol requirements are triggered when genetic resources are ‘utilized’ for R&D purposes outside the provider country.
- ⇒ Contracts and other documents for the simple sale of seeds, plants or vegetables for consumption purposes would not trigger the Protocol, but if research is conducted using these commodities, then the requirements would be triggered. In practice, many sales contracts do not specify what needs to happen in the case the objective for which a genetic resource is provided changes.

1) Temporal Scope of the Treaties

In the Nagoya Protocol negotiations, there was an extensive debate over whether the final instrument is meant to cover genetic resources acquired prior to its entry into force. Like many other issues, the debate at Nagoya took place over largely North-South lines and the text of the Protocol avoids providing a clear answer to this question. The extent to which the Protocol dealt with this question was to simply suggest that the Parties consider the establishment of a global multilateral benefit-sharing mechanism to address the sharing of

¹⁶ Laird and Wynberg (2012), p. 12.

benefits derived from the utilization of genetic resources and related TK for which it is not possible to grant or obtain PIC (Nagoya Protocol, Article 10).

On one hand, many genetic resources were acquired by user countries before the Protocol, as well as before the CBD. Up until 12 October 2014 when the Protocol comes into force, genetic resource transfers to outside the provider country in fact continue to be pre-Nagoya (in the absence of Nagoya-compliant ABS legislation). It could be argued that the exclusion of pre-Nagoya/pre-CBD resources condones misappropriation and merely encourages countries to delay ratification, with a view to avoiding otherwise applicable PIC and MAT requirements.¹⁷

The problem with an approach applying the Protocol to pre-Nagoya/pre-CBD acquisitions is that such acquisitions include not only those resources that had been accessed without PIC and MAT, but also those that had been the subject of agreed transfers. Plants that are part of *ex situ* collections or animals that reside in zoos are examples of such genetic resources. Such resources are also in gene banks around the world. To declare that Nagoya Protocol requirements apply to genetic resources already acquired also means that the Protocol would be applied retroactively, which is generally frowned upon as a matter of law. The economic consequences could be significant if the Protocol were used to invalidate earlier agreements, pre-Nagoya or pre-CBD. As pointed out by the United Nations University Institute for Advanced Studies (UNU-IAS):

*“Requiring pre-CBD collections to produce evidence of a legal right to use resources, based on the existence of a sound legal title obtained from a country of origin, would have significant impact on their commercial value. The wide distribution of genetic resources over centuries – many of which are mainstays of global food security – is frequently posited as a reason to avoid extending control over pre-CBD collections.”*¹⁸

As a matter of national law, it is unlikely that courts in most jurisdictions (as well as government officials administering ABS laws) would seek to apply laws retroactively to genetic resources acquired before a Protocol compliant domestic ABS regime had been put in place, absent a clear intent in the ABS law to do so.

In order to address the problem of pre-Nagoya/pre-CBD acquisitions, some authors have suggested that national ABS laws make the Protocol requirements applicable to new uses of genetic resources acquired prior to that law, making the timing of the acquisition irrelevant.¹⁹ This would at least help to ensure that some benefit sharing occurs with respect to new applications of genetic resources acquired prior to a Nagoya Protocol-compliant ABS law. There is nothing in the Protocol that would prevent Parties from including such a requirement in their respective laws.²⁰

¹⁷ Nijar (2011a), p. 19.

¹⁸ Tobin, Burton and Fernandez-Ugalde (2008).

¹⁹ See, for example, Nijar (2011a), p. 20.

²⁰ Benefit sharing under Article 5 of the Nagoya Protocol is not linked to access conditions under Article 6, so the benefit sharing obligation could also extend to GR and TK accessed pre-Nagoya, whether the resource was accessed with or without PIC.

Key Points

- ⇒ The Nagoya Protocol never clearly stipulates whether it is intended to cover the utilization of genetic resources that had been acquired prior to Nagoya-compliant ABS legislation. Nonetheless, judges (and government officials) will often be unwilling to retroactively apply ABS legislation unless there is a clear intent in the law to do so.
- ⇒ National ABS legislation can 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).

2) Traditional Knowledge (TK)

Aside from the genetic resources themselves, the CBD and the Nagoya Protocol also address the treatment of TK associated with genetic resources and genetic resources held by ILCs. As regards genetic resources held by ILCs as a matter of law, the same PIC and MAT requirements would apply as genetic resources that fall under the jurisdiction of national authorities. The only major difference would be that the ILC has the standing under domestic law to grant PIC and negotiate MAT, rather than the national competent authority. The former, i.e., associated TK, are governed by different provisions of the Nagoya Protocol, and are discussed below in historical context.

During the preparations for the 1992 Earth Summit, the efforts of a number of indigenous organisations resulted in greater visibility of TK and biodiversity-related innovations on the global agenda. In February 1992, the Charter of the Indigenous and Tribal Peoples of the Tropical Forests was adopted in Penang, Malaysia.²¹ Article 45 on "Intellectual Property" states:

*"Since we highly value our technologies** and believe that our biotechnologies can make important contributions to humanity, including 'developed' countries, we demand guaranteed rights to our collective intellectual property in both national and international law, and control over the development and manipulation of this knowledge."*

At the Earth Summit, the indigenous organisations adopted the Kari-Oca Declaration and the Indigenous Peoples' Earth Charter.²² Selected articles of the Charter with specific relevance to TK, genetic resources and IPR in the context of this chapter are:

"25. Indigenous peoples should have the right to their own knowledge, language, and culturally appropriate education, including bicultural and bilingual education. Through recognizing both formal and informal ways, the participation of family and community is guaranteed."

²¹ International Alliance of Indigenous and Tribal Peoples of the Tropical Forests, (as revised in 2002) http://www.international-alliance.org/charter_eng.htm, accessed in Jan 2012 (**author's comment: the first version of this Charter dealt with IP in Article 44 and spoke of "traditional technologies", see Posey (1999), pp. 556 ff).

²² Text and more information available at: <http://dialoguebetweennations.com/IR/english/KariOcaKimberley/KOCharter.html>, accessed in Jan 2012 (** authors' comment: this last, and in the light of the recent developments, crucial sentence is deleted from paragraph 102 presented at the mentioned webpage, but contained in the original Charter, see Posey (1999), pp. 560 ff).

26. *Our health rights must include the recognition and respect of TK held by indigenous healers. This knowledge, including our traditional medicines and their preventive and spiritual healing power, must be recognized and protected against exploitation.*

96. *The TK of herbs and plants must be protected and passed onto future generations.*

97. *Traditions cannot be separated from land, territory, or science.*

98. *TK has enabled indigenous peoples to survive.*

99. *The usurping of traditional medicines and knowledge from indigenous peoples should be considered a crime against peoples.*

100. *Material culture is being used by the non-Indigenous to gain access to our lands and resources, thus destroying our cultures.*

102. *As creators and carriers of civilizations which have given and continue to share knowledge, experience, and values with humanity, we require that our right to intellectual and cultural properties be guaranteed and that the mechanism for each implementation be in favour of our peoples and studied in depth and implemented. [This respect must include the right over genetic resources, gene banks, biotechnology, and knowledge of biodiversity programs.]****

103. *We should list the suspect museums and institutions that have misused our cultural and intellectual properties."*

The 1992 Kari-Oca Declaration was reaffirmed by the Indigenous Peoples Global Conference at the Rio+20 and Mother Earth conference in 2012. The Rio+20 meeting in addition adopted a Kari-Oca 2 Declaration that states: "[w]e reject the assertion of intellectual property rights over the genetic resources and traditional knowledge of Indigenous peoples which results in the alienation and commodification of Sacred essential to our lives and cultures."²³

Agenda 21²⁴ in its Chapter 26 "*Recognizing & Strengthening the Role of Indigenous People & Their Communities*" laid down an informal action plan for national governments on how to establish processes to empower indigenous people and their communities to strengthen the active participation of indigenous people and their communities in the national formulation of policies, laws and programmes relating to resource management. Agenda 21 also touches the controversial issues of self-determination and land rights when it suggests that governments could:

"(a) Consider the ratification and application of existing international conventions relevant to indigenous people and their communities (where not yet done) and provide support for the adoption by the General Assembly of a declaration on indigenous rights;

(b) Adopt or strengthen appropriate policies and/or legal instruments that will protect indigenous intellectual and cultural property and the right to preserve customary and administrative systems and practices."

²³ Text available at: <http://indigenous4motherearthrioplus20.org/kari-oca-2-declaration/>, accessed in June 2010.

²⁴ Text and more information available at: http://www.un.org/esa/dsd/agenda21/res_agenda21_00.shtml, accessed in Jan 2012.

The 1992 Rio and the Rio+20 documents treat TK as one of the many aspects of sustainable development and environmental protection, which should be dealt with in policy and legal activities at the national level. The Rio Summit did not, however, adopt any language to formally recognise customary rights of indigenous peoples at the international level. Instead, Principle 22 of the Rio Declaration on Environment and Development²⁵ states:

"Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development."

The documents are, nonetheless, important in so far as they affirm the collective position of ILCs that they ought to maintain some control over their TK and practices. Of the three legally binding conventions adopted in Rio, the CBD²⁶ recognises in its Preamble:

"the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of TK, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components."

Article 8(j) of the CBD promotes the sharing of benefits arising out of the utilization of such traditional knowledge but leaves any measures to achieve this objective to the domestic policies of the CBD members. It states, in relevant part, that:

"Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate: [...]

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;"

The second article of relevance to indigenous and local communities is CBD Article 10(c), which states:

"Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;"

²⁵ Text available at: <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>, accessed in January 2012.

²⁶ Text and more information available at: http://treaties.un.org/Pages/ViewDetails.aspx?src=UNTSOnline&tabid=2&mtdsg_no=XXVII-8&chapter=27&lang=en and <http://www.cbd.int/convention/text/>, accessed in Jan 2012

It has been suggested that “Article 10(c) requires Contracting Parties to protect and encourage customary uses of biological resources derived from traditional cultural practices which are compatible with the requirements of biological diversity conservation or the sustainable use of its components. The TK, innovations and practices of ILCs directly derive from the customary use of biological resources.”²⁷ Therefore, Article 8(j) and Article 10(c) are closely interrelated and need to be implemented synergistically. As with Article 8(j), Article 10(c) drew criticism because the language neither explicitly mentions customary rights nor promotes their recognition at the international level.

While Articles 15, 16, and 19 of the CBD deal strictly with genetic resources and do not deal with TK, the 7th Conference of the Parties to the CBD (COP) in 2004 decided to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, with the collaboration of the Ad Hoc Open Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, to ensure “the participation of indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention”.

The work of these bodies was eventually incorporated into Article 7 of the Nagoya Protocol, which stipulates that Parties to the Protocol need to ensure that access to TK associated with genetic resources is based on prior informed consent (PIC) and that benefit sharing will take place (without defining traditional knowledge and its utilization). These obligations cover only benefits from research and development (R&D), however, and not commercialization, on the condition that these groups have been granted the right to determine access to their genetic resources.

Also, it should be emphasized that the Protocol governs only that TK which is associated with genetic resources, rather than all TK. The Protocol does not define what kind of TK would be associated with genetic resources, leaving it up to national laws to determine what TK would be covered. Chapter 5 of this handbook examines the question of TK in more detail.

Key Points

- ⇒ During the preparations of the Earth Summit, indigenous organisations placed the issue of TK and biodiversity-related innovations successfully on the international agenda. In February 1992, the Charter of the Indigenous and Tribal Peoples of the Tropical Forests was adopted, and at the Earth Summit, the indigenous organisations adopted the Kari-Oca Declaration and the Indigenous Peoples' Earth Charter that laid down the basic policy and legal issues dominating the debate to this day.
- ⇒ The Earth Summit documents treat TK as one of the many aspects of sustainable development and environmental protection. The Rio Summit did not adopt any language to formally recognise customary rights of indigenous peoples at the international level, however.

²⁷ Glowka et al. (1994), p. 60.

- ⇒ Article 8(j) of the CBD links the principle of benefit sharing not only to the utilisation of genetic resources but also to the utilisation of "*TK, innovations and practices*", and subjects any such measures to national legislation. Article 8(j) served as the point of departure for the inclusion of TK issues in the 2010 Nagoya Protocol on ABS.
- ⇒ Article 7 of the Nagoya Protocol requires countries to ensure that access to associated TK is based on PIC and that benefit sharing will take place. Such benefits are required to cover benefits from R&D, but not commercialization.
- ⇒ The Protocol governs only TK associated with genetic resources, and not all TK.

3) Plant Genetic Resources for Food and Agriculture

The International Treaty on Plant Genetic Resources for Food and Agriculture (the ITPGRFA) entered into force on 29 June 2004. The Treaty is overseen by a Governing Body composed of the 152 countries that have so far ratified it as of October 2014. The Governing Body is supported by a secretariat, located in Rome, Italy, which is part of a UN specialized agency, the United Nations Food and Agriculture Organization (FAO). This secretariat is also the body which administers the common fund for benefit sharing under this treaty.

The ITPGRFA establishes, *inter alia*, a multilateral system to facilitate access to plant genetic resources for food and agriculture and to share the benefits arising out of their use in a fair and equitable manner. Under the ITPGRFA's multilateral system, parties to the Treaty agree to make freely available genetic diversity and related information stored in gene banks concerning, at present, 81 forage species from 29 genera and an undefined number of crop species from 51 genera (covering the vast majority of plant crops consumed by humans but with important exceptions such as cocoa, coffee, cotton, soya or tomato). Breeders and scientists who wish to utilize the plant genetic resources and improve on these varieties are required to seek access in accordance with a standardized material transfer agreement (MTA) (Article 12.4, ITPGRFA). Those who access genetic materials through the system are required not to claim any rights that "limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received" (Article 12.3(d)), ITPGRFA. If plant genetic resources accessed from the multilateral system are commercialized, the recipient "shall pay ... an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment" (Article 13.2(d)(ii), ITPGRFA). A pre-fixed percentage of the benefits from commercialization flow into a common fund that is used to support future research, breeding and training projects. The system is operationalized through the standard MTA (see Annex III).²⁸

²⁸ An MTA, which can be a type of Access and Benefit Sharing (ABS) Agreement, is an agreement between provider and receiver of genetic resources governing terms of access, including, PIC, conditions of use, benefit sharing. In genetic resources, the MTA primarily consists of the transfer of specific genetic resources by the competent authority of the providing country, or other entity to recipients, such as research centers, pharmaceutical, biotechnology and other R&D based companies, or to other countries, under MAT. The term 'MTA' is also used in the context of an agreement for the transfer of tangible research materials between two entities, for example, between a university that undertook basic research on a genetic resource or a molecule and a private company that will develop the products for commercialisation.

The ITPGRFA also requires parties to implement in their national legislation measures to protect farmers' rights. The relevant provisions on farmers' rights are set out in Box 4 below. In the context of ABS and TK, it is important to note that the farmers' rights as codified in the ITPGRFA deal with benefit sharing but not with access aspects. During the ITPGRFA negotiations it was argued by some parties that farmers' rights should also cover free access to and exchange of IP-protected plant material as acknowledgement of farmers' contribution to the creation of the existing diversity of plant genetic material without which modern plant breeding could not exist. Such interference with the IP system was not accepted by countries with strong commercial plant breeder interests. The ITPGRFA finally was equipped with a provision in Article 9.3 that the national implementation of farmers' rights shall not "limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." The only international treaty that currently provides for such rights, though only on a voluntary basis, is the International Treaty for the Protection of New Varieties of Plants (hereafter the UPOV Convention).

Box 4
Article 9. Farmers' Rights

9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

- a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
- c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Source: ITPGRFA (2001).

Negotiated post-Earth Summit, a conscious effort was made to ensure that the ITPGRFA is fully consistent with the provisions of the CBD. A provision that is of relevance in the ABS context can be found in Article 12.3(h) which says that "[w]ithout prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in *in situ* conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body." According to the definition of "*in situ*" given by the ITPGRFA as well as by the CBD, this case would cover those plant genetic resources in natural surroundings as well as on farmers' fields if they have "developed their distinctive properties" in these locations. In 2010, the ad hoc Advisory Technical Committee on the

Standard Material Transfer Agreement and the Multilateral System of the ITPGRFA started its work on compiling information and views on such standards.

The Nagoya Protocol, having been negotiated after the ITPGRFA, has a provision that ensures that the latter treaty (and not the Nagoya Protocol/CBD) governs plant genetic resources for food and agriculture covered by the ITPGRFA for those countries that have ratified it. Under Article 4(4) of the Protocol, “[w]here a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument”, except, as stipulated in Article 4(1) of the Protocol, “where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.”

Key Points

- ⇒ The ITPGRFA establishes, *inter alia*, a multilateral system to facilitate access to plant genetic resources for food and agriculture, which is regarded as a major component of sharing the benefits arising out of the use of these genetic resources in a fair and equitable manner.
- ⇒ Under the ITPGRFA’s multilateral system, parties to the Treaty agree to make freely available genetic diversity and related information stored in *ex-situ* collections concerning, at present, 81 forage species from 29 genera and an undefined number of crop species from 51 genera (covering the majority of major plant crops that are important for human food security). The system is operationalized through a standard material transfer agreement (MTA).
- ⇒ Those who access genetic materials through the system are required not to claim any rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received. If plant genetic resources accessed from the multilateral system are commercialized, the recipient is required to pay an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.
- ⇒ A pre-fixed percentage of the profits from commercialization flow into a common fund that is used to support future research, breeding and training projects. This system is established as a means of benefit sharing under the ITPGRFA.
- ⇒ The Nagoya Protocol, having been negotiated after the ITPGRFA, has a provision that ensures that the latter treaty (and not the Nagoya Protocol/CBD) governs plant genetic resources for food and agriculture covered by the ITPGRFA for those countries that have ratified it.

4) Viruses and other Pathogens

A pathogen is typically defined as an infectious organism, and includes viruses, bacteria and fungi, among others.²⁹ Some definitions also include biological substances such as prions.³⁰ The characteristic of pathogens is that they cause diseases. In humans, examples of such viruses include human immunodeficiency virus (HIV), Ebola, smallpox and influenza, while examples of bacteria include *Mycobacterium tuberculosis* (tuberculosis), *Escherichia coli* (gastro-intestinal disorders) and *Salmonella typhi* (typhoid). Examples of pathogenic fungi include *Candida* species (yeast infections) and *Trichophyton* species (athlete's foot). Abnormal prions can be pathogenic such as those that cause bovine spongiform encephalopathy (i.e., "mad cow disease"). Pathogens need not, of course, be limited to those that affect humans and could include those affecting other animals or plants as well.

Pathogens are important because they are used in research on the diseases which they cause and in the development of treatments for those diseases, as in the case of vaccines or monoclonal antibodies. According to the World Health Organization (WHO), IP is often not a barrier to the production of vaccines in developing countries. In many cases, modern vaccines embody multiple levels of technology licensed from multiple partners, implying that a would-be vaccine manufacturer in a developing country should be able to 'work around' any refusal by one IP holder to license any specific technology. Additionally, there is also vaccine production technology in the public domain, particularly for developing countries where patent owners have not opted to file a patent application in respect of the technology.³¹ The same may not be true for some of the newer vaccines, however, and WHO and others caution that Patent Cooperation Treaty (PCT) applications on vaccine technology have been steadily rising over time. For example, an April 2011 report from the non-governmental organization (NGO) Third World Network catalogues a number of increasingly broad PCT patent applications in recent years for medicines, vaccines, microbes, peptides, nucleic acids and immunoassays with the term "H5N1" and/or "H1N1" in the claims.³²

Various interpretations exist with respect to the status of pathogens under the CBD and the accompanying Nagoya Protocol. One interpretation is that pathogens such as viruses, which are innately harmful, are not linked to the first objective of the CBD, which is the conservation of biological diversity, and are therefore outside the scope of the Convention (and the NP).³³ Another view acknowledges that pathogens are covered within the scope of the CBD and NP, but that work done by the WHO on virus sharing takes precedence over the NP.³⁴ Yet another view supports the argument that pathogens are genetic material covered under the CBD and not specifically excluded by the NP or elsewhere.³⁵ The arguments in favour of the last view are summarized in Box 5 below.

²⁹ <http://www.medterms.com/script/main/art.asp?articlekey=6383>.

³⁰ <http://en.wikipedia.org/wiki/Pathogen>.

³¹ See Friede (2011). Note, however, that it cannot be assumed that any given developing country would be able to immediately make use of vaccine production technology in the public domain.

³² Ibid. and Hammond (2011).

³³ See Abbott (2010) and Nijar (2011a).

³⁴ Nijar (2011a).

³⁵ Nijar (2011a) argues that a proposal to exclude human pathogens was considered and failed in the negotiations leading up to the Conference of the Parties that adopted the NP. Biotechnology industry groups have countered that at different points, draft texts have both included and excluded pathogens, indicating that no agreement on the inclusion of pathogens in the NP. See <http://patentlybiotech.wordpress.com/2010/12/07/pathogens-and-the-nagoya-protocol-of-the-convention-on-biological-diversity/>.

Box 5

Main Arguments Why Pathogens Are Covered by the CBD/Nagoya Protocol

The CBD was designed to preserve biological diversity that, among other things, would permit future research and development on biological resources that might yield treatments for disease.³⁶

The CBD and NP were designed to allow developing countries to share in benefits from the exploitation of biodiversity resources. Pathogen materials, including virus materials, have a value in so far as they may be used to develop drugs or vaccines for human or animal use, and they have potential monetary value.³⁷

A plain reading of the definition of ‘genetic material’ covered by the CBD leads to the conclusion that pathogens, such as certain bacteria or viruses, contain functional units of heredity and are replicable; nothing in the CBD, NP or other international agreement otherwise excludes pathogens from the scope of coverage.³⁸

The work done by WHO on developing standard material transfer agreements (SMTAs) for the sharing of viruses (see Annex 2) is not a binding treaty that guarantees a fair access and benefit sharing regime for pathogens.

Source: authors.

The CBD does not refer to the term “pathogen” as such, but defines genetic resources as material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD). Paragraph 16 of the preamble to the Nagoya Protocol contains the only explicit reference in this document to pathogens, and stipulates that the Protocol is being adopted bearing in mind “the International Health Regulations (2005) of the WHO and the importance of ensuring access to human *pathogens* for public health preparedness and response purposes” (emphasis added). Further, Article 8(b) of the Protocol obligates each Party to the CBD, when formulating their access and benefit-sharing legislation and regulations, to “[p]ay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.” This clause goes on that state that Parties may “take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.”

Article 8(b) of the Nagoya Protocol may have to a limited extent eliminated the need to continue the debate on the status of pathogens. While the Protocol does not specify what “due regard” means, it is quite possible that courts could interpret this clause to mean that in the formulation of national ABS legislation, Parties are obliged to grant user access to pathogens in certain emergency cases. Moreover, the Protocol does not provide guidance as to what constitutes an “emergency”, but it could be assumed, for instance, that a declaration of a pandemic by the WHO could potentially provide the necessary trigger. National declarations of emergency by health authorities could also potentially suffice as a trigger. This means, for example, that an Ebola outbreak declared in a developed country Member could potentially be grounds for that country to demand access to a virus sample from an African country such as

³⁶ Abbott (2010), p. 13.

³⁷ Ibid.

³⁸ Nijar (2011a), p. 3.

Uganda. For provider countries, the second clause of the Article is designed to provide some assurance of benefit sharing for developing countries in the event a pathogen is shared with a user country in those emergency situations. Notably, the Nagoya Protocol does not specify how a Party could take into consideration the need for expeditious fair and equitable sharing of benefits arising out of the sharing of the pathogen, leaving it up to each Party to negotiate an appropriate response.

Key Points

- ⇒ There has been a longstanding debate among delegates on whether the CBD and Nagoya Protocol cover pathogens.
- ⇒ Article 8(b) of the Nagoya Protocol, however, arguably requires Member States to take into consideration the need for expeditious access to pathogens in emergency situations and expeditious benefit-sharing arising out of the use of such genetic resources. This could happen when a national health authority or the WHO declares an outbreak, for instance.

5) Derivatives

Prior to the conclusion of the Protocol, there was an intensive debate over whether the final text ought to cover access to derivatives of genetic resources. The debate on whether derivatives should be covered by the benefit sharing provisions of the Nagoya Protocol was not as controversial because the CBD Parties had already decided that the sharing of benefits arising from the use of derivatives can be covered by contractual MAT clauses when they adopted the Bonn Guidelines.³⁹

‘Derivative’ is a defined term under the Nagoya Protocol. According to Article 2(e) of the Protocol, ‘derivative’ means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources. The term ‘derivative’ is defined to clarify another defined term, i.e., ‘biotechnology’. Biotechnology is defined in Article 2(d) of the Protocol as “any technological application that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products or processes for specific use” (emphasis added). The term ‘biotechnology’ is, in turn, used in another definition, i.e., the ‘utilization of genetic resources’, which means to conduct research and development (R&D) on the genetic and/or biochemical composition of genetic resources, including through the application of *biotechnology* as defined under the CBD (Article 2(c) of the Protocol, emphasis added). Interestingly, apart from clarifying another definition, the term ‘derivative’ does not otherwise appear in the substantive provisions of the Nagoya Protocol.⁴⁰

The debate over whether the Nagoya Protocol should cover derivatives exists at least partly because of different interpretations of the CBD definition of genetic material, i.e., those materials that contain functional units of heredity. Negotiators disagreed whether this means

³⁹ The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of their Utilization (2002).

⁴⁰ Interestingly, derivatives as defined in this way will never contain functional units of heredity, they are a result of the activity of these functional units, and if biological material contains functional units, it is a genetic resource according to the CBD.

that the material contains functional units of heredity only or can also contain other biological compounds apart from the functional units. If the second interpretation holds true, developed and developing countries differed in their positions as to whether the Protocol obligations should extend to these non-genetic compounds, i.e., derivatives, as for example proteins or medicinal active substances. The debate over the issue was heated, and the solution that negotiators came up with was not to interpret or rewrite the fundamental CBD definitions but to clarify the types of utilization of genetic resources that would trigger the provisions of the Protocol.

With respect to benefit sharing obligations, Article 5(1) of the Protocol states that “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.” Thus, the text of the Nagoya Protocol makes clear that benefit sharing obligations of the Protocol extend to genetic resources and subsequent applications and commercialization. This text formulation potentially covers a wide range of items, and, based on the definitions of utilization of genetic resources, derivatives and specifically biotechnology, would also include the utilization of items that are not naturally occurring but have been manufactured through its use. Nijar indicates that this broad interpretation is both supported by the negotiation history of the Nagoya Protocol, and makes sense since it is mostly through the development of products that are based on genetic resources that one could reap commercial benefits from such resources.⁴¹

Beyond benefit sharing, the status of products that are based on genetic resources remains subject to some interpretation. It seems reasonable, however, that PIC would be required for users who seek access to undertake R&D with a view to developing products based on genetic resources (this is because Article 6 of the Nagoya Protocol requires PIC as a prerequisite for access to genetic resources for their utilization, which by definition encompasses biotechnology R&D, i.e., any technological application that uses biological systems, living organisms, or derivatives thereof (Article 2(d), Nagoya Protocol)). PIC does not appear to be required under the Protocol for access to a derivative in the provider country, but only for the resource itself. National ABS laws could still provide, however, that access to derivatives be conditioned upon PIC, as is required for genetic resources.

Key Points

- ⇒ The Nagoya Protocol stipulates that the utilization of genetic resources as well as subsequent applications and commercialization are subject to benefit sharing obligations. The Protocol leaves it open to interpretation which substances or even which types of information generated from genetic resources through the application of biotechnology are subject to benefit sharing obligations.
- ⇒ While the Nagoya Protocol is less clear as to whether derivatives of genetic resources are subject to PIC requirements for access, there is nothing in the Protocol that prevents countries from adopting ABS legislation that introduces such a requirement.

⁴¹ Nijar (2011a), p. 13.

III. Conclusion

The global ABS system for genetic resources and associated TK is set up by the CBD and the Nagoya Protocol. These multilateral treaties require that access to genetic resources be based on PIC and MAT. Parties also need to ensure that genetic resources and associated TK utilized in the area under national jurisdiction have been accessed based on PIC and MAT as required by the provider country. These treaty requirements need to be embedded in national law. The CBD is nearly universal, and the Protocol recently received the 50 ratifications required to come into force.

There has been some debate as to what is covered by the Protocol in terms of genetic resources. These debates have been with respect to genetic resources and TK accessed prior to the CBD and the Protocol, the status of pathogens and derivatives, and the scope of TK that is covered by these treaties. Certain plant genetic resources are excluded from the scope of the Protocol and are instead covered by the ITPGRFA.

Chapter 2

Beyond the CBD and the Nagoya Protocol: Other Instruments that Affect ABS and Intellectual Property

I. Introduction

Chapter 1 provided a brief overview of the access and benefit sharing (ABS) system as established under the Convention on Biological Diversity (CBD) and the Nagoya Protocol. This background is necessary to understand how ABS is supposed to operate both at the national and international levels. This chapter is dedicated to a brief overview of international instruments on intellectual property (IP) and on other instruments that may help to interpret questions of ABS and IP issues, while the chapters that follow will address discrete topics where the two interface. The intent of this particular chapter is therefore not to go into detail on any particular issue, but to understand the various sources of international law of relevance to ABS and IP beyond the CBD and the Nagoya Protocol.

II. Intellectual Property Treaties

Intellectual property (hereafter IP) refers to various sets of exclusive rights that are granted to applicants as a reward or incentive for intellectual endeavour. They include patents, copyrights, trademarks/trade names, utility models, plant variety protection laws, geographical indications, *sui generis* traditional knowledge laws, among others. Like ABS, IP is generally a system that is governed by national laws. IP treaties which countries have signed may contain commitments that will dictate the contours of when exclusive rights ought to be granted and what should remain in the public domain. The key IP treaties that affect ABS are described below, along with a brief discussion of the state of play on relevant intergovernmental discussions that are taking place at the hosting institution on related issues.

A. The TRIPS Agreement

As one of the agreements to which all Members of the World Trade Organization (hereafter WTO) must adhere, the Agreement on Trade-related Aspects of Intellectual Property Rights (hereafter the TRIPS Agreement) has had a major impact on the scope of intellectual property protection around the world. The TRIPS Agreement establishes minimum standards of IP protection, which must be incorporated through national legislation by WTO Members unless specifically exempted by the WTO as in the case of the Least Developed Countries (hereafter LDCs).⁴² Such standards are established for a variety of IP instruments including patents, copyrights, trademarks, geographical indications (hereafter GIs), industrial designs, plant variety protection, integrated circuit designs and undisclosed information. The treaty body for the TRIPS Agreement is the TRIPS Council, which is an intergovernmental body serviced by the WTO Secretariat in Geneva, Switzerland.

⁴² A waiver currently exempts LDCs from complying with the substantive provisions of the TRIPS Agreement through 1 July 2021 (and through at least 2016 for granting product patent protection for pharmaceuticals and protection from unfair commercial use of pharmaceutical test data).

From the perspective of potential impact on ABS, the forms of IP that are the most important are patents, copyrights, trademarks, plant variety protection and GIs.

While incorporating many of the provisions of the Paris Convention for the Protection of Industrial Property, TRIPS requires that patents may only be granted to inventions that are new, involve an inventive step and are capable of industrial application (Article 27.1). Under Article 28.1 of the TRIPS Agreement, patents are a public authorization that grants to the owner the right to preclude others from the acts of making, using, offering for sale, selling or importing a protected product or process for at least 20 years. WTO Members may define the respective criteria of novelty, inventive step and industrial application in light of their policy priorities and needs, but may not offer patent protection for less than 20 years. Various exceptions to this right are recognized both in the TRIPS Agreement as well as through WTO Dispute Settlement decisions and widely recognized national judicial and administrative practices. Petty patents (otherwise known as utility models) are not governed by the TRIPS Agreement.

The TRIPS Agreement does not itself define the contours of a copyright and instead incorporates the substantive provisions of the Berne Convention of 1971, including the term of protection as the life of the creator plus 50 years. Article 9 of the TRIPS Agreement does stipulate, however, that copyright protection extends to expressions and not ideas, procedures, methods of operation or mathematical concepts as such. TRIPS does guarantee copyright protection to computer programs (Article 10, TRIPS), and recognizes rental rights (Article 11, TRIPS) and the rights of performers, producers of phonograms and broadcasting organizations (Article 14, TRIPS). The scope of copyrights is discussed further in the section below on World Intellectual Property Organization (WIPO) treaties.

According to Article 15 of the TRIPS Agreement, “[a]ny sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including persona names, letters, numerals, figurative elements and combinations of colours as well as any combinations of such signs, shall be eligible for registration as trademarks.” The term of protection for a trademark is potentially indefinite, following an initial registration for a term of no less than 7 years. Members may require that the trademark be actually used in order to maintain a registration (Article 19, TRIPS). Distinctive signs are one means by which misappropriation can occur, as well as a vehicle that provider countries could use to prevent misappropriation (see Chapter 6).

Plant variety protection is not governed directly by the TRIPS Agreement. Among its many functions, the TRIPS Council periodically reviews certain substantive provisions of the TRIPS Agreement. The interface between the TRIPS Agreement and the CBD was first examined by the TRIPS Council in its 1999 review of Article 27.3(b), which allows governments to exclude some kinds of inventions from patenting, i.e. plants, animals and “essentially” biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). It was at this time that developing countries argued for the need to re-examine the implications of allowing the so-called ‘patenting of life’, including examining the impact of patenting genes, viruses and other living organisms. The TRIPS Agreement, under Article 27.3(b), mentions only that plant varieties

are eligible to receive some form of either *sui generis*⁴³ or patent protection, or a combination of both. Additional information on plant variety protection can be found in the section on the International Union for the Protection of New Varieties of Plants (UPOV) below.

The examination of the relationship between TRIPS and the CBD was given a higher mandate in 2001, when the WTO Ministerial Conference that launched the Doha Development Round decided in its Declaration that the TRIPS Council should “examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension”.⁴⁴ Despite the mandate, this issue, along with GIs (see below), remain outside the set of issues being negotiated to conclude the Doha Development Round. Further, a debate exists among WTO Members as to whether this means that the issue should instead be addressed by the WTO Trade Negotiations Committee rather than the TRIPS Council. As a result of the continuing impasse in negotiations, the Director General of WTO launched consultations at his own initiative, attempting to resolve the outstanding issues of the CBD/TRIPS relationship and GIs in 2009.

The WTO’s work on TRIPS and the CBD has thus generally focused on the question of whether or not there is a conflict between the two treaties, and whether an amendment of the TRIPS Agreement is necessary to ensure that these treaties are implemented in a ‘mutually supportive’ manner.⁴⁵ The discussion, more specifically, focuses primarily on the question of if there ought to be an amendment of Article 29 of the TRIPS Agreement to include a mandatory disclosure of origin requirement for patent applications containing genetic resources and/or associated TK. Article 29 of the TRIPS Agreement requests Member States to require patent applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. While this debate had been framed as a CBD issue, neither the CBD nor the Nagoya Protocol requires mandatory disclosure of origin. To the extent that the Nagoya Protocol requires effective checkpoints to ensure implementation, however, a disclosure of origin or source requirement could potentially be considered as a mechanism to assist national competent authorities should IP offices be designated as a checkpoint.

This handbook discusses in detail the substantive issue of TRIPS compatibility and disclosure requirements in Chapter 3. It suffices for purposes of this chapter simply to indicate that governments remain, despite the numerous studies tabled and government submissions to the TRIPS Council since the 2001 mandate, divided on this issue mainly along North-South lines as far as the consequences of non-compliance with a disclosure requirement are concerned. Most recently, in April 2011, a group of developing countries including Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the African, Caribbean and Pacific Group of States (the ACP Group) and the African Group, tabled a draft decision calling for the amendment of the TRIPS Agreement at the Trade Negotiations Committee introducing a mandatory disclosure requirement as part of the Agreement’s minimum standards on IP.⁴⁶ The draft Article 29*bis* proposes the following:

⁴³ *Sui generis* is a Latin term that simply means ‘of its own kind.’

⁴⁴ Doha Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/1, para. 19.

⁴⁵ See WTO document IP/C/W/368/Rev.1 of 8 February 2006, para. 6.

⁴⁶ See WTO document TN/C/W/59 of 19 April 2011.

“1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Convention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing.

2. Where the subject matter of a patent application involves utilization of genetic resources and/or associated traditional knowledge, Members shall require applicants to disclose:

(i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and

(ii) the source in the country providing the genetic resources and/or associated traditional knowledge.”

Applicants are also required to “provide a copy of an International Recognized Certificate of Compliance” under the Nagoya Protocol, or alternately “relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge.” No action has yet been taken by the Trade Negotiations Committee Members on this draft.

While not classified strictly speaking as a CBD and TRIPS compatibility issue (but relevant nonetheless from the perspective of enabling the mutual supportiveness of the two treaties, as noted in Chapter 6 of this text), the TRIPS Council is also the forum where debates are occurring on the possible amendment of the TRIPS provisions on geographical indications. GIs are place names (in some countries also words associated with a place) used to identify products that come from these places and have certain specified characteristics. GIs are considered as potential tools to promote benefit sharing and preserve certain traditional practices associated with genetic resources (see Chapter 6). Article 22 of the TRIPS Agreement establishes that Members must provide a measure of protection for GIs in order to prevent misleading the public as to the geographical origin of a good, and to prevent unfair competition. A higher level of protection is accorded under Article 23 for GIs for wines and spirits, where they must be protected even where the public may not necessarily be misled. These obligations are subject to certain exceptions enumerated in Article 24, such as for names that have already become commonplace.

Currently, the debates on GIs in the TRIPS Council focus around two issues. The first deals with the establishment of a multilateral system of notification and registration of GIs for wines and spirits, and the second deals with the extension of the higher level of protection currently afforded to wines and spirits under Article 23 to all goods. Despite having discussed these topics for numerous years, WTO Members continue to differ widely on these two issues. With respect to the former issue, the debate is currently focused on the legal effect of the multilateral register, with some countries (including the European Union (EU)) arguing that TRIPS ought to be amended to call for the establishment of a register that establishes a “rebuttable presumption” that the GI is to be protected in other WTO members — except in a

country that has lodged a reservation within a specified period.⁴⁷ Others have called for establishing a voluntary system where GIs could be notified and entered into a database. Proponents of this view, which includes a number of developed and developing countries, oppose an amendment of the TRIPS Agreement.⁴⁸ A compromise proposal has been put forward by Hong Kong SAR, China. No convergence of views appears to be imminent, however.⁴⁹

With respect to the second issue, here too Member governments are divided over whether or not the protection granted under the current regime of Articles 22 and 23 of the TRIPS Agreement are adequate. The Director-General of the WTO summarized the current impasse best in a report submitted as an official TRIPS Council document:

*“Delegations continued to voice the divergent views that have characterized this debate, with no convergence evident on the specific question of extension of Article 23 coverage: some Members continued to argue for extension of Article 23 protection to all products; others maintained that this was undesirable and created unreasonable burdens.”*⁵⁰

A number of countries treat the issue of a multilateral register for GIs as linked with negotiations on the mandatory disclosure requirement. There has been no formal decision linking the two even though a linkage has been proposed by some countries, and the future of how issues are linked is uncertain. Despite the lack of progress in reaching consensus on these issues, they remain a standard agenda item at the regular meetings of the TRIPS Council.

Key Points

- ⇒ The TRIPS Agreement establishes minimum standards of protection for WTO Members over a variety of IP instruments including patents, copyrights, trademarks, geographical indications, industrial designs, plant variety protection, integrated circuit designs and undisclosed information. As such, it is considered an important reference point for international IP rules.
- ⇒ The TRIPS Agreement was not designed as a treaty that inherently promotes CBD objectives. There are provisions in the treaty which have an impact on those objectives, including the provisions on patents, plant variety protection and geographical indications.
- ⇒ There has been a longstanding discussion at the TRIPS Council about whether a disclosure of origin requirement (and in particular patent law-related sanctions in case of non-compliance) is compatible with the TRIPS Agreement. While this debate had been framed as a CBD issue, neither the CBD nor the Nagoya Protocol requires mandatory disclosure of origin or source.
- ⇒ Ongoing discussions at the TRIPS Council include debates surrounding a possible amendment of the TRIPS Agreement to include a mandatory disclosure requirement, the establishment of a multilateral register for geographical indications and whether a

⁴⁷ See WTO document TN/C/W/26 of 14 June 2005.

⁴⁸ See WTO document TN/C/W/10/Rev.2 of 24 July 2008.

⁴⁹ See, WTO, document TN/IP/W/8, 2003.

⁵⁰ See WTO document TN/C/W/61 of 21 April 2011.

higher level of protection should be accorded to all goods, rather than just wines and spirits. While these are standing items on the agenda of the TRIPS Council meetings, there does not appear to be any major breakthroughs as governments do not seem to be able to reach consensus.

B. The WIPO Treaties

Established as a specialized agency of the United Nations in 1967, the World Intellectual Property Organization (WIPO) provides secretariat services for many of the substantive IP treaties and is also the venue for the negotiation of many new IP treaties. These include the treaties which the TRIPS Agreement incorporates substantive provisions of IP protection, i.e., the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works. Among its functions, the WIPO Secretariat, located in Geneva, Switzerland, also provides the administrative backbone for the Patent Cooperation Treaty (PCT), which creates a mechanism to facilitate cross-border patent applications.

As mentioned above, WIPO serves as the treaty secretariat for the Berne Convention on copyrights. Copyrights take on significance with respect to the interface between ABS and IP as they have an impact on how certain TK may be treated. Article 2(1) of the Berne Convention enumerates a non-exhaustive list of items that must be protected by copyright:

“Every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression, such as books, pamphlets and other writings; lectures addresses, sermons and other works of the same nature; dramatic or dramatico-musical works; choreographic works and entertainments in dumb show’ musical compositions with or without words; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, architecture, sculpture, engraving and lithography; photographic works to which are assimilated works expressed by a process analogous to photography; works of applied art; illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science.”

Works are protected by the granting of exclusive rights on a work for a minimum term of life of the creator plus 50 years. Various limitations and exceptions have been carved out of copyright, such as for fair use. Two other copyright treaties were also negotiated under WIPO auspices, i.e., the so-called WIPO Internet treaties, which include the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. These treaties deal specifically with the effects of the digital environment on copyright.

Of particular note is that WIPO is currently engaged in potentially standard setting discussions on the interface between biodiversity and IP. In October 2000, the General Assembly of WIPO established the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (hereafter the IGC). The WIPO General Assembly has given the mandate to the IGC to conduct negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of TK, traditional cultural expressions (TCEs)/folklore and genetic resources. These negotiations have at the time of this writing

produced draft texts on these respective topics that remain heavily bracketed⁵¹, indicating that the IGC Members are as yet not in agreement on a number of issues. The international work on developing suitable legal frameworks for TK aims at the following objectives:

- Recognising its cultural and spiritual value
- Recognising the right to self-determination and customary laws and practices
- Respecting basic principles as e.g. free and prior informed consent
- Ensuring the protection against misappropriation
- Ensuring sharing of the benefits generated through its utilisation
- Regulating the application in scientific work and industrial processes
- Responding to the specific needs of TK holders

The IGC draft text on genetic resources discusses, *inter alia*, defensive databases, a proposed mandatory disclosure requirement and intellectual property clauses calling for mutually agreed terms for access and equitable benefit sharing. Major issues in the negotiations concerning the text on TK include the question of what constitutes public domain, the subject matter of protection, the beneficiaries of protection, and exceptions and limitations. A draft text also exists for TCEs. Debate continues to exist also on whether these topics should be covered under a single treaty or three separate ones.

No date has yet been announced for a diplomatic conference leading to any treaty instrument(s). The IGC is serviced by the WIPO Secretariat, and a number of studies on the topic of the interface between biodiversity, TCEs, TK and IP have been commissioned and published by WIPO over the years. Negotiations continue as of the date of writing.

Key Points

- ⇒ Many of the substantive provisions of basic WIPO treaties such as the Berne and Paris Conventions have been incorporated into the TRIPS Agreement by reference.
- ⇒ The activity of WIPO most relevant to the interface between biodiversity and IP is the work of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC). The WIPO General Assembly has given the mandate to the IGC to conduct negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of traditional knowledge (TK), traditional cultural expressions (TCEs)/folklore and genetic resources. At this point, it is not yet clear whether disclosure requirements will form part of the treaty text emanating from the IGC.
- ⇒ Negotiations at the IGC continue as of the date of writing. WIPO has not yet announced a date for any diplomatic conference leading to the adoption of a treaty.

⁵¹ See WIPO document WO/GA/40/7 of 12 August 2011 and the Facilitators' Draft of a Consolidated Draft Relating to Intellectual Property and Genetic Resources, 7 February 2013, available at <http://www.ip-watch.org/weblog/wp-content/uploads/2013/02/IGC-consolidated-document-Rev-2-Feb-2013.pdf>.

C. UPOV

As noted above, Article 27.3(b) of the TRIPS Agreement gives WTO Members the option of providing patent protection for plant varieties or for setting up a *sui generis* system for plant breeders' rights, or for some combination of the two. The International Union for the Protection of New Varieties of Plants (UPOV) is a multilateral treaty that facilitates the international protection of new varieties of plants through a *sui generis* system of plant breeders' rights for such new plants that meet certain minimum standards. It is therefore a treaty that is of interest to users who seek to commercialize a newly developed variety of a plant. The minimum standards that must be contained in national legislation differ depending upon whether a country has acceded to the UPOV treaty as amended in 1991 or an earlier version of the UPOV treaty.

As plants are genetic resources, the interface of UPOV with the Nagoya Protocol and the CBD is essentially similar to that for patents, in so far as the grant of a plant breeders' right confers the right to exclude others from the use of the variety without a license, subject to a number of possible exceptions. To that end, plant breeders' rights can be used to misappropriate genetic resources and related TK, and it can also serve as the basis for benefit sharing. The UPOV Secretariat appears to hold the view that disclosure of origin cannot be accepted as an additional requirement for protection, since the conditions for plant variety protection under the UPOV Convention have already been established and cannot be increased.⁵² Objections to this view have been raised by certain civil society groups.⁵³

With regard to farmers' rights, the 1991 text took up access-related elements of farmers' rights to a very limited extent. While such elements traditionally comprise saving, exchanging and selling of farm-produced plant material, Article 15(2) contains an optional exception to the breeder's right giving UPOV parties the opportunity to, "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety." If this farmers' exception is implemented domestically, it often is restricted to small-scale farmers or coupled with a specific license fee system. UPOV 1991 essentially abandons any practices of exchanging and selling farm-produced seeds according to customary law⁵⁴ if these practices involve protected material.

UPOV is governed by a Council of its members, and is serviced by a secretariat (its Office) that is housed in the WIPO building in Geneva, Switzerland. There are currently 70 countries that have, to date, become a member of UPOV.

That a country has not ratified UPOV does not mean that they do not have a system in place to protect new plant varieties. Rather, some biodiversity rich countries such as India and Thailand have opted to establish a *sui generis* system of plant variety protection outside of the UPOV framework, which contains, *inter alia*, provisions that go farther in protecting farmers'

⁵² Vivas-Eugui and Oliva (2010), p. 7.

⁵³ See, for example, Dutfield (2011).

⁵⁴ Customary Law- covers 'customs that are accepted as legal requirements or obligatory rules of conduct, practices and beliefs that are so vital and intrinsic part of a social and economic system that they are treated as if they are laws' (*Black's Law Dictionary*, 7th edition, 1999). Traditional communities maintain their own customary laws governing their community and use of the environmental resources.

rights and recognizes the development of domestic varieties based on traditional means of exchange of seeds. Such an option is available under the TRIPS Agreement to meet the requirements of Article 27.3(b).

Key Points

- ⇒ The International Union for the Protection of New Varieties of Plants (UPOV) is a multilateral treaty that facilitates the international protection of new varieties of plants through a *sui generis* system of plant breeders' rights for plants that meet certain minimum standards.
- ⇒ The interface of UPOV with the Nagoya Protocol and the CBD is essentially similar to that for patents, in so far as the grant of a plant breeders' right confers the right to exclude others from the use of the variety without a license, subject to a number of possible exceptions (such as, for example, the farmers' right to save seeds if contained in national legislation).
- ⇒ Some biodiversity rich countries such as India and Thailand have opted to establish a *sui generis* system of plant variety protection outside of the UPOV framework.

D. Free Trade Agreements

Multilateral treaties are not the only sources of international law that can address the interface between biodiversity and intellectual property. Free trade agreements (FTAs), often concluded on a bilateral basis, can sometimes contain IP provisions that affect the CBD objectives. Like the abovementioned multilateral treaties, the obligations contained in FTAs often require changes in national legislation or the adoption of new legislation.

It would be beyond the scope of this handbook to examine all the possible variants of biodiversity-related IP provisions in FTAs. It suffices for the purposes of this chapter to note that many of the provisions dealing with the interface had heretofore been so-called 'TRIPS-plus', i.e., requiring countries to adhere to standards that were more stringent than called for by the TRIPS Agreement. For example, Japanese FTAs with countries such as Chile (2007) and Indonesia (2007) oblige these countries to adhere to UPOV 1991 standards even though the TRIPS Agreement does not oblige countries to do so (as noted above, it only stipulates that some form of plant variety protection be offered to new plant varieties if patent protection is not offered).

Another provision that has raised a lot of concern is the rule in some US FTAs that the disclosure of an invention shall be considered as sufficiently clear if it provides sufficient information to be carried out by a person skilled in the art, and that an invention is sufficiently supported by its disclosure if the latter conveys that the applicant was in possession of the claimed invention at the filing date. This could arguably make it difficult for FTA partners to maintain patent-related sanctions for non-compliance with disclosure of origin, source, etc.⁵⁵ Such provisions potentially obligate the countries party to the FTA to adhere to standards that

⁵⁵ See Articles 16.9.9 and 16.9.10, of the FTA between USA-Peru. Similar provisions are found in the FTA between USA-Morocco, see Articles 15.21.10 and 15.21.11.

in effect offer, through most-favoured nation principles, TRIPS-plus IP protection standards to all countries despite not having been negotiated multilaterally.

The International Centre for Trade and Sustainable Development (ICTSD) finds, however, in a 2010 study that “an increasing number of North-South FTAs have incorporated biodiversity related provisions into these bilateral trade agreements in addition to traditional IP provisions, seeking a more balanced and sustainable approach”.⁵⁶ The study cites, in particular, the examples of understandings made by Colombia and Peru, respectively, pursuant to concluding FTAs with the United States. These understandings make an attempt to preserve policy space where TK and biodiversity interests are at stake.⁵⁷

Key Points

- ⇒ Free trade agreements (FTAs), often concluded on a bilateral basis, can sometimes contain IP provisions that affect the CBD objectives.
- ⇒ Many of the provisions dealing with the interface had heretofore been so-called ‘TRIPS-plus’, i.e., requiring countries to adhere to standards that were more stringent than called for by the TRIPS Agreement. Some studies show that more recently, biodiversity and TK rich developing countries are increasingly resisting the call to narrow the policy space available to them on IP provisions that have an impact on their biodiversity and TK resources.

III. The WHO Pandemic Influenza Preparedness Framework

The World Health Organization (WHO), a United Nations specialized agency headquartered in Geneva, Switzerland, has been engaged in work, *inter alia*, on vaccines, and potentially interfaces with the ABS provisions of the Nagoya Protocol/CBD. While there exists a debate as to whether pathogens are covered under the NP, this handbook takes the position that they are not excluded by the work done at WHO (see the section in Chapter 3 on Pathogens).

Member States of the World Health Assembly adopted in May 2011 a resolution endorsing the report of the Open-Ended Working Group on Pandemic Influenza Preparedness on the sharing of influenza viruses and access to vaccines and other benefits, and the resulting ‘Pandemic Influenza Preparedness Framework’, which includes as annexes standard material transfer agreements (SMTAs) for the sharing of pathogens with entities that are first, part of the WHO network for influenza monitoring, and second, for entities outside of that network, including between private companies.⁵⁸ These SMTAs are essentially contractual obligations between the signatories. WHO network participants are obliged to use the first SMTA, while the second SMTA serves as a guideline text for negotiations of MTAs between a network member and parties that are not part of the WHO network. The text of these SMTAs is contained in Annex II of this handbook.

⁵⁶ Vivas-Eugui and Oliva (2010), pp. vi-viii.

⁵⁷ Ibid., pp. 8 and 9.

⁵⁸ World Health Assembly Resolution 64.5 of 24 May 2011.

Unlike the ITPGRFA (see Chapter 1), the WHO SMTAs do not confer upon any government any treaty obligation. Under Article 4(3) of the Protocol, “[d]ue regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol”. This language serves largely as a reminder that unless specifically excepted by a separate treaty, the ABS system established by the Protocol may be interpreted by courts to cover influenza viruses.

Key Points

- ⇒ The World Health Assembly endorsed in May 2011, the use of standard material transfer agreements (SMTAs) for the sharing of pathogens with entities that are first, part of the WHO network for influenza monitoring, and second, between network entities and entities outside of that network. These SMTAs are contractual obligations between the signatories. WHO network participants are obliged to use the first SMTA, while the second SMTA serves as a guideline text for negotiations of MTAs between a network party and parties that are not part of the WHO network.
- ⇒ Unlike the ITPGRFA, the SMTAs do not confer upon any government any treaty obligation.

IV. Protecting Traditional Knowledge

The CBD and the Nagoya Protocol cover traditional knowledge associated with genetic resources. This begs the question how TK is to be protected. Various human rights instruments are the starting point for recognition of customary rights for ILCs, including over their TK. While these treaties may not specifically address ABS and IP issues as such, to the extent that rights of ILCs are grounded in them mean that they are important documents that may be used to interpret the more technical treaty provisions on ABS and IP in other treaties. Below is a brief survey of the most important of these treaties. A later chapter examines the appropriateness of various IP tools for protecting TK (see Chapter 5).

A. ILO Convention 169

Headquartered in Geneva, Switzerland, the International Labour Organisation (hereafter ILO) was the first UN body that specifically dealt with indigenous matters. Work started in 1926 with the development of standards for the protection of indigenous workers. ILO first focused more on the integration of indigenous workers into mainstream society than on dealing with and securing customary indigenous rights. This approach changed when in 1989, Convention 169 (the Convention Concerning Indigenous and Tribal Peoples in Independent Countries) was adopted. This treaty entered into force in 1991. Convention 169 focuses on land rights, labour, social security and education. While Article 15(1) provides for a rights-based approach to natural resources and thus complements the 1992 Rio documents, the issues of TK and IPRs are beyond the scope of Convention 169⁵⁹:

⁵⁹ Text available at: <http://www.ilo.org/ilolex/cgi-lex/convde.pl?C169>, accessed in January 2012.

"The rights of the peoples concerned to the natural resources pertaining to their lands shall be specifically safeguarded. These rights include the right of these peoples to participate in the use, management and conservation of these resources."

The Convention does not define who the indigenous and tribal peoples are, but provides criteria for describing the peoples it aims to protect. Article 1(2) states: *"Self-identification as indigenous or tribal shall be regarded as a fundamental criterion for determining the groups to which the provisions of this Convention apply."* Article 1(1) describes the difference between tribal and indigenous peoples which is also of relevance for the interpretation of the CBD and the Nagoya Protocol. These treaties speak of *"indigenous and local communities"* without giving any indications who might be the actual members of these groups. According to Convention 169, the following distinction is made:

1) Tribal peoples:

Their social, cultural and economic conditions distinguish them from other sections of the national community

Their status is regulated wholly or partially by their own customs or traditions or by special laws or regulations

2) Indigenous peoples:

Are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonisation or the establishment of present state boundaries

Do, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions

The main drawback of Convention 169 is the very limited membership of currently 22 states, of which 14 are located in Latin America. Although it is legally binding for its members, it does not include an enforcement and compliance mechanism.

The specific importance of this Convention for indigenous peoples living in its Member States specifically in the context of TK and IPRs was recently underlined by a judgement of the Supreme Court of Costa Rica. While supporting the future patentability of inventions *"essentially derived from the knowledge associated with traditional biological practices or cultural practices in the public domain"* in Costa Rica, the Supreme Court also stated that such an amendment *"is a change that directly affects the interests of indigenous communities, and, as a result, in conformity with the 169 Convention this amendment must be consulted..."*⁶⁰ This judgement supports the call by indigenous peoples' organisations to be formally included in the development of national ABS and IP regulations that would cover their genetic resources and TK.

Key Points

⁶⁰ Cabrera Medaglia (2010), p. 286.

- ⇒ ILO Convention 169, while limited to the 22 states that signed it, is important in helping interpret the term ‘indigenous and local communities’ within the context of ABS.
- ⇒ A judgment in Costa Rica supported the formal inclusion of ILC organizations in the development of national ABS and IP regulations.

B. Universal Declaration of Human Rights and ICESCR

Rights in TK need to be discussed in the light of the provisions of the Universal Declaration of Human Rights 1948 (UDHR)⁶¹ and the International Covenant on Economic, Social and Cultural Rights 1966 (ICESCR, entered into force in 1976)⁶². While the former is a recitation of important universally accepted human rights norms, the latter is a treaty with obligations for which the United Nations Office of the High Commissioner for Human Rights, headquartered in Geneva, Switzerland, services the treaty body charged with implementing the ICESCR. Read in a sequence, several articles of these two instruments shed some light on the human right status of the protection of TK as intellectual property (see Box 6 below).

Box 6 Basic Human Rights Instruments and their Potential Impact on ABS and IP	
ICESCR Article 1 1. All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development. 2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.	Establishes the right to self-determination, including the right to dispose of natural resources, implying also the right to protect these resources incl. intellectual property
UDHR Article 7 All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.	The equal protection under the law implies that protection of intellectual property should also be available for indigenous peoples
UDHR Article 17 (1) Everyone has the right to own property alone as well as in association with others. (2) No one shall be arbitrarily deprived of his property.	Providing the right for collective property and protection against being deprived of that property
UDHR Article 27 (1) Everyone has the right freely to participate in the cultural	Implying the protection of rights

⁶¹ Text and more information available at: <http://www.un.org/en/documents/udhr/>, accessed in January 2012.

⁶² Text and more information available at: <http://www2.ohchr.org/english/law/cescr.htm>, accessed in January 2012

life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

over advancements and innovations based on TK

Source: based on Posey.⁶³

The UDHR and ICESCR are instruments that help to define basic rights. While making no specific reference to IP, ABS or TK as such, they may provide interpretive guidance.

Key Points

⇒ Various provisions of both the UDHR and ICESCR are also helpful interpretive tools for cases that involve TK associated with genetic resources.

C. UNDRIP

The United Nations Declaration on the Rights of Indigenous People (UNDRIP) is a comprehensive statement addressing the rights of indigenous peoples. It was drafted and formally debated for over twenty years prior to being adopted on 29 June 2006 during the inaugural session of the UN Human Rights Council. The UNDRIP protects indigenous peoples against discrimination, and recognizes their rights to internal self-determination, culture, land, spirituality and religion, and health. The UNDRIP acknowledges the collective nature of indigenous peoples' rights as a basic principle. UNDRIP emphasizes the rights of indigenous peoples to maintain, control, protect and develop their cultural heritage, TK and TCEs, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines and knowledge of the properties of fauna and flora. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, TK and TCEs.

The UNDRIP is to date the most explicit recognition in a human rights instrument of a specific set of rights over various items that are potentially covered by the ABS regime, including TK and TCEs, as well as the manifestations of their sciences, technologies and cultures. Although the UNDRIP is not legally binding and consequently does not provide for compliance and enforcement mechanisms, its provisions add to the existing body of customary international law, and is a valuable reference point when articulating the rights of indigenous peoples. Relevant provisions of the UNDRIP are reproduced below.

Box 7

United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

Article 31.

⁶³ Posey (1994), pp. 125-26.

1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

Source: UNDRIP (2007).

Key Points

- ⇒ While not legally binding, UNDRIP affirms a positive right of indigenous people to maintain, control, protect and develop their cultural heritage, TK and TCEs, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts.

D. UNESCO

Adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) General Conference in 2003, the Convention for the Safeguarding of Intangible Cultural Heritage (hereafter CSICH) exists as a means to identify and preserve intangible cultural heritage for future generations, as defined under Article 2 of that Convention:

“1. The “intangible cultural heritage” means the practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artefacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity. For the purposes of this Convention, consideration will be given solely to such intangible cultural heritage as is compatible with existing international human rights instruments, as well as with the requirements of mutual respect among communities, groups and individuals, and of sustainable development.

2. The “intangible cultural heritage”, as defined in paragraph 1 above, is manifested inter alia in the following domains:

(a) oral traditions and expressions, including language as a vehicle of the intangible cultural heritage;

(b) performing arts;

(c) social practices, rituals and festive events;

(d) knowledge and practices concerning nature and the universe;

(e) traditional craftsmanship.”

This breadth of coverage therefore includes various practices that might overlap with certain TK associated with genetic resources, such as in item 2(d). “Safeguarding” is further defined as measures aimed at ensuring the viability of the intangible cultural heritage, including the identification, documentation, research, preservation, protection, promotion, enhancement, transmission, particularly through formal and non-formal education, as well as the revitalization of the various aspects of such heritage. While the Convention obliges parties to the Convention to take necessary measures for safeguarding (Article 11(a), CSICH), it stops short of granting any specific rights when a country has identified an intangible cultural heritage.⁶⁴ At the international level, a Committee maintains a Representative List of the Intangible Cultural Heritage of Humanity and a List of Intangible Cultural Heritage in Need of Urgent Safeguarding. Registration on either List is thought to be a means for countries to mobilize assistance to protect the intangible cultural asset. Registration as a UNESCO intangible heritage may, nonetheless, be useful for ILCs in making the case that certain TK associated with genetic resources belongs to them, and not to others.

The Convention is administered by UNESCO’s Secretariat, located in Paris, France.

Key Points

⇒ UNESCO’s Convention for the Safeguarding of Intangible Cultural Heritage provides for the listing by countries of intangible cultural heritage on a Representative List of the Intangible Cultural Heritage of Humanity and a List of Intangible Cultural Heritage in Need of Urgent Safeguarding. International registration may be useful for ILCs in making the case that certain TK associated with genetic resources belongs to them, and not to others.

V. Conclusion

The international policy making landscape for issues that straddle both IP and biodiversity issues is complex. A number of forums have concluded treaties at the international level that will have an impact on biodiversity issues, and many forums continue to be engaged in discussions that could potentially change the landscape of the interface. To make matters even more complex, the same issue (for example, disclosure of origin) may be discussed in more than one forum (WTO and WIPO/IGC), or be a subject dealt with at both the multilateral and bilateral levels (for example, plant variety protection). Countries may be bound by one treaty, but not by another (China is bound by CBD, but not by the ITPGRFA). Some obligations are treaty obligations, while others are contractual (the WHO SMTAs on pandemic influenza).

⁶⁴ On the other hand, the Convention would not prevent any Party from granting such specific rights either.

The situation of each country therefore needs to be analyzed on the basis of which treaties it has become a party to, and defies easy analysis.

The remainder of this handbook is dedicated to the nearly-universal CBD, the links between the ABS system established by the Nagoya Protocol and the TRIPS Agreement obligations that affect the CBD objectives. References to other agreements will be made throughout where relevant. Readers should keep in mind, however, that new rules could emerge from the forums mentioned above. As a general observation, however, many of the issues being considered are contentious, and may take some time to come to an agreement.

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 novelty⁷¹). 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 applications⁷⁶; 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 mandatory⁷⁹; 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 extent⁸⁰, 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 MAT⁸¹, 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 BRDR⁸⁵) 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 provenance⁹⁴, 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 ferns, 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 fashion¹⁰⁰, 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 unenforceability¹⁰³, 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 priority¹⁰⁸ 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 <i>Lepidium</i> (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 <i>Plukenetia</i> volubilis and its cosmetic use. (WO/2006/048158)	PCT	Retired
Sacha inchi	Utilisation d’huile et de protéines extraites de graines de <i>Plukenetia</i> volubilis linneo dans des préparations cosmétiques, dermatologiques et nutraceutiques. (FR 2880278)	France	Retired
Camu camu	Preserves of fruit of <i>Myrciaria</i> dubia (Publicación N° 09 – 215475)	Japan	Abandoned

Pasuchaca	Inhibitor of glycosidase (P2005-200389 ^a)	Japan	Abandoned
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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 provenance 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.

Chapter 4

Additional Mechanisms beyond Disclosure

I. Introduction

In Chapter 3, this handbook examined how disclosure requirements in the national patent legislation could potentially help act as an indicator for possible misappropriation for the national competent authority under the Nagoya Protocol and indigenous and local communities and related stakeholders, as well as to provide patent authorities with relevant information to make an informed decision on whether relevant patent criteria are met when a patent application has been filed with the national patent office and is being assessed for the potential grant of rights. A range of other mechanisms exist, though, that could potentially exclude the consideration of certain subject matter from patentability altogether, without proceeding to the question of whether patentability criteria are met, or which could be used as grounds to defeat or revoke a patent. These mechanisms are examined in this chapter.

From a strategic perspective, many of these patent law mechanisms can be classified as ‘defensive’, meaning that they are designed to prevent or reduce the misappropriation of genetic resources and associated traditional knowledge (TK) through the intellectual property (IP) system by others, rather than to use IP to secure benefits for the provider country or indigenous and local communities (ILCs) accruing from research done on genetic resources and related TK. Importantly, the mechanisms apply, through the national treatment principle, equally to foreigners and nationals of any given country. These patent law mechanisms are generally grounded on rationales that have developed over time, but with little consideration of Convention on Biological Diversity (CBD) or Nagoya Protocol objectives. Chapter 4 will discuss these mechanisms and their background so that users of this handbook are able to make informed decisions about how to shape their domestic legislation and negotiation strategies.

II. Life Forms and their Patentability

A. Biotechnology, GRs and Derivatives: Key Exclusions

National IP laws, appropriately tailored, may assist a country in addressing the situation where individuals seek to patent products based on genetic resources without having met CBD/Nagoya Protocol obligations. A first line of argument against those who seek such patents may be that the patent law cannot grant protection to the product in question, at least in the provider’s jurisdiction. It is also important because stakeholders in provider countries need to be aware of the realistic range of possibilities when granting access to genetic resources and negotiating benefits (i.e., to what extent will it really be possible to obtain a patent over the fruits of the user’s R&D for which benefits may be shared?).

The question of whether derivatives are subject matter covered by the Nagoya Protocol is discussed in Chapter 1. Unfortunately, the terminology used in the Protocol concerning genetic resources and their derivatives does not translate easily into the language used by IP practitioners. The language of the Protocol was drafted in a way that largely avoids linkages

to the IP system and is therefore difficult to utilize in clarifying IP-related ABS issues. Moreover, the IP law in this area is also quite complex.¹¹¹ From the perspective of patent law, many countries have traditionally excluded from patent protection naturally existing substances. This is permitted under the TRIPS Agreement for WTO Members, since Article 27.1 of TRIPS requires that patent protection be available only for *inventions* that otherwise meet patentability criteria, and not for *discoveries* of substances existing in nature. Article 27.3(b) of the TRIPS Agreement provides that plants and animals can also be excluded from patentability, but that some measure of patent protection must be available for micro-organisms.

Members are generally free to determine definitions for, or the scope of, the terms invention, discovery and micro-organism, respectively, as they are not defined under the TRIPS Agreement. Because countries have this flexibility in the implementation of Article 27 of the TRIPS Agreement, they often differ widely in the extent to which a substance found in nature needs to be changed, if at all, in order to be patentable. A number of countries, especially in Latin America, exclude from patentability the mere extraction or isolation of a naturally existing substance.¹¹² In these jurisdictions, the underlying biological material must have undergone a structural change in order to be patentable. With respect to micro-organisms, some countries such as Brazil have required that in order to be patentable, micro-organisms must have been genetically modified.¹¹³ Under US¹¹⁴, Japanese and EU practice, however, the process for isolating a substance existing in nature may qualify for patent protection; further, a process patent claim may include the underlying substance.¹¹⁵ It should also be noted that the various approaches to define what is patentable have not been challenged in WTO dispute settlement to date.

The distinction, from a legal perspective, is that by removing certain genetic resources from patentable subject matter, there is no question of whether the claimed product or process meets the three patentability criteria of novelty, inventive step and industrial applicability. It remains in the public domain unless it is the subject of another exclusive right, such as plant variety protection or *sui generis* TK laws. IP law can therefore make it more difficult to (mis)appropriate certain genetic resources. National patent law could exclude from patentability mere discoveries, and ensure that some change in the underlying genetic resources must have taken place in order to proceed to the question of whether or not to grant a patent. This would render it impossible to appropriate plants and animals via patents as such¹¹⁶, and remove the possibility of patenting the isolation or extraction of a naturally existing substance.¹¹⁷ This approach would also, by definition, remove from patentability all

¹¹¹ The term 'derivatives' means something very different in patent law than it does under the CBD; it is a term of art used to describe a products that are similar to an originally patented product, but nevertheless not identical. In the case of medicines, for example, it could be used to describe a chemical entity with a slightly different chemical structure.

¹¹² See examples from Argentina, Brazil and the Andean Community. UNCTAD (2011b), pp. 48-49.

¹¹³ The South Centre, V. II (2008), pp. 11-12.

¹¹⁴ A US Supreme Court case is currently examining the question of whether gene sequences can be patented. See the discussion of the Myriad case below.

¹¹⁵ Ibid. See also *Diamond v. Chakrabarty* 447 U.S. 303 (1980); Enforcement Standards for Substance Patents of Japan; and Article 3.2 of the European Directive on Biotechnological Inventions.

¹¹⁶ Plants and animals as such can also be excluded from patentability wholesale under Article 27.3(b) of the TRIPS Agreement.

¹¹⁷ The authors do not imply that extraction or isolation is not a laborious process that merits some type of compensation; the authors argue only that the patent system is not intended to provide a reward for activities that are closer to discoveries than inventions.

derivatives under the Nagoya Protocol, since by definition derivatives are naturally occurring biochemical compounds.

Commentary suggests that micro-organisms should be treated in a manner similar to plants and animals notwithstanding the requirement in Article 27.3(b) of the TRIPS Agreement that micro-organisms should remain patentable subject matter. There is general worldwide consensus that micro-organisms, which include fungi, bacteria and viruses (including those that can be classified as pathogens) as found in nature cannot be patented.¹¹⁸

While provider countries may adopt a bar for patentability along the lines of the preceding paragraph, this may not prevent an individual or company that bioprospects from seeking a patent over certain isolates and extracts where that is permitted.¹¹⁹ As noted above, US, Japanese and EU law would currently allow genetic resources and derivatives which had been extracted and isolated, without any change to their structure, to be considered for patentability under certain circumstances, even where they are not patentable under provider country legislation. Moreover, patent laws should not prevent the patentability of a *bona fide* new invention that utilized an unchanged genetic resource. Even in such cases, disclosure could nonetheless be used to help assess, to some extent, the three criteria that must be met in order to grant a patent (see discussion of disclosure requirements in the previous chapter). In this regard, it should also be recalled that the question of mandatory disclosure of origin/source through a revision of Article 27.3(b) remains tabled at the WTO, although delegates do not appear to be any closer to agreement on this issue than they were when the proposal was first made in 2008. Further, in a best case scenario, where access to genetic resources has been provided to a user under MAT which include the appropriate sharing of benefits, providers may potentially even benefit where a *bona fide* user decides to seek commercialization of the fruits of his or her research in a jurisdiction of broad patentability standards.

Depending upon the level of sophistication of their R&D capacities, some provider countries may find that they can incentivize local firms to seek commercialization of the fruits of their research by allowing the patentability of isolates and extracts of micro-organisms. India, for example, has followed this approach.¹²⁰ Still relatively few developing countries that are home to rich biodiversity will be able to take advantage of the availability of patents over extracts and isolates of micro-organisms, though, and the simplicity of exclusion where the ability of the patent office to assess patent applications adequately is low may be a more practical TRIPS-compliant alternative of helping prevent misappropriation.

A final question relates to the status of genes and other sub-cellular components. R&D on the genetic code of the plants, animals and micro-organisms which have their origin in a provider country, as well as R&D into practical applications of that code, would be subject to applicable ABS requirements of the Nagoya Protocol, as this treaty applies to all such genetic resources. On the IP side, to the extent that a sub-cellular component is not an organism, there is no particular obligation in Article 27.3 of the TRIPS Agreement to provide any measure of protection for genes or sequences of genetic code.¹²¹ In most jurisdictions, the genetic code of living things are generally regarded as a substance found in nature (hence, excludable from patentability). Yet, advances in genetic research are increasingly the subject of patent

¹¹⁸ UNCTAD-ICTSD (2005), p. 392.

¹¹⁹ South Centre V. II (2008), pp. 15-16.

¹²⁰ See Somasekhar (2005).

¹²¹ UNCTAD-ICTSD (2005), p. 393.

applications in jurisdictions where much of that R&D is taking place. This is because the genetic code of living things, including humans, animals, plants and micro-organisms, can be mapped and isolated, and used in diagnosis and therapy. DNA can be synthesized from messenger RNA (cDNA). Jurisdictions where the fruits of genetic research are being patented argue that this takes the gene out of its naturally-existing environment, changes it and makes it patent-protectable.

But even in those jurisdictions that are permitting the patenting of genes, the status of what exactly is or is not patentable is subject to debate. In a recent case in the US, a District Court judgment decided to invalidate the patents on two isolated gene sequences that had been granted to Myriad Genetics, Inc. These two gene fragments are useful in the diagnosis of some hereditary forms of breast and ovarian cancer. A recent Court of Appeals for the Federal Circuit decision reversed the earlier 2010 District Court judgment and held that isolated gene fragments are potentially patentable.¹²² The majority of the Court of Appeals argued that while genes themselves are products of nature, patents should continue to be granted to applicants who "isolate" nucleic acid sequences from their natural environment, sequence them, and identify functions and uses for those sequences in line with existing USPTO practice. The majority concluded that the isolation resulted in a change of molecular structure, even if it did not change the underlying genetic code of the isolated sequence. One judge dissented, however, and argued that mere isolation of the two BRCA gene sequences was not an invention, since there was no substantive change in the isolated gene from the larger gene sequence.¹²³ The US Supreme Court recently reversed the Court of Appeals decision, holding that the mere isolation of a gene, as in the case of the two BRCA genes, is not patentable.¹²⁴ The Supreme Court decision on the issue of the patentability of genetic code is likely to have an effect on practice not only in the US but elsewhere as well.

From the perspective of provider countries, keeping gene sequences of genetic resources from the country of origin off-patent is certainly one means to help prevent misappropriation. This is especially true for genetic resources that are potentially not covered by the Nagoya Protocol, including those that are already in the hands of user countries (i.e., pre-dating the CBD and/or the Nagoya Protocol). At the same time, as in the case of plants, animals and micro-organisms more generally, if there exists a material transfer agreement under MAT, where benefits are to be shared (as is required under the Protocol), then commercialization would potentially offer the possibility for the provider country stakeholders to gain from patenting.

Key Points

- ⇒ The Nagoya Protocol stipulates that the utilization of genetic resources as well as subsequent applications and commercialization are subject to benefit sharing obligations. The Protocol leaves it open to interpretation which substances or even which types of information generated from genetic resources through the application of biotechnology are subject to benefit sharing obligations.

¹²² See, for example, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* (Case No 2010-1406, decided 29 July 2011 by the US Court of Appeals for the Federal Circuit).

¹²³ The dissenting judge's view is similar to the position taken by the European Patent Office (EPO) Technical Board of Appeal that while the diagnostic methods developed by Myriad are patentable, the underlying isolated gene in its normal or mutated form is not.

¹²⁴ *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* (Case No. 12-398, slip op, decided by the Supreme Court of the United States on 13 June 2013).

- ⇒ The TRIPS Agreement permits Members to exclude from patentability substances existing in nature, since they can be classified as discoveries, and not inventions. Plants, animals and micro-organisms in their natural form can therefore be excluded from patentability.
- ⇒ The TRIPS Agreement requires that some level of patent protection must be available for micro-organisms, such as viruses, bacteria, fungi, etc. Some countries have addressed this requirement by stipulating that some genetic change needs to have occurred in order for a micro-organism to be patentable. Other jurisdictions have been willing to entertain patent application claims for mere isolation or extraction.
- ⇒ Because genetics examines sub-cellular units, and micro-organisms are cellular, it falls outside the obligation relating to the patentability of micro-organisms under TRIPS Article 27.
- ⇒ IP law concerning the patentability of the fruits of genetic research is as yet evolving. There is little global consensus on what ought to be patentable. Key questions in these cases include whether the gene has been taken out of its naturally-existing environment; whether isolated gene sequences are patentable; and the extent to which such gene sequences need to be modified or applied in order to be patentable.
- ⇒ Exclusions from patentability will dispense with the need for patent offices to substantively examine an application. The result will be that the excluded item will be in the public domain unless covered by some other form of IP, at least in the provider country. This may be an attractive TRIPS-compliant alternative for developing countries that have little capacity to assess certain complex biotechnology patents.

B. Pathogens

Chapter 1 discussed the debate about whether pathogens are covered in under the Nagoya Protocol, and concluded that there did not appear to be any language in the text of the Protocol that would seem to exclude it. The link between pathogens under Article 8(b) of the Nagoya Protocol and IP surfaces when user country firms use the acquired pathogen to create vaccines and treatments for the diseases which they cause, and seek patents over the resulting medical product or process. For example, the Government of Indonesia decided in 2007 to withhold H5N1 virus samples from WHO's Collaborating Centres until a mechanism offered fairer terms for developing countries. Indonesia's action was initiated after it discovered that the sample viruses it had transferred to WHO Collaborating Centres were given to vaccine manufacturers without its knowledge or permission under material transfer agreements and patents had been granted to such manufacturers for the fruits of their research based on those samples.¹²⁵

Article 8(b) of the Nagoya Protocol, which stipulates that Parties need to take due regard in the ABS legislation to emergency situations including those involving public health, could potentially provide a limited amount of relief in the event a user country firm uses a pathogen obtained from a provider country to create a vaccine that is then patented by that firm. Nothing would, for example, exclude the consideration by developing countries to grant the issuance of compulsory or government-use licenses to either import or produce the vaccines

¹²⁵ Shashikant (ed.) (2010), pp. 24 and 31.

locally, assuming that a patent exists over the vaccine in the provider country. National patent legislation would need to provide the legal underpinning for this eventuality, however. Specifically, compulsory and government-use licenses would need to be made available in order to address emergency situations. National ABS legislation should also include language that indicates that the access provided to pathogens under Article 8(b) must take into consideration the expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need. In order to make clear that the national ABS legislation has jurisdiction over such pathogens, there is nothing preventing Member States from stipulating that, notwithstanding the debate over whether the CBD and Nagoya Protocol cover pathogens, their ABS law covers all genetic resources, including pathogens.

A more difficult question is to determine the impact of the work done at the WHO on the sharing of virus pathogens on the Nagoya Protocol, and how developing countries should take this work on board in formulating a strategy to deal with the situation of demands made by user countries for access to pathogens found locally, as well as how this may affect the options available to developing countries in non-emergency situations.

At the May 2011 World Health Assembly, Member States adopted a resolution endorsing the report of the Open-Ended Working Group on Pandemic Influenza Preparedness on the sharing of influenza viruses and access to vaccines and other benefits, and the resulting 'Pandemic Influenza Preparedness Framework', which includes as annexes SMTAs for the sharing of pathogens with entities that are first, part of the WHO network for influenza monitoring, and second, between network entities and entities outside of that network.¹²⁶

In the negotiations of the Open-Ended Working Group and at the 64th World Health Assembly (WHA) in May 2011 where the output of the Working Group was ultimately endorsed¹²⁷, government delegates largely avoided including any language in the draft SMTAs that would clarify the relationship between these SMTAs and the Nagoya Protocol. The concept of ABS so prevalent in the Nagoya Protocol is, nonetheless, also present in the two SMTAs, even in the absence of language directly linking the SMTAs with the Protocol. In the SMTA for the WHO network (SMTA1), recipients are obliged to actively seek the participation of scientists from the originating laboratories, especially those in developing countries, and participating entities are required to refrain from seeking any intellectual property (IP) protection over vaccines and other treatments made using the underlying materials.¹²⁸ Onward transfer under this SMTA to an entity outside the WHO network is permitted provided the outside entity agrees to be bound by the terms of the SMTA.

In the SMTA for contracts between WHO network entities and entities outside the WHO network (SMTA2), the recipient of the virus must commit to at least two benefit sharing options in exchange for access to the virus sample, which potentially includes royalty-free licenses to manufacturers in developing countries, creating a reserve for developing countries antiviral medicine in pandemic situations at affordable prices or donating 10% of vaccine production to WHO, among others.¹²⁹ Even if there was a conscious decision on the part of

¹²⁶ World Health Assembly Resolution 64.5 of 24 May 2011.

¹²⁷ Saez (2011).

¹²⁸ Assuming that pathogens are covered under the Nagoya Protocol, this requirement to refrain from patenting would be stricter than the standards as required by the Protocol.

¹²⁹ Ibid.

governments negotiating these instruments to avoid any reference to the Nagoya Protocol, it would make sense that the drafters would still wish to see these documents consistent with the Protocol, in the event the relationship between the work of the WHO and the Protocol were ever to be decided by a court of law. Both SMTA1 and SMTA2 are included in Annex II to this handbook.

However, while WHA Resolution 64.5 urges Member States to implement the Pandemic Influenza Preparedness Framework (which includes an endorsement of the SMTAs and stipulates the situations in which the SMTAs are to be used), unlike a binding treaty obligation, there is no means beyond general contract law to enforce compliance by a Member State or to ensure the use of and adherence to the terms of the SMTAs; countries and participating entities in the WHO Collaborating Centre network will, though, be bound by SMTA1. From a legal standpoint, it may therefore be prudent to consider the SMTAs as a contractual (as opposed to a treaty-based) safeguard against those that may seek to obtain IP protection over vaccines and other treatments produced using the underlying genetic materials (and related TK) without the permission of the country granting access, and recourse for violations of the SMTAs is, in principle, limited to the dispute resolution mechanism stipulated in these agreements. This is perhaps what was meant when Article 3*bis*(3) of the Nagoya Protocol requires that “[d]ue regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol”, in so far as the negotiations of the WHO Working Group were still taking place during the Nagoya Protocol negotiations.

As a matter of strategy, developing countries which have to deal with issues of ABS over virus pathogens would be best advised to: 1) grant access to such pathogenic resources under the WHO network to avail of SMTA1, as this document grants the greatest measure of protection against the unauthorized patenting of products and processes developed from pathogens; and 2) review their ABS and IP laws to ensure that compulsory license and government-use license remedies are available under the second clause of Article 8(b) of the Protocol, i.e., in emergency outbreak situations. The latter will be necessary where, for one reason or another, access has to be granted to pathogens outside the WHO Collaboration Centre framework. In such cases, governments could cite the second clause of Article 8(b), as justification for negotiating a material transfer agreement with user firms for appropriate benefit sharing in emergency situations (perhaps by using SMTA2 as a template). In order to better ensure benefit sharing notwithstanding the debate over whether pathogens are covered under the CBD and NP in non-emergency cases, the national ABS law should make clear that the law is intended to govern issues related to access and benefit sharing for all genetic resources within national borders, including pathogens.

In other forums, discussions continue at the Geneva-based Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which takes place under the auspices of the World Intellectual Property Organization (WIPO). Established in October 2000, this forum’s mandate¹³⁰ is to shape an international *sui generis* regime for the protection of TK and traditional cultural expressions, as well as an IP regime that addresses the misappropriation of genetic resources. Discussions at the IGC have been examining disclosure requirements and the feasibility of databases under such an international

¹³⁰ See Decision 28 of the 38th WIPO General Assembly (2009). The mandate for this Committee was extended in 2011.

instrument(s), but have so far avoided the issue of how the evolving *sui generis* regime would interface with the CBD and the Nagoya Protocol, and how pathogens ought to be treated. At this stage, it is as yet unclear how the IGC discussion will shape the international regime for ABS and pathogens, and its implications on IP.

Key Points

- ⇒ There has been a longstanding debate among negotiators on whether the CBD and NP cover pathogens. Article 8(b) of the Nagoya Protocol, however, arguably requires Member States to take into consideration the need for expeditious access to pathogens in emergency situations and expeditious benefit-sharing arising out of the use of such genetic resources.
- ⇒ Where possible, developing countries should consider granting access to pandemic virus pathogens in cooperation with WHO Collaboration Centres using the SMTA1, as called for under WHA Resolution 64.5.
- ⇒ Developing countries should review their ABS and IP laws to ensure that compulsory license and government-use license remedies are available under the second clause of Article 8(b) of the Protocol, in emergency situations.
- ⇒ Where it is not possible to provide access to pathogens through WHO Collaboration Centres, developing countries should negotiate with the user country firm, possibly using SMTA2 as a template. In emergency situations, Article 8(b) of the Nagoya Protocol could be cited to obtain appropriate benefit sharing.
- ⇒ In non-emergency situations, access to pathogens should be made conditional on benefit sharing through national ABS legislation, which should make clear that the scope of domestic law includes ABS related to pathogens.

III. Limitations and Exceptions to IP Laws

A. The Research and Experimentation Exception for Patents and PBRs

Exceptions to patent law acknowledge the existence of a patent, but allow certain activities using the protected subject matter to take place notwithstanding an absence of permission by the patent holder. The research and experimentation exception in patent law is an exception to the right of a patent holder to be able to exclude others from the use of the patented subject matter if that subject matter is being used for certain research activities.¹³¹ The effect of the exception is to shield scientists from liability when they conduct research using patented subject matter that falls under the exception without the permission of the patent holder. Most countries have included a research and experimentation exception in their national patent law.

Language from a World Trade Organization (WTO) dispute settlement case in 2000 perhaps captures the rationale behind such an exception best: “a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to

¹³¹ UNCTAD-ICTSD (2005), pp. 437-38.

the public.”¹³² WTO Members have relied on this language to formulate explicit research exceptions in their domestic patent law under Article 30 of the TRIPS Agreement.¹³³

Practices between countries vary, though, as to exactly what kind of research and experimentation actually falls under this exception. Some countries have extremely broad language that permits virtually all scientific and technological research activities, irrespective of how the fruits of that research may be used (for example, Brazil, the Bangui Agreement). Other countries attempt to distinguish between commercial and non-commercial research, excepting the latter but not the former (for example, Indonesia, Kenya, Lebanon). Still other countries make a distinction between research “with” a patented product or process and research “on” a patented product or process (for example, the continental European countries generally make an exception for research “on” a patented product or process but not on research “with” a patented product or process). There is therefore no uniform practice among the countries of the world. Moreover, the exact scope of the exception has not, to date, been the subject of WTO dispute settlement beyond the suggestive language in the EC-Canada case cited above.

It should be noted that IP regimes other than patents can also have a research and experimentation exception. Of particular relevance in the CBD context, is the area of plant variety protection, otherwise known as plant breeders’ rights (PBRs). PBRs are a *sui generis* form of IP protection over new varieties of plants that meet certain criteria.¹³⁴ Article 15 of the 1991 International Convention for the Protection of New Varieties of Plants (UPOV), for instance, makes acts done for experimental purposes a mandatory exception to PBRs. UPOV permits free use of protected varieties by any breeder for the purpose of developing a new variety. Countries that have opted to have *sui generis* systems of PBRs outside the UPOV regime, such as Thailand, also include a statutory research exception in their PBR legislation.¹³⁵ Research exceptions can also be built into utility model legislation.

Arguably, a research and experimentation exception in the patent law is fully consistent with the Nagoya Protocol and supports certain provisions. Notably, Article 8(a) of the Protocol states that “[i]n the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall . . . [c]reate conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including though simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.” A potential conflict exists with PBR laws, however. PBR laws with a broad R&D exception allow a breeder to utilize genetic resources for developing new varieties, provided he already (legally) possesses those genetic resources.

It is important to note, however, that a research and experimentation exception in the national patent law will not eliminate the need for PIC under Nagoya compliant national ABS legislation in the event that someone seeks to access genetic resources for research purposes.

¹³² *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000, para. 7.69.

¹³³ Article 30 of the TRIPS Agreement provides that “Members may provide limited exceptions to the exclusive rights conferred by patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.”

¹³⁴ The criteria for a plant variety to receive protection under PBR legislation are generally novelty, distinctiveness, uniformity and stability.

¹³⁵ See Section 33 of Thailand’s Plant Varieties Protection Act, B.E. 2522 (1979), as amended.

Under Article 6(1) of the Protocol, “access to genetic resources for their utilization shall be subject to the prior informed consent of 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, unless otherwise determined by that Party.” Utilization of genetic resources is further defined in Article 2 of the Protocol to mean research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined under the CBD. Unlike Article 8(a) of the Protocol, the PIC requirement makes no distinction between commercial and non-commercial research.

The interface of the provisions concerning R&D in the national patent law and national ABS legislation sets up an interesting situation. Patent holders are unable to prevent R&D activities involving their inventions that contain or are based on genetic resources, provided that R&D falls under the scope of the research and experimentation exception. Researchers are, however, not completely free to conduct that research without risk of legal liability as they may still be subject to PIC of the provider country when they seek to access those same genetic resources, subject only to the requirement that, under Article 8(a) of the Nagoya Protocol, simplified measures for access need to be available if the research is non-commercial.

This situation does not necessarily reflect an incompatibility of the two sets of laws. The patent holder has an economic incentive that may work against the development of technologies that could potentially render the subject invention obsolete. A research exception in the patent law helps to preserve some of the ‘freedom to operate’ and conduct such research in furtherance of the advancement of technical knowledge. The PIC requirement is the basic check against misappropriation. The economic dynamic of patent holders is not present in the case of PIC and provider countries. In fact, provider countries are interested in seeing genetic resources and associated TK become successful commercial products, provided the benefits accruing from those products are shared with the provider country and/or the indigenous communities.

Given that the treatment of the freedom to operate under these two sets of laws is compatible, how should countries structure their research and experimentation exception in the patent law? Before answering this question, it is important to consider a number of trends in R&D worldwide.

First, there is an increasing tendency for universities to seek patent protection over their research results as a consequence of certain national and university policies. A number of developing countries have passed legislation or are considering passing legislation that encourages the patenting of research results by universities. Such countries include India, Jordan, Malaysia and South Africa. These laws are often modelled at least in part on the US Bayh-Dole Act (1980), which, *inter alia*, actively endorsed the practice of universities seeking patents, in an effort to bridge the gap between scientific research and commercialization.¹³⁶

A second related trend is that there is an increased blurring of the lines between commercial and non-commercial research, with courts in certain common law countries such as the United Kingdom and the United States using this ambiguity to limit the scope of a research exception under patent law.¹³⁷ The increasing presence of public-private partnerships in research in

¹³⁶ See Sampat (2009).

¹³⁷ Adachi and Misati (2010).

areas such as biotechnology seems to have led to less clarity as to what constitutes commercial and non-commercial research. Courts in common law countries have generally not been favourable to arguments that universities, who are now encouraged to patent themselves, should be shielded from having to obtain the permission of patent holders in their research activities. A notable example is the US case of *Madey v. Duke University*, which in 2002 held that universities, which had previously relied on a wide research exception to conduct scientific research activities using patented subject matter without the consent of the patent holder based on their charters that commit them to non-profit objectives, could no longer rely on an exception to conduct such research where such research is in furtherance of the university's legitimate business interests.¹³⁸ While the US is not a Party to the CBD or the Nagoya Protocol at present, its court cases are still widely influential, and US universities conducting research are bound by the terms of the decision when they collaborate with international partners in scientific research.

These trends argue in favour of a relatively wide research exception if the objective is to preserve a relatively wide freedom to operate. Such an exception arguably need not distinguish between commercial and non-commercial research. It is increasingly becoming difficult to delineate between basic and applied research, as shown by the increasing trend to patenting the fruits of publicly funded university research under recent policies, partially as an incentive to encourage commercial actors to pick up the research with a view to eventual commercialization.

As noted above, researchers are still bound by the terms of the national ABS laws (which implement the Nagoya Protocol) and the requirement of PIC if they are accessing genetic resources of a provider country. Far from limiting the freedom to operate, however, the PIC requirement under the Protocol will act as a means to ensure that access to genetic resources for R&D purposes has taken on board the sharing of appropriate benefits for the provider country in the event of commercialization.

Key Points

- ⇒ The research and experimentation exception in patent law is an exception to IP rights that permits researchers to conduct research on a patented product or use a patented process without a license. The scope of what research and experimentation falls under this exception varies from jurisdiction to jurisdiction, however. Some jurisdictions permit a wide research exception, while others limit the exception to non-commercial research.
- ⇒ As a result partly of policies that encourage patenting of the fruits of university and other publicly funded research, it is becoming increasingly difficult to distinguish between what constitutes non-commercial and commercial research.
- ⇒ Research exceptions to patent law are generally seen as permitted under the TRIPS Agreement. According to a WTO Dispute Panel decision, it would frustrate the dissemination and advancement of technical knowledge, and the purpose of the disclosure requirement, if one were to allow the patent owner to prevent experimental use during the term of the patent.

¹³⁸ *Madey v. Duke University*, 307 F.3d 1351 (Fed.Cir. 2002), cert. denied 539 U.S. 958, 123 S.Ct. 2639, 156 L.Ed.2d 656 (2003).

- ⇒ Research exceptions need not be limited to patents; plant variety protection and utility model legislation may also build in research exceptions to the exclusive rights conferred.
- ⇒ A research and experimentation exception in the national patent law will not eliminate the need for PIC under Nagoya compliant national ABS legislation in the event that someone seeks to access genetic resources for research purposes.
- ⇒ The incentive of patent holders to try to prevent the emergence of competing technologies is not present in the case of PIC and provider countries. In fact, provider countries are interested in seeing genetic resources and associated TK become successful commercial products, provided the benefits accruing from those products are shared with the provider country and/or the indigenous communities.

B. The Medical Treatment Exception

Article 27.3(a) of the TRIPS Agreement permits Members that wish to do so to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Many jurisdictions have chosen to incorporate a medical treatment exception in their patent law, albeit for varying reasons. The initial justification under the European Patent Convention (EPC) for the exclusion of methods of medical treatment was that methods of treatment are not subject to industrial application. The rationale had changed by 2000, when the EPC was being revised: here, medical methods are excluded from patent protection in the interests of public health.¹³⁹

Developing countries have generally justified the inclusion of the exception in their patent law by claiming the need for local availability of treatment methods, and on moral grounds.¹⁴⁰ Other jurisdictions, such as the US and Australia, have opted not to make an exception to patentability for methods of medical treatment on the grounds that methods of treatment are no different from pharmaceuticals.¹⁴¹ Ventose lists a number of other reasons why an exception to patent rights for methods of medical treatment may or may not be justified.¹⁴² An interesting argument in favour of excluding medical treatment from the ambit of patentability is that patent protection for methods of medical treatment is “diametrically opposed” to “the Hippocratic Oath and its constituent fiduciary duties that bind them to act solely in the interests of their patients.”¹⁴³ Moreover, the exclusion guarantees that the activities of physicians when they treat their patients are not hampered by patents.¹⁴⁴ A more cynical view of the historical evolution of the medical treatment exception is presented by Piper.¹⁴⁵

The exclusion of methods of treatment from patent protection needs to be distinguished from the requirement under TRIPS to provide for the patentability of pharmaceutical products and the processes used to produce those pharmaceutical products (as noted elsewhere in the handbook, pharmaceutical products are no longer excludable under the TRIPS Agreement

¹³⁹ See Ventose (2011), p. 45.

¹⁴⁰ UNCTAD-ICTSD (2005), p. 384.

¹⁴¹ Ibid.

¹⁴² See Ventose (2011), Chapters 2 and 3.

¹⁴³ Ibid., p. 63. In this regard, the United States, under the 1996 Medical Procedures and Affordability Act, provides immunity to medical practitioners in suits relating to patents for methods of medical treatment.

¹⁴⁴ Ibid., p. vi.

¹⁴⁵ See Piper in Castle (ed.) (2009).

except for the LDCs). The distinction is that while drug X may be patentable provided it meets the three patentability criteria, and the industrial process to manufacture drug X may be patentable as a process patent, patent law exclusions for medical treatments would prevent the patentability of using drug X to treat condition Y. Likewise, a new vaccine may be patentable, but the procedure to administer that vaccine may not be patentable.¹⁴⁶

The term “medical treatment” is not defined under the TRIPS Agreement, however, and there is an increasing grey area between pharmaceuticals and methods of medical treatment. Some medical technologies may defy a classification either as a pharmaceutical product or therapy, including, for example, certain gene therapies and genetic diagnostic testing technologies, or stem cell technologies.

The medical treatment exception is often used to prevent the patenting of new uses of known substances, for instance when an existing medicine is found to treat a condition for which it had not originally been intended.¹⁴⁷ In some countries, such as New Zealand and Switzerland, it is possible to try to circumvent the exception and to patent a new use of a known substance through a claim for patent protection over the use of a known drug method of manufacturing a product for treating an ailment.¹⁴⁸

From the perspective of the CBD and Nagoya Protocol, there are two areas of particular relevance: the first is the issue of traditional medicine; and the second is the issue of genetically based medical technologies. With respect to the former, in the absence of a widely accepted definition of methods of treatment, there does not appear to be any reason why an exception to patent rights for such methods ought to extend only to methods of treatment as understood in Western medicine. A more difficult question, however, is delineating the boundaries of traditional medicine. Efforts exist in many developing countries to catalogue their traditional medicine practices. Some countries, such as China and India, have a far more regulated and codified system of traditional medicine than other developing countries, making it easier to define methods of treatment in the traditional medicine context. Of particular note is India’s database of traditional medicines, which extends to well over 200,000 entries.¹⁴⁹ While developed partially as a means to help other countries assess prior art in cases where a disclosure in a patent application has triggered a case where the claimed invention has its origin in Indian traditional knowledge (see Chapter 3), jurisdictions that have incorporated a wide medical treatment exception in their patent law can also rely on this database to exclude medical treatments included in this database from patentability.

Many of the attempts to patent traditional medicines involve either cosmetic, health or pharmaceutical products and may not fall within the ambit of a ‘method of treatment’.¹⁵⁰ But in many respects this is applying Western notions of medicine and health. From the perspective of a defensive CBD/Nagoya Protocol strategy, removing from patentability methods of treatment related to traditional medicine has the potential to go beyond treatments of known medical conditions in Western medicine and could incorporate notions of, for

¹⁴⁶ Administration of vaccines would in any event arguably fail for lack of novelty and inventive step even if patentable.

¹⁴⁷ Some countries explicitly provide for an exception from patentability of new uses of known substances, such as Article 21 of the Andean Community’s Decision 486 (14 September 2000).

¹⁴⁸ See <http://www.ajpietras.com/media.html> (last accessed on 14 December 2011).

¹⁴⁹ See R Randeep, “India moves to protect traditional medicines from foreign patents - India fights to protect ancient treatments from Western pharmaceutical companies” in *The Guardian*, 22 February 2009 (accessed at <http://www.guardian.co.uk/world/2009/feb/22/india-protect-traditional-medicines>).

¹⁵⁰ Ibid. These include the attempt to patent products based on Indian turmeric and the neem tree.

example, preventive medicine and health. Chinese traditional medicine practice, including acupuncture, for example, places great emphasis on preventive medicine.¹⁵¹ It is important to keep in mind, though, that exclusion of traditional medicine from patentability would not affect any protections granted to traditional medicine under TK laws.

As in other areas discussed in this handbook, a medical treatment exception contained in the provider country's patent legislation will only affect directly those patent applications under that law. It does not affect patentability in a foreign jurisdiction. But to the extent that a medical treatment exception is widely accepted in jurisdictions even in many developed countries, it would appear to be important that medical treatment be defined as broadly as possible under the domestic medical treatment exception in provider countries, to the extent that patent applications in foreign jurisdictions could potentially take that into consideration. Countries that have not done so may therefore wish to consider specifying in their legislation that the medical treatment exception extends also to traditional medicine.

The other area in which there is a potential interface between the medical treatment exception to patent law and the CBD/Nagoya Protocol is in the area of genetics and related therapies. There have been huge advances in gene-based therapies in recent years, due at least in part to successes in mapping the human genome. The interface occurs when patents are sought over therapies that have its origins in genetic resources that are covered by CBD/Nagoya-compliant legislation in provider countries. This potentially includes not only treatments derived from genetically manipulating plant and animal species (as in the case of plant-derived vaccines involving the introduction of a gene into a plant species to produce a vaccine or medicine), but also pathogens, a topic that is covered earlier, and which may be manipulated genetically in order to produce vaccines more conventionally.

From the perspective of the ABS stakeholder in the provider country, particular attention needs to be paid to the scope of the claim being made, and whether a medical treatment exception exists under the domestic patent law. In jurisdictions that exclude methods of treatment from patentability, while the medicines and vaccines used in treatment and the way in which they are industrially produced may in principle be potentially patentable, the modes through which those medical products are administered to patients could be excluded from the scope of patentability. The exclusion could be used to object to overbroad claims that cover the method of administration. Aside from patent law, there will still be a need to examine whether applicable ABS laws have been fully complied with.

Key Points

- ⇒ The TRIPS Agreement permits Members that wish to do so to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The EU and many developing countries exclude these methods from patentability, while the US, Australia and other countries permit the patentability of medical treatment methods.
- ⇒ The term “medical treatment” is not defined under the TRIPS Agreement and there is an increasing grey area between medicines and methods of medical treatment. Some medical technologies may defy a classification either as a pharmaceutical product or

¹⁵¹ See Hillier and Jewel (1983), Chapter 2.

therapy, including, for example, certain gene therapies and genetic diagnostic testing technologies.

- ⇒ Countries are free to define medical treatment in their domestic laws to include traditional medicine. Countries that have not done so may wish to consider specifying in their legislation that the medical treatment exception extends also to traditional medicine.
- ⇒ Databases, such as the one set up by India to document their traditional knowledge, may help to define the contours of the medical treatment exclusion in domestic law, and serve as a reference point for user countries that likewise have such exclusion in their domestic patent legislation.
- ⇒ Patents can be sought over therapies that have its origins in genetic resources that are covered by CBD/Nagoya-compliant legislation in provider countries. This potentially includes not only treatments derived from genetically manipulating plant and animal species, but also pathogens. From the perspective of the ABS stakeholder in the provider country, particular attention needs to be paid to the scope of the claim being made, and whether a medical treatment exception exists under the domestic patent law.

C. The ‘Clean Hands’ Doctrine

As discussed in Chapter 3, there remains a debate over whether a mandatory disclosure of origin requirement that is enforced or includes a condition that obliges having complied with existing ABS legislation in provider and user countries as a pre-requisite for the granting of a patent that otherwise meets basic patentability criteria, is TRIPS compliant. Proponents of the idea that patent rights should not be granted when an applicant cannot affirmatively establish compliance ground their argument in the doctrine of ‘clean hands’. According to the UK’s IPR Commission’s 2002 report on Integrating Intellectual Property Rights and Development Policy:

“The principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge in contravention of any legislation governing access to that material. In such cases the burden should generally lie with the complainant to prove that the IP holder has acted improperly. However, a precursor for any action is knowledge of the wrong. It is to assist in this respect that we believe that a disclosure requirement of the type discussed above is necessary.”¹⁵²

The potential problems of a policy of not granting patents that otherwise meet TRIPS patentability criteria are covered in Chapter 3, and need not be repeated here. It suffices to say that if a country were to err on the safe side in this as yet unresolved debate, the patent office may require disclosure of origin and proof of legal provenance, but that this is relevant for the patent office only in so far as it is taken into consideration in the assessment, respectively, of novelty, inventive step and industrial application, or otherwise to determine whether the claimed invention covers patentable subject matter. This would not in any way, however, prevent any sanction for violation of ABS laws by the ABS authority in the country concerned.

¹⁵² See Commission on Intellectual Property Rights (2002), chapter 4.

This may not be the end of the story with respect to the possibility to prevent would-be patent seekers who have not abided by applicable ABS laws, though. The ‘clean hands’ doctrine states that “equity will not grant relief to a party, who, as actor, seeks to set judicial machinery in motion and obtain some remedy, if such party in his prior conduct has violated conscience or good faith or other equitable principle.”¹⁵³ ‘Clean hands’ is a judicial doctrine that traces its origin to US case law and other common law precedents.¹⁵⁴ While theoretically it may be possible to codify a ‘clean hands’ concept that nullifies a patent if applicable ABS laws had not been followed, this raises again the spectre of potential TRIPS non-compliance (i.e., does it add another requirement to obtain a patent?).

There are, though, ways in which a ‘clean hands’ doctrine could be applied so that there is little question as to TRIPS compatibility. A conservative approach consistent with TRIPS would be to invoke ‘clean hands’ in a lawsuit by ABS right holders who become aware of a problematic patent having already been granted. The two important criteria to underline here are first, that the patent has already been granted, and second, that the doctrine is the basis of a civil lawsuit and not an administrative proceeding such as in the course of an application for a patent. If the technology in question were still at the application stage, then the appropriate channel would in principle be to raise the issue of non-compliance with ABS in pre-grant oppositions, and the applicant would need to be given an opportunity to cure the non-compliance. In the absence of compliance with ABS laws even given the opportunity to do so, the patent may still be issued (so that there is no question of TRIPS consistency), but domestic ABS law would give ABS right holders the opportunity to file a suit in a court of law, pleading any range of remedies from non-enforcement of the patent, requiring that a share of royalties be given to the rights holder(s), compulsory licenses that permit the rights holder(s) to work the technology in question with the payment of an applicable royalty, compulsory cross-licenses¹⁵⁵, as well as damages.

Of these remedies, of particular note is the legal concept of non-enforcement of a patent. This concept is analogous to the situation of copyrights, where the enforcement of certain available remedies is distinguished from the existence of the copyright as such. The US, for example, has provisions within its copyright law which deny certain types of damages and fees for unregistered foreign copyright works. It was argued on behalf of the US, and accepted by WIPO, that the US registration provisions were compatible with the national treatment and formalities rules within the Berne Convention since the US registration requirement affects certain specific remedies rather than the ability to obtain redress at all. A number of commentators agree, stating that the Berne Convention, and hence the TRIPS Agreement and WIPO Treaties, do not prohibit formalities as a condition to certain types of remedies, licences, exemptions etc.¹⁵⁶ A similar doctrine could conceivably be applied to the case of

¹⁵³ Black’s Law Dictionary definition (ed. 1983).

¹⁵⁴ The ‘clean hands’ doctrine has its origins in the US Supreme Court case of *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942). Subsequent decisions have shaped the doctrine as it is practiced in the US courts today.

¹⁵⁵ This is a term that originates from the European Directive 98/44 on the Legal Protection of Biotechnological Inventions (passed by the European Parliament on 12 May 1998 and adopted by the Council and published on 30 July 1998). Article 12(2) of the Directive stipulates that where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention. A similar provision exists for plant breeders’ rights (Article 12(1), Directive 98/44).

¹⁵⁶ See, for example, William Belanger, “U.S. Compliance with the Berne Convention”, 3 *Geo. Mason Indep. L. Rev.* 373, 393 (1995); Final Report of the Ad Hoc Working Group on U.S. Adherence to the Berne Convention, reprinted in 10 *Colum.-*

non-compliance with underlying ABS laws in the case of patents, though this has not been tested to date under a WTO dispute resolution panel.

Going further, there may in certain specific cases even be room to argue in a civil lawsuit for the revocation of a patent in the event of non-compliance with ABS laws, or to prevent the receipt of certain patent applications that contain TK. Under a proposed amendment to New Zealand's Patent Law, inventions that use Maori TK without PIC are potentially in violation of public morality. A determination of violating public morality is made by the Commissioner for Intellectual Property upon the advice of a Maori Advisory Committee.¹⁵⁷ The determination enables the Commissioner to refuse an application or revoke an existing patent.¹⁵⁸ In order to ensure TRIPS compliance, each application invoking Maori TK is considered on a case-by-case basis and is designed to assess whether the patent application is consistent with Maori values. Public order and morality is a recognized exception to patent law under Article 27.2 of the TRIPS Agreement. Similar mechanisms could conceivably be devised for indigenous groups in other countries. It should be noted that the New Zealand legislation is not yet in place, however, and that, as is the case with clean hands in general this sort of mechanism has never been tested in WTO dispute settlement.

A similar argument was lodged in an opposition filed at the European Patent Office by the Alice Community by the African Center for Biosafety along with other interested parties, to certain patents that had been granted to Schwabe Pharmaceuticals in Germany over a method of producing extracts of two varieties of the *Pelargonium* plant. The plants were collected from the wild in the Eastern Cape region of South Africa by communities in the Alice region, from which extracts have traditionally been used to treat a variety of infections. Schwabe had obtained a patent over the extraction method for the manufacture of medicaments used to treat infections associated with HIV and AIDS. A preliminary opinion from the EPO¹⁵⁹ shows that the opposition that was filed that plead, among a number of other arguments, that the Schwabe patent should be rejected on grounds of public order and morality in so far as the patentee had not established compliance with PIC and MAT under the CBD. The analysis contained in the preliminary opinion, however, makes it clear that the EPO will not treat absence of the evidence of non-compliance with PIC and MAT as a *per se* violation of public order and morality. It is possible, states the preliminary opinion that a threat to the environment could potentially constitute a public order and morality rationale for an exception to patentability, but the text suggests that those moving to establish this argument must establish "seriously harm the environment or contravenes the generally accepted codes of conduct". This seems to be rooted, at least in part, because Article 53(a) of the European Patent Convention states that public order and morality cannot be used as a ground for non-patentability merely because it is prohibited by law or regulation in some or all of the contracting states, and must be examined on a case-by-case basis. In the end, the opposition claim was upheld and the patents revoked by the EPO on 26 January 2010 on alternate grounds, i.e., that it did not meet the inventive step criteria for patentability.

Under US legal precedents, patents may be invalidated or rendered unenforceable if it can be shown that the patentee intentionally misrepresented or omitted material facts during the

VLA J.L. & Arts 513 (1986); Melville B. Nimmer & David Nimmer, Nimmer on Copyright §17.01(B) (2008). Nimmer & Nimmer, *supra* note 29, §17.01(B).

¹⁵⁷ A similar committee exists under New Zealand's Trademark Act.

¹⁵⁸ This is done through application of Section 17, Patent Act of New Zealand (1953, as amended).

¹⁵⁹ See European Patent Office document 02 777 223.5 of 14 July 2009.

patent application process.¹⁶⁰ While no US court case has voided a patent based on a failure to disclose facts related to source, origin or legal provenance as such, the intentional misrepresentation of facts to distinguish the subject matter with prior art, as well as an earlier court's finding that implied that the patentees had performed an experiment when in fact it had not, were upheld by the Federal Circuit in the 2003 case of *Hoffman-La Roche, Inc. v. Promega Corp.* This case concerned an enzyme that could be used in polymerase chain reaction - a process which generates copies of DNA, over which a patent had been granted. The application referred to DNA polymerase derived from Taq bacterium as prior art, and asserted that the subject matter enzyme was an advance over the prior art. Promega challenged the patent, arguing that certain assertions in the patent application were intentionally and materially misleading, and the District Court agreed. The Federal Circuit agreed with the findings of the District Court and remanded the case back to the District level to determine whether the appropriate remedy would be to invalidate or render unenforceable the patent. This case was settled between the parties thereafter. While this precedent leaves open the possibility to render unenforceable patents that fail to disclose material facts, the finding of intent is crucial, and is usually inferred from facts, including the wording of the patent application.

Key Points

- ⇒ The 'Clean Hands' doctrine states that "equity will not grant relief to a party, who, as actor, seeks to set judicial machinery in motion and obtain some remedy, if such party in his prior conduct has violated conscience or good faith or other equitable principle."
- ⇒ Clean hands could potentially be invoked in a lawsuit by ABS right holders who become aware of a problematic patent having already been granted. The two important criteria to underline are first, that the patent has already been granted and second, that the doctrine is the basis of a judicial proceeding.
- ⇒ Domestic ABS law could give ABS right holders the opportunity to file a suit in a court of law, pleading any range of remedies from non-enforcement or revocation of the patent, requiring that a share of royalties be given to the rights holder(s), compulsory licenses that permit the rights holder(s) to work the technology in question with the payment of an applicable royalty, compulsory cross- licenses, as well as damages.
- ⇒ In some cases, it may be difficult to establish an intent to mislead. Intent to mislead needs to be established from the facts surrounding each case.
- ⇒ A public order and morality argument could potentially be made to even revoke a patent, as in the case of draft New Zealand legislation.

D. Unfair Competition, Competition and Unjust Enrichment Based Theories

An alternative legal means to address the situation where an applicant attempts to obtain exclusive patent rights in the absence of compliance with applicable ABS laws is to justify

¹⁶⁰ See *Hoffman-La Roche, Inc. V. Promega Corp.*, 323 F.3d 1534 (Fed. Cir. 2003).

refusal of the application or to revoke a patent utilizing the doctrine of unfair competition. Black's Law Dictionary explains unfair competition as follows:

*"A term which may be applied generally to all dishonest or fraudulent rivalry in trade and commerce, but is particularly applied to the practice of endeavoring to substitute one's own goods or products in the markets for those of another, having an established reputation and extensive sale, by means of imitating or counterfeiting the name, title, size, shape, or distinctive peculiarities of the article, or the shape, color, label, wrapper, or general appearance of the package, or other such simulations, the imitation being carried far enough to mislead the general public or deceive an unwary purchaser, and yet not amounting to an absolute counterfeit or to the infringement of a trade-mark or trade-name. ... As used in statute prohibiting unfair competition and defining the same as meaning and including 'unlawful, unfair or fraudulent business practice' 'unfair competition' is not confined to practices involving competitive injury but extends to practices resulting in injury to consumers."*¹⁶¹

While often used to address situations of misleading marks or names, the doctrine also applies to patents and trade secrets. Under US practice, unfair competition is used for injunctive relief to prevent the importation of products that are covered by a patent in the US, but not abroad, as well as to prevent the importation of products using processes that are patented in the US, but not necessarily abroad.¹⁶² Courts generally protect trade secrets under unfair competition laws to prevent the theft of something that the owner of the trade secret has made a reasonable effort to keep secret. It could be argued that seeking patent rights over a technology that has its origins in TK obtained in violation of PIC potentially amounts to 'stealing' and should be prohibited under unfair competition theory.

There are potential difficulties with this argument, though. TK may not fit neatly into any of the abovementioned cases. The authors are unaware of any instance in which non-compliance with ABS laws was used to invalidate a patent using unfair competition grounds. Moreover, TK may or may not be secret, and may not necessarily be considered a 'trade secret' in the strict legal sense of the term. If an indigenous group had allowed, for example, certain traditional medicine practices to be observed by an outsider, for example, that in the strict legal sense may be sufficient to deny trade secret protection. Moreover, in common law jurisdictions, the unfair competition doctrine is shaped by case law, which may limit the scope of a claim to those involving passing off and related deceptive practices. Finally, the rights conferred by ABS laws is as yet not well defined in many jurisdictions - and while it is clear that ABS laws require PIC and MAT, whether courts will interpret this as amounting to a property right in favour of indigenous groups remains to be seen.

Finally, unfair competition claims need to be distinguished from competition law claims. Unfair competition law addresses certain unfair commercial practices while competition legislation, as a general body of law, exists to act as a check on the abuse of IPRs, as envisaged in Articles 8 and 40 of the TRIPS Agreement. But these clauses generally act as a check on the exercise of granted rights in the context of a situation where the owner of the patent yields certain market power. Market concentration and power may be difficult to establish in the indigenous context, and while it would potentially become relevant perhaps in

¹⁶¹ See Black's Law Dictionary (ed. 1983).

¹⁶² See Blenko (1990) at <http://www.tms.org/pubs/journals/jom/matters/matters-9010.html>.

cases involving refusals to license, it is difficult to think of a situation where competition law could be successfully deployed to address situations of patent applications which have not complied with applicable ABS laws.

Aside from competition law and unfair competition theories, one could also theoretically frame a legal argument that those who have misappropriated resources, especially through obtaining IP rights, should not be allowed under an unjust enrichment theory. Unjust enrichment refers to a general principle that stipulates that “one person should not be permitted unjustly to enrich himself at the expense of another, but should be required to make restitution of or for property or benefits received, retained or appropriated, where it is just and equitable that such restitution be made, and where such action involves no violation or frustration of law or opposition to public policy, either directly or indirectly.”¹⁶³ The theory is generally used in civil actions. While a provider could use the argument that a user patented an invention that utilized a genetic resource or associated TK without PIC or MAT, or in violation of an ABS agreement, one could argue that allowing the user to appropriate 100% of any benefits arising from that patent would amount to unjust enrichment. In a court of law, however, this strategy is also likely to entail arguments about the extent to which the original resource or TK contributed to the patented invention.

Key Points

- ⇒ Unfair competition theories generally exist to address certain deceptive trade practices, while competition law theories exist to address the abuse of market power.
- ⇒ The use of these theories to combat instances where there has been non-compliance with ABS laws may be limited, however, as it may be difficult to establish the legal requisites for these theories.
- ⇒ Apart from competition law, providers could attempt to frame arguments based on a theory of unjust enrichment.

VI. Conclusion

A variety of tools exist in patent law and related jurisprudence that can potentially help to address the problem of misappropriation. A first line of defence is to apply patent law to exclude the possibility of a would-be ‘biopirate’ from being able to obtain a patent. This can be done by arguing, for example, that the subject of the application is not patentable subject matter (i.e., not an invention.). As a second line of argument, one could try to establish that the criteria for patentability have not been met. Various exceptions to patent law also exist that shield users engaged in R&D activity and medical treatment. Patent authorities could, however, utilize those same arguments in the event that a domestic party sought to obtain a patent on an invention that utilizes a genetic resource or associated TK as well.

If a case must be litigated to defeat a patent held by a would-be ‘biopirate’, there are theories of equity that can be deployed to support the argument that a patent should be revoked or some remedy given to an aggrieved party. These theories include ‘clean hands’ and unjust

¹⁶³ Black’s Law Dictionary definition (1983 ed.).

enrichment, among others. They could also include violation of the terms of a material transfer agreement (MTA), the subject of chapter 7.

Chapter 5

Protection of Traditional Knowledge

I. Introduction

Chapter 1 described the extent to which the Convention on Biological Diversity (CBD) and the Nagoya Protocol laid down new rules concerning access and benefit sharing (ABS) over, *inter alia*, TK associated with genetic resources. Article 7 of the Protocol requires that access to traditional knowledge (TK) associated with genetic resources must be based on prior informed consent (PIC) and that benefit sharing must take place in the event that such TK is accessed. The benefit sharing need not be directly linked to the TK, however, and may be made by means, for example, via a contribution to a pooled fund. The Protocol leaves it up to national legislation to define what TK is associated with genetic resources, as well as the type and modalities of benefit sharing that can take place. It requires only the sharing of benefits from research and development (R&D), and not necessarily from commercialization. For associated TK, there is no corresponding mutually agreed terms (MAT) requirement, as Articles 5 and 6 of the Protocol deal with genetic resources only. Articles 5 and 6 would nonetheless apply if an indigenous/local community (ILC) were legally responsible for a genetic resource being accessed within a geographic area for which it has autonomy.

The protection of TK takes place within a context much wider than just TK associated with genetic resources for purposes of the CBD and the Nagoya Protocol. In the ABS context, the immediate reaction may be to think of associated TK as, for example, the medicinal plant-or animal-based preparations utilized by shamans or in traditional Chinese medicine.¹⁶⁴ However, the concerns expressed by ILCs to protect TK arose in conjunction with greater recognition that ILCs had certain rights based on customary law and human rights laws. Existing national regimes and negotiations at the international level that seek to protect TK may therefore cover a wider scope, including traditional cultural expressions (TCEs) such as folklore and music in the oral tradition, as in the case of ongoing negotiations at the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC). TK could also encompass therapies that have little to do with genetic resources, such as massage or yoga. In other cases, laws may seek to regulate only TK that deals with biological or genetic resources.

This chapter will examine the larger context of what it means to protect TK, the limitations of Western notions of IP in protecting TK and how TK protection regimes could be utilized by countries to preserve their interests and maximize their opportunities when faced with questions of access to associated TK.

Key Point

- ⇒ Legal frameworks that seek to protect TK may cover more than TK associated with genetic resources.

¹⁶⁴ WIPO (2002), p. 15.

II. Defining TK

Before proceeding to the question of what it means to protect TK, it helps to review what TK actually means. From the ABS perspective, neither the CBD nor the Nagoya Protocol defines what TK is. Ongoing intergovernmental negotiations at WIPO's IGC (and at WTO) have not resolved the issue of how TK should be defined either. Existing definitions of TK may be gleaned from national or regional laws and academic literature, though there is no uniform treatment of TK in these laws as well. With respect to cases where TK is defined broadly, Section 2 of the African Regional Intellectual Property Office (ARIPO) Swakopmund Protocol on the Protection of TK and Expressions of Folklore¹⁶⁵ defines TK as knowledge developed in a traditional context and embodied in traditional lifestyle or knowledge systems. TK includes know-how, skills, innovations, practices and learning. National laws that are designed to address the narrow issue of CBD and/or Nagoya Protocol compliance tend to define TK as only TK associated with genetic resources. Article 4 of the Pacific Islands Forum (PIF) Traditional Biological Knowledge, Innovations and Practices Act¹⁶⁶ focuses on traditional biological knowledge, innovations and practices. The Andean Community (AC) Decision as ABS-related legislation covers TK so long as it is associated with biological resources as defined in the CBD. The Andean Community Decision 391 on a Common Regime on Access to Genetic Resources¹⁶⁷ adds by-products of genetic resources to this definition.

With respect to influential academic literature, the International Institute for Environment and Development (IIED) project on "*Protecting Community Rights over Genetic Resources*"¹⁶⁸ provides a useful classification based on different types of TK:

Sacred Knowledge that is held by e.g. elders, healers or shamans and must be kept secret.

Specialised Knowledge that is restricted to a family, clan or kin; the holder of this knowledge must ensure its proper use usually in the context of the community to which the holder belongs.

Communal Knowledge that has been made available to the public with the consent of the original developers and holders.

The implication of this typology is that while sacred knowledge must be kept secret, third parties should be prepared to recognise individual as well as collective rights and address community needs when requesting access to specialized knowledge, while access to communal knowledge must be kept free for all; third parties are not supposed to restrict access to the knowledge, but also to the products developed therewith.

¹⁶⁵ The Swakopmund Protocol will enter into force when six ARIPO Member States either deposit instruments of ratification or instruments of accession; nine of them have signed the Protocol already. ARIPO has 18 members: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

¹⁶⁶ The Pacific Islands Forum represents 16 independent States in the Pacific region: Australia, Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Republic of Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu. The TK Act was adopted by a diplomatic conference and is currently under national implementation in several of its members.

¹⁶⁷ The Andean Community has four Member States: Bolivia, Colombia, Ecuador and Peru. Decisions of the Andean Community are binding for its members.

¹⁶⁸ International Institute for Environment and Development (IIED) (2010).

These definitions show that TK is not uniformly defined. There is even disagreement on the scope of the qualifier ‘traditional’ when talking about TK. Some voices assume that TK equates to old, if not outdated knowledge which essentially became obsolete by the development of modern knowledge based on the application of scientific methodologies. For such kind of knowledge there would be no justification for legal protection. Others stressed that ‘traditional’ more or less reflects the societal context in which a certain type of knowledge evolves and is used, namely in a setting with traditional lifestyle and values.¹⁶⁹

From a strictly legal viewpoint, the definition of TK serves the limited function of delineating what is protected under a given law and what is not. So when TK is defined narrowly for purposes of ABS of genetic resources and associated TK in legislation, this does not necessarily mean that TK as a concept is confined only to that dealing with biological resources and their use by ILCs, nor does it exclude defining TK differently for purposes of another law. Indeed, the same TK could indeed be potentially covered under two different laws.

Key Points

- ⇒ There is no internationally agreed definition of TK. National/regional laws and literature may define TK broadly or narrowly.
- ⇒ The definition of TK will delineate the coverage of ‘protection’ within the meaning of a given law.
- ⇒ Within the confines of ABS laws, a narrow definition of TK may focus exclusively on TK associated with genetic or biological resources for purposes of CBD and Nagoya Protocol compliance. This would not prevent a country from adopting a wider definition of TK in different laws, however.

III. Protecting TK

The sheer variety of subject matter that could potentially constitute TK or TCEs means that it will by no means be easy to establish optimal protection mechanisms. Possible mechanisms to protect TK and TCEs may range from putting samples of weaving or costumes in a museum, taking video footage of ceremonies, or writing a book containing stories passed down from generation to generation. It may involve establishing a database of traditional medicines, or it may mean creating laws that grant certain rights to ILCs with respect to biological resources that they have traditionally used for food or medicine. The term ‘protection’ can therefore have different meanings. This chapter will focus on three possible meanings of the term ‘protection’: first, defending TK and TCEs against misappropriation by others; second, preserving TK and TCEs for future generations; and third, giving the opportunity to ILCs to exploit their TK and TCEs for their own benefit. The term ‘positive law’, in this context, refers to the ability to give some legal recognition to TK and TCEs as a means for providing this protection.

¹⁶⁹ Dutfield (2006), p.1; WIPO (2003), p. 9; Barsh (1999), pp. 74-75.

A. The Limits of Modern IP Laws

Modern IP instruments, which include patents, utility models, industrial designs, copyrights, trademarks and the like, have been considered as one possible means to protect TK and TCEs. Historically, these modern IP tools developed as a means to provide a temporary monopoly to an inventor or creator as an incentive by rewarding their innovative and creative outputs. The notion that IP is a system to ‘protect’ intellectual or creative endeavour is thus a metaphor for the ability to prevent others from acts of misappropriation, and to enable the owner of the subject matter to exclusively benefit from that invention or creation for a fixed term. In order for such a system to work for TK and TCEs, however, the respective criteria for protection of patents, plant variety protection, copyrights, etc. would have to be met.

Table 1 lists the various options to protect TK under existing IPR instruments, and the limitations that have been highlighted by various experts. While protection under modern IP instruments would indeed confer rights to the applicant thereby protecting the successful applicant from misappropriation of the subject matter and making it easier to commercialize the subject matter, the major problem lies in the contrasting features of IPR on the one hand, and TK as grounded on customary rights, including:

- the temporal limitation of the major instruments;
- unknown or collective inventor/authorship;
- that most TK does not fulfil the requirements for patenting or registration of plant varieties; and
- the lack of protection of TK itself but only of its manifestations or certain features

For example, TK is passed on from generation to generation to disciples, such as the potions used in certain ceremonies by shamans, or by practitioners of traditional medicine. Many IP instruments are, however, time bound – 20 years from the date of application in the case of patents, and 50 years plus the life of the author in the case of copyrights. TK and TCEs are not novel in the sense that they embody a technology that was created possibly ages ago and has been passed on, and would not constitute a novel technology for purposes of patents or utility models, or a new seed in the case of plant variety protection. Some TK may be spread more or less widely in the public and might even be documented in publications, hence would not fulfil the basic criteria to receive patent protection. Geographical indications and collective trademarks offer a means of protecting a mark or a name, rather than the underlying TK or TCE, though this does not mean that they could not be important tools for preventing misappropriation or for ILCs to exploit certain assets.

Some of the limitations might be corrected through adaptation of the IPR, for example the possibility to claim collective authorship or to let an institution function as a substitute for unknown authors under copyright laws. Similarly it could be possible that patents are given to an institution that represents a collective of inventors. While literature and existing national legislation and experience show that solutions to the listed limitations cannot be developed through amending existing IPR solely but through a combination with *sui generis* options (see below), it is also apparent that governments are not free to change current or create new systems. An increasing number of countries are members of the WTO TRIPS Agreement and

the WIPO IPR treaties, and have concluded free trade agreements that contain IP-related obligations, and are thus bound to meet certain international standards and limitations in setting their IP laws.¹⁷⁰

Key Points

- ⇒ The major differences between IPR and TK as grounded on customary rights are:
- the temporal limitation of the major instruments;
 - unknown or collective inventor/or authorship;
 - most TK does not fulfil the requirements for patenting or registration of plant varieties;
 - the lack of protection of TK itself but only of its manifestations or certain features; and
 - the issue of protection of TK that has been brought into the public domain without consent of the original developers and custodians.
- ⇒ Both literature and existing national legislation and experience show that the limitations and problems to protect TK through existing IPR cannot be overcome through amending existing IPR solely. Moreover, countries may not be free to adapt legislation to accommodate changes to the criteria of existing IPR categories.

¹⁷⁰ Currently, the WTO has 159 members, WIPO has 186 members.

Table 1: Options to Protect TK Under Existing IPRs

Applicable IP instrument	Currently Applicable IPR Conditions	Limitations and Problems:
Industrial property		
• trade secret	<ul style="list-style-type: none"> • needs to be of commercial value • knowledge needs to be kept confidential • no time limit for protection 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - the commercial value has to be shown to receive protection; protection could easily be broken if another group who utilizes the procedure makes it public <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - effective steps need to be taken to keep it secret; specialized or communal knowledge is not necessarily kept secret
• patent	<ul style="list-style-type: none"> • the invention needs to be new, inventive and susceptible of industrial application • the invention needs to be based on previously undisclosed information • protection for 20 years from the date of application 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - these criteria might only apply to secret TK but certainly not to the usual forms of TK which are widely spread and in many cases already documented - the holder of the TK often is not the inventor - if new elements are introduced to the TK, the inventive step might be too small or face other technical problems <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - TK needs to be made public in the application - limited temporal protection - after expiration of protection term, the knowledge about the invention goes into the public domain - difficulties in granting protection title to larger communities
• utility model	<ul style="list-style-type: none"> • novelty and utility required, but not necessarily inventive step • protection may vary depending upon the 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - no specific limitations <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - with some TK, functional

	jurisdiction; generally for 10 years from the application date or shorter	<p>features might only be of value as a ceremonial element</p> <ul style="list-style-type: none"> - TK as such is not protected - limited temporal protection
• industrial design	<ul style="list-style-type: none"> • need not to be new but must exhibit new esthetical features • protection spans over 15 years 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - no specific limitations <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - with some TK, functional features might only be of value as a ceremonial element - TK as such is not protected - limited temporal protection
• trademarks and GIs	<ul style="list-style-type: none"> • need to meet requirements of trademarks; must be a sign capable of being represented graphically, capable of distinguishing goods or services of one undertaking from another • potentially perpetual if used 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - some marks are already well known - must fit into existing system of classification of goods or services <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - TK as such is not protected - difficulties in managing GI or collective trademark systems
Rights over plant varieties		
• plant breeders' rights	<ul style="list-style-type: none"> • the plant's geno- and phenotype needs to be new, stable, distinct and uniform • protection spans over 15 - 25 years 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - TK is mostly connected to the use of wild plants and land races of cultivated plants which do not fulfil these requirements <i>per se</i> <p>b) from a TK perspective</p> <ul style="list-style-type: none"> - TK associated with the plant as such is not protected - limited temporal protection
Copyrights and related rights		
• copyright	<ul style="list-style-type: none"> • religious text or prayer needs to contain original expressions of intellectual creations • religious text or prayer 	<p>a) from an IPR perspective</p> <ul style="list-style-type: none"> - the author cannot be determined in many cases <p>b) from a TK perspective</p>

	<p>needs to be fixed, thus incorporating material objects</p> <ul style="list-style-type: none"> • the shaman as performer can be accorded the right to authorise the fixation of the performance • no need to register as prerequisite for protection • protection spans over 50 years 	<ul style="list-style-type: none"> - the value of protection the words of the prayer might be very small because it is element of a ceremony acting through many elements (symbolic values) - TK as such is not protected - only applies to individual authors not to collectives - limited time frame
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Source: Based on Vivas Eugui and Muller (2002); Alvarez Núñez (2008); and Milius (2009).

B. The Public Domain

Underlying the problem of modern IP systems is that failing any legal protection over subject matter, it falls into the so-called public domain. Boyle describes the public domain as that which is not property, i.e., that which is not otherwise the subject matter of proprietary rights and free for everyone to use.¹⁷¹ Numerous scholars such as Boyle and Suthersanen point out that the public domain remains an important part of the modern IP system. The latter suggests, for instance, the relevance of certain variants of the concept of public domain such as information commons, open access and open source, as being vitally important for technological development in this day and age.¹⁷² Developing countries at WIPO have called on the need to have a robust public domain in order to further facilitate access to knowledge and technology transfer, a topic that has been examined by the Committee on Development and Intellectual Property at WIPO under its Development Agenda.

While greater access through expanding the public domain may be desirable in certain development contexts such as in facilitating access to knowledge and technology transfer, the problem is that in the event that there is no appropriate vehicle under existing IP tools to protect TK and TCEs, the subject matter falls into the public domain by default rendering it difficult, if not impossible, for ILCs to extract commercial value therefrom. While this may prevent misappropriation in so far as it makes it more difficult for a third party to claim the subject matter as his or her own either after an IPR has expired or if it is not possible to obtain an IPR over the subject matter in the first place, benefit sharing to be derived from the subject matter becomes more difficult. A major debate on the draft text of a possible treaty on genetic resources, TK and TCEs at WIPO reveals a gap in positions where developing countries favour a more limited definition of the public domain for purposes of the treaty and developed countries favour a broader public domain.¹⁷³ An important point to remember is that the

¹⁷¹ Boyle (2008) p. xiv.

¹⁷² Suthersanen (2008), p. 2.

¹⁷³ Saez (2013). This IP Watch article reports also that “[a]s noted by a developing country delegate, in the IGC, developing countries are the demandeurs of a legally binding instrument protecting TK, GR and traditional cultural expressions. In this context, developed countries put forward much of the same arguments that developing countries present in other negotiations in order to retain flexibility and policy space. For example, the delegate said, developed countries in the IGC are keen to reduce the subject matter of protection, and its scope, but are insistent that exceptions and limitations are widely available.”

public domain is, however, a concept of IP law, and does not exclude the possibility of applying ABS requirements to TK and TCEs under national legislation.

Many governments and stakeholders have therefore concluded that defensive protection alone would not be sufficient to serve the needs and expectations of holders of TK and TCEs. To develop positive protection - be it through existing IPR, expanded IPRs with *sui generis* elements for TK and TCEs or *sui generis* options granting new rights may be needed. The following section discusses what these *sui generis* laws look like.

Key Points

- ⇒ The public domain consists of that which is not protected by IPRs, and therefore freely accessible by all to utilize.
- ⇒ An international debate exists as to the extent some TK and TCEs would fall into the public domain in so far as it cannot be protected by an IPR.
- ⇒ Even if certain TK and TCEs are not protected under IPRs, they may still be the subject matter of ABS requirements under national legislation.

C. *Sui Generis* Systems

Literally translated from Latin, the term *sui generis* means ‘of its own kind or class’.¹⁷⁴ In the realm of IP, the term is often used to mean systems of protecting intangible property, i.e., granting certain rights to those who have a legitimate claim to them, in a manner that is outside the commonly recognized concepts of IP protection such as industrial property (i.e., patents, industrial designs, trademarks) and copyrights. The term has often been used, for example, to describe the respective systems established to protect plant breeders’ rights (plant variety protection), integrated circuit designs and utility models, outside of the framework for patents and designs.

In the context of TK and TCEs, a basic *sui generis* system establishes the criteria for protection, defines the rights granted, the period of time for which those rights are granted, defines the exceptions to those rights and sets out a means to enforce those rights. As there is no uniform definition or criteria under any treaty to which the terms of such a *sui generis* system to protect the subject matter must adhere, countries have complete leeway to craft legislation in a manner that suits their particular objectives. In this regard, various countries and regional groups have attempted to frame legislation that establishes certain *sui generis* rights over TK and TCEs.

A number of these laws are examined in this section. The hope is that by examining a number of these laws, policy makers will be able to understand the potential scope and impact of these laws. It should be added that many countries are still experimenting and making refinements to these laws based on practical experience. For purposes of analysis, the presented legal texts comprise three regional and four national examples:

¹⁷⁴ See Black’s Law Dictionary (2009).

- Andean Community - 2002: Decision 391 Common Regime on Access to Genetic Resources
- Pacific Islands Forum - 2008: Traditional Biological Knowledge, Innovations and Practices Act
- African Regional Intellectual Property Organization - 2010: Swakopmund Protocol on the Protection of TK and Expressions of Folklore¹⁷⁵
- Thailand - 1999: Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, H.E. 2542
- Portugal - 2002: Decree-Law No. 118/2002
- South Africa - 2004: National Environmental Management: Biodiversity Act
South Africa - 2008: Regulations on Bio-Prospecting, Access and Benefit-Sharing
- Guyana - 2006: An Act to provide for the recognition and protection of the collective rights of Amerindian Villages and Communities, the Granting of Land to Amerindian Villages and Communities and the Promotion of Good Governance within Amerindian Villages and Communities¹⁷⁶

Relevant text of the four national examples is contained in Annex I of this handbook, should readers be interested in examining the relevant text.

The selected examples cover a wide range of regional and national legislation looking at access to genetic resources and associated TK, defensive and positive protection of TK, ownership rights over genetic resources and associated TK - from different historical perspectives and geo-political backgrounds - and thus provide a range of approaches and solutions. As this handbook focuses on the interface between ABS and IP, the examples do not include laws that cover TCEs in addition to TK as such. This chapter neither lists all available regulations¹⁷⁷ nor analyses all provisions of the presented regulations but provides a selection which contain exemplary approaches to address and solve some of the critical issues and problems highlighted in the previous sections of this chapter.

Due to the specific objective and scope of each of these seven regulations, certain issues of interest might not be covered by a specific text while others are covered extensively. But as a whole, these texts present a range of options for following critical areas:

- Subject matter definition
- Holder of rights
- Scope of rights

¹⁷⁵ The Swakopmund Protocol will enter into force when six ARIPO Member States either deposit instruments of ratification or instruments of accession; nine of them have signed the Protocol already. ARIPO has 18 members: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe

¹⁷⁶ The Amerindian Act was adopted in 2006 and implemented in the following years when it became apparent that due to formal errors it actually never entered into force. In 2010, Parliament adopted the Act for a second time and the administration followed all rules for its effective entry into force.

¹⁷⁷ A large collection of related regulations, contracts etc. is presented at http://www.wipo.int/tk/en/legal_texts/.

- Acknowledgement of rights
- TK in the public domain
- ABS elements
- Elements of positive IPR protection
- Elements of defensive IPR protection

It should be noted that the rights conferred can be contained in stand-alone IP legislation as in the Pacific Islands Forum (PIF), African Regional Intellectual Property Office (ARIPO) and Thai examples, be part of ABS laws as in the Andean Community (AC), Portuguese and South African examples, or part of human rights legislation as in the case of Guyana.

1) Subject Matter Definition

While an effective and unambiguous definition of the subject of a law - here TK and its rightful holders - is desirable, its usefulness to fulfil the needs of the holders of TK can only be tested in real cases of access to TK and benefit sharing. As mentioned above, there is at present no internationally accepted definition of TK, although several countries have agreed on national or regional definitions which will inform and certainly influence the international debate at the WIPO IGC.

Section 2 of the ARIPO Protocol deals with the protection of TK as such, while Article 4 of the PIF Act focuses on traditional biological knowledge, innovations and practices. The AC Decision as ABS-related legislation covers TK so long as it is associated with biological resources as defined in the CBD. The CBD definition sees genetic resources as a subset of biological resources; as mentioned above, the AC Decision adds by-products of genetic resources to this definition.

The ARIPO Protocol defines TK as knowledge developed in a traditional context and embodied in traditional lifestyle or knowledge systems. TK includes know-how, skills, innovations, practices and learning. The PIF Act defines three subject categories: traditional biological knowledge, traditional biological innovations and traditional biological practice. The AC Decision defines TK as the intangible component of biological resources (based on the CBD definition), consisting of know-how, innovation and practices of communities that are totally or partially governed by their own customs, traditions or special legislation. All three definitions stress the specific roots of TK, its relevance for the daily routines of a community, as well as its innovative elements, and thus take up the essential points of the international debates as described in the previous sections.

These three examples illustrate the basic approach of the two groups of laws dealing with regulating ownership of and access to TK associated with genetic resources, its use and benefit sharing: while legal texts emerging from the field of IP policy and regulations as the ARIPO Protocol and the PIF Act deal in depth with the definition of TK and its holders, texts emerging from the field of ABS policy and regulations as the AC Decision might cover TK in certain provisions but tend to leave basic terms undefined. This approach also holds true for

the Nagoya Protocol. The task of defining TK remains to be solved by national governments and ILCs; negotiators usually referred to the ongoing WIPO IGC negotiations which they saw as the appropriate forum to define such IPR-related matters.

The four national laws in Annex I look at the issues of interest from different perspectives: the Thai Act covers the use and further development of traditional medicinal intelligence, the Portuguese Decree-Law covers the commercial use of local and autochthonous plants for agricultural use, the South African Act and Regulations relates to the traditional and customary use of and knowledge about biological resources and the Guyanese Act deals with human and land rights of the Amerindian peoples including basic elements on TK and ABS. The Thai Act specifically covers traditional medicinal procedures such as diagnosis and treatment, traditional drugs and devices as well as medicinal TK as such. While the Act focuses on knowledge issues, it also deals with medicinal plants - meaning genetic resources - as sources for drugs. The Thai Act is the first national legislation aiming at the protection of “Thai local intelligence”, although the protection of other types of TK is still under discussion.¹⁷⁸

The Portuguese Decree instead starts with a scope applicable to all local and autochthonous plant material that is not covered by IPR. Compared to the AC Decision and in line with ABS-related legislation in general, it regards TK as the intangible component of these genetic resources associated with their commercial or industrial utilization by local communities but does not provide specific definitions. The South African Regulations also does not refer to the concepts of traditional lifestyle and intergenerational context of knowledge creation as used in IP-related legislation but simply defines that TK is the knowledge used by indigenous communities.

The Guyanese Act due to its broader nature does define genetic resources and associated TK but states that all native and aboriginal peoples and their descendants are subjects of the Act, where it leaves it up to the communities to self-identify themselves as Amerindian peoples. The Act deals with genetic resources and TK in separate paragraphs. The Guyanese draft ABS Regulations of 2009 attempt to define traditional use as: “[t]he customary utilisation of genetic resources whether written or otherwise by Amerindian or local communities in accordance with TK, usages, customs and practices observed, accepted and recognised by them”. The Guyanese IPR system does not address genetic resources and TK specifically and may need to be reformed in that regard. The drafting of a *sui generis* system is announced.¹⁷⁹

Key Points

- ⇒ While an international definition of TK associated with genetic resources still awaits its finalisation in the context of the ongoing WIPO ICG negotiations, regional treaties as the ARIPO Protocol and the PIF Act already provide for such definitions.
- ⇒ In general, the definitions of associated TK exhibit common elements as:
 - its relatedness and dependency on traditional lifestyle
 - its relevance for the daily routines of a community

¹⁷⁸ Kudngaongarm (2011).

¹⁷⁹ Environmental Protection Agency of Guyana (2007); Environmental Protection Agency of Guyana (2009).

- its innovative elements and dynamic nature
- ⇒ Biodiversity-related legislation such as the Nagoya Protocol and the AC Decision provide ABS-related rules for associated TK but in general refrains from defining it as such.

2) Holder of Rights

In the context of protection of TK and ABS issues, the question of (customary) ownership and its (formal) recognition is of prime importance. The 2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) acknowledges the rights of indigenous peoples over their genetic resources and TK including IPRs but these rights would still need to be granted through national legislation. Furthermore the exercise of these rights needs to be supported and protected by appropriate judicial and administrative procedures. Also, the Nagoya Protocol acknowledges these rights but does not provide for international standards. Parties to the Nagoya Protocol merely need to involve indigenous and local communities in ABS procedures “in accordance with domestic legislation regarding the established rights of these indigenous and local communities”.

The Nagoya Protocol establishes three categories of right holders: state sovereignty over its genetic resources, the ownership rights of indigenous and local communities over their genetic resources if established through domestic legislation and the rights over associated TK “held by indigenous and local communities” where it does not specify how these rights are granted. Following this approach which originates in the CBD provisions, the AC Decision Article 5 regards states as the owners of genetic resources. According to Article 7, the member states, also through national legislation, need to recognize the rights and authority of traditional communities to decide over their TK. This provision seems to imply that the ownership rights over TK lie with the respective traditional communities. As already mentioned in the section above, Article 6 of the PIF Act, as IP-related legislation, clearly determines that ownership over traditional biological knowledge, innovations and practices lies with specific social groups. Similarly, Section 6 of the ARIPO Protocol states that the owners of TK are traditional communities, but also extends ownership to recognized individuals.

The four national laws in Annex I offer different concepts of ownership. Section 17 of the Thai Act empowers the government to notify national formula and texts, Section 20 also allows for individuals to register personal formula and texts as intellectual property. The Thai Act does not foresee traditional communities as holders of rights and it does not refer to specific areas within the country in which right holders need to live.

The three other laws apply a “*terroir*” approach, which is reminiscent of the concept used for geographic indications (see chapter 6). Article 9 of the Portuguese Decree-Law empowers any legal entity - individual or corporate, public or private - that represents the interests of the geographic area in which the local variety is found to register as the owner. Depending on the applicable Portuguese laws and regulations, this provision would not exclude associations or communities as owners. The South African Regulations links the status of being an indigenous community to “living or having rights or interests in a distinct geographical area ... with a leadership structure” without laying down details on how to specify the interests or

determine the area. It also does not explain to which rights it refers to. Individuals cannot be the rightful holders of TK. Guyanese Act Article 10 appoints the Village Council as a collective body that holds, *inter alia*, all rights over genetic resources and TK, where the respective population is living in a self-demarcated area approved by their territory by the government. Again, it seems that individuals cannot be the holders of TK.

The examples implement different concepts of who can be the owner of TK:

- The AC Decision, the PIF Act, the South African Regulations and the Guyanese Act seem to restrict ownership to communities;
- The ARIPO Protocol and the Portuguese Decree-Law foresee ownership by communities and individuals; and
- The Thai Act defines the government and individuals as the two possible groups of owners.

The provisions in the Thai Act follow a general policy line that many Asian governments and some European countries have advocated during the negotiations of the Nagoya Protocol.¹⁸⁰ Delegates frequently rejected the application of a concept of “indigenous peoples” as being specific groups within a country whose traditional rights have been suspended through colonial times and need to be restored by current governments. Governments, as the representative of the different societal groups and individuals, are seen as the rightful owner of property rights. Such a policy can certainly also explain the different approach to owners of TK and their relation to a certain geographic area. The Thai Act does not link TK to a certain area or lifestyle. In this regard, the Thai Act follows the approach of current patent and copyright legislation in which such linkages are irrelevant to describe the owner of the IP.

Key Points

- ⇒ In general, the presented legal texts determine traditional communities as the principal owner of TK. Some examples also allow individuals as owners of TK.
- ⇒ In countries which do not follow a policy of acknowledging specific, customary community-based property rights, ownership rights over TK might only be given to the government and/or individuals.

3) Scope of Rights

In the context of the Nagoya Protocol, only utilisation for R&D triggers the access provisions for genetic resources while the benefit sharing provisions also include the phase of commercialisation. The corresponding scope of rights with regard to associated TK remains undefined, requiring solutions to be negotiated in other forums such as the WIPO IGC and/or formulated in national legislation. The exclusion from the Nagoya Protocol of access to genetic resources which are only traded was designed to ensure that trading with genetic resources for purposes of consumption and manufacturing are not hindered by ABS rules. In order to close foreseeable loopholes, the Nagoya Protocol obliges its members to ensure that

¹⁸⁰ See, for example, Chouvin *et al.* (2004).

through domestic legislation, any utilisation - also of traded goods - for research purposes will be covered by appropriate ABS rules. The three regional legislations have very different approaches towards the determination of the scope of granted rights, which to a large extent are rooted in the fact that two of them do not concentrate on access issues but on property rights and utilisation.

The AC Decision was adopted long before the Nagoya Protocol and reflects the approach of the countries of the region to include all types of biological material and utilisation under ABS rules. Of specific interest for the implementation of the TK related provisions of the Nagoya Protocol are the PIF Act and the ARIPO Protocol. The PIF Act does not deal with the scope issue specifically. With regard to the strict ownership concept it can be assumed that the scope of the ownership rights comprise all activities using TK, innovation and practices for any purpose. The provisions of Article 3 of the AC Decision are applicable to all genetic resources for which the member states are the countries of origin, to their by-products and to associated TK. Again, specific activities and their purposes are not mentioned implying that all possible cases are included. Section 4 of the ARIPO Protocol instead explicitly mentions that the owners have the exclusive right to authorize the exploitation of their TK. This comprises the right to exclude anyone from using the TK without PIC. In addition, the ARIPO Protocol extends these rights to the utilization of products and processes beyond the traditional context. These provisions clearly show that the ARIPO Protocol has been developed in the domain of an intellectual property organisation and aims at establishing legal certainty when transforming TK into products and processes that enter the formal market. The two other laws do not specifically deal with issues of commercialisation of TK, but mainly with ABS issues.

These two different approaches are also reflected in the Thai, Portuguese and South African texts. The Guyanese text remains silent on the issue of the scope of rights. According to information from the Environmental Protection Agency of Guyana, specific ABS legislation regulating these issues is under development.¹⁸¹ In practice, Guyana has set up a PIC system under the Amerindian Act for regulating research on biodiversity where commercial research seems to be forbidden:

“The Amerindian communities are also consulted as part of the Biodiversity Research Process. [...] It should be noted that only academic and not commercial research is permitted. Furthermore, researchers are prohibited from entering Amerindian territory without the requisite permission from the Ministry of Amerindian Affairs and Village Captains.

The aforementioned Process is as follows:

- 1. Applications for biodiversity research or filming documentary are submitted to the EPA [Environmental Protection Agency].*
- 2. Applications are reviewed by the National Biodiversity Advisory Committee - The MOAA [Ministry of Amerindian Affairs] is an active member of this committee.*
- 3. If required, the applicant seeks permission from Ministry of Amerindian Affairs and Village Captain.*

¹⁸¹ Author's personal communication with EPA Guyana in October 2011.

4. Having met all criteria, a Biodiversity Research Permit is issued.

This process should be completed within three months.”¹⁸²

Section 34 of the Thai Act grants the owners all rights over the research, distribution, improvement or development of formulas on traditional Thai drugs or IPR under the registered text on traditional Thai medicine. Article 10 of the Portuguese Decree-Law entitles the owners to receive part of the benefits from all uses of the genetic resource and the right to be heard before the authority where the resource had been registered gives its PIC. While the owner of the genetic resource and the associated knowledge according to these provisions has only limited rights on typical ABS matters as PIC and MAT, the Decree-Law gives the “owner of the registration” the full responsibility to take care for the *in situ* conservation of the plant. The South African Act concentrates on all activities aiming at commercialisation of biological resources, including any organism and any parts thereof. The Regulations adopted four years later close the gap on research activities. With that the South African ABS system covers a large area of activities with biological resources and - through the provisions on the permit system and the definitions - associated TK. In Section 6 80 2(b), the Act excludes human genetic material, exotic organisms that have not been altered by biotechnology or indigenous biological resources listed in the ITPGRFA. The Act does not define what exotic species are and refers to those genetic resources that are listed in Annex 1 of the ITPGRFA. These exclusions reflect the intense debates during the negotiations of the Nagoya Protocol. The final compromise text of the Nagoya Protocol abandoned the concept of multiple exclusions from its scope and according to its Article 3, to be read in conjunction with Article 15 of the CBD, only excludes genetic resources accessed beyond the area of jurisdiction of its members.

Key Points

- ⇒ The scope of rights vary significantly among the national examples and the Nagoya Protocol:
 - The three regional legislations do not mention the different phases of the value chain and therefore probably include all research, development and commercialisation activities using associated TK; they go beyond the scope of the Nagoya Protocol with regard to its access provisions;
 - The Thai Act and the Portuguese Decree-Law include all uses of associated TK in the value chain; and
 - While the South African Act concentrates on the commercialisation phase in the value chain, the later adopted Regulations which also include the R&D phases under the ABS rules that include associated TK.
- ⇒ The South African Act is the only example that excludes certain genetic resources and associated TK from its scope, namely human genetic resources and genetic resources listed in the ITPGRFA.

¹⁸² Ministry for Foreign Affairs of Guyana (2009).

4) Acknowledgement of Rights

Beside the definition of who the holders of rights over associated TK are, a clear procedure of how to acknowledge rights over concrete fields of TK for specific holders is necessary to add certainty and predictability to the legislation and its implementation. As already mentioned, the Nagoya Protocol does not clarify how ownership over TK amongst ILCs should be formalised. In this regard, the task falls to regional and national legislation. Beside these basic challenges, one issue of technical concerns in the debate are the procedures, hurdles and costs for registration of these rights.

The AC Decision does not contain any provisions on registration of TK which is an activity left to the member states, a typical feature of ABS-related legislation. Article 4 of the PIF Act prescribes that any owner must self-identify himself at the competent authority, and that details will be left to the national implementation of this Act. Section 4 of the ARIPO Protocol speaks of communities that are recognized to hold specific TK, customary practices, laws and protocols are mentioned as suitable instruments. These two regional treaties at least give some guidance, but still the selection of applicable instruments and detailed procedures is left to national implementation.

The analysis of the four national examples in Annex I reveals that they also remain largely silent on the technicalities of registration of rights. The duty to set up rules and procedures to allow indigenous and local communities to register their TK lies with the responsible institutions identified in the four respective pieces of legislation. Section 15 of the Thai Act stipulates that the Institute for Traditional Thai Medicine acts as registrar but does not include details on procedures and costs of a typical registration process. The institute has until now not enacted effective rules to protect IPRs especially of the individual right holders, but focuses on the application of traditional medicinal knowledge in the national health care system.¹⁸³ Article 4 of the Portuguese Decree utilizes a comparable approach: the registration of a plant variety can be done at the National Centre for the Registration of Protected Varieties, but details are not provided. The South African Act and Regulations do not provide for any procedures on how claims of rights on TK can be announced by indigenous communities themselves. Contrary to the widely recognised approach of self-identification of the holders of customary rights, the Regulations in Article 8(1)(a) foresees that the applicant for a bioprospection permit - which would also cover access to TK - identifies the relevant stakeholders including the indigenous communities holding the sought after TK. The Guyanese Act does not contain any provisions on registration of genetic resources and TK. It has to be noted that in the first place, the full land, and thus resource ownership rights, are granted to the Village Council upon self-identification and acknowledgement by the Ministry of Amerindian Affairs. Details concerning a possible registration of TK will probably be dealt with when drafting the national ABS law.

Key Points

- ⇒ Registration procedures facilitate the acknowledgement of rights over TK.
- ⇒ The regional and national examples generally adhere to the commonly accepted principle of self-identification of the holders of customary rights over associated TK.

¹⁸³ Kudngaongarm (2011).

- ⇒ The South African Regulations determine that the applicant for a bioprospection permit identifies the holders of associated TK and charges the registrar with the verification of such claims.
- ⇒ None of the examples set rules and procedures for the technical processing of registration.

5) Publicly Available TK

A highly contentious issue is the concept of public domain when applied to TK and related ABS issues. Representatives of indigenous peoples during the WIPO IGC negotiations and elsewhere view the public domain concept as flawed because it does not consider the process (and its related legitimacy/legality) leading to the placement of the knowledge in the so-called public domain. They cannot agree that their customary ownership rights cease when TK is made available publicly - especially when no PIC was granted.¹⁸⁴ This argument is mainly based on a redress provision in Article 11 2 of the UNDRIP that says:

“States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs.”

In the case of many Asian states, governments claim ownership of certain forms of TK that is in the public domain, as for example traditional ayurvedic medicine or - as exemplified in this section - traditional Thai medicine. Thailand has a long history of publishing traditional medicinal knowledge so it is available for everybody.¹⁸⁵ A respective draft provision in the Nagoya Protocol to deal with ABS issues related to publicly available TK was championed by the governments of China, India and Nepal, but firmly rejected by the EU and some supporting governments which see any knowledge in the public domain as freely available and outside of the scope of any IP protection legislation.¹⁸⁶ It was exactly this controversy over which the open ABS negotiations failed on the last night of the CBD COP-10. During the finalisation of the Nagoya Protocol in a closed-door process excluding the vocal Asian countries, this provision was deleted.

The only regional legislation that provides for language on TK in the public domain is the PIF Act in Article 6. The Competent Authority is entitled to claim ownership over knowledge, innovations and practices when an owner does not exist or cannot be found. The authority will act as a trustee in case a rightful owner eventually surfaces.

Section 18 of the Thai Act gives government the power to register formulae and texts which are widely used or for which the IPR has expired, thus following the policy of many Asian countries on this issue. Article 3 of the Portuguese Decree deals with the public domain indirectly. It allows for classical IPR rights - exclusive ownership rights and prohibition of unauthorised use by third parties - over such genetic resources and associated TK which have not been used in industrial production or which have been unknown outside the local

¹⁸⁴ See, for example, statements in WIPO (2010), pp 36-38.

¹⁸⁵ Kudngaongarm (2011).

¹⁸⁶ Nijar (2011b), pp 28-29.

community until the event of registration. The effect of this provision is that those resources and knowledge which are in the public domain cannot any longer be protected under the Decree-Law. This provision also applies to genetic resources and TK that were brought into the public domain after the entry into force of the legislation in cases where the legitimate owners had not (yet) registered them. This approach follows the logic of typical IPR legislation that does not consider the conditions and procedures under which TK was put in the public domain, but the fact that it is in the public domain is relevant with regard to its free availability. The South African Act and Regulations as well as the Guyanese Act do not deal with the issue of publicly available TK.

Key Points

- ⇒ As noted earlier, the question whether TK in the public domain may be covered by IP protection is controversial. Representatives of indigenous peoples view the public domain concept as flawed because it does not consider the procedure and its legitimacy/legality leading to the placement of the knowledge in the public domain. They cannot agree that their customary ownership rights cease when TK is made available publicly - especially when no PIC was granted.
- ⇒ Provisions on protection of publicly available TK are a major deviation from existing IPRs and therefore require *sui generis* provisions if it were to be protected.
- ⇒ Only two of the examples - the PIF and the Thai Act - provide for the protection of publicly available TK under specific circumstances.
- ⇒ The Portuguese Decree-Law follows the approach of existing IPR legislation and explicitly excludes genetic resources and associated TK from protection which is already used in industrial production or is known outside the local community before registration.

6) ABS Elements

The Nagoya Protocol applies a “tandem approach”¹⁸⁷ under which it, on the one hand, integrates the issues of associated TK in its core provisions on access and benefit sharing and on the other hand, its Article 12 is a stand-alone provision aiming at clarifying the understanding of associated TK at the international level and giving guidance for national implementation as recognition of customary laws and practices, but without strong obligations for Parties.

Sui generis laws that treat TK as a form of IP may therefore contain provisions that refer to PIC and MAT. For example, the AC Decision contains detailed ABS provisions in Titles V, VI and VII which, to a certain extent, are also applicable if TK associated with genetic resources is accessed and utilised. Amongst the national examples in Annex I, the Portuguese Decree-Law in Article 7 contains typical ABS elements as PIC by the owner of TK, application at the registration authority and benefit sharing agreements with the user who may perform research or commercialisation activities. The South African Act and Regulations almost exclusively deal with ABS issues related to genetic resources. Its provisions on PIC,

¹⁸⁷ Frein & Meyer (2012).

MAT and benefit sharing as laid down in several articles will also apply to TK, however. Articles 10 and 11 of the PIF Act install a PIC procedure where a potential commercial user of TK has to apply at the Competent Authority. Based on the PIC of the registered owner, an ABS agreement will be negotiated under supervision of the Authority. Section 9 of the ARIPO Protocol determines that the holders of TK are entitled for benefit sharing based on MAT. Section 15 prescribes that authorisation to access associated TK does not imply a consent to access the genetic resource itself. Section 19 of the Thai Act states that anybody who wishes to use registered formulae and texts and to pay for this use needs to apply at the licensing authority. Section 46 adds that nobody shall conduct research, transformation for commercial purposes or export with controlled herbs unless authorised by the licensing authority. The lack of typical “ABS language” such as PIC and MAT might be explained by the fact that the Act was finalised in 1999, years before the negotiations of the Nagoya Protocol and increased awareness on ABS issues started. Article 5 of the Guyanese Act clarifies that access to indigenous territory is only possible after consent by the Village Council. In addition, research activities on biological diversity and natural resources need a separate PIC by the Village Council, all permits required under applicable law and permission by the Minister for Amerindian Affairs. Article 6 requires that PIC has also been sought for the use of materials derived from research, and that a benefit sharing agreement needs to be negotiated with the Village Council.

Key Points

- ⇒ Based on the respective provisions of the CBD, the UNDRIP and the Nagoya Protocol, the application of the principles of (free) PIC and MAT on access to associated TK and the sharing of the benefits arising from its utilisation has been firmly established.
- ⇒ The two regional IP-related examples from the Pacific and African region apply these principles, but they are not yet implemented in respective national IP legislation.
- ⇒ It appears to be likely that future national *sui generis* systems on the protection of TK will contain ABS-related elements implementing the provisions of the Nagoya Protocol.

7) Elements for Positive IPR Protection

This section analyses examples which contain elements for positive protection of associated TK. Of the regional laws, only the ARIPO Protocol presents a list of both traditional and *sui generis* IP provisions. The AC Decision, as an ABS law, does not deal with positive protection of IPR. Article 8 of the PIF Act gives the owner of traditional biological knowledge, innovations and practices the right of exclusive use in addition to any other applicable IPR, but it remains silent about the nature of the applicable IPR, with details left to the PIF member states. This will depend to a large extent on the future outcome of the WIPO IGC negotiations or could be taken by reference from the ARIPO Protocol. The Nagoya Protocol is not helpful in this context, as any substantial references to the IP system have been deleted from its final text.

The ARIPO Protocol devotes the entire Part II to the protection of TK with many typical elements of existing IPR legislation as already described above. Section 8 states that owners have the right to assign licensing agreements to third parties. Section 12 introduces the concept of compulsory licenses “in order to fulfil national needs” where TK “is not being sufficiently exploited by the rights holder, or where the holder of rights in TK refuses to grant licences subject to reasonable commercial terms and conditions”. Other provisions reflect the specific situation under which traditional communities live and differentiate between traditional use and commercialisation. Section 11 requires that the exclusive rights granted by the Protocol shall not be used to restrict the use of TK in the traditional context. This concept is also the basis of Article 12(4) of the Nagoya Protocol that says “Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated TK within and amongst indigenous and local communities in accordance with the objectives of the Convention.” Section 13 of the ARIPO Protocol deviates from the usual time frame for IP protection. Protection for TK is granted as long as the traditional context exists. If individual owners register TK for its use beyond the traditional context, the protection expires after 25 years.

Amongst the national examples, only the Thai Act in its Section 14 establishes an IPR over traditional formulae and texts. Section 16 in addition prescribes three categories of IP: national, general and personal formulae and texts. It has been noted that the implementation of these provisions remains unsatisfactory to this day.¹⁸⁸ Article 14 of the Guyanese Act gives the Village Council the right to certify products made by residents using traditional methods which may result in a kind of geographic indication. The Portuguese Decree-Law and the South African Act and Regulations do not contain any provisions on positive protection of TK.

Key Points

- ⇒ Due to the largely missing provisions on positive protection of associated TK in the examples, no general conclusions can be drawn on the requisite elements for positive IPR protection. It is likely that in the following years more national examples of legislation that provides for traditional and *sui generis* options for the positive protection of TK associated with genetic resources will be drafted.
- ⇒ The ARIPO Protocol adopts a mix of traditional IP provisions as the exclusive rights of access to TK and giving licences to third parties or compulsory licences “in order to fulfil national needs”, and *sui generis* provisions providing for unrestricted access to protected knowledge for use in the traditional context or for a protection period as long as the traditional context exists.

8) Elements for Defensive IPR Protection

The establishment and strengthening of rules that protect associated TK against misappropriation and the stringent application of the criteria of patentability are central elements of the debates on genetic resources, associated TK and IPRs. While it is largely uncontested amongst governments and stakeholders that such defensive rules are useful and necessary, there is still discussion on the consequences of non-compliance ranging from none

¹⁸⁸ Kudngaongarm (2011).

to the possible nullification of granted patents. Therefore, it is interesting to note that amongst the three regional examples, only the AC Decisions, as biodiversity-related legislation, contains strong defensive protection elements. The two IP-related regional texts do not deal directly with the topic.

The AC Decision in its Complementary Provisions Second prohibits the granting of IPRs on genetic resources, by-products and associated TK that was accessed in violation of the provisions of the Decision. Member states may also request nullification of such unlawfully granted IPR. Furthermore, applications for IPRs containing genetic resources and associated TK need to disclose their legal provenance. These provisions reflect the strong position of many Latin-American governments against the misappropriation of genetic resources and TK through the IP system.

The PIF Act does not contain strong elements for defensive IPR protection. Article 7 requires the Competent Authority to maintain a register, but the Act does not foresee that this register should be used as a means to check for prior art in IPR applications. Article 3 prescribes that this Act prevails whenever there is an inconsistency with IP laws. Section 5 of the ARIPO Protocol foresees the maintenance of registers but does not specifically require its use in IPR examinations. Section 10 requires every user of TK beyond its traditional context to indicate its source and origin and to respect the cultural values of its holders. While the ARIPO Protocol, in contrast to the AC Decision, does not explicitly prohibit the granting of IPRs on TK, it can be assumed on the basis of Section 10 and other provisions of the Protocol that ARIPO would not grant IPRs over TK.

Section 22 of the Thai Act prohibits the registration for IPRs on traditional Thai medicine when the registrar is of the opinion that the formula or text belongs to one of the three IP categories of traditional medicine. Article 3 of the Portuguese Decree protects TK against reproduction and commercial use as long as it is registered and its use described in sufficient detail in this registration. The South African Act and Regulations do not provide for defensive protection measures. Article 14 of the Guyanese Act entitles the Village Council to make rules on the recording and publishing of intellectual property and TK that belongs to the village. The Act does not contain any concrete defensive protection measures.

The inclusion of such measures may raise considerations of TRIPS compatibility similar to the discussion on the addition of disclosure and patentability criteria contained in Chapter 3. In this regard, one option available is to require disclosure of origin/source through the patent law, while sanctioning failure to comply in the ABS law.

Key Points

- ⇒ Defensive protection of associated TK can often be built into IP laws. This does not necessarily preclude the subject matter from being treated in *sui generis* laws covering TK.
- ⇒ The two regional IP-related texts from the Pacific and African region do not contain explicit provisions on defensive protection of associated TK.
- ⇒ The AC Decision prohibits the granting of IPR on genetic resources, by-products and associated TK that was accessed in violation of the provisions of the Decision.

Member states may also request nullification of such unlawfully granted IPR. Furthermore, applications on IPR on genetic resources and associated TK need to disclose their legal provenance.

- ⇒ The Thai Act Section 22 prohibits the registration for IPR on traditional Thai medicine when the registrar is of the opinion that the formula or text belongs to one of the three IP categories of traditional medicine.

9) Pay and Use Systems

One concept which aims at accommodating the concerns of TK holders suggests that IP rights protecting TK should be set up in the form of a liability regime. Such a use-now-pay-later system would allow for simple registration procedures, and R&D based on the TK without an elaborated benefit sharing agreement. Such an agreement would be negotiated when the marketing of products became likely. Still such systems need some form of legal certainty and effective monitoring - and will be very likely part of *sui generis* systems.

An example that follows this approach has been reported from Namibia - but only with regard to access to genetic resources, and not to TK. The Namibian government gave PIC for the transfer of Marula fruits (*Sclerocarya birrea* subsp. *caffra*) to a foreign institution for the sole purpose of research on its chemical composition. Oil from Marula seeds is of special interest for the cosmetic industry. The agreement on the one side does not foresee benefit sharing at this early stage in the value chain, but on the other hand forbids the user to publish any results and to commercialise any products derived from the research. In case the research would result in an outcome with a considerable market potential, a new PIC and a fully fledged benefit-sharing agreement need to be negotiated to enter the phase of product development.¹⁸⁹

Key Point

- ⇒ Use and pay systems may be one way to address the need for benefit sharing with respect to associated TK.

D. Databases

A number of countries, including China, Costa Rica, India, Peru and Thailand, have attempted to catalogue their existing TK and to enter the relevant information into a database. From a defensive perspective, the information contained in the database can have value for anyone wishing to examine the state of prior art in the event that a patent application builds upon TK, or in the case of non-disclosure, appears to build upon it. Accurate, up-to-date information on an easily searchable database therefore helps efforts to combat misappropriation through IP channels abroad. The difficulty lies, however, in maintaining the database and ensuring that it is updated as domestic TK evolves. The Indian database, containing over 1,200 formulations,

¹⁸⁹ Presentation by Pierre du Plessis, Expert Meeting on "ABS and Intellectual Property Rights", September 2011, Addis Ababa, Ethiopia. On file with the authors.

is accessible online to patent examiners at <http://www.tkdil.res.in/tkdil/langdefault/common/Home.asp?GL=Eng>.

Of the above mentioned countries, only India does not tie the information located in the database to domestic legal effect, in so far as the other countries consider their databases more as ‘registers’. In the cases of these other countries, the underlying TK law grants to the registrant the various rights and obligations discussed earlier in this chapter.

Though not without some limitations¹⁹⁰, there is general agreement within the international community that databases of existing TK are a useful tool to combat misappropriation. The current debate at the WTO revolves around whether countries should go further than databases and require mandatory disclosure of origin/source through an amendment of the TRIPS Agreement and whether the registration in a database should have automatic legal effect, rather than a debate over whether databases are useful or not.

Key Points

- ⇒ Databases are useful tools to help ensure against the misappropriation of local TK abroad. Much effort is required to establish and maintain an updated database.
- ⇒ The act of registration in a database may be the last step in a procedure for obtaining rights under a *sui generis* TK law.
- ⇒ Current intergovernmental debates focus on whether countries should agree to go beyond the establishment of databases and require mandatory disclosure of origin/source, and the legal effect of registration in a TK database.

IV. Conclusion

While the ABS system established through the Nagoya Protocol and the CBD are designed to provide a measure of protection to TK associated with genetic resources, the process of establishing a system to ‘protect’ such TK is a challenging one. First, there is little agreement as to what constitutes TK, in so far as neither treaty, nor the TRIPS Agreement for that matter, defines the term. Second, there are difficulties in ascertaining appropriate vehicles for ‘protection’. Such protection may mean preservation for future generations, and it may also mean protection from misappropriation. Protection may mean creating a means to secure monetary or non-monetary benefits from the application of the TK in foreign markets.

The deficiencies of protecting TK using IP tools that originated in the Western world has been pointed out numerous times in existing literature, and include the problems of who is the ‘owner’ of the TK, the lack of novelty when it is a condition for obtaining exclusive rights, and the temporal scope of modern IP tools, combined with the fact that the TK falls into the public domain after the term expires for some IP categories. Due to these limitations, many scholars propose *sui generis* laws that confer tailored rights and obligations to TK holders. The experience of countries that have such systems show, however, that these laws are still very much in their infancy as countries are as yet experimenting on ways and means of granting some recognition for a set of rights over TK.

¹⁹⁰ See footnote 109.

Most countries agree, nonetheless, that in order to combat misappropriation of TK abroad, it would be useful to catalogue existing TK and to establish a database which patent examiners abroad could access to assess prior art.

Chapter 6

Distinctive Signs, Biodiversity Derived Products and Protection of Traditional Knowledge

I. Introduction

Geographical indications (GI) are signs¹⁹¹ that identify goods as originating in a specific locality, region or territory, an origin that confers upon them a noted quality, reputation or characteristic.¹⁹² From a global perspective, GI is a broad collective umbrella denomination for distinctive signs linking products with their source, and includes subcategories of trademarks (collective and certification trademarks) as well as several *sui generis* forms of protection.¹⁹³ Among the *sui generis* subcategories, the most widely known are protected geographical indications (hereafter PGI) and protected denominations of origin (hereafter PDO).¹⁹⁴ In addition to the mentioned ‘positive’ forms of protection, GI protection is also pursued through the doctrine of unfair competition and passing off, as well as through administrative schemes for protection,¹⁹⁵ which are considered as ‘preventive’ or ‘passive’ forms of protection.

Biological resources are widely used as inputs for products that could be covered by GI protection. Climatic factors and ecosystems are natural frameworks that directly influence the quality and the particular features of GI products. The manufacture of GI products can also mirror or be inspired by traditional practices and methods of production that are linked to local livelihoods. All these aspects can create direct linkages between this intellectual property (IP) category and the conservation of biodiversity if properly designed in the technical standards and in the organizational structure. In this regard, GIs are voluntary schemes that can allow and valorize the introduction of sustainable practices and well as TK preservation measures.

GIs provide a contribution to the conservation of biodiversity and the sustainable use of its components (objectives 1 and 2 of the Convention on Biological Diversity (CBD)).¹⁹⁶ The relationship of GIs to the third CBD objective - the fair and equitable sharing of the benefits arising from the utilisation of genetic resources - is by far less clear. GI products mostly incorporate biological resources that in many cases are later processed and ultimately consumed. However, in some cases the GI protected products may include units of heredity (e.g., a fresh fruit or vegetable). In such cases, while the trade of the product as a “commodity” is allowed, such trade does not imply an authorization for the purposes of “utilization” under the Nagoya Protocol. In a case where a genetic resource covered by the GI is utilised for research and development (R&D) purposes (e.g., when seeking to improve some of the natural features of the genetic resource), the obligations under Nagoya Protocol

¹⁹¹ These may include words or phrases, distinctive marks, symbols, icons or groups of characters or traits linking the product with the territory.

¹⁹² See Article 22, TRIPS Agreement.

¹⁹³ In this broad sense, more than 10,000 have been reported to exist globally.

¹⁹⁴ The 167 countries that actively protect GIs as a form of intellectual property fall into two main groups: 111 nations with specific or *sui generis* systems of GI laws and 56 that prefer to use their trademark systems. D. Giovannucci *et al* (2009) p. 14.

¹⁹⁵ See UNCTAD-ICTSD (2005), pp. 274-279; D. Giovannucci *et al* (2009), pp. 49-53.

¹⁹⁶ See Article 1 of the CBD (1992).

will apply. This does not mean that other CBD and Nagoya Protocol provisions such as the need to develop biodiversity strategies and the protection of associated traditional knowledge (TK) are not relevant. On the contrary, if GIs are properly designed, they can constitute suitable instruments that contribute to biodiversity conservation and sustainable use.

This chapter seeks to introduce the main links between biodiversity, TK, access and benefit sharing (ABS) and GIs. The chapter will also provide the reader with a better understanding of the benefits and costs of making use of GIs from a sustainable development perspective. Finally, it will produce a checklist of issues that needs to be taken into consideration for maximizing the potential of GIs for biodiversity conservation and sustainable use.

Key Points

- ⇒ GIs can be protected through different modalities of distinctive signs including trademarks (certification or collective), as well as *sui generis* forms of GI protection.
- ⇒ GIs, if properly designed, can make a significant contribution to conservation of biological resources and to sustainable use objectives under the CBD.
- ⇒ GIs are a voluntary scheme that can allow and valorize the introduction of sustainable practices as well as TK preservation measures.
- ⇒ The links between GIs with access and benefit sharing provisions under the CBD and the Nagoya Protocol is limited, as GIs tend to mostly use biological resources as inputs in the manufacturing process. Nevertheless, sometimes GIs may cover genetic resources (e.g. fresh fruits and vegetables) and that any 'utilization' within the context of the Nagoya Protocol may trigger its access and benefit sharing (ABS) provisions.

A. PGIs and PDOs

Originally from Europe, PGI and PDO are forms of protection specifically conceived to link the territory with the 'indicated' product. There are some conceptual and terminological variations across countries and products, but these two remain the most widely used.¹⁹⁷

An important qualitative difference between PGI and PDO refers to the intensity, form and objectiveness of the link between the product and the geographic area of origin. In effect, the linkage between the *terroir* and the product is stronger for PDO, since the good must be produced, processed and prepared within the identified geographic area. Moreover, in the case of PDO the product must display characteristics or qualities fundamentally owed to that area. By contrast, as far as PGIs are concerned, only one of the mentioned operations must actually be performed in the indicated area, thus allowing more flexibility in the conditions so long as the product has a certain quality, reputation or characteristic attributable to that area.¹⁹⁸

¹⁹⁷ For wines and spirits, the term used in Europe is 'controlled denomination of origin', that can be further specified in terms of assuring a specific level of quality by referring to 'controlled denomination of origin guaranteed'.

¹⁹⁸ See article 2.1 (a) and (b) of the COUNCIL REGULATION (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ L 93, 31.3.2006, p. 12)

Key Point

- ⇒ In the case of PDO, the good must be produced, processed and prepared within the identified geographic area, and it must display features owed to that area. In the case of PGI, it is enough if the products display certain quality, reputation or characteristic attributable to the identified area, as long as it is produced, processed or prepared within the identified geographic area.

B. Trademarks, Certification Trademarks and Collective Trademarks

Some laws protect GI as trademarks, although in principle mere geographic names cannot be registered as trademarks for products. Despite this general prohibition, when the product and the geographic name are identified as referring to a particular source, producer or manufacturer, the name is considered to have gone beyond the geographic meaning (i.e., it has achieved ‘secondary meaning’) and fulfills a product identification function. Additionally, two particular categories of trademarks are employed to identify the goods’ geographic origin: certification and collective marks.

Certification marks consist of words, names, symbols, or devices that identify the quality and nature of the product and state that it meets certain pre-established standards. These standards or quality characteristics can be linked to the place of origin of the product, this being its nexus with GIs. By contrast with other forms of GI protection, the owner or owners of the mark do not use it. On the contrary, the role of the trademark proprietor consists in administering the regime and its use cannot be denied to applicants fulfilling the established criteria. The use of the mark is normally limited to the product that it certifies, so it does not extend to other areas of production or for other products unless its use to other products was specifically requested at the registration phase.

GIs can also be protected by means of collective marks, which are signs distinguishing the goods or services as having a connection with a specific group, and with the standards set up by that community. Collective marks are used exclusively by the members of the collective, who obtain proprietary rights to use a common identifier. The owner of the mark is the parent body, a collective group or organization obliged to administer the mark in the interest of the members of the collective. Although they can imply a geographic origin, they do not necessarily have a geographic content. In fact, a variety of factors distinct from the geographic origin of the goods or services may be at the origin of the collective.

Key Points

- ⇒ Two categories of trademarks are employed to identify the goods’ geographic origin, certification and collective marks.
- ⇒ Certification marks indicate that the product meets pre-established standards, which can be linked to its place of origin. Collective marks distinguish the goods or services as having a connection with a specific group, and can imply a geographic origin.

C. Key Requirements under TRIPS

The WTO TRIPS Agreement lays down the common characteristics and legal requirements for the protection of GIs. Under Article 22 of TRIPS, Members are obliged to provide legal means of protection – which may include protection against unfair competition as well as statutory and administrative methods of protection – to indications that identify goods as originating in the territory of a Member. ‘Goods’ is a wide term potentially covering all sorts of products, but not services, whose protection is left to national consideration.

The TRIPS Agreement establishes that a link between the product and the indicated origin must exist. More precisely, the good must ‘originate’ from the place identified by the GI. The specific meaning of ‘originating’ is flexible and allows, for instance, the partial manufacture of the good in a distinct place. On the other hand, the features of the product must be ‘essentially attributable’ to its origin, which means that they need not be entirely attributable to the designated territory.

TRIPS also states that a “given quality, reputation or other characteristic of the good” must be “essentially attributable to its geographic origin”. This opens the door to three distinct possibilities. First, the specific *quality* is essentially attributable to its geographic origin. Second, the specific *reputation* is attributed to its geographic origin, which opens the door to a link based on favorable considerations in respect of the good. Third, characteristics distinct from quality and reputation may also form the basis of the protection of the GI, thus permitting the consideration of issues such as the color or aromatic traits of the good. These possibilities confirm that the product may be distinguished by characteristics beyond its physical properties.

The scope covered by the GI will be broader or narrower depending on the reading of the term ‘territory’. If it is limited to the physical aspect, the notion becomes narrow. By contrast, if ‘territory’ also includes its inhabitants, as commonly understood, it will be possible to protect more products. This becomes of particular relevance when considering issues such as the links between TK and GI, since “cultural geography can also lead to the association of unique or superior quality with a particular geographic area. This often relates to traditions or particular skills or talents possessed by certain residents in the area.”¹⁹⁹

Provided the aforementioned requirements are met, interested parties must be offered the legal means of protection necessary to avoid any use of the indication that misleads the public regarding the true origin of the product. The means of protection may also prevent any use that constitutes an act of unfair competition.²⁰⁰ In adjudicating conflicts, the key discussion will be focused on the act to “mislead the public”. The specific meanings of ‘public’, ‘mislead’ and ‘deceit’ are key to determining the existence of infringement.²⁰¹ On the other hand, the same article bars the registry of trademarks if they contain a GI that may mislead the public as far as the real origin of the goods.

¹⁹⁹ Giovannucci *et al* (2009), p. 16.

²⁰⁰ Article 22(2), TRIPS.

²⁰¹ On the possible interpretation of these terms, see UNCTAD-ICTSD (2005), pp. 292-295.

Key Points

- ⇒ Article 22 of TRIPS obliges WTO Members to provide legal means of protection of GIs, which may include protection against unfair competition as well as statutory and administrative methods of protection.
- ⇒ The good must ‘originate’ from the place identified by the GI and a given quality, reputation or other characteristic of the good must be essentially attributable to its geographic origin.

D. Links between GI and Biodiversity Conservation

GIs can be a useful tool for biodiversity conservation, provided that the market values the GI, conservation practices are incorporated in the GI’s technical specifications and that consumers are willing to pay a price differential for origin-based products. If successfully established, the added value of the product should stimulate the preservation of the genetic resources used, the associated TK applied or the ecosystem and landscape within which both have been created. More precisely, GIs “may promote biodiversity conservation directly through the use of a specific genetic resource or indirectly through production and management practices that include landscape and ecosystem considerations”.²⁰² As it becomes clear from this rationale, the preservation of genetic resources and TK is a consequence of an economic activity and interest, but it is not necessarily the purposed goal of the GI protection.

The rise of agro-industrial generic products has caused difficulties to small and medium farmers. The difficulty to compete in terms of price and volume against large agro-industrial corporations has often obliged small farmers and collectivities to focus its efforts in market niches that value environment conservation, organic food and landscape preservation. As Larson underlines, GI and informative labeling “give them the possibility of commercializing products that have a link to a particular area with a differentiated identity; in this way they [can] avoid competition based on volume, low prices and marketing”.²⁰³ As GIs tend to value the land and its particular agro-ecological characteristics that impart unique organoleptic²⁰⁴ aspects,²⁰⁵ they have proved to be useful in distinguishing products and producers with direct ties with that land and resources.

The benefits for conservation arising from GI protection are not the same, however, for developed and developing countries. Comparative case studies²⁰⁶ have proven so far that positive and relevant effects on genetic resource conservation are easier to take place in developed than in developing countries. This has been the consequence of a higher level of integration of environmental requirements (such as species and races preservation, or grass protection and landscape considerations) in the GI schemes of certain developed countries. For example, in the case of *Comté* cheese in France, there are between 30 to 65 botanical species with the areas covered by the PDO²⁰⁷. Such a field variety in botanical species has a direct impact over the quality of the milk and the organoleptic properties of the cheese. This

²⁰² Larson (2007), p. x.

²⁰³ Larson (2007), p. 4.

²⁰⁴ Properties that can be perceived by sense organs.

²⁰⁵ Giovannucci *et al* (2009), p. 37.

²⁰⁶ Larson (2007).

²⁰⁷ Comité Interprofessionnel du Gruyère de Comté (2013). Comté AOP Contributions au Développement Local.

contrasts with non-PDOs artificial fields where the level of botanical diversity is less than 10 botanical species²⁰⁸.

In many developing countries, many potentially GI protectable products are of informal nature and therefore have faced problems in integrating environmental requirements. This does not mean that developing countries cannot benefit from positive spillovers, but that some other factors must also be present to ensure that conservation practices are embodied in the GI design. Among these, mention is usually made of institutional strengthening, IP protection, and management of natural, biological and genetic resources.²⁰⁹

Among the main lessons that can be learnt regarding the relationship between GIs and genetic resources are that:

*“i) direct contributions to landscape and ecosystem conservation are important in GI production systems based on natural vegetation, perennial crops or extensive low input livestock management; ii) in GIs based on intensive agricultural systems, direct environmental benefits may only result from convergence with organic production methods; iii) direct conservation of genetic resources results from GI implementation when they are intrinsic to the product itself; iv) endangered genetic resources can be recovered directly when a successfully marketed GI is developed and management of germplasm is carried out by producers, the governing body of a GI (GB) and in alliance with regional research institutions; v) GI production systems based on well managed extractive activities promote the conservation of natural vegetation and forested areas with the consequent benefits to ecosystem and landscape conservation; vi) the existing biological and cultural diversity in developing and transformation countries is an asset that can be developed through GI differentiation”.*²¹⁰

Key Points

- ⇒ GI is a useful tool for the protection of genetic distinctiveness if the market values the GI and conveniently rewards it.
- ⇒ GIs have proved to be useful in distinguishing products and producers with direct ties with that land and resources. This allows small farmers and collectivities to focus its efforts in market niches that value environment conservation, organic food and landscape preservation.

E. Links between GIs and TK

GIs can support local cultures, groups and traditions while fostering rural development.²¹¹ If successfully granted and promoted, GI “can provide the structure to affirm and protect the

²⁰⁸ Ibid.

²⁰⁹ Larson (2007).

²¹⁰ Ibid. pp. 39 and 57.

²¹¹ According to Escudero (2011), the most important “category of intellectual property right that may be directly applied to the protection of TK is that of geographical indication”. S. Escudero, International Protection of Geographical Indications and Developing Countries. Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working Papers 10. South Centre: Geneva. 2001, available at: <http://www.southcentre.org>

unique intellectual or socio-cultural property embodied in indigenous knowledge or traditional and artisanal skills that are valued forms of expression for a particular community”.²¹² Rangnekar claims that GIs are at the intersection of culture and geography. For him, GI protection is merited due to the link between a specific origin and a cultural manifestation, or the link between the product and a culture.²¹³

GIs are aimed at fostering the protection of cultural and local agro-ecological characteristics and techniques. For instance, local farming techniques, food preservation methods or processing procedures resulting in distinguishable products may become eligible for GI protection.²¹⁴ The key mechanism to strengthen local characteristics and techniques through GI is the reward provided by the market. If successfully established, the added value of the product thanks to the valorization of the knowledge implied should increase the return to local communities and stimulate the preservation of the conditions or traditions that allowed producing the protected product. As mentioned in Chapter 5, however, GIs do not protect the underlying TK itself.

Since the local culture may be essential in shaping the uniqueness of the protected product, and this uniqueness may be the main market asset of the product, GIs can potentially become a powerful conservationist stimulus of local TK. Its focus on the local sphere, moreover, enables the development of small-scale economies, frequently based on sustainable methods of exploitation. In a related fashion, a positive link between TK and genetic resource conservation can be established, since GIs may help at recovering traditional practices linked to the use of underutilized genetic resources that were neglected by industrialization.²¹⁵

The alluded synergies are not always easy to achieve. It has to be taken into account that GIs are difficult to establish and require good planning and an institutional framework. Moreover, if the quality of the product is not adequate, or farming communities are too poor to become involved in the institutional and regulatory aspects of the GI, this may not only limit its usefulness, but even damage the population, their environment, economy or culture. Also in this negative context, practices resulting from the homogenization of products that are GI protected, frequently trying to standardize the quality of the products to enable mass production, may lose differentiation and act as an impetus against the preservation of TK.²¹⁶

Key Points

- ⇒ GIs can foster the protection of cultural and local agro-ecological characteristics and techniques, the key incentive being the reward of the market. As far as the local culture is essential in shaping the uniqueness of the product, GIs may become a powerful conservationist stimulus of local TK.
- ⇒ Good planning, strong institutional framework, the quality attributes of the product, and the wealth of the local community are decisive factors to achieve any positive outcome from GI protection.

²¹² Giovannucci *et al* (2009), p. xviii.

²¹³ Rangnekar (2004), pp. 20-21.

²¹⁴ The link with the local context is emphasized in some laws. For instance, the French law on appellations of origin law alludes to “local, fair and constant practices”.

²¹⁵ Larson (2007), p. 40.

²¹⁶ *Ibid.*

F. Are Genetic Resources Protected by a GI subject to ABS rules?²¹⁷

In principle, it will be very unlikely that GIs can trigger access provisions based on the Nagoya Protocol²¹⁸ because utilization is defined as R&D on the genetic and biochemical composition of genetic origin. As mentioned above, on most occasions GIs incorporate biological resources that are later processed and ultimately consumed directly by consumers. Also, R&D on the genetic resources is in general not included in the establishment and implementation of GIs. Certain operations under GIs will use material of biological origin that due to processing and refinements do not contain substantial amounts of functional genetic information any longer - for example oils or spirits - while other material still contains functional genetic information which if used at all can be used for DNA fingerprinting and identity control - for example wines.²¹⁹ The operational value of the CBD definition of genetic resources that is based on the physical presence or absence of genetic information has decreased over the last decades because detection limits for DNA have increased manifold and the CBD does not operate with threshold values. This limited operability was one of the reasons why negotiators of the Nagoya Protocol finally chose the manner of utilization of genetic resources as the trigger for ABS rules in addition to the physical nature of the accessed material.

In some cases, the GI product matches the genetic resource. This is for example, the case of *Jinxiang Da Suan* (a local garlic variety from Jinxiang district in Shandong Province of China), which recently was registered as a PGI in Europe.²²⁰ This, however, does not imply that the garlic has been used for R&D purposes outside China. One option that countries have at hand to avoid confusion between the trade of the “special products/commodities” covered by a GI and the transfer of genetic resources under ABS rules, is to indicate in the export documentations and labels that those products are not authorized for utilization in the context of the CBD and the Nagoya Protocol. For example, Decision 391 of the Andean Community²²¹ in its complementary provision number four, stipulates that health certificates for the export of biological resources must clearly indicate that “use of this product as a genetic resource is not authorized”.

Because the benefit sharing obligations of the Nagoya Protocol with regard to genetic resources²²² also include the “commercialization” of such resources including their derivatives²²³, user countries need to discuss the implementation of these provisions also with regard to GIs. One issue to be solved is whether additional profits due to the willingness of consumers to pay a higher price for GI-protected products can be defined as benefit sharing under the Nagoya Protocol. In this regard, there are already cases where producers have made use of exclusive sourcing contracts of raw materials as a way to provide some benefit sharing. This has been, for example, the case of one cosmetic company in the business of producing

²¹⁷ This section is mostly based on kind comments provided by Harmut Meyer.

²¹⁸ See Articles 6, 1 and 2 (c) of the Nagoya Protocol.

²¹⁹ UC Davis (1999).

²²⁰ This GI is already protected geographical indication under EU regulations since 2011. See Official Journal of the EU (2011/C 37/11), EC No: CN-PGI-0005-0622-16.07.2007.

²²¹ Andean Common Regime on Access to Genetic Resources. Decision 391 of 1996.

²²² See Article 5(1) of the Nagoya Protocol.

²²³ See Article 2 (c to e) of the Nagoya Protocol.

argan oil²²⁴, which has offered local communities exclusive sourcing of all its inputs from them as a form of benefit sharing.²²⁵

A reverse picture arises when the TK elements of GIs are discussed in the light of the Nagoya Protocol. Access to TK associated with genetic resources is not linked, according to Nagoya Protocol²²⁶, to a specific form of utilization. This is based on the fact that the Nagoya Protocol does not define traditional knowledge and has not included it in the definition of “utilization”. Whether the utilization of TK in the context of GIs qualifies as access is dependent on the actual provisions of national ABS and TK legislation and can only be discussed on a case-by-case basis. The benefit sharing obligations with regard to associated TK under Article 5(5) of the Nagoya Protocol may lead also to the conclusion that the utilization of such knowledge in the context of GIs would trigger the rules of the Nagoya Protocol. In this regard, and when assessing the application of associated TK rules in the Nagoya Protocol to a particular GI, it would be important to determine the level of engagement of the community within the GI scheme as in most cases production facilities within the GI territory are owned by “locals” or “employ locals”, so benefits may already be generated or directly shared with the community.

Key Points

- ⇒ The product covered by a GI can in some cases also be a genetic resource. If R&D activity is undertaken over such a resource that is accessed, the provisions of the Nagoya Protocol will be triggered. Rules indicating the type of activity authorized in export documentation and labeling could be of assistance in avoiding confusion between “special products/commodities” for direct consumption and the authorization of utilization of the genetic material under the Nagoya Protocol.
- ⇒ According to benefit sharing provisions under the Nagoya Protocol, any benefit arising from the commercialization of genetic resource or its derivatives needs to be shared with the countries of origin. There is a need to determine whether the additional profit obtained through a GI scheme can be considered as a benefit sharing modality under the Protocol.
- ⇒ The application of associated TK protection provisions in the Nagoya Protocol to TK embodied in a GI product will depend on the national legislation and the particular case, especially because in many cases the producers or employees in the GI value chain are ILCs.

G. Can Distinctive Signs Address Misappropriation Concerns?

One important concern of biodiversity and TK rich countries is that the IP system has generated incentives for access, utilization and misappropriation of GRs and TK without the authorization or compensation of the countries of origin and TK holders. These incentives have been attributed in large part to the consequence of the emergence of biotechnology industries and the expansion of the scope of patentability over life forms and their

²²⁴ A request to protect argan oil as a PGI under EU regulation was submitted in 2011. The EU Commission is currently considering this request.

²²⁵ See Lybbert (2007).

²²⁶ See Article 7 of the Nagoya Protocol.

components.²²⁷ GRs and TK may sometimes be significant inputs in R&D processes leading to biotechnological inventions. However, the conditions set in national ABS and TK regulations have not always been fulfilled when utilising those resources and knowledge and introducing IP applications. Today, several international processes are directly addressing this problem (see sections on Disclosure Requirements and TK in Chapter 3).

Claims about misappropriation (appropriating the value of GRs and TK without compensating TK, and misuse (acting beyond access conditions and mutually agreed terms) have been quite common since the early 1980s and they continue to arise. To this, one can also add situations of non-patent ‘biopiracy’ (which applies to other types of IP control of biological resources and TK, including plant breeders’ rights and trademarks).²²⁸ Examples of controversial cases of trademarks applications/use over generic plant names, indigenous terms or existing regions in developing countries include “*Rooibos*” by an exporter in the United States²²⁹ (an herbal tea name from South Africa), Maori terminology in Lego’s bionicle toys²³⁰, and “*Barlovento*” for a chocolate bar by Nestle (the name of a cocoa-producing region in Venezuela).²³¹

While the literature tends to see GIs and other distinctive signs as potential tools to support sustainable use of biological genetic resources and TK preservation²³², their effect to address biopiracy and misappropriation concerns in patent filing and granting is less clear. GIs and other forms of distinctive signs give protection to the use of an “indication/sign” and to the “reputation” of the product but not to “knowledge” *per se*. So in principle, they cannot directly impede the filing of a new invention built on genetic resources or TK. However, the reputational content (including of the particular qualities of biological resources used), the codification of TK practices in technical standards/specifications, and continuity of protection under a GI can provide information of relevance in the novelty and prior art analysis in patent and breeders’ rights examination and should improve the quality of the patent and breeders’ rights subsequently granted (a defensive function). It has been reported that in the case of Darjeeling tea, which was the first GI registered in India, prevention of misappropriation was one of the motivations for the request of protection.²³³ Similar motivations were found in the registration of a PDO for *Quinoa Real* in Bolivia as a consequence of the granting of patent on *Quinoa* in the late 1990’s (later abandoned due to the opposition of indigenous peoples and civil society organizations).²³⁴

The reputational value of an “indication/trade name” protected in the country of origin can facilitate the oppositions for the registration of trademarks in third countries for similar products or related services. For example in 2006, the Ethiopian Patent and Trade Mark Office initiated an opposition procedure against a trademark application introduced in the United States by Starbucks Corporation on *Shirkina* sun-dried *Sidamo* coffee. This opposition succeeded and the United States Patent and Trade Mark Office decision recognized the likelihood of confusion with the trademark “Sidamo” and the reputational value of the Ethiopian Sidamo coffee. As consequence of this successful opposition Starbucks Corporation abandoned its trademark application.²³⁵

²²⁷ Pastor S. and M R Muller (2009), p 11.

²²⁸ Robinson (2010), p. 77.

²²⁹ See FAO (2009-10), p. 155.

²³⁰ Morgan (2003).

²³¹ Vivas Eugui (2001a), p. 703.

²³² Vivas Eugui and Muller (2001b) and Robinson (2010).

²³³ Kumar Datta (2010), p.132.

²³⁴ Larson (2007), p. 49.

²³⁵ DePass (2010).

In the case of utilization of indigenous terms/designs in trademark applications, the legislation of some countries includes explicit prohibitions to register words that might offend a community or consist of names of indigenous and local communities. There are examples in this regard in New Zealand²³⁶ and the Andean Community.²³⁷ In addition, the United States has recently developed a database of Native American Tribal Insignia (which is a larger concept than trademarks)²³⁸ that could be used in the examination process of trademarks in order to avoid potential cases of misappropriation. This type of database could be expanded to also include relevant indigenous terms and designs worldwide.

Key Points

- ⇒ GIs do not directly address biopiracy or misappropriation concerns.
- ⇒ The existence of a GI over a biological resource, its reputation, and TK contained in the technical standards may be useful to defeat certain patents, breeders' rights and their claims in novelty and prior art examinations.
- ⇒ Practical examples have evidenced that the pre-existence of GIs or trademarks will be key in preventing misappropriation through trademarks in third countries.
- ⇒ Some countries have introduced exceptions and measures linked to trademark/design registration of indigenous names, words and signs in order to avoid misappropriation.

H. Summary Comparative Table with Main Features

As mentioned above, 'GI' is a wide denomination for distinctive signs that link goods with their source. It embraces categories of trademarks such as collective and certification trademarks, and includes also several *sui generis* forms of protection. Despite several common features, the foundational principles behind each category differ, and differ as well in its ownership, enforcement mechanisms, the link of the protected good with its origin, the conditions set up for the use of the GI and other issues such as the ties with quality and technical standards. From the point of view of producers, it is vital to choose the legal institution that best suits their interest, the characteristics of the goods, the area of production and the collectivity behind the GI.

²³⁶ New Zealand, Trade Marks Act 2002 No 49, section 17.

²³⁷ See Article 136 g) of Decision 486 of the Andean Community of Nations (2002).

²³⁸ See <http://www.uspto.gov/trademarks/law/tribal/index.jsp>.

Table 2: Compared Characteristics of PGI, PDO, Certification Marks and Trademarks

	PGI and PDO	Certification marks	Collective trademarks
Foundational principles	Links GIs to certification and quality and indirectly to rural development, increase of farmer incomes and group development	Industrial property rights, differentiation and marketing tool	Industrial property rights, differentiation and marketing tool
Ownership	Collective or public	Privately owned, generally by government agencies or producer organizations	Privately owned by groups of proprietors, public or private
Name	Preexistent and linked to the territory. No chronological order, but linkage with the territory	Can be invented and without link with the territory. The first to register the name has full rights.	Can be invented and without link with the territory. The first registering the name has full rights
Link with the geographic origin	Strict. In the case of PDO all inputs must be produced within the territory For PGI this requirement is more flexible	Certification marks do not necessarily require distinctiveness for geographic terms. They can certify various features such as material, methods, quality and origin.	In the case of collective marks, distinctiveness is required for geographic terms
Ties with quality	Strong: it is conceived as a device signaling quality	Not so strong: general marketing tool. However, it can be built in the design	Not so strong: general marketing tool. Linked on the reputation or the producers.
Trade Access	They cannot be sold or delocalized Are accessible to any producer within the specified region of origin that meets the criteria	They can be sold and licensed Certification marks allow free entry to any producer who fulfills all the specifications for certification	They can be sold and licensed Collective marks can only be used by the members of the community
Technical standards	Publicly specified and obligatorily linked to origin.	In general standards are privately elaborated, although some exceptions exist	Private. They are not needed. The collective trademarks can be used to only identify producers.
Duration of the protection	Usually unlimited, can be maintained while condition for protection remain. In some jurisdictions, protection limited to 10 years (renewable)	Limited period of time, usually 10 years (renewable)	Limited period of time, usually 10 years (renewable)
Enforcement	Public, with the occasional collaboration of individuals concerned	Private enforcement. Additionally, a party who believes that a certifier is not following its own standards or is unfairly denying use of a mark can file an opposition, a cancellation proceeding, or an action in court	Owners of marks can take action without waiting for government enforcement

Source: Seuba and Vivas, partially based on M. Stéphan *et al.* (2007) pp. 4-7; and D.Giovannucci (2009), p.55.

II. Main Benefits and Costs when Making Use of GIs

Numerous factors need to be taken into account to, first, decide whether or not it is desirable to develop a GI and, second, which category among the diverse options will best suit the characteristics of the good, *terroir* and collectivity involved. Although the benefits are numerous and important, they do not take place automatically, and usually are case-specific. On the other hand, expected benefits depend on investments made in areas such as institutional framework and standards-setting. Moreover, benefits are not without parallel effects on welfare, and potential difficulties for access to goods produced under a GI may arise given its impact on prices. The overall picture, however, is fairly positive if institutions are rightly chosen and enough flexibility exists to adjust them to local conditions.

Both benefits and costs can have an impact on the overall society and on collectivities and individuals with a relationship to the GI. Benefits such as preservation of TK and genetic diversity are indeed public goods, and its reach is far wider than the involved geographic area. Economic benefits obtained by virtue of GI protection is in principle a profit that is reaped by those marketing the product, but other related factors such as increases in tax collection must be also considered. As far as costs are concerned, sometimes these are borne privately, while in other cases public institutions manage issues such as quality control, legal protection or setting up administrative or judicial bodies for the surveillance of the GI.

A. Benefits

GIs and other forms of distinctive signs were not directly designed to support the sustainable use of genetic resources or to protect TK. However, there are many potential positive effects/externalities that could be generated by the correct use of these instruments in practice. The most important effects include the following.

1) Market differentiation and the prime price.

Geographical indications and informative labelling mechanisms give the possibility of commercializing products that have a link to a particular area with a differentiated identity. This allows avoiding competition based on volume, low prices and mass marketing.²³⁹ GIs can also permit lower levels of price volatility as volumes are limited and quality is fixed by technical standards and practices. From a legal point of view, having a GI allows a defense from others free riding on the existing indication/reputation of a particular product originated or processed in a specific geographical area, and is a means of preventing misleading labelling.

GIs tend to target niche and local markets where the population is willing, due to cultural and consumer preferences and qualitative considerations, to pay a better price for something different.²⁴⁰ The so-called prime price is this marginal difference that the consumer is willing to pay for acquiring a different product if compared with a generic commodity. The main drivers of this willingness are the special quality of the product and the reputation, which is identified and certified by a GI scheme. If GI producers want to ensure a prime price, the application of quality controls

²³⁹ Larson (2007), p. 4.

²⁴⁰ Paz and Pomareda (2009), p.14.

and reputation need to be carefully preserved. Any attack on the reputation may decrease or destroy the prime price margin.

Without market differentiation and a prime price GIs make little sense. For example, Blue Mountain coffee from Jamaica has a prime price of USD14.50 compared with soft Colombian coffees.²⁴¹ In France, the average price of cheeses protected by a PDO in 2007 was 10.42 Euros/kg against an average of 8.11 Euros/kg for all other cheeses (which equates to about a 27 per cent differential). In the case of the Nuoc Mam sauce (a fish sauce from Vietnam), pushes in domestic and foreign demand have brought the price up about 200 per cent since the introduction of GI protection.²⁴²

One of the reasons why GI protected products usually have higher prices is that they have higher costs due to, *inter alia*, investments in quality (equipment, sourcing and grading), standard setting, controls, certification and monitoring.²⁴³ However, GI schemes can provide opportunities for lower costs and economies of scale in inputs acquisition, common manufacture and stock facilities, joint labelling, legal defense and marketing.

2) Organisation of Producers and Protection against De-localization

Cooperative agreements are a fundamental piece of the GI governance structure and their functioning. The fact that GIs cannot work effectively without a minimum level of organisation pushes producers to explore options for cooperative arrangements. In principle, GI offer incentives toward the emergence of cooperative arrangements such as opening niche markets, obtaining a prime price, distributing labour within the value chain and achieving economies of scale.

However, these agreements have not arisen automatically in the experience of many developing countries, especially when dealing with small producers. Technical and financial support by IP offices, ministries of agriculture and industries, regional authorities, enterprise development agencies and research centres has to be present in order to support the building of a governance structure that effectively represents all stakeholders in the value chain and the production reality. For example the Kampong Speu Palm Sugar Producer Association in Cambodia was formed by a task force comprising representatives of producers and government representatives as well as scientific support organizations.²⁴⁴ The task force was responsible for discussing and drafting the by-laws of a future producer association. After several months of work, the association was created in 2007. Today, the association is composed of 142 producers and is proceeding with official registration of Kampong Speu Palm Sugar as a GI product.²⁴⁵ There is also a pilot project lead by the Ministries of Commerce and Agriculture of Cambodia and the French Cooperation Agency seeking to support the development of technical standards and quality control mechanism for the GI²⁴⁶ in order to make it fully functional.

Another advantage offered by GI, is that they assist in preventing the delocalization of production.²⁴⁷ A GI can be produced only in a given area that confers specific characteristics on the

²⁴¹ Paz and Pomareda (2009), p. 14.

²⁴² D. Giovannucci *et al* (2009), p. 34

²⁴³ *Ibid*, p.33.

²⁴⁴ FAO (2009-2010), p. 100.

²⁴⁵ *Ibid*.

²⁴⁶ Ministries of Commerce and Ministry of Agriculture, Fisheries and Forestry of Cambodia (2010).

²⁴⁷ Ngo Bagal and Vittori (2011) p. 16.

product. As a result, large corporations are prevented from “capturing” the added value of origin products and related methods through the appropriation of these techniques and production outside the geographical area.²⁴⁸ This type of “capture” can easily occur in the case of companies that rely on trademarks, as they can be acquired as part of the company assets and the production moved to places or countries where production costs are lower. In the case of GIs, the production and value addition is attached to the territory and linked to local practices so the name/sign, qualities and reputation cannot be sold or transferred.

3) Self-Standard Setting and Environmental Management

One particularity of the GI and certification trademarks is that the producers are the ones that design, adopt and implement technical standards. These standards are binding for those producers that want to use the GI name/sign or obtain certification. Technical standards can embody the main features of the production process including the acquisition of raw materials, their treatment, transformation as well as quality specifications.

Environmental management is not always embodied in the technical standards, but may be reflected in the practice and objectives of producer associations. In the case of *Limon of Pica* from Chile, the low use of pesticides and chemicals is a fundamental practice of producers. While the low use of these inputs is not part of the technical standards, in the by-laws of the producers association the preservation of natural resources linked to the production process has been included as an objective.²⁴⁹ The association of producers of *Mezcal Papalote de Chilapán*, within the PDO de Mezcal, has adopted extensive forestry management programmes of a wild species instead of intense cultivation.²⁵⁰ Sometimes environmental regulations determine the use of natural resources by GI producers even if they are not part of the technical standards. For example, part of the production of *Cacao de Chuao* (PDO) in Venezuela is done within the territory of the Henri Pittier National Park. The governing national park regulations allow the production of cocoa as part of the ancestral practices of local communities²⁵¹, but at the same time requires the sustainable management of cocoa trees, the surrounding forest, soil, water and landscape. The surrounding tropical forest provides shade for cacao trees and preserves the soil from degradation.²⁵²

4) Enables the Revalorization of Biodiversity-Derived Products

As GIs seek to bring to the market origin-based special products, they often utilise endemic or locally and specifically adapted races, varieties and species. These diverse uses of plant and animal resources include those that were utilised in the past for food security purposes or for their particular qualities (i.e., nutritional, organoleptic, functional or aesthetical). The utilisation and promotion of products utilizing diverse plant or animal resources can assist in resisting pressures toward increased homogenisation and standardisation, therefore preventing the disappearance and deterioration of the habitat, landscapes, ecosystems and genetic diversity. GIs can then be an interesting platform for marketing products with a wider biodiversity base while allowing the preservation of specific and potentially commercial species. In the case of food products, a wider

²⁴⁸ *Ibid.*

²⁴⁹ Vandecandelaere and Mery (2007).

²⁵⁰ Larson (2007) p. 44.

²⁵¹ González Jiménez E. (2007), p. 31.

²⁵² *Ibid.*, p. 10.

diversity of food products also contributes to food security objectives and a larger nutrition and dietary base.

An example of a traditional variety that has been recently revalorised by GI protection is the case of *Mais Blanco Gigante del Cuzco* (white giant corn of Cuzco) in Peru. *Mais Gigante del Cuzco* is an ancient and high altitude variety of maize with important nutritious, tradition and religious functions.²⁵³ Its protection as a PDO since 2005 has allowed the recognition of the value of indigenous agricultural knowledge and has clear synergies with the efforts of the Cuzco region's tourist and restoration services. In Germany, the protection of the *Swabian Hall* pork meat as a PGI has allowed conservation and increased numbers of a highly endangered population of pig breed.²⁵⁴ The production of meat from this pig bred under the PGI is subject to outdoor management, which has positive environmental benefits compared to intensive pork production. In some cases, GIs can potentially contribute in providing an economic value to a species while facilitating protection and reproduction efforts. The *Guanaco* wool from Argentina, Chile and Peru, while not yet protected through a GI, could be a potential example in this regard. *Guanaco* wool is highly appreciated in both local and international textile markets. The *Guanaco* is a camelid protected under Annex II of the CITES Convention²⁵⁵ and the majority of the population is still wild. The use of a GI strategy for *Guanaco* wool that includes the protection and management of populations as part of the technical standards could facilitate the involvement of locals in the conservation and production efforts, allow income for their survival and protection for the species.

5) Preservation of Traditional Methods of Production

GIs, jointly with copyrights and industrial designs, may be the most relevant existing category of IP that may be directly applied to the protection of TK, including production methods and traditional cultural expressions (TCEs).²⁵⁶ All these IP categories may allow the protection of distinctive and creative aspects of signs, expressions and designs that could be present in traditional practices. Also, TK holders could in many cases meet the requirements for protection (i.e., distinctive, original or aesthetic features)²⁵⁷. Other categories of IP protection such as patents and breeders' rights are more difficult to obtain due to the certain limitation in the criteria for protection including novelty and industrial application in the case of patents, and novelty and homogeneity in the case of breeders' rights.²⁵⁸

In this regard, GIs can capture the distinctive aspects that emerge from a *terroir* and its associated traditional methods of production and processing that are often difficult to duplicate in other regions or countries.²⁵⁹ More specifically, GIs can provide the legal, governance and marketing structure needed to affirm and protect the unique intellectual or socio-cultural property embodied in indigenous knowledge or traditional and artisanal skills that are valued forms of expression for a particular community. Locally unique farming, harvesting, selection and preservation practices plus

²⁵³ FAO (2009-2010), p. 24.

²⁵⁴ Larson (2007), p. 39.

²⁵⁵ Convention on the International Trade of Endangered Species of Wild Fauna and Flora of 1973.

²⁵⁶ Vivas and Muller (2001b).

²⁵⁷ *Ibid.* Nevertheless, these IP categories may need some adaptation in order to facilitate protection or registration. WIPO is currently negotiating a new set of instrument(s) that would seek to protect traditional knowledge and cultural expressions.

²⁵⁸ Chapter 3 of the Handbook defines and explains with more detail the potential advantages and limitations that the IP system offers to TK as a mean of protection and why stakeholders consider there is a need to a sui generis system more suitable to indigenous and local communities needs and expectations.

²⁵⁹ *Ibid.*

processing procedures, designs and packaging embody key aspects of differentiation in GI products. Traditional processes also give quality value (i.e., handmade) and generate consumer interest due to qualitative features of final output.

An increasing and successful strategy to use GIs to protect and promote traditional techniques and knowledge is the case of GIs for textile products in India. By 2010, India had already 53 textiles GIs protected, showing the increasing importance of GI in the developing country context. It also shows that GIs can go well beyond traditional farming knowledge, including skills and practices in manufactured goods such as textiles.²⁶⁰ All these textile GIs incorporate as part of their production process traditional techniques for input harvests (e.g., flower and mineral selection), spinning, weaving, colour preparation, dyeing, knitting, processing, printing and labelling. Part of the process may also include different dressing techniques that bring additional aesthetic effects and societal recognition. Examples of famous Indian textile protected by GIs include *ochampalli ikat* (fabric), *Chanderi sari* (textiles) and *Mysore silk* (fabric). It has been reported that in these cases, GI protection has helped the producers to boost their economic returns significantly.²⁶¹ According to T.C. James, former Director of the Department of IP of India:

*“[g]etting products on the GI registry was only the first step towards realising their economic potential. Even this itself has been a major challenge. Most of the people engaged in the production of such products are small households or small units, although in the same area. Convincing them to organise into associations to move the application for registration was and continues to be a Herculean task in many instances. It is also necessary to draw up standards and inspection mechanisms to ensure quality. These, however, are just teething troubles; once the system gets organised it should be able to take care of itself”.*²⁶²

In many cases, local supply chain actors, including ILCs, play a key role in utilizing and preserving TK systems. Actors within this supply chain can be diverse. In many cases, key aspects of the process are entrusted to women, elderly people, shamans and families. In fact, the local community members may see the product as an element of their local culture and at the core of local activities.²⁶³ An example of the role of particular members of the community in adding value can be found in cocoa of *Chuao* where women dry cocoa beans in the traditional way in front of the village church. The particular type of flooring in the church gives special drying conditions and facilitates the fermentation process, thereby improving quality and aroma.

It is important to note that TK practices and techniques are not always codified. The use of a GI scheme can assist in the codification of these practices and sustain their continuity. In cases where practices are “secret or sacred”, additional forms of *sui generic* TK protection will be needed (see chapter 5 on TK protection).

²⁶⁰ Based on data from the Government of India and Intellectual Property India (2010). *Geographical Indications Journal*.

²⁶¹ James (2009).

²⁶² *Ibid.*

²⁶³ FAO (2009-2010), p. 14.

Key Points

- ⇒ While GIs and other forms of distinctive signs were not directly designed to support sustainable use of GRs or protect TK, they can be used for the identification and promotion of biodiversity-derived products.
- ⇒ GIs can facilitate the market differentiation of biodiversity-derived products in the market and to move away from the commodity market. Due to the special features of GI products, they can ensure consumer acceptance and allow a better margin of benefit (also called prime price).
- ⇒ GIs can be a means to promote the creation of new productive and organisational structures focusing on origin and quality. This would allow producers to move up in the value chain and to create market niches.
- ⇒ GIs can incorporate sustainable harvest, production and management practices. While not mandatory, these practices can become the base for differentiation.
- ⇒ GIs allow self-regulation leaving to the producers the selection of the best technical standard for ensuring quality and safeguarding reputation.
- ⇒ GIs allow the use of a wider variety of inputs including products linked to biodiversity and food security in the local context. They can also allow the revalorisation and sustainable reproduction of biological resources not being used any more or endangered.
- ⇒ The fact that GI implies production within a particular locality or region creates disincentives for delocalization and mass production.
- ⇒ TK and other traditional methods can be transferred into the production process and technical standards of the GI allowing their preservation and economic sustainability. GIs can also facilitate the protection and promotion of cultural goods such as textiles and handicrafts, as well as the preservation of livelihoods.

B. Costs

1) Distinction between costs and effects on welfare

The implementation of schemes for the protection of GIs has resource effects which can be grouped in two different categories. On the one hand, it is possible to identify the value of additional resources required to implement new obligations and frameworks for the protection of GIs. This is the investment that needs to be made to implement the GI scheme. Although GI protection is essentially a public policy, some of the investments needed can either be borne by the public authorities or left to the producers or collectivities. On the other hand, the impact or effects of GI protection on the economy and on society can be observed, and sometimes quantified. In this second category, impact may be defined as effects on public goods, prices, consumption, production and, ultimately, on welfare.²⁶⁴ This second group of resource effects can be both positive, for instance in terms of employment protection and growth, and negative, a dimension that has to do with aspects such as restriction of access to goods and negative environmental externalities. Moreover, it is not uncommon in the literature dealing with GIs to use of terminology that

²⁶⁴ The same distinction has been made as regards IP enforcement obligations. *Vid.* X. Seuba *et al.* (2011).

distinguishes between direct and indirect costs.²⁶⁵ In this regard, “[t]he costs of developing a GI extends far beyond the direct costs of actually filing for registration; there are greater indirect costs to consider and to weigh against the benefits.”²⁶⁶ Various costs and effects on welfare can be identified. With respect to costs, one could start by classifying among the direct costs those incurred to perform basic activities such as laying down the criteria and standards, developing information and education programs, establishing a system of quality control, promoting the GI, and setting up the infrastructure for the management of the GI. As far as examples of the effects on welfare are concerned, mention must be made of the probable impact on prices of GI exclusivity, the potential decrease of innovation or improvement of products under GI protection and the reduction of competition.

2) Institutional and organizational structures

Setting up institutional and organizational structures is a vital task for any GI scheme. The strength, management and adequacy of the institutional and organizational framework will largely have an impact on the probability of success of the GI. Institutional and organizational structures are necessary for some of the most essential aspects of the GI system. They will determine which products are eligible for the GI, since the established councils or authorities are in charge of the recognition of producers’ membership. These authorities also have the responsibility to ensure that regulations are followed, and usually perform activities aimed at marketing the product, basically through the strengthening of goodwill.

It has been rightly stated that, for the GI to be successful, the existence of strong institutional structures bears as much importance as does the GI reputation and quality achievements.²⁶⁷ For instance, *Antigua Café*, in Guatemala, has been successful thanks to the existence of a local association of exporters and producers (*Asociación de Productores de Café de Antigua*) that planned a multi-year effort that led first to register domestically the trademark “Genuine Antigua Coffee”, and in 2008 to obtain GI protection. By contrast, in the case of the Gobi desert camel wool “difficulties in participatory organization have resulted in only a few stakeholders grasping the rights and obligations of the GI.”²⁶⁸ In this regard, governance structures must be designed to attain a fair distribution of benefits, so that these reach producers and do not concentrate in distributors or other middlemen.

In establishing the institutional and administrative settings, the point of departure will be very different in the case of developed and developing countries. In developing countries, a significant share of the economic activity is of informal nature, production is atomised, and products are sold in many cases directly to consumers. Constructing a GI implies the creation of cooperative governance structures. Without such structures it not possible to obtain formal GI protection and make the GI scheme functional. This cooperation suggests common agreements over the delimitation of the territory, treatment of the raw material, harmonization of production processes, standards setting, quality and verification controls and joint labelling and marketing strategies. The institutional framework will probably be weaker and underdeveloped in many developing countries. Developed countries, by contrast, have a large tradition of cooperative institutions, such as farmers or artisans

²⁶⁵ The categories may not always be coincidental. For instance, the costs associated to reorganize production have been considered indirect costs, while in this case would be considered an investment and, therefore, a direct cost.

²⁶⁶ Giovannucci *et al.* (2009), p. 20

²⁶⁷ Larson (2007), p. ix.

²⁶⁸ Giovannucci *et al.* (2009), p. 2.

cooperatives. These cooperatives can often be more readily transformed in the new institutional structure in charge of administering the GI.

3) Costs of Establishing and Enforcing Standards

The aforementioned institutional and organizational frameworks are closely related with the establishment of legal and administrative structures for the protection of GI.²⁶⁹ At the same time, this activity implies a prior endeavor, which is the demarcation of the formal geographic area of the GI. This area is, in fact, the territorial jurisdiction of the institutions created, and the area of application of the legal and administrative standards adopted.

Given the interests at stake and the envisaged outcomes, the demarcation of the GI physical boundaries can be a contentious and resource consuming activity. Many stakeholders will be positively or negatively affected by the outcome, hence the decision must be well-grounded, something which commonly requires investing time and money. Probably not only the first step but also the final goal is to clearly define the area that matches with the claimed characteristics of the product. This activity will require meetings with representatives of the economic sectors involved, naturalists, geographers and maybe even sociologists.

While the design and implementation of standards is necessary to generate a certain level homogeneity among GI products and to ensure the fulfillment of safety regulations, the transfer of TK into a standard can generate tension with TK knowledge systems. TK systems are evolutionary, so standards will imply a codification and harmonization of relevant practices. In this regard, local and other communities involved in the value chain need to be clear that such codification and harmonization is only applicable to the production process. Also, standards can be periodically changed so the evolutionary aspect can be introduced in the standard review in order to maintain the authenticity of the process and the outcome.

From the institutional point of view another needed investment arises from the adoption of the administrative standards derived from GI rules. Because of the need to adjust the product to the organoleptic properties claimed, and to keep with the features claimed, standardization becomes a key feature of GI frameworks. Empowering local communities when setting up standards and achieving a sense of ownership of the adopted standards are important to avoid exclusions of legitimate producers. Following the adoption of the relevant standards, further investment will be needed to keep a record of their fulfillment, for instance through the establishment of a registry and through inspections. Moreover, both producers and collectivities will necessarily incur costs associated with the fulfillment of the adopted standards, and the former will probably be obliged to pay fees for activities such as certification. In this regard, the institutional design of the GI “should have a transaction cost adequate to the economic scale of the production process and the product.”²⁷⁰ Activities undertaken by a GI framework to guarantee the claimed characteristics must be as effective and as simple as possible.²⁷¹

Both the adoption of administrative standards and the design and implementation of a legal strategy for the protection of the GI are “steps to protect the reputation inherent in the GI from

²⁶⁹ See *infra*.

²⁷⁰ Larson (2007), p. 72.

²⁷¹ *Ibid.*

devaluation.”²⁷² Legal protection to avoid misuse of the GI name is central for the success of any GI. This protection can consume a significant amount of money if the product is sold in numerous countries and protection overseas is sought in many jurisdictions. For instance, it has been reported that Parma DO spends approximately USD 1 million per year in prosecuting infringements.²⁷³ Another example is the conflict over the registration of *Rooibos* as a trademark in the United States. In order to achieve recognition of the “genericness” of the term, and therefore to cancel the trademark registered in the United States, South African producers and stakeholders spent approximately 750,000 Euros to date.²⁷⁴

Legal protection does not only imply litigating, but also prevention. This is why bigger GIs pay institutions that function as sentries in different countries: these institutions visit both formal and informal markets and conduct regular inspections of products in search of illicit versions. While strong GIs can pass these costs on to the final market price of the good, neither the strength to undertake global surveillance activities nor to transfer its costs to the products’ price is possible for the small GI. Hence, small producers necessarily assume standardization and certification costs that end up affecting their competitiveness in terms of price.

4) Higher production costs and targeted marketing strategies

The investment made to develop a GI and the costs associated to produce goods distinguished and protected by its origin and particularities have an impact on the final price. Studies in Europe show that some GI protected products’ production price can be as much as 300% higher in comparison with non-protected GIs.²⁷⁵ These differences may be a positive factor in terms of assuring a good return to GI producers, but in some instances may also become a barrier to economic accessibility. Furthermore, selective marketing techniques may also restrict the availability of the product, and an overall impact on accessibility may arise.

As mentioned above, GI protected products usually have higher costs, including due to investments in quality, standard setting, controls, certification and monitoring. More labour hours, different machines, more expensive equipment and other basic factors of production contribute to higher or distinctive quality traits. In fact, even raw materials tend to become more expensive, since the technical specifications of the GI may oblige the consumption of a specific product, hence limiting options for the producer and diminishing competition. The characteristics of numerous GIs imply lower levels of production and productivity, since automation, industrial and agro-industrial techniques are usually excluded and new standards exclude the market goods that do not meet the criteria. Regarding certification, international standards govern the accreditation of qualified certification bodies, which increasingly are private organizations. Certification has become a business inextricably connected to product distinctiveness, and it has, obviously, a price. The costs associated with certification may be relevant: in 80% of cases, certification costs range from 0.6% to 0.8% of the turnover (excluding organizational costs).²⁷⁶

²⁷² Josling (2006), p. 4.

²⁷³ Giovannucci *et al.* (2009), p. 22.

²⁷⁴ Larson (2007), p. 48.

²⁷⁵ London Economics (2008).

²⁷⁶ Data provided by ECOCERT, a French control and certification body working in several developing countries. *Cfr.* M. Ngo Bagal and Vittori (2011), p. 18

These costs can be both at the collective and at the individual level. A varying number of local producers may be forced to adapt their methods, facilities and skills to the new GI technical standards and specifications. The adaptation may imply changes of a very different nature and impact. For instance, local producers wishing to benefit from the new GI may need to change the raw materials currently in use, or to undertake courses on hitherto neglected aspects. The investment may be more important, and imply a change in manufacturing process that also requires important changes either in the construction or in the machinery used for land or cattle-management. In the end, the certification costs are closely linked with the code of rules and the control plan, which will largely condition the direct certification costs.²⁷⁷ For instance, in the case of the *Pecorino Toscano* cheese, a code of rules was adopted that was not very prescriptive so that the different typologies of cheese that were produced could easily fit in the PDO.²⁷⁸

The quality and distinctive characteristics of products belonging to a GI enables one to charge a premium price and target high end markets. Competition in terms of price ceases to be a central issue, since the product is allegedly unique. The usual focus on quantity and volume is substituted by an interest in quality. Moreover, it is very probable that mass distribution will be substituted by selective marketing. Overall, these characteristics permit higher turnover, since the product will be probably sold in high-end niches or, at the least, in better off markets.

GIs also have the potential of negatively affecting access to “nutritious and culturally valuable resources by local and low income populations”²⁷⁹. This may be caused either by a rise in exports and concomitant undersupply of the domestic market, or by large-scale conversion of agriculture in the GI area leading to a neglect of production of local products and food, a situation that may occur when prices become higher and availability of the GI products or inputs lower as a consequence of an increase in demand and the success of the GI brand. Allowing the production of unbranded versions of exactly the same product at a lower price for the local consumption, incentivizing sustainable production of inputs or creating input quotas for local populations could be of assistance in addressing these problems.

5) Environmental degradation

Environmental factors such as land and climatic conditions can have a significant impact over quality. However, GIs do not necessarily generate positive environmental externalities if the production process does not include environmental management practices. Even in some cases, especially when the GI becomes a large-scale operation, it could have negative effects over the surrounding environment. In this regard, breed and landrace specialization may result in loss of genetic diversity, while intensive agriculture, either by means of irrigation or fertilization, may change the original links between the product and territory that make up the GI.²⁸⁰

A notorious example can be found in the use of agave stems to produce Tequila. Only one of the varieties of *Agave tequiliana* can be used in the Tequila DO. The introduction of green biotechnology has allowed massive reproduction of *Agave* plants, while also enabling the standardization of the quality and the control of the maturation periods. The success of tequila sales has also generated a very low level of diversity in the inputs used, as only one *Agave* variety is required by technical standards for the production of Tequila. This has not been the case of *Mezcal*

²⁷⁷ Belletti *et al.*, (2007).

²⁷⁸ *Ibid.*

²⁷⁹ Larson (2007), p. 58.

²⁸⁰ *Ibid.*, pp. 39 and 56.

as it allows a wider use of *Agave* varieties in the production process. Besides this, the intensive use of pesticides, some agricultural techniques and the deforestation caused in order to gain cultivable hectares, has made the Tequila production a criticised example environmentally.²⁸¹

Sustainable practices, based or not on traditional practices, (i.e., selective harvesting, organic production, or soil and water management) can be incorporated in the technical standard or practices but they need to be clear, explicit and to some extent homogenous. There is always a risk that environmental management considerations do not make it into the technical standards, as they may reflect the power relations within the supply chain and some producers may not be willing to introduce additional costs into the price structure.²⁸²

Key Points

- ⇒ Resource effects of GI protection can be grouped in two different categories: the investment that needs to be made to implement the GI scheme, and the effects that its protection may pose on public goods, prices, consumption, production, and ultimately, on welfare.
- ⇒ The strength and management of the institutional and organizational structures are vital for the success of any GI scheme. Developing countries generally have more difficulties to ensure the adequacy of those structures, both in terms of funding and traditions.
- ⇒ A number of important activities imply significant costs: the demarcation of the geographic area of the GI, the enactment of the administrative standards derived from GI rules, setting up legal and administrative structures for the protection of GIs, the creation of a registry, the conduction of inspections and engaging in legal protection.
- ⇒ Economic accessibility to goods that become GI protected may become more difficult. The investment made to develop a GI, the costs associated to produce goods distinguished and protected by its origin and particularities, the increase in demand and selective marketing techniques may increase the overall price of the product.

III. A Checklist of Issues for Sustainable Use of Biodiversity and TK Protection

When making use of GIs and other distinctive signs, stakeholders need to take into consideration several key issues regarding GI protection and an “origin” based business model in order to ensure that the potential for sustainable use of biodiversity and TK protection is maximised. These issues include an enabling regulatory environment, administrative capacity, organisational aspects, verification and quality control mechanisms, and marketing and labelling strategies. All these issues need to be considered and integrated from the beginning with environmental and social criteria. Such criteria²⁸³ could include:

- conservation of ecosystems, wild populations and genetic variety to the extent possible;
- management of natural inputs (water, land, biological resources and raw materials);

²⁸¹ *Ibid*, p. 43.

²⁸² *Ibid*, p. 56.

²⁸³ These minimum environmental and social criteria are inspired in existing principles and criteria of the UNCTAD’s Biotrade Initiative (2007).

- involvement of all relevant stakeholders in the design and creation of the GI governance structure;
- introduction of sustainable agriculture and manufacturing practices, including traditional ones, into the technical standards;
- inclusiveness and sharing of benefit throughout all the GI value added chain; and
- fulfillment of all relevant environmental and social regulations.

This section will analyze key aspects of GI protection and “GI” business model with the purpose of introducing some entry points to ensure that environmental and social criteria are included in the GI and its governing policies. Relevant stakeholders in this process include, *inter alia*, governmental authorities (IP offices, ministries of agriculture, industry and environment and sanitary authorities), producers associations and ILC organizations.

A. Enabling regulatory environment

Clear, transparent and enforceable GIs and/or distinctive signs regulations must be in place in order to ensure the possibility of protection over the sign/name that identifies the origin-based product. As mentioned above, countries may have the option of choosing a *sui generis* system, a collective/certification trademark system or both. In the absence of the first two modalities of protection, laws against unfair competition can be of assistance, but this usually implies litigation to obtain protection (e.g., passing off). For countries that have signed free trade agreements with the United States and/or the European Union, the parallel protection of both GI and certification/collective trademarks is an option.

When defining the criteria of protection, countries may choose to accord specific value to environmental (e.g., climate, land, and the use of certain biological resources) and social factors (e.g., traditional methods of selection, production and packaging) that have a fundamental impact over the quality and specificities of the product in question.

Countries also need to choose the level of IP protection to be given. The minimum level of protection at the multilateral level is provided in Articles 22 and 23 of the TRIPS Agreement. In general terms, GIs must be protected against false statements of source and acts of unfair competition (Article 22, TRIPS). A higher level of protection is given to wines and spirits, which must be protected against misuse and imitation (use of terms such as “kind”, “style”, “imitation” or “like” even if the information written in the label is accurate). Countries may choose a two-layer level of protection as mandated in the TRIPS Agreement. However, if there is great interest in protecting biodiversity-derived products or products with TK content, the provision of a higher level of protection to other products other than wines and spirits need to be evaluated, as the great majority of these products are neither wines nor spirits. Countries may also go beyond the TRIPS Agreement and provide for exclusive rights to the authorised users (e.g., the possibility to exclude any commercial use of the sign). This latter option is a default one when the modality for protection chosen is collective or certification trademarks.

Countries need also to clarify the incorporation of GI exceptions and limitations in light of Article 24 of TRIPS Agreement²⁸⁴. Those exceptions include the following:

- prior use for at least 10 years;
- prior trademark registry;
- genericness;
- wine variety names;
- personal names; and
- the lack of national protection.

Beside these exceptions, in the European Union and Switzerland there is a prohibition to register GIs that could enter into conflict with plant varieties and animal breeds names and that can generate confusion over the true origin of the product.²⁸⁵ Typical cases of confusion under this provision would be those where the plant variety or the animal breed indications does not originate in the territory covered by the GI request. An example of a case of animal breed name that has been registered as a GI as it did not generate confusion over the true origin of the product would be the Portuguese PDO Carnalentejana for meat²⁸⁶.

In some other cases, granting protection to a plant variety name has been used to protect the product against misappropriation, as is the case of “Basmati” for rice and other agricultural products.²⁸⁷ Another important limitation for GI protection at the international level is to ensure domestic GI protection before seeking protection abroad. No country will protect foreign GIs that are not already protected in the country of origin.

Regulations may also include incentives for facilitating or promoting GI registration including waiving fees for associations of small or artisanal producers, financial support for the preparation of business plans and support documentation for making the GI request, as well as tax exemptions for a limited period of time in order to absorb the initial cost of setting the GI governance system and quality control systems.

B. Administrative Capacity

There are important needs for trained personnel and equipment in the IP office in order to examine GI requests. In cases where trademark registers are already in place, administrative and infrastructural costs to introduce a GI system are usually lower. IP offices and ministries of agriculture and industry may also need to play a role in facilitating the “creation” of the GI, especially in countries where the experience is limited. These authorities may need to actively engage in supporting the request for protection and facilitate the transfer of practices into technical standards.

Once the GI regulation is in place, national authorities also need to ensure the existence of verification systems in order to avoid fraud regarding the origin of products, volumes produced and the fulfilment of technical standards. In case technical standards include environmental

²⁸⁴ For more information on the scope, interpretation and specific use of these exceptions, see UNCTAD-ICTSD (2005).

²⁸⁵ See article 6.2 of the EU Regulation No 1151/2012 of 21 November 2012 and article 4b) of Swiss ordinance 910/12 of 28 of May of 1997 regarding the protection of appellations of origin and protected geographical indications for food products.

²⁸⁶ EU/China IPR2 Project (2011). *Q&A Manual on the EU Legislation on Geographical Indications*.

²⁸⁷ Government of India and Intellectual Property India (2010).

considerations, involvement by agriculture and environmental authorities will be required to certify the soundness/impartiality of the private control/inspection bodies when they are in place or to undertake directly the verification when that falls within their competencies. The capacity to verify implies the availability of laboratories and other quality control facilities.

C. Organisational and Infrastructural Aspects

The creation of a producers' organization and the delimitation of the geographical area are challenging activities in the preparation of the request for protection. Many producers of biodiversity-derived products are not fully organized and might face difficulties in filing an application for GI protection. Also in many cases, products are of an "informal" nature as they might not be registered with sanitary authorities and taken directly into popular markets. Land issues can also be a problem, especially in areas where property or rights of indigenous peoples are not clearly defined.

Associations of producers may use different models for "incorporation" including the formation of cooperatives or professional corporations (created under public or private law depending on the country). In some countries, these associations are named "regulatory councils". Important aspects in the creation of the association are open and transparent consultations, inclusiveness and ensuring the self-financing of the association. In some cases, the participation of governmental and technical authorities in the creation of the producers association can generate trust and avoid the *de facto* capture of the association by bigger producers.

The main functions to be entrusted to the producers association include:

- delineation of the geographical area;
- standardization;
- verification and quality controls;
- certification and labelling;
- maintenance of a list of authorised producers and statistical data; and
- possible promotion of the GI, collective marketing and tourism management.

In the case of biodiversity-derived products, preservation of land and ecosystems and traditional methods should also be part of the key functions, especially when they have not been included in the technical standards. Recording and review of sustainable practices does not have to be a static function but can be managed proactively in order to attain the highest possible quality and performance.

Self-financing of activities by the producers association is also a challenge, especially for small producers' associations. There are different models for financing activities including members' contributions that can be linked to levels of sales or production, or by setting a label fee. The label fee model has been used in the case of *Tequila* in Mexico leading the creation of a very successful

regulatory council²⁸⁸, which achieved USD 725 million in export sales by 2007²⁸⁹. The *Tequila* regulatory council has also been successful in attracting financing related services activities such as tourism. In 2010, the *Tequila* regulatory council obtained USD 3 million support from the Inter-American Development Bank for the development of the *Tequila* touristic route.²⁹⁰ This example also shows how GI producers' associations can also become local development engines and assist in economic diversification.

D. Technical standards

Setting technical standards (also called “technical specifications”) is a core aspect of the “GI” business model. Technical standards harmonize production processes and ensure the emergence of the particular qualities of the product. The application of technical standards jointly with verification and labelling schemes assist in reducing information asymmetries between producers and consumers. They also give confidence to consumers on the maintenance and preservation of the quality and traditional methods of production.

Technical standards tend to include the following elements²⁹¹:

- *Description of the product*: The main physical, chemical, microbiological or organoleptic characteristics of the product, focusing on features that can be easily monitored.
- *Inputs and raw materials*: The inputs and raw materials that should be used or avoided in the production process. This aspect is very relevant in the case of biodiversity-derived products.
- *Definition of the process*: The method for obtaining the GI product in all the phases of the production process (agricultural production, transport, processing, conditioning, seasoning/maturing and final packaging), including, if needed, an explicit prohibition for using some production methods.
- *List of the specific quality linked to geographical origin*: Focus on the objective elements justifying the link between the specific quality and the resources in the geographical area (natural and human).
- *Environmental and social considerations*: These include sustainable use, environmental/social management and TK practices. Depending on the case and especially when there are R&D activities surrounding a particular genetic resource, there is a need to observe the CBD and Nagoya Protocol provisions, as incorporated into national ABS regulations (see below).

Producers set technical standards in a voluntary manner, as the standards do not comprise a regulatory act by the state. However, they are “mandatory” for producers within the association in order to enjoy GI protection and be able to use the GI signs and labels. Today, there is a proliferation in international trade of various forms of “voluntary standards” (e.g., fair trade, organic farming, good agricultural practice, etc.) that are used by producers to provide consumers

²⁸⁸ See <http://www.crt.org.mx/>

²⁸⁹ Data from the Ministry of Economy of Mexico (2008).

²⁹⁰ “Empresas Jaliscenses diversifican servicios hacia el sector turístico”. *La Jornada*, 31 May 2010.

²⁹¹ Partially taken and adapted from FAO (2009-2010). List of main contents of the code of practice.

with information concerning certain qualities of products and the way they are produced.²⁹² Within this context, the GI model has been raising particular interest among developing countries since the implementation of the TRIPS Agreement has advanced among developing countries.

To provide credibility, technical standards have to be objective, measurable, verifiable and available to the public. They also have to be approved collectively by the association of producers so they are a form of self-regulation. While standards may seek to respect tradition and authenticity, they are not static. Standards setting need certain innovation and adaptation to achieve specific or diverse qualities, introduce more efficient/healthy production processes and respond to evolving local needs. Traditional and new techniques can coexist when they do not affect the main qualities of the product. As a form of self-regulation, standards can always be reviewed and adapted to the evolving conditions including environmental conditions and consumer choice. Also, there can be several standards within a GI that reflect different qualities and a variety of products. For example, in the production of spirits, GIs such as various Caribbean rums, the age and level of maturation generates products that are quite different in qualitative terms and are consumed in a different manner. White rums are used for cocktail preparation (e.g., daiquiris) and aged rums are usually consumed in a similar manner as *Brandy/Jerez* and enjoyed with cigars (e.g. *Habanos*, which is another GI in Cuba).

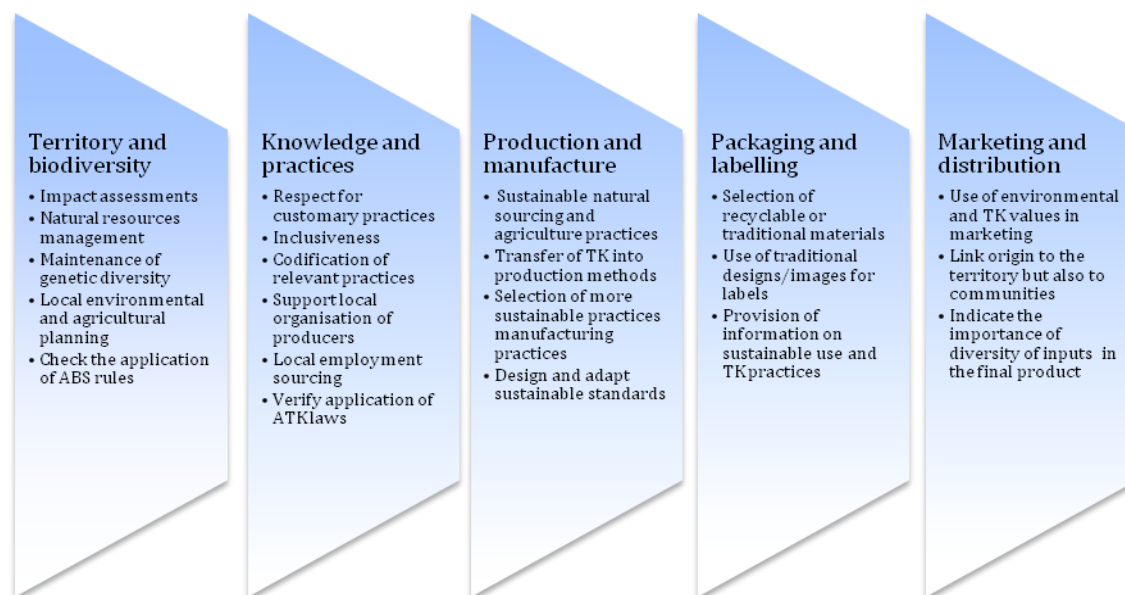
When seeking to use GIs for promoting sustainable use of biodiversity and to protect TK, the role of the technical standards is essential. Technical standards embody intangible aspects of the production process and apply to all phases of the value chain from harvesting to labelling. Environmental and social considerations as well as TK practices can be perfectly incorporated in the design of GI standards. Table 3 below illustrates the different phases of the GI value chain and what type of sustainable and TK practices can be incorporated in a GI standard.

²⁹² Ngo Bagal and Vittori, (2011) p.10.

Table 3

Flow Chart

Phases of the GI Value Chain and Relevant Sustainable and TK Practices



Source: Vivas and Seuba (2012) based on the simple GI value chain model recognising biological and cultural inputs proposed by Larson (2007).

However, the transfer of environmental and TK practice considerations is neither automatic nor without cost. Introducing environmental and social considerations and TK practices (e.g., by only using hand labour) into the standards will make their implementation binding for participants and will probably raise production costs. Depending on the GI in question and the consumer response, the level of incorporation of these considerations and practices into the standards can be higher. This is why some GI associations have introduced them within the functions of the producer association and not into the standards themselves. Also, the selection of relevant environmental and social considerations may depend on the quality and specificity of the final product and consumer acceptance. So the higher the impact on quality and consumer acceptance, the more incentives there will be for their incorporation into the final standards.

E. Quality controls and verification systems

Setting quality controls and verification systems are essential GI requirements and should not be overlooked when setting up a GI scheme. As mentioned above, they provide the base for ensuring minimum levels of homogeneity and maintaining reputational value. Quality controls are not specific to GIs as they can apply to all products. The particularity of quality controls in the GI scheme is to ensure that qualities sought are safeguarded during the entire production process. Quality controls also include hygiene, safety, traceability and environmental considerations. For example in the case of *Miel Corse* PDO (honey from Corsica), quality controls go all the way to the specific locality and date of collection, and samples of each are analysed for compliance with health,

quality and sensorial standards, before marketing.²⁹³

Verification systems seek to ensure that all technical standards are properly applied in the production process. Verification systems also provide information over the total and partial outputs and difficulties faced in the production process. There are different modalities for verification systems. Some of the most common include:²⁹⁴

- *Self-verification*: consists of guarantees provided by producers themselves based on auto controls (by individual producers) or internal controls (association of producers).
- *Participatory guarantee system*: based on the active participation of stakeholders, both internal and external to the GI value chain (even consumers) and built on a foundation of trust, social networks and knowledge exchange. This system can be particularly attractive for GIs where the association of producers also hold the TK knowledge and practices.
- *Third-party certification system*: involves an independent and external body (private, public or joint public-private) without direct interest in the economic relationship between the supplier and the buyer and which provides assurance that the relevant requirements have been followed. For example, standards for certified products are now recognized worldwide (independent third party certification – ISO/IEC 65 or the European standard for PDOs and PGIs EN 45011). This system can be particularly useful when the producer wants to also certify other aspects of the product (e.g. organic and fair trade standards).

F. Labeling and marketing

GI labelling allows producers to differentiate themselves in the market and to communicate such differences to consumers in global, national and regional markets. In this regard, labels are the main means to transmit to consumers the product specificities including origin and production methods and to reduce information asymmetries. Labels can include a variety of information including mandatory regulatory information (such as ingredients), but also relevant information contained in the technical standards.

Labels also have aesthetical and marketing functions making the differentiation easier for consumers. Signs within labels can also convey messages regarding the territory and its resources, as well as the work, knowledge and practices of the people whose livelihoods are linked to the particular product. Differentiation can also be demonstrated through packaging (e.g., different bottle forms).

Governments can design specific labels to certify the product conformity as a registered GI by public authorities as well. This is the case of the EU where specific labels accompany the producers association ones when the GI is registered and protected under EU regulations (see Figure 1).

Figure I

²⁹³ Larson (2007) p. 32.

²⁹⁴ Partially taken and adapted from FAO (2009-2010) p. 74.

EU label for Protected Geographical Indication



EU label for Protected Denomination of Origin



Collective marketing and financing mechanisms for producers' associations need to be operational to optimise benefits and ensure wider consumer acceptance. Collective marketing by the producers' association allow economies of scale and wider label outreach. Finally, unified labelling and collective marketing helps when undertaking joint legal defense of the GI signs/names in third country markets. This involves a continuous effort by producers' associations in order to maintain the value of the GI even if the GI is already well positioned. Perhaps, the best example of a successful collective marking and branding strategy (including its GI and organic brands) is *Café de Colombia*. The Federación Nacional de Cafeteros of Colombia, an organisation representing more than half a million producers, estimates that since it started its differentiation strategy the additional revenues obtained surpass USD 3.3 billion.²⁹⁵

Key Points

- ⇒ Developing a checklist of issues for maximizing the potential of GIs is a dynamic and evolving process. While there is no one-size-fits-all solution, a checklist is useful and can take on board the local knowledge and the national context.
- ⇒ The GI business model can integrate social and environmental criteria. Such criteria may include conservation practices, sustainable management, inclusiveness, benefit sharing, and the fulfillment of all applicable social and environmental regulations.
- ⇒ A clear, transparent and enforceable GI and/or distinctive signs regulation must be in place in order to ensure protection over the sign/name that identifies the origin-based product. As mentioned above, there are different modalities for GI protection available to producers including *sui generis* models, certification marks and collective marks.
- ⇒ Administrative capacity by relevant authorities is key in order to be able to register, protect, and verify GIs.
- ⇒ The creation of an organizational structure is an essential aspect for the success of the GI business model. The creation of such structures may require technical assistance, guidance and support during the initial phase of the organization, especially in relation to farming communities in developing countries. Measures to promote competition and avoid capture by bigger producers may need to be in place in order to avoid abuses.

²⁹⁵ Ngo Bagal and Vittori, (2011) p. 17.

- ⇒ The design of technical standards is fundamental to ensure the quality and particular features of the final product. Technical standards may also embody biodiversity conservation and sustainable use considerations throughout the value chain.
- ⇒ Quality controls and verification systems ensure that technical standards are fulfilled. They also provide credibility for the GI scheme and generate confidence on the consumer side. There are different models of verification systems available that need to be considered by producers in light of their own needs and capacities.
- ⇒ Labeling is a fundamental aspect of product differentiation, consumer recognition and public acceptance. They are developed by the producers and can be used to convey the particular qualities of the product, the origin and links to biodiversity and TK.
- ⇒ Governments can introduce institutional certification schemes to guarantee to the public conformity and to facilitate protection nationally and internationally.

IV. Conclusion

GIs and related distinctive signs have the potential to be both offensive and defensive tools for provider countries and ILCs. Such signs are a way to add value to an underlying product, signifying to a potential buyer that certain standards have been met in its production (organic, traditional, fair trade, etc.). Buyers may therefore be willing to pay a premium, which moves the underlying good up the value chain. The marks do not, however, protect the underlying product *per se*, but only the goodwill associated with it.

In order to preserve the potential value added, communities must manage the distinctive sign/GI, delineating the geographical boundaries of a product, and carefully ensuring that collectivities follow a prescribed methodology in production so as to maintain the added value associated with the sign. This is not always easy given the constraints faced by ILCs and communities in poorer developing countries. They nonetheless remain one option, within the existing framework of IP, to provide a measure of protection to traditional methods of production in realms such as agriculture. On the defensive side, GIs help make the case that others are attempting to misappropriate the goodwill of a provider community through the use of marks, as in the case of Ethiopian *Sidamo* coffee.

The use of marks developed without consideration of overall CBD objectives of environmentally sustainable access, benefit sharing and use of genetic resources and associated TK. Certain practices can be built into the GI management practices that help to ensure compatibility and preservation of sustainable practices, however, including international certification schemes. By moving up the value chain into more niche markets, it is also hoped that the underlying products are also protected economically from mass consumption.

Chapter 7

Private Contract Law

I. Introduction

Ultimately, genetic resources and associated traditional knowledge (TK) are transferred for R&D and other purposes from provider to users through private contracts which are legally binding documents between the two parties. Such contracts can take a number of forms, including bioprospecting agreements, material transfer agreements (MTAs) and collaborative research agreements.²⁹⁶ These contracts may be considered benefit sharing agreements under the Nagoya Protocol provided they contain the terms for the sharing of benefits that may arise from the access and removal of the genetic resource and its utilization. The keepers of those genetic resources in the provider countries, whether they are the national ABS authority or an indigenous group, must therefore negotiate the terms of such contracts carefully in order to safeguard their interests.

Recent trends in ABS agreements show that “natural product discovery is found largely in smaller discovery companies, semi-governmental or governmental entities and universities around the world. Elements of large pharmaceutical natural products programs have been spun off into non-profits or semi-governmental entities, and compound libraries have been given away or sold off cheaply.”²⁹⁷ The International Federation of Pharmaceutical Manufacturers Association (hereafter IFPMA) estimates that of 19 pharmaceutical multinationals that previously had natural products programs, only 7 currently have such programs, most of them Japanese.²⁹⁸ Laird and Wynberg point out that there is greater use of genetic resources and TK by the cosmetic industries, while ABS principles are not always understood in other industries such as botanicals and food/beverages.²⁹⁹

Negotiating contracts using knowledge of the law takes time and practice. Moreover, developing country negotiators often face informational and other disadvantages when entering into contract negotiations. A major factor limiting the ability of parties to freely agree to the terms and conditions in an MTA, which is the focus of this chapter, is that these contracts must respect applicable provisions in the respective IP and ABS laws, among other relevant legislation. It is for this reason that the bulk of this handbook is spent discussing these policies and regulations. While good negotiation will not overcome all inherent handicaps in negotiations, knowledge of policies, laws and some foresight will enable negotiators to come up with fairer MTAs that respect international and national ABS rules, and hopefully ensure outcomes that more adequately preserve and support provider interests.

This chapter is therefore written, like the other chapters, from the provider country perspective, and is designed to deepen understanding of issues which the provider country negotiator will want to bear in mind when negotiating such contracts. The chapter provides a concise guide to key points that developing country providers will want to bear in mind when negotiating an MTA, focusing on provisions that have a particular relationship to IP-related ABS issues. IP represents an issue that

²⁹⁶ Some of the salient differences between various contracts are discussed in section II of this Chapter.

²⁹⁷ Laird and Wynberg (2012), p. 7.

²⁹⁸ Presentation of Mr. Andrew Jenner, Director of Innovation, Intellectual Property and Trade at UNCTAD’s Ad Hoc Expert Group Meeting on the Development Dimensions of Intellectual Property: Biological Diversity and Access and Benefit Sharing, 16 April 2013. On file with the authors.

²⁹⁹ Laird and Wynberg (2012), p. 7.

potentially cuts across a number of the terms and conditions contained in an MTA. The references to PIC and MAT requirements herein are therefore discussed in this context.

Key Points

- ⇒ A variety of contracts could come up in the course of ABS procedures including bioprospecting agreements, material transfer agreements (MTAs), joint research agreements, among others. They are benefit sharing agreements only to the extent that their terms contain a potential or actual benefit to the provider.
- ⇒ Genetic resources are often transferred from provider to user through private contracts called Material Transfer Agreement (MTAs).
- ⇒ Providers in developing countries may be at a disadvantage when negotiating contracts, and will want to know how to negotiate MTAs to safeguard their interests.

II. MTAs and other Private Contracts

A brief digression on terminology will help to focus the discussion of this chapter. First, an MTA needs to be distinguished from a general license. An MTA is the contract that underlies the physical transfer of a genetic resource from the provider to a user. It will be used to specify terms and conditions when, for example, a plant is provided to a botanical garden in a user country or when a monkey specimen is provided to a primate research center. An MTA will also be used when an actual virus sample is provided from a provider to a user, as in the case of the WHO SMTAs in Annex II.

The MTA will embody the conditions attached to that physical transfer, including what the user will be able to do with the genetic resource obtained, including, for example:

- what R&D the user will be able to undertake using the genetic resource;
- the extent to which replication, alteration or breeding of the genetic resource is permitted;
- how the benefits would be shared from any commercialization of the fruits of R&D on the biological resource being transferred;
- limitations on third party transfer, if any; and
- prohibition or permission to commercialize the transferred resource and associated TK, including the results of R&D.

The contract will also specify what ought to happen in the event that a party fails to honor the terms of the contract.

By contrast, a *license* is, under contract law, broadly speaking a legal agreement that embodies permission.³⁰⁰ For example, a driver's license grants permission to drive, and a fishing license grants the licensee permission to fish in a given geographical area. These licenses basically grant

³⁰⁰ Black's Law Dictionary, ed. 1999.

certain privileges by the government to the licensee. In the context of IP, a license refers to the permission to make or utilize certain intangible property that is owned by a licensor.³⁰¹ Such contracts set out the terms and conditions for the license, including how the licensee can utilize the intangible property, in what jurisdiction, for how long, and for how much (i.e., royalties). Patents, trademarks and know-how, in addition to other forms of IP, can all be licensed, and sometimes, depending upon the terms of the license, sub-licensed.

Underlying the notion behind an MTA and a license is that under both types of contracts the owner of the subject matter does not change. Licensors remain the owners of the intangible property in a license; the CBD makes clear that States have sovereign rights over their own biological resources. The underlying contracts simply set out the terms and conditions that bind the use of the underlying subject matter. Notwithstanding the use of the possible confusion created by the use of the term “deed”, which is used to describe the model MTAs used by Australia, neither the MTA nor the license contract is considered a *sales* contract, which calls for a change in ownership and allows the new owner to freely dispose of the subject matter once title has passed. In this regard, MTAs may also be understood as a variation on a loan contract, where a physical object (the genetic resource) is leased without any change in ownership.

The distinguishing feature of the MTA, as compared to an IP license is that the subject matter involves a physical transfer (i.e., the genetic resource). In many cases, an MTA will permit certain R&D on the genetic resources being transferred. The fruits of R&D on the genetic resource under an MTA may, therefore, give rise to intangible property that forms the subject matter of a later license agreement (for example, patents, plant breeders’ rights or trade secrets). In this regard, the Organization for Economic Co-operation and Development (hereafter OECD) has promulgated in 2006 guidelines for the licensing of genetic inventions, which provides advice to, *inter alia*, developing countries on how to negotiate licenses.³⁰²

Sample MTA contracts can be found at the websites for the Secretariat of the CBD (<http://www.cbd.int/abs/resources/contracts.shtml>), which provides model agreements from Argentina, Australia and Switzerland; the WHO’s SMTAs under the Pandemic Influenza Preparedness Framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf); and the ITPGRFA SMTA (http://pgrc3.agr.gc.ca/itpgrfa/smta_e.html). In this regard, the NGO Biodiversity International has developed a guide to the ITPGRFA SMTA, which is available online.³⁰³ The SMTAs will need to be used for transfers of genetic resources under the ITPGRFA or in the context of the WHO network for the sharing of pandemic virus samples, respectively. The WHO and ITPGRFA SMTAs are included in Annexes II and III of this handbook, respectively.

One final note is that provisions contained in a typical MTA may also form part of larger agreements intended for joint R&D activity, or where permission is granted to locate biological material within a specified area and to extract it for research. Such provisions are contained in so-called ‘*bioprospecting*’ agreements where, according to the definition utilized by the Association of Southeast Asian Nations (hereafter ASEAN), the user is permitted to access territory of the provider in order to search for wild species with genes that produce better crops and medicines, or the exploration of biodiversity for commercially valuable genetic and biological resources.³⁰⁴ The bioprospecting agreement is in essence a permit to look for and remove a defined set of biological

³⁰¹ *Ibid.*

³⁰² <http://www.oecd.org/dataoecd/39/38/36198812.pdf>

³⁰³ http://www.biodiversityinternational.org/training/training_materials/international_treaty/treaty_module.html.

³⁰⁴ See the draft text of the ASEAN Framework Agreement on Access to Biological and Genetic Resources (2000).

resources in a defined area under the jurisdiction of the permit giver. It can be used as evidence of PIC, but for purposes of this chapter, the terms and conditions on such contracts for extracting and transferring a resource also needs to cover the subjects delineated in this chapter.

Key Points

- ⇒ MTAs do not envisage the transfer of ownership despite the physical transfer of the genetic resource. In this regard, they are closer and more similar to licenses and loan agreements, than to sales contracts.
- ⇒ Typical provisions that are contained in MTAs are also found in joint research agreements and bioprospecting agreements, where the user is permitted to access territory of the provider in order to search for wild species with genes that produce better crops and medicines, or the exploration of biodiversity for commercially valuable genetic and biological resources.

III. Substantive Provisions of MTAs with IP Implications

A. Parties to the Agreement

As noted above, an MTA is concluded between a provider and a user. In contracts, only an authorized representative is empowered to enter into obligations that bind the respective provider and user institution. Negotiators should ensure that the person negotiating and signing the contract has the authority to do so.

It is relatively easy to determine the user in question, whether this is a research institution, a zoo, botanical garden or the like. On the other hand, the provider institution may be more difficult to determine. For genetic resources that are linked to practices by a local or indigenous group, especially in the absence of national ABS/TK legislation, it may not be clear whether the group or the national government will have the authority to enter into the contract. While the Nagoya Protocol establishes three cases of ownership giving rise to certain rights (giving PIC and negotiating MAT): first, genetic resources of the State; second, genetic resources of ILCs; and third, associated TK of indigenous and local communities, national legislation is needed to ensure that these rights can be operationalized and enforced. Where there is a question as to the ability of, for example, a provider government institution to authorize the transfer of a resource that is found in territory on which a ILC lives, it is likely that a user will want some assurance that the State has the requisite authority to execute the MTA. The user may want to see that the government institution has been provided with authorization to negotiate on their behalf (for example, through a power of attorney), or that some underlying law grants to the government institution this authority.

Ascertaining the provider of record is important from an IP perspective because if benefit sharing includes joint ownership over any IP or the payment of a proportion of the royalties in the event that the fruits of R&D over the genetic resource transferred gives rise to patent or other IP rights, the party to whom those benefit accrue need to be sufficiently established under the MTA. Depending upon what the national legislation stipulates, it may be possible for the government ABS authority to negotiate and execute the contract, but to ensure that payment goes to a representative indigenous group in the event that the MTA covers subject matter that originates on land held by that group.

Key Points

- ⇒ The parties to an MTA need to be firmly established. The provider of record is important from an IP perspective because benefit sharing could include joint ownership over any IP or the payment of a proportion of the royalties in the event that the fruits of R&D over the genetic resource transferred give rise to patent or other IP rights.
- ⇒ For genetic resources that are linked to practices by an ILC, especially in the absence of national ABS/TK legislation, it may not be clear whether the group or the national government will have the authority to enter into the contract.

B. Description and Treatment of the Subject Matter

In a typical MTA, the underlying genetic resource that is being transferred must be described in a manner that makes it identifiable. Often, the resource being transferred is contained in an annex that contains various specifications. One key difference between an MTA and a bioprospecting agreement is that in the latter, one is not sure of what one is going to find given access, and therefore the specification of the resource being transferred becomes difficult. In such cases, it is necessary, nonetheless, to specify the geographic area which is subject to the bioprospecting, to have an idea as to what the party being granted access is bioprospecting for, and what the bioprospector is allowed to do with any specimens found. Like the description of the genetic resource, this can be contained in an annex to the agreement.

Aside from these general issues, there are certain conditions that can be placed upon the genetic resources being transferred that have an IP implication. A typical restriction on the subject matter being transferred in an MTA is that it grants to the user the ability to conduct R&D using the genetic resource in question. Sometimes, clauses containing this restriction limit R&D to non-commercial research. The model MTA from Argentina contains in the minimum clauses common to all MTAs that “[w]hether provided temporarily or permanently, the material shall be used by the Recipient Institution exclusively for non-commercial research.” Similarly, the Swiss model MTA assumes that the transfer is for non-commercial purposes, and if the purpose changes, a new contract will need to be negotiated (Article 7). Other model MTAs, such as the relevant clauses in the Australian model MTAs, affirm the ability of a user to commercialize by obtaining IP rights over the fruits of R&D. The ability to apply for patents and plant variety protection are therefore often restricted through MTAs.

As noted in Chapter 4, it is increasingly difficult to distinguish between commercial and non-commercial research. There is always a risk that courts may deem the research being done to be commercial in nature if the eventual goal is commercialization. At the same time, the MTA could potentially be used as evidence in a dispute that the research being conducted should be considered non-commercial in nature.³⁰⁵ Of course, if the existing research exception under the patent law was wide and encompassed all scientific research, the question of whether the research is commercial or non-commercial becomes moot.

³⁰⁵ Chapter 3 notes that the existence of a research exception in the patent or plant variety law will not eliminate the need for permission to conduct research under an MTA.

Key Points

- ⇒ The genetic resource being transferred needs to be described sufficiently in the contract. For bioprospecting agreements, the area made available needs to be specified, what kinds of resources they are looking for, as well as what the bioprospector is allowed to do with any specimens identified and taken.
- ⇒ Research to be undertaken using the genetic resource that is the subject matter of the MTA may be limited to non-commercial research by contract, even where there is a broad research exception that would permit otherwise.

C. Third Party Transfer

The onward transfer of the underlying genetic resource should be a concern to the provider since the MTA binds only the provider and the user as parties to the contract. This means that a third party to whom the genetic resource is physically transferred by the user may assume that s/he is not bound by any provisions related to IP, including any covenants not to seek IP protection or benefit sharing obligations that involve IP that had restricted the user. The main point for provider countries to keep in mind is that absent a clause in the MTA that prevents the user from transferring the physical genetic resource to a third party, users may do so if they deem it to be in their best interests. As a legal matter, however, users are only able to transfer rights to the genetic resource only to the extent of the rights which s/he has been granted by the provider. This is due to the fact that the MTA is not a contract that envisages the change of ownership of the genetic resource; otherwise the recipient would be able to freely dispose of the resource.

To be safe, provider countries will generally want to include text in an MTA that restricts the user from providing the genetic material to a third party absent the consent of the provider. The model MTA for Argentina states, for example, that “[n]o sample component of genetic heritage, provided temporarily or permanently, shall be released to a third party by the Recipient Institution without the prior execution of a new material transfer agreement between the original provider Institution and the new Recipient Institution. No part of by-product shall be lent or transferred to another researcher or institution without prior written authorization, which shall require a new procedure” (minimum clauses common to all MTAs). The Swiss model MTA provides in Article 8 that the “[t]ransfer of the Genetic Resources for the purposes of academic research and collections, and for training, teaching and education, or any other non-commercial activities is allowed under the condition that the User ensures that the subsequent person or institutions (Third Party) is informed about the provisions under this Agreement and undertakes to pass on the Genetic Resources under the same obligations to any further recipient”, including, presumably any PIC and MAT requirements. The WHO system for the sharing of pathogens obliges the User to ensure that any onward transfer of viruses to third parties be based on SMTA1 for entities within the WHO network (Article 5.1.4). The consent of the provider to onward transfer is only granted for entities that are not part of the WHO network if SMTA2 is used (Article 4.3), otherwise there is no authorization for onward transfer and a new agreement must be concluded. The ITPGRFA SMTA obligates the recipient to ensure that onward transfers are made “under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement” (Article 6.5(a)).

A contractual clause that specifies the rights and obligations of parties in the event that the genetic resource or associated TK is to be transferred thus helps to assure legal certainty for the parties concerned.

Key Points

- ⇒ As a legal matter, a user will be able to transfer only to the extent of the rights s/he has been granted under the MTA.
- ⇒ From the perspective of the provider, any subsequent transfer should be subject to the same conditions that the initial transfer was subject to, which include PIC and MAT. Otherwise, the provider is opening the door to potential misappropriation.

D. Intellectual Property Rights

MTAs will differ in how IP rights, such as patents and plant breeders' rights, related to the subject matter material will be treated. At one end of the spectrum, the MTA can prohibit the user from obtaining any IP rights on the material, as in the case of WHO's SMTA 1 (Article 6.1). This presumably would include a prohibition on the user from seeking patent protection on gene sequences and other parts of pathogens covered by the SMTA. The public health interest in securing the greatest possible access to a pathogen for which a vaccine is being sought may help to explain the restrictive language in this SMTA. It should be noted, however, that this language may not prevent the patenting of a vaccine derived from the pathogenic material, as the contractual text limits itself to IPRs over only the material itself. In any event, provider countries may not wish to prevent the outright possibility to obtain IPRs over the subject matter, since it can be assumed that the material is being transferred because the user is in a better position to conduct R&D with the genetic resource than the provider, and therefore more likely to find a way to develop and commercialize the material being transferred. A blanket prohibition on seeking IPRs by the user over products and processes that contain or utilize the material would effectively mean that the contract is precluding a way for the provider to secure any benefits.

Other MTAs therefore leave open the possibility for the user to commercialize via IPRs or otherwise products/processes that contain the material, or are derived therefrom. In this regard, commercialization may not necessarily be through the application for IPRs, as many cosmetic and nutraceutical products are brought to market without IPR protection. The question then becomes one of benefit sharing, and here there are numerous possible variations. Argentina's model CBD MTAs generally stipulate, for example, that the Government of Argentina exclusively retains all IPRs related to the material used and its derivatives. It is unlikely that a user would find such term acceptable, however, since this would effectively prevent him or her from using the IPR to recoup costs related to the underlying R&D. At the other end is the Australian model MTAs for the CBD, which grants to the user IPRs arising from R&D activity using the material (Article 5.2.). Under the Swiss model agreement, if commercialization is sought of the fruits of R&D, new PIC and MAT have to be negotiated (Article 14 and Option 15.3), and the user has the opportunity to file an application for an IPR within an agreed amount of time, after which the provider exercises his or her right to publish the research, thereby placing it in the public domain (Option 15.4). The Annex to the Nagoya Protocol also contemplates the possibility of joint ownership of relevant IPRs (Annex 1(j)).

Beyond the issue of ownership, there are other means by which IPR benefits can be shared. A proportion of the royalties or sales from the commercialization of a product (including through IPRs) can be used to share benefits. This is the model adopted by the SMTA for the ITPGRFA, which states in Article 6.7 that “[i]n the case that the Recipient commercializes a Product that is a plant genetic resource for food and agriculture and that incorporates Material as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay a fixed percentage of the Sales of the commercialized Product into the mechanism established by the Governing Body for this purpose, in accordance with Appendix 2 to this Agreement.” The Annex to the Nagoya Protocol stipulates the possibility of royalty payments in respect of relevant IPRs (Annex 1(d)) as a possible means of benefit sharing.

Key Points

- ⇒ MTAs may prohibit the application by the user of IP rights. At the same time, in so doing, the provider would be foreclosing a possibility of benefiting commercially.
- ⇒ There are a variety of means to share in benefits from IP rights obtained over the fruits of R&D utilizing the genetic resource in question. These include possible joint ownership of any IP rights, a percentage of the sales of the commercialized product, priority access to the product developed, etc.

E. Benefit Sharing

Benefit sharing as defined by the Nagoya Protocol is directed to the provider. As noted above, IPRs may be a means of benefit sharing, but there is clearly no direct link or obligation in the Nagoya Protocol that requires that IPRs serve the purpose of benefit sharing. Thus, cash flows directly related to IPRs such as royalties or through joint ownership of IPRs is by no means the only way by which there can be benefit sharing under the Nagoya Protocol. In fact, the Protocol lists a number of means to share in the benefits if a product is commercialized from resources accessed under the CBD. The Annex to the Protocol divides, in non-mutually exhaustive lists, benefits into monetary and non-monetary categories. Examples of the former, aside from joint ownership and license fees, milestone payments, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, research funding and access fees. Examples of the latter include sharing of R&D results, collaboration, cooperation and contribution in scientific R&D (particularly in biotechnology and where possible in the party providing genetic resources), access to databases, education and training, food and livelihood security benefits, as well as various forms of technology transfer.

While these monetary and non-monetary sharing of benefits may be the subject of a separate agreement, they are often equally built into the underlying MTA. For example, WHO’s SMTA2 requires the recipient of a pathogen to either donate at least 10% of real time pandemic vaccine production to WHO, or to make it available at affordable prices to WHO, and/or to donate or make available at an affordable price an unspecified number of treatment courses of needed antiviral medicine for the pandemic to WHO. SMTA2 also leaves open the possibility of granting a sub-license to WHO (Article 4). The ITPGRFA SMTA requires the payment of a fixed percentage of the sale of the commercialized product into a trust fund that supports R&D projects for new plant varieties that are designed to benefit developing countries (Article 6.7). The Australian model

MTA contains a schedule that lists the benefits, including a schedule for threshold payments (Schedule 3). One of the model MTAs from Argentina is designed as a joint research collaboration agreement (Model 2).

From the perspective of the provider of a resource, two general negotiation principles should be kept in mind. The first is that the more restrictive the conditions attached to access, the more limited will be the benefits that a user is going to be willing to provide. The Argentinian model MTAs, for example, stipulate that any IP rights arising from R&D related to the material used and its derivatives belong to the Government of Argentina. Users are likely to argue that the provider has already received a fair deal in the event of commercialization, and may be reluctant to consider other possible benefits. The second is that it will be more the exception than the rule that a resource transferred may end up being commercialized. Monetary benefits would, in such case, be illusory. In that case, at least one author argues that developing country providers are better off placing emphasis on opportunities for technology transfer.³⁰⁶ Given the high risk nature of bioprospecting and the low success rate of finding and developing a genetic resource that can be commercialized³⁰⁷, users may often be quite willing to spread this risk with joint collaborative R&D. The wide range of possible benefits needs to be assessed when negotiating an MTA, with a view to reaching a satisfactory conclusion acceptable to both the provider and the user. These non-IP benefits need to be strategically considered alongside IP-related benefits.

Key Points

- ⇒ The Annex to the Nagoya Protocol divides, in non-exhaustive lists, benefits into monetary and non-monetary. Examples of the former, aside from joint ownership and license fees, are milestone payments, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, research funding and access fees. Examples of the latter include the sharing of R&D results, collaborative research, training and strengthening capacities in technology transfer, among others.
- ⇒ From the perspective of the provider of a resource, two general negotiation principles should be kept in mind. The first is that the more restrictive the conditions attached to access, the more limited will be the benefits that a user is going to be willing to provide. The second is that it will be more the exception than the rule that a resource transferred may end up being commercialized, and that any profits will be generated from development.
- ⇒ The wide range of possible benefits needs to be assessed when negotiating an MTA, with a view to reaching a satisfactory conclusion acceptable to both the provider and the user. Since it is hard to foresee the potential of a candidate resource, non-IP benefits need to be strategically considered alongside IP-related benefits.

F. Jurisdiction and Dispute Settlement

Jurisdiction refers to which set of laws will govern the interpretation of contractual terms and will be applied in the event of a dispute. While in some respects contract law will have some common

³⁰⁶ Morioka (2009), Chapter 6.

³⁰⁷ See the example of Japanese pharmaceutical firm Eisai Co., Ltd.'s venture to commercialize products from biological resources in Indonesia in the Indonesia case study found in UNCTAD (2011a). The venture was discontinued due to the inability to commercialize products from samples taken from bioprospecting.

elements from country to country, laws can and do differ substantively, as well as in how judges in the country may interpret certain contractual terms. It is beyond the scope of this handbook to discuss such differences, however. In the context of negotiating a contract across borders, parties will need to assess whether the designation of a certain jurisdiction as controlling law will be more or less advantageous to their interests. Generally, in the context of an MTA, the choice will be whether the controlling law will be that of the provider country or that of the user country.

The question of what happens in the event of a dispute is made even more important because the location of the arbiter of a dispute may have an impact on the provider's ability to access the justice system. If the arbiter is to be the domestic courts, developed countries tend to argue that developing country courts are unreliable and unfamiliar with IP issues. If the provider agrees to the designation of a foreign court of law to resolve disputes that cannot be settled amicably, then the provider may be forced to defend him or herself at great expense in a foreign and often distant court of law, and subject to their civil procedure rules which may be disadvantageous (such as a rule that requires all filings to be submitted in a language foreign to the provider).

Some contracts will call for arbitration in the event of a dispute. Arbitration is basically a private, professional court. Recourse to arbitration may be binding (mandatory) or non-binding. The idea behind the choice of arbitration as a dispute resolution forum is generally that it is private and that it tends to be quicker than a court of law. As mentioned above, one argument used by parties in developed countries is that the courts in developing countries do not necessarily have the capacity to adjudicate on technical cases. Arbitration venues may be located anywhere in the world. The choice of arbitration forum will also determine the choice of applicable procedural rules.

It is acknowledged that courts in many developing countries will not have sufficient expertise to address a case on IP, PIC and/or MAT. Article 18(a) of the Nagoya Protocol recognizes this and obliges each Party to take effective measures regarding access to justice.³⁰⁸ This may not hold true for all developing countries, though, and a case-by-case consideration is required. From the perspective of the developing country provider, the distance issue could potentially be addressed by choosing an arbitration forum close to home and applying provider country laws as the law governing the underlying MTA. Furthermore, a check to ensure that arbitration does not favor one party over another is to require a panel of arbiters, where one is nominated by the user, one by the provider and a third by mutual agreement. These choices would not, however, address the question of whether there would be a strategic advantage in having the relevant dispute proceedings subject to public scrutiny.

Key Points

- ⇒ In the context of an MTA, the choice will be whether the controlling law will generally be either that of the provider country or that of the user country.
- ⇒ Indigenous groups and other rights holders in many poorer countries will often have difficulty when having to litigate to preserve their rights in a foreign jurisdiction. At the same time, users may point out the limitations of some jurisdictions in hearing cases related to IP, PIC and MAT.

³⁰⁸ A proposal was put forth in the Nagoya Protocol negotiations for the creation of an informal dispute resolution mechanism calling for an 'ombudsman', but this proposal was not adopted in the final text.

- ⇒ Arbitration is one option which allows parties to tailor make a solution with respect to venue. Part of the issue of having to litigate in distant jurisdictions may be addressed by choosing an arbitration forum closer to home.
- ⇒ Recourse to private arbitration may take a case out of public scrutiny, to the extent that litigation in the courts is a public process where documents are often available for all to see.

G. Term/Duration of the Agreement

The duration of the agreement establishes the length of time for which the parties are bound by the contract. Samples of genetic material transferred under an MTA may be transferred temporarily (loaned) or permanently. If the genetic material is to be transferred temporarily, then the contract should stipulate for how long the material is to be loaned to the user, and this will often determine the duration of the contract. This is the case when an animal is loaned to a zoo, for example.

Genetic material can also be transferred permanently, for example in the case of certain cell samples. In such cases, it makes little sense to ask for the original sample back after a certain period of time, as the sample is being given to a user who intends to cultivate the cell and perform R&D on it. The term of the contract will, however, often be shorter than the perpetuity that the permanent transfer implies. In such cases, providers will want to ensure that certain commitments entered into in respect of the material transferred survive beyond the duration of the contract (i.e., Argentina's model MTA no. 3, paragraph 9). These may include covenants not to seek IPRs or benefit sharing that arises out of IPRs, for example. In some jurisdictions, courts will interpret whether the restrictions that survive the end of a contract are reasonable.

In other cases, the contract may provide that the resource be destroyed if an MTA is terminated for default or cancellation of permit, as in the model Australian MTA (Article 13.4.1.b). While practical for certain resources such as virus samples, this may not be practical or ethical in the case of endangered species.

The term of a contract may be renewed. In such cases, the renewal should also stipulate that PIC and MAT continue to be met.

Key Points

- ⇒ Resources may be transferred under an MTA temporarily or permanently.
- ⇒ The term of an MTA contract will often be shorter than the perpetuity that the permanent transfer implies. In such cases, providers will want to ensure that commitments entered into in respect of the material transferred survive beyond the duration of the contract.
- ⇒ A contract may provide that the resource be destroyed at the end of a contract term. While practical for certain resources such as virus samples, this may not be practical or ethical in the case of certain animal or plant species.

H. Termination

Termination refers to the end of the agreement. A good deal of thought needs to be given to what will trigger the termination of the agreement, and what the consequences of that will be.

Generally, contracts may be terminated voluntarily or mandatorily through the occurrence of an event. In the case of voluntary termination, parties may agree on a period of time to give written notice of termination, such as three months. Generally, there is no legal requirement for the time required to be give notice of termination to be equal for both parties to a private contract, beyond a general standard of reasonability.

Contracts may also be terminated involuntarily. The cases where the contract is terminated involuntarily must, however, be clearly spelt out in the MTA, otherwise the contract may be deemed by courts to continue to remain in force. A particular case that providers should be aware of is the potential for *insolvency*. Insolvency refers to the situation where a person either has ceased to pay debts or meet their contractual obligations in the ordinary course of business or cannot pay debts as they fall due, or is otherwise bankrupt under the national insolvency law of the country of the user.³⁰⁹ Biotechnology firms are often engaged in high risk activity, and consequently face a potential risk of insolvency. If a user firm defaults and becomes insolvent, a trustee may assign user assets to other parties to whom the provider never intended. This may include the genetic resource transferred, reproductions of that genetic resource, products or variants derived from that genetic resource as well as any IPRs that the user had sought and obtained over any of these.

It is clear that in the case of insolvency, it is possible to stipulate in the MTA that the actual genetic resource transferred be returned to the provider. This would provide a clear instruction to the trustee in bankruptcy on the disposition of the genetic resource in question. At the other end of the spectrum, the IPR is an intangible asset of the defaulting user. The trustee is therefore at liberty to dispose of this in settlement of debts, and the IPR could end up with an unintended user. One possible defense from the perspective of the provider is to request when establishing an MTA an inexpensive (or cost-free) irrevocable license for any IPRs obtained by the user using the transferred genetic resources, as part of the benefit sharing package. Another option would be to agree at the outset that any IPRs over the fruits of R&D would be jointly owned by the provider and the user, and that any disposal thereof would require the agreement of both parties.

The most difficult question concerns what to do with reproductions of that genetic resource, or with variants or products derived from that genetic resource that represent R&D in progress, but not yet at a stage where they can be embodied in a registered IPR. From a strictly defensive position, one could obligate the user to destroy these in the event of termination, as in the case of the Australian model MTA (see section above). While this would presumably prevent the work in progress from falling into unintended hands, the disadvantage of this is that the fruits of the R&D are potentially lost.

A contract may also be terminated if there is a material breach of the agreement that cannot be cured. What constitutes a material breach can be defined by the parties. If, for example, the MTA stipulates that the recipient would not seek to obtain IPRs on the genetic materials provided, a user who sought and obtained patent protection over the material could be deemed in material violation of the contract. In order to be sure that such act would be treated as a material violation, the parties may expressly stipulate this in the MTA. If the contract does not stipulate what a material breach is,

³⁰⁹ This definition borrows from the definition contained the Uniform Commercial Code of the United States.

a court may decide on the question of whether a deviation from the contractual obligations constitutes such a breach, and whether that breach warrants termination or damages. In other words, there is no guarantee that, in the absence of a clear written indication, a covenant to refrain from seeking IPRs on the genetic materials provided would be considered a serious breach.

Key Points

- ⇒ Contracts may be terminated voluntarily or mandatorily through the occurrence of an event. The cases where the contract is terminated involuntarily must, however, be clearly spelt out in the MTA, otherwise the contract may be deemed by courts to continue to remain in force.
- ⇒ If a user firm defaults and becomes insolvent, a trustee may assign user assets to other parties to whom the provider never intended. This may include the genetic resource transferred, reproductions of that genetic resource, products or variants derived from that genetic resource as well as any IPRs that the user had sought and obtained over any of these. The termination clause should give the trustee guidance in such cases.
- ⇒ There is no guarantee that, in the absence of a clear written indication in the MTA, a covenant to refrain from seeking IPRs on the genetic materials provided would be considered a serious breach.

I. Confidential Information

Firms that seek to access genetic resources and related traditional knowledge for the purpose of eventual commercialization of a product developed from that resource seek to maintain as much of a competitive advantage over potential rivals as possible. Many of these firms bring R&D and related know-how to bear on the resource for possible development, and generate data from experiments which they may seek to keep secret from their rivals. For this reason, many MTAs will include in a schedule or annex information which the parties to the contract oblige to keep confidential (see, for example, the model Australian MTA).

From a legal point of view, there is nothing that prevents the designation of certain information as confidential in a private contract, or even to treat the entire MTA contract as confidential provided both parties agree to it. The TRIPS Agreement, in Article 39, ensures that WTO Members shall protect undisclosed information and data submitted to governments or its agencies. The Nagoya Protocol places no limits on what can be treated as confidential in a private contract, subject, however, to the limitation that national regulatory authorities may require the submission of the underlying contract in order to obtain a national (and international) certificate of compliance. The regulatory authorities concerned are obliged in such case to maintain the confidentiality of the information designated as such by the underlying contract. Articles 14 and 17(a)(iii) of the Protocol stipulate that information that is submitted to the ABS Clearing House shall be “without prejudice to the protection of confidential information”. Article 17(4) provides that the internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

- (a) issuing authority;
- (b) date of issuance;

- (c) the provider;
- (d) unique identifier of the certificate;
- (e) the person or entity to whom prior informed consent was granted;
- (f) subject matter or genetic resources covered by the certificate;
- (g) confirmation that mutually agreed terms were established;
- (h) confirmation that prior informed consent was obtained; and
- (i) commercial and/or non-commercial use

In this regard, if it was hoped that outside groups and checkpoints could monitor the implementation of the ABS rules against misappropriation, in practice the certificate system's actual value may be limited to certifying that, in the view of the national competent authority, PIC and MAT have been complied with. From a public policy perspective, providers may want to resist demands to treat the entire MTA contract as confidential and insist that at least those items contained in Article 17(4) of the Protocol above remain non-confidential in order to facilitate monitoring.³¹⁰ National legislation on the right to access environmental information, if it exists at all, may help support this position in certain circumstances.

Key Points

- ⇒ The Nagoya Protocol places no limits on what can be treated as confidential in a private contract.
- ⇒ From a public policy perspective, providers may wish to resist demands to treat the entire MTA contract as confidential and insist that at least those items contained in Article 17(4) of the Protocol above remain non-confidential.

IV. Conclusion

IP and ABS are regulatory functions, but ultimately both these systems rely heavily on private law for their actual implementation. Key terms in ABS agreements will therefore be important means to secure the rights of the provider in any given situation where access is being considered. Those negotiating such contracts need to be aware of the meaning of these provisions in order to ensure that the contract does not unwillingly permit or lead to misappropriation or other unintended consequences. As much as knowledge of the law is important, so are the negotiating skills of the provider.

³¹⁰ It should be noted that Article 21(6) of the Cartagena Protocol significantly limits the range of confidentiality, but a similar text was not adopted in the final text of the Nagoya Protocol.

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Annex I: Regional and national TK and ABS-related Legislation

Legislation	Thailand - 1999 Act on protection and promotion of traditional Thai medicinal intelligence, H.E. 2542	Portugal - 2002 Decree-Law No. 118/2002	South Africa - 2004 National Environmental Management: Biodiversity Act (below: NEMB Act) South Africa - 2008 Regulations on Bio-Prospecting, Access and Benefit-Sharing (below: Regulations BPABS)	Guyana - 2006 An Act to provide for the recognition and protection of the collective rights of Amerindian Villages and Communities, the granting land to Amerindian Villages and Communities and the promotion of good governance within Amerindian Villages and Communities
Objectives		Article 1. Object (1) This Decree establishes the legal regime for the registration, conservation, legal safeguarding and transfer of autochthonous plant material of current or potential interest to agrarian, agroforest and landscape activity, including the local varieties and spontaneously occurring material referred to in Article 2, as well as associated knowledge, [...]	NEMB Act Chapter 1 Interpretation, Objectives and Application of Act Objectives of Act 2. The objectives of this Act are - (a) within the framework of the National Environmental Management Act, to provide for - (i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity; (ii) the use of indigenous biological resources in a sustainable manner; and (iii) the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources; NEMB Act CHAPTER 6 Bioprospecting, access and benefit-sharing Purpose and application of Chapter 80. (1) The purpose of this Chapter is - (a) to regulate bioprospecting involving indigenous biological resources; (b) to regulate the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any other kind of research; and (c) to provide for a fair and equitable sharing by	

			stakeholders in benefits arising from bioprospecting involving indigenous biological resources.	
Subject Definition	<p>"traditional Thai medicinal Intelligence" means the basic knowledge and capability concerned with traditional Thai medicine;</p> <p>"traditional Thai medicine" means the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention or, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production traditional Thai drugs and the invention of medical devices, on the basis of knowledge or text that has been passed on from generation to generation;</p>	<p>Article 2. Scope (1) This Decree-Law applies to all local varieties and other spontaneously occurring autochthonous material of plant species that are of current or potential interest to agricultural, agroforest or landscape activity, regardless of their genotypical composition, with the exception of varieties protected by intellectual property rights or concerning which the grant of such protection is pending.</p> <p>Article 3. TK (1) TK comprises all intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non-systematic manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations. That includes, but is not limited to, knowledge of methods, processes, products and designations with applications in agriculture, food and industrial activities in general, including traditional crafts, commerce and services, informally associated with the use and preservation of local varieties and other spontaneously occurring autochthonous material covered by this Decree.</p>	<p>NEMB Act Chapter 1 Interpretation, Objectives and Application of Act 1.(1) In this Act, unless the context indicates otherwise -</p> <p>“stakeholder” means - (a) a person, an organ of state or a community contemplated in section 82(1)(a); or (b) an indigenous community contemplated in section 82(1)(b);</p> <p>Regulations BPABS Interpretations and purpose of regulations Definitions 1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -.</p> <p>"indigenous community" means any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and- (a) whose traditional uses of the indigenous biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or (b) whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting;</p> <p>"traditional use or knowledge" refers to the customary utilisation or knowledge of indigenous biological resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised</p>	<p>"Amerindian" means any citizen of Guyana who - (a) belongs to any of the native or aboriginal peoples of Guyana; or (b) is a descendant of any person mentioned in paragraph (a);</p>

			by them, and includes discoveries about the relevant indigenous biological resources by that community.	
Holder of Rights	<p>Section 17. The Minister has the power to notify that formulas on traditional Thai drugs or text on traditional Thai medicine that is of benefit, or has special medical or public health value as the national formula on traditional Thai drug, or the national text on traditional Thai medicine, as the case may be.</p> <p>Section 20. Personal formula of traditional Thai drugs or personal text on traditional Thai medicine under section 16(3) may be registered for protection of intellectual property rights and may be promoted according to the provisions of this Act by applying for registration to the registrar.</p>	<p>Article 9. Applicant for Registration (1) An application for the registration of plant material covered by the provisions of Article 4(1) may be filed by any entity, whether public or private, individual or corporate, that fulfils the following conditions: (a) as required by paragraph (2) below, it represents the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring autochthonous material displays the greatest genetic variability; (b) it complies with the provisions of Article 10(3). (2) To satisfy the conditions mentioned in (1)(a) above, the applicant shall be recognized by the competent municipal chamber by means of a document affirming the entity's fitness to protect the interests referred to in paragraph (1).</p>	<p>Regulations BPABS Interpretations and purpose of regulations Definitions 1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates - "indigenous community" means any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure</p>	<p>Village Councils. 10. (1) A Village Council is established to administer a Village (2) A Village Council is a body corporate. (3) In discharging its function the Village Council shall act collectively.</p> <p>Functions of Village Councils. 13. (1) The functions of a Village Council are to - [...] (d) hold for the benefit and the use of the Village all rights, titles and interests in and over Village lands; [...] (h) ensure that places and artefacts located within the Village lands and which hold sacred or cultural values to the Village are protected and cared for; (i) protect and preserve the Village's intellectual property and TK; [...]</p>
Scope of Rights	<p>Section 34. The right holder would have the sole ownership on the production of the drug and have sole right over the research, distribution, improvement or development of formulas on traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine.</p>	<p>Article 10. Rights and Obligations of the Owner of the Registration (1) The entity owning the registration has the right to receive part of any benefits resulting from the use provided for in Articles 7(1) and (2). (2) The performance of any of the acts provided for in Article 7(1) in the case of registered plant material may only be authorized after the owner of the registration has been heard. (3) The owner of the registration shall be responsible for the maintenance in situ of the registered plant material [...]</p>	<p>NEMB Act Chapter 1 Interpretation, Objectives and Application of Act 1.(1) In this Act, unless the context indicates otherwise— “bioprospecting”, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes - (a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; (b) the utilisation for purposes of such research or development of any information regarding any</p>	

			<p>traditional uses of indigenous biological resources by indigenous communities; or</p> <p>(c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation;</p> <p>NEMB Act CHAPTER 6 Bioprospecting, access and benefit-sharing</p> <p>Purpose and application of Chapter</p> <p>80. (2) In this Chapter -</p> <p>“indigenous biological resources” -</p> <p>(b) excludes -</p> <p>(i) genetic material of human origin;</p> <p>(ii) any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in paragraph (a)(iii); and</p> <p>(iii) indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.</p> <p>Regulations BPABS Definitions</p> <p>1. In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -</p> <p>"any other kind of research" means research other than bioprospecting and -</p> <p>(a) includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a bona fide research institute or organisation to generate scientific knowledge; but</p> <p>(b) excludes incidental surveys and searches;</p>	
Acknowledgement of Rights	Section 15. The Institute for Traditional Thai Medicine shall be responsible for compiling information on traditional Thai medical intelligence concerned with formulas of traditional Thai drugs and text on traditional Thai medicine from throughout the country, for registration.	Article 4. Registration of Plant Material (1) Plant material that falls within the scope of this Decree, as defined in Articles 2(1) and (2), may be registered in the RRGV, which shall be kept at the DGPC's National Center for the Registration of Protected Varieties.	Regulations BPABS Conditions subject to which issuing authorities may issue permits 8. (1) The Minister may only issue a bioprospecting permit or an integrated export and bioprospecting permit, if the Minister is satisfied that - (a) the relevant stakeholders have been identified in accordance with the principles set out in	Grants of land. 60. (1) An Amerindian Community may apply in writing to the Minister for a grant of State lands provided - (a) it has been in existence for at least twenty-five years; (b) at the time of the application and for the immediately preceding five years, it

			section 82 of the Act;	comprised at least one hundred and fifty persons.
Publicly Available TK	Section 18. The Minister has the power to notify the formulas of traditional Thai drugs or text on traditional Thai medicine that have been widely used or whose intellectual property protection has expired under section 33, general formula of traditional Thai drugs or general text on traditional Thai medicine, as the case may be.	Article 3. TK (4) The registration of TK that until it is requested has not been used in industrial activities or is not publicly known outside the population or local community in which it originated shall afford its owners the right to: (i) object to its direct or indirect reproduction, imitation and/or use by unauthorized third parties for commercial purposes; (ii) assign, transfer or license the rights in the TK, including transfer by succession; (iii) exclude from protection any TK that may be covered by specific industrial property registrations.		
ABS Elements	Section 19. Whoever wishes to use the national traditional Thai drugs for registration and permission for production of drugs according to the Drug Law or wishes to use it for research on improvement or development of new drug formulas for commercial benefit, or wish to research the national text on traditional Thai Drugs for development and improvement for commercial benefit, shall forward their application to obtain benefits and pay fees and the remuneration for making use thereof to the licensing authority. Section 46. No person shall research or export controlled herbs or sell or transform them for commercial purposes, unless a licence has been obtained from the licensing authority.	Article 7. Access to and Allocation of Benefits (1) Access to the germ plasm of the plant material referred to in Articles 2(1) and (2) for the purposes of study, research, improvement or biotechnological applications shall be subject to prior authorization by CoTeRGAPA, the owner of the registration having been heard. (4) Access as defined in paragraphs (1) and (2) requires a fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration.	The Act and Regulations contain numerous ABS provisions which are not reproduced in this place	Entry and access; 5. (1) A person [...] who wishes to enter Village lands shall apply for and obtain the permission of the Village Council. (3) A person [...] who wishes to conduct any scientific, anthropological or archaeological research or any other research or study which relates to biological diversity, the environment or natural resources or to any use of knowledge thereof within Village lands shall apply for and obtain in advance - (a) permission of the Village Council; (b) all permits required under any other written law; and (c) the permission of the Minister. Report; use of scientific and other research. 6. (1) A person who wishes to make use of any material derived from research or study under this section shall - (a) apply for an obtain the permission of

				the Village Council, the Minister, the Minister with responsibility for culture, and the Environmental Protection Agency [...]; (b) in good faith negotiate and enter into a benefit sharing agreement with the Village Council.
Positive IPR Elements	<p>Section 14. The intellectual property rights on traditional Thai medicine to be protected under this Act shall be the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine.</p> <p>Section 16. There shall be three types of traditional Thai medicinal intellectual property rights as follows: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine; (2) general formula of traditional Thai drugs or general traditional Thai medicine document; and Thai medicine document; and (3) personal formula of traditional Thai drugs or personal text on traditional Thai medicine.</p>			<p>Powers of Village Council to make rules. 14. (1) Subject to the other provisions of this Act, a Village Council may, in the exercise of its functions, make rules governing - [...] (n) the certification of products made by residents using traditional methods;</p>
Defensive IPR Elements	<p>Section 22. Registration for protection of intellectual property rights on traditional Thai medicine is prohibited if the registrar is of the opinion that: (1) the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine, or is a general formula on traditional Thai drug, or general text on traditional Thai medicine, or (2) the drug formula is a personal formula on traditional Thai drug that has been developed on non-medical basis like the use of extracts of plants, animals</p>	<p>Article 3. TK (2) That knowledge shall be protected against reproduction or commercial or industrial use or both as long as the following conditions of protection are met: (a) the TK shall be identified, described and registered in the Register of Plant Genetic Resources (RRGV); (b) the description referred to above shall be so phrased that third parties may reproduce or utilize the TK and obtain results identical to those obtained by the owner of the</p>		<p>Powers of Village Council to make rules. 14. (1) Subject to the other provisions of this Act, a Village Council may, in the exercise of its functions, make rules governing - [...] (m) access to research into and recording and publication of intellectual property and TK which belongs to the Village;</p>

	or microorganisms that have not be obtained from natural extracts or the transformation that is not considered rough transformation.	knowledge.		
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Issues	Andean Community 2002 Decision 391 Common Regime on Access to Genetic Resources	Pacific Islands Forum - 2008 Traditional Biological Knowledge, Innovations and Practices Act	African Regional Intellectual Property Organization - 2010 Swakopmund Protocol on the Protection of TK and Expressions of Folklore
Objectives / Purpose	Article 2.- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to: a) Establish the conditions for just and equitable participation in the benefits of the access; b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;	to protect the rights of owners of traditional biological knowledge, innovations, and practices	Section 1 Purpose of Protocol 1.1. The purpose of this Protocol is: (a) to protect TK holders against any infringement of their rights as recognized by this Protocol; and (b) to protect expressions of folklore against misappropriation, misuse and unlawful exploitation beyond their traditional context.
Subject Definition	BIOLOGICAL RESOURCES: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products. INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes. NATIVE, AFRO-AMERICAN OR LOCAL COMMUNITY: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them.	4 Definitions traditional biological knowledge means knowledge whether embodied in tangible form or not, belonging to a social group [which means: family, clan, tribe, village or similar social organisation] and gained from having lived in close contact with nature, regarding: (a) living things, their spiritual significance, their constituent parts, their life cycles, behaviour and functions, and their effects on and interactions with other living things, including humans, and with their physical environment; (b) the physical environment; (c) the obtaining and utilising of living or non-living things for the purpose of maintaining, facilitating or improving human life. traditional biological innovation means a product, belonging to a social group, which has resulted from biological material whose usefulness has been enhanced by the application of traditional biological knowledge.	Section 2 Definitions “TK” shall refer to any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources.

		traditional biological practice means a process, method or way of doing things, belonging to a social group and gained from having lived in close contact with nature.	
Holder of Rights	<p>Article 5.- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.</p> <p>Article 7.- The Member Countries, in keeping with this Decision and their complementary national legislation, recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.</p>	<p>6 Ownership</p> <p>(1) For the purposes of this Act, ownership by a social group [which is a family, clan, tribe, village or similar social organisation] over an item of knowledge or an innovation or a practice is established according to the history and traditions and customs and usages of that social group.</p>	<p>Section 6 Beneficiaries of protection of TK</p> <p>The owners of the rights shall be the holders of TK, namely the local and traditional communities, and recognized individuals within such communities, who create, preserve and transmit knowledge in a traditional and intergenerational context in accordance with the provisions of section 4.</p>
Scope of Rights	<p>Article 3.- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.</p>		<p>Section 4 Protection criteria for TK</p> <p>Protection shall be extended to TK that is:</p> <ul style="list-style-type: none"> (i) generated, preserved and transmitted in a traditional and intergenerational context; (ii) distinctively associated with a local or traditional community; and (iii) integral to the cultural identity of a local or traditional community that is recognized as holding the knowledge through a form of custodianship, guardianship or collective and cultural ownership or responsibility. Such a relationship may be established formally or informally by customary practices, laws or protocols. <p>Section 7 Rights conferred to holders of TK</p> <p>7.1. This Protocol shall confer on the owners of rights referred to in section 6 the exclusive right to authorize the exploitation of their TK.</p> <p>7.2. In addition, owners shall have the right to prevent anyone from exploiting their TK without their prior informed consent. 7.3. For the purposes of this Protocol, the term “exploitation” with reference to TK shall refer to any of the following acts:</p>

			(a) Where the TK is a product: [...] (b) Where the TK is a process: [...]
Acknowledgement of Rights		<p>4 Definitions own in relation to knowledge, innovations and practices, includes the following: (a) own as a trustee; (b) own as a custodian; (c) own as a steward; and its meaning in any particular context is to be determined according to the history and traditions and customs and usages of the social group which claims ownership over that knowledge, innovation or practice.</p> <p>10 Identity of owner and prior informed consent (3) Any social group claiming ownership must identify itself to the [Competent National Authority] within 30 days from the date the application is publicised and satisfy the [Competent National Authority] of its claim to ownership.</p>	<p>Section 4 Protection criteria for TK Protection shall be extended to TK that is: (iii) integral to the cultural identity of a local or traditional community that is recognized as holding the knowledge through a form of custodianship, guardianship or collective and cultural ownership or responsibility. Such a relationship may be established formally or informally by customary practices, laws or protocols.</p>
Publicly available TK		<p>6 Ownership (2) The [Competent National Authority] may assert ownership over an item of knowledge or an innovation or a practice in either of the following situations: (a) where it is satisfied there is no immediately verifiable owner of that knowledge or innovation or practice. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of the eventual owner. (b) where it is satisfied, after having made extensive efforts to locate an owner of an item of knowledge or an innovation or a practice, that an owner will not be found. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of [the enacting country].</p>	Not covered by Section 4
ABS Elements	<p>TITLE V ON THE ACCESS PROCEDURE</p> <p>TITLE VI ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT</p>	<p>10 Identity of owner and prior informed consent (1) A prospective user wanting to use an item of knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, must in all</p>	<p>Section 9 Equitable benefit-sharing 9.1. The protection to be extended to TK holders shall include the fair and equitable sharing of benefits arising from the commercial or industrial use of their knowledge, to be determined by mutual agreement</p>

	TITLE VII ON THE LIMITATIONS TO ACCESS	<p>cases apply to the [Competent National Authority] in the form prescribed by the [Competent National Authority].</p> <p>11 Access and Benefit Sharing Agreement (1) Where the owner gives its prior informed consent to the proposed use, an agreement between the owner and the user, to be known as an Access and Benefit-Sharing Agreement, must be negotiated under the supervision of the [Competent National Authority] setting out the terms under which use is permitted and having regard to the following matters, amongst others:</p>	<p>between the parties.</p> <p>Section 15 Access to TK associated with genetic resources Authorization under this Protocol to access protected TK associated with genetic resources shall not imply authorization to access the genetic resources derived from the TK.</p>
Positive IPR Elements		<p>8 Economic rights (1) In addition to any rights available under applicable intellectual property laws an owner of an item of knowledge, an innovation or a practice has the exclusive right to use or to authorise the use of its knowledge, innovation or practice: (a) for a commercial purpose, or (b) for an activity that is likely to assist in achieving a commercial purpose.</p>	PART II: PROTECTION OF TK
Defensive IPR Elements	<p>Complementary Provisions SECOND.- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.</p> <p>THIRD.- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained</p>	<p>7 Database of traditional biological knowledge, innovations and practices (1) The [Competent National Authority] is to establish and maintain a database of knowledge, innovations and practices and shall enter into it such information as it receives or collects pertaining to knowledge, innovations and practices. (2) An owner may enter its knowledge, innovations and practices in the database. (3) Where the owner does not specify who can access the information, access will be limited to the owner. The [Competent National Authority] may also access the information for the purpose only of seeking the identity of an owner pursuant to section 10 of this Act.</p> <p>3 Application (1) Where there is an inconsistency with intellectual property laws, this Act, is to the extent of the</p>	<p>Section 5 Formalities relating to protection of TK 5.2. In the interests of transparency, evidence and the preservation of TK, relevant national competent authorities of Contracting States and ARIPO Office may maintain registers or other records of the knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of the TK holders concerned.</p> <p>Section 10 Recognition of knowledge holders Any person using TK beyond its traditional context shall acknowledge its holders, indicate its source and, where possible, its origin, and use such knowledge in a manner that respects the cultural values of its holders.</p>

	or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries. The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.	inconsistency, to prevail.	
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Annex II: WHO's Standard Material Transfer Agreements

SMTA 1

Standard Material Transfer Agreement within the WHO GISRS (SMTA 1)

In furtherance of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the "Framework"), this Standard Material Transfer Agreement ("Agreement" or "SMTA 1") has been developed.

Article 1. Parties to the Agreement

1.1 Parties to SMTA 1 are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference. In this Agreement: The Provider is the laboratory sending Materials, as herein defined, (name and address of the provider or providing institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Provider")³¹¹

and

The Recipient is the laboratory receiving Materials, as herein defined, (name and address of the recipient or recipient institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Recipient")³¹²

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

Article 2. Subject Matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter "Materials") transferred from the Provider to the Recipient are subject to the provisions of this Agreement.

Article 3. General Provisions

The Provider or recipient will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries.

Article 4. Rights and Obligations of the Provider

4.1 The Provider undertakes the following with respect to the Materials:

4.1.1. To comply with its respective WHO GISRS terms of reference.

4.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.³¹³

4.2. The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO GISRS, on the same terms and conditions as those provided in SMTA 1.

³¹¹ To be completed if signature is required pursuant to Article 11 below.

³¹² To be completed if signature is required pursuant to Article 11 below.

³¹³ "WHO Guidance on Regulations for the Transport of Infectious Substances". Document WHO/CDS/EPR/2007.2. Geneva, World Health Organization 2007 and "WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection". See http://www.who.int/csr/resources/publications/swineflu/storage_transport/en/index.html.

4.3 The Provider consents to the onward transfer and use of the Materials to entities outside the WHO GISRS on the condition that the prospective recipient has concluded an SMTA 2.

4.4. The Provider shall inform the WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the IVTM.

Article 5. Rights and Obligations of the Recipient

5.1 The Recipient undertakes the following with respect to the Materials:

5.1.1 To comply with its respective WHO GISRS terms of reference.

5.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

5.1.3. To inform WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the IVTM

5.1.4 In the event of further transfers within the WHO GISRS, to do so in accordance with SMTA 1.

5.2. The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.

5.3. The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

Article 6. Intellectual Property Rights

6.1 Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.

6.2 The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the Framework by the World Health Assembly will not be affected by SMTA 1.

6.3 The Provider under SMTA 1 may have used technology protected by IPRs for the generation and/or modification of the Materials. Any recipient of such Materials acknowledges that such IPRs shall be respected.

Article 7. Dispute resolution

7.1. In the event of a dispute under SMTA 1, Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other amicable means of their own choice. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

7.2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, one of the Parties concerned may refer the dispute to the Director-General, who may seek advice of the Advisory Group with a view to settling it. The Director-General may make recommendations to the Parties regarding its resolution and shall report to the World Health Assembly on any such matters.

7.3. The Parties also acknowledge the role of the Director-General under the Framework, in particular 7.3.4.

Article 8. Warranty

The Provider makes no warranties as to the safety of the Materials, or as to the accuracy or correctness of any data provided with them. Likewise, the provider does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Materials being furnished. The Provider and the Recipient assume full responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials.

Article 9. Duration of Agreement

This contractual agreement shall remain in force until December 31, 2021 and shall be automatically renewed until December 31, 2031 unless the World Health Assembly decides otherwise.

Article 10. Acceptance and Applicability

10.1.1 Recipients or Providers in the WHO GISRS at the time of the adoption of the Framework by the World Health Assembly: Acceptance by such laboratories of their WHO terms of reference, as contained in the Framework, constitutes acceptance of SMTA 1.

10.1.2 Recipients or Providers that join the WHO GISRS after adoption of the Framework by the World Health Assembly: Acceptance of designation or recognition by WHO to become a WHO GISRS laboratory will constitute acceptance of SMTA 1.

10.2. Applicability: SMTA 1 shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO GISRS or upon mutual agreement of the WHO and the laboratory. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under SMTA 1.

Article 11. Signature

Further to Article 10 above entitled “Acceptance & Applicability”, unless either party requires this Agreement to be executed by signature of a printed document, no further evidence of acceptance is required.

SMTA 2

Standard Material Transfer Agreement outside WHO GISRS (SMTA 2)

Article 1. Parties to the Agreement

WHO and Recipient.³¹⁴

Article 2. Subject matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter “Materials”) transferred to the Recipient are subject to the provisions of this Agreement.

Article 2. bis Definitions

(a) As provided for in Section 4 of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits.

(b) Other terms as agreed by the parties.

Article 3. Obligations of the Provider

To be agreed by the parties.

Article 4. Obligations of the Recipient

4.1 The recipient agrees to comply with the commitments selected below, in accordance with the terms set out in the Annex to this agreement.

4.1.1 The recipient shall comply with the commitments selected on a timetable determined by the WHO in consultation with the Advisory Group established by the PIP Framework and in coordination with the recipient, based on optimal pandemic preparedness and response considerations.

A. For manufacturers of vaccines and/or antivirals, the recipient shall commit to at least two of the following options:

A1. Donate at least 10%³¹⁵ of real time pandemic vaccine production to WHO

A2. Reserve at least 10%³¹⁶ of real time pandemic vaccine production at affordable prices to WHO

A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO

A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices

A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of

³¹⁴ Recipients are all entities that receive “PIP Biological Materials” from the WHO GISRS, such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.

³¹⁵ Recognizing that flexibility is important in negotiating with all manufacturers, in a range of 5-20%.

³¹⁶ Recognizing that flexibility is important in negotiating with all manufacturers, in a range of 5–20%.

affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.

A6. Grant royalty free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on granted licenses and the status of implementation of the licensing agreement. WHO shall provide such information to the Advisory Group.

B. Manufacturers of products relevant to pandemic influenza preparedness and response, that are not manufacturing vaccines or antivirals, shall commit to one of the following options: A5, A6, B1, B2, B3, B4.

B1. Donate to WHO at least X³¹⁷ diagnostic kits needed for pandemics

B2. Reserve for WHO at least X³¹⁸ diagnostic kits needed for pandemics, at affordable prices

B3. Support, in coordination with WHO, the strengthening of influenza specific laboratory and surveillance capacity in developing countries

B4. Support, in coordination with WHO, transfer of technology, know-how and/or processes for pandemic influenza preparedness and response in developing countries

C. The recipient shall, in addition to the commitments selected under A or B above, consider contributing to the measures listed below, as appropriate:

- Donations of vaccines
- Donations pre-pandemic vaccines
- Donations of antivirals
- Donations of medical devices
- Donations of diagnostic kits
- Affordable pricing
- Transfer of technology and processes
- Granting of sublicenses to WHO
- Laboratory and surveillance capacity building.

4.2 The Recipient shall ensure that the PIP biological materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

4.3 If applicable, the Recipient shall appropriately acknowledge in presentations and publications, the contributions of WHO laboratories providing the materials identified in Article 2, using existing scientific guidelines.

³¹⁷ Recognizing that flexibility is important in negotiating with all manufacturers.

³¹⁸ Recognizing that flexibility is important in negotiating with all manufacturers.

4.4 The recipient shall only further transfer the PIP biological materials if the prospective recipient has concluded an SMTA with the World Health Organization. Any such further transfer shall be reported to the World Health Organization. The Director-General may, under exceptional circumstances, allow the PIP biological materials to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an SMTA, and report to the “Advisory Group” accordingly.

4.5 The recipient may exchange PIP biological materials with any other holder of an SMTA concluded with the World Health Organization.

Article 5. Dispute Resolution

If a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties.

Article 6. Liability and Indemnity

To be agreed by the parties.

Article 7. Privileges and immunity

Nothing in or relating to these clauses shall imply the obligation of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

Article 8. Name and Emblem

To be agreed by the parties.

Article 9. Warranties

To be agreed by the parties

Article 10. Duration of Agreement

To be agreed by the parties.

Article 11. Termination

To be agreed by the parties.

Article 12. Force Majeure

To be agreed by the parties.

Article 13. Governing law

To be agreed by the parties.

Article 14. Signature and Acceptance

In WITNESS Whereof, this Agreement has been duly executed by the parties.

SIGNED for and on behalf of WHO

Signature

Name

Title

SIGNED for and on behalf of Recipient

Signature

Name

Title

Annex

To be agreed by the parties.

Annex III: Standard Material Transfer Agreement under the ITPGRFA

STANDARD MATERIAL TRANSFER AGREEMENT UNDER THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

PREAMBLE

WHEREAS

The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as “the **Treaty**”)³¹⁹ was adopted by the Thirty-first session of the FAO Conference on 3 November 2001 and entered into force on 29 June 2004;

The objectives of the **Treaty** are the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture** and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security;

The Contracting Parties to the **Treaty**, in the exercise of their sovereign rights over their **Plant Genetic Resources for Food and Agriculture**, have established a **Multilateral System** both to facilitate access to **Plant Genetic Resources for Food and Agriculture** and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis;

Articles 4, 11, 12.4 and 12.5 of the **Treaty** are borne in mind;

The diversity of the legal systems of the Contracting Parties with respect to their national procedural rules governing access to courts and to arbitration, and the obligations arising from international and regional conventions applicable to these procedural rules, are recognized;

Article 12.4 of the **Treaty** provides that facilitated access under the **Multilateral System** shall be provided pursuant to a Standard Material Transfer Agreement, and the **Governing Body** of the **Treaty**, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement.

³¹⁹ Note by the Treaty Secretariat: as suggested by the Legal Working Group during the Contact Group for the Drafting of the Standard Material Transfer Agreement, defined terms have, for clarity, been put in bold throughout.

ARTICLE 1 — PARTIES TO THE AGREEMENT

1.1 The present Material Transfer Agreement (hereinafter referred to as “**this Agreement**”) is the Standard Material Transfer Agreement referred to in Article 12.4 of the **Treaty**.

1.2 **This Agreement** is:

BETWEEN: (name and address of the provider or providing institution, name of authorized official, contact information for authorized official³²⁰) (hereinafter referred to as “the **Provider**”),

AND: (name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official³²¹) (hereinafter referred to as “the **Recipient**”).

1.3 The parties to **this Agreement** hereby agree as follows:

ARTICLE 2 — DEFINITIONS

In **this Agreement** the expressions set out below shall have the following meaning:

“**Available without restriction**”: a **Product** is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the **Treaty**.

“**Genetic material**” means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

“**Governing Body**” means the **Governing Body** of the **Treaty**.

“**Multilateral System**” means the **Multilateral System** established under Article 10.2 of the **Treaty**.

“**Plant Genetic Resources for Food and Agriculture**” means any **genetic material** of plant origin of actual or potential value for food and agriculture.

“**Plant Genetic Resources for Food and Agriculture under Development**” means material derived from the **Material**, and hence distinct from it, that is not yet ready for **commercialization** and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the **Plant Genetic Resources for Food and Agriculture under Development** shall be deemed to have ceased when those resources are **commercialized** as a **Product**.

³²⁰ Insert as necessary. Not applicable for shrink-wrap and click-wrap Standard Material Transfer Agreements.

- A “shrink-wrap” Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the **Material**, and the **Recipient’s** acceptance of the **Material** constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.
- A “click-wrap” Standard Material Transfer Agreement is where the agreement is concluded on the internet and the **Recipient** accepts the terms and conditions of the Standard Material Transfer Agreement by clicking on the appropriate icon on the website or in the electronic version of the Standard Material Transfer Agreement, as appropriate.

³²¹ Ibid.

“Product” means **Plant Genetic Resources for Food and Agriculture** that incorporate³²² the **Material** or any of its genetic parts or components that are ready for **commercialization**, excluding commodities and other products used for food, feed and processing.

“Sales” means the gross income resulting from the **commercialization** of a **Product** or **Products**, by the **Recipient**, its affiliates, contractors, licensees and lessees.

“To commercialize” means to sell a **Product** or **Products** for monetary consideration on the open market, and **“commercialization”** has a corresponding meaning. **Commercialization** shall not include any form of transfer of **Plant Genetic Resources for Food and Agriculture under Development**.

ARTICLE 3 — SUBJECT MATTER OF THE MATERIAL TRANSFER AGREEMENT

The **Plant Genetic Resources for Food and Agriculture** specified in Annex 1 to **this Agreement** (hereinafter referred to as the **“Material”**) and the available related information referred to in Article 5b and in Annex 1 is hereby transferred from the **Provider** to the **Recipient** subject to the terms and conditions set out in **this Agreement**.

ARTICLE 4 — GENERAL PROVISIONS

4.1 **This Agreement** is entered into within the framework of the **Multilateral System** and shall be implemented and interpreted in accordance with the objectives and provisions of the **Treaty**.

4.2 The parties recognize that they are subject to the applicable legal measures and procedures, that have been adopted by the Contracting Parties to the **Treaty**, in conformity with the **Treaty**, in particular those taken in conformity with Articles 4, 12.2 and 12.5 of the **Treaty**.³²³

4.3 The parties to **this Agreement** agree that (the entity designated by the **Governing Body**),³²⁴ acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**, is the third party beneficiary under **this Agreement**.

4.4 The third party beneficiary has the right to request the appropriate information as required in Articles 5e, 6.5c, 8.3 and Annex, 2 paragraph 3, to **this Agreement**.

4.5 The rights granted to the (the entity designated by the **Governing Body**) above do not prevent the **Provider** and the **Recipient** from exercising their rights under **this Agreement**.

ARTICLE 5 — RIGHTS AND OBLIGATIONS OF THE PROVIDER

The **Provider** undertakes that the **Material** is transferred in accordance with the following provisions of the **Treaty**:

³²² As evidenced, for example, by pedigree or notation of gene insertion.

³²³ In the case of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) and other international institutions, the Agreement between the Governing Body and the CGIAR Centres and other relevant institutions will be applicable.

³²⁴ Note by the Treaty Secretariat: by Resolution 2/2006, the Governing Body “invite[d] the Food and Agriculture Organization of the United Nations, as the Third Party Beneficiary, to carry out the roles and responsibilities as identified and prescribed in the Standard Material Transfer Agreement, under the direction of the Governing Body, in accordance with the procedures to be established by the Governing Body at its next session”. Upon acceptance by the FAO of this invitation, the term, “the entity designated by the Governing Body”, will be replaced throughout the document by the term, “the Food and Agriculture Organization of the United Nations”.

- a) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;
- b) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the **Plant Genetic Resources for Food and Agriculture** provided;
- c) Access to **Plant Genetic Resources for Food and Agriculture under Development**, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;
- d) Access to **Plant Genetic Resources for Food and Agriculture** protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;
- e) The **Provider** shall periodically inform the **Governing Body** about the Material Transfer Agreements entered into, according to a schedule to be established by the **Governing Body**. This information shall be made available by the **Governing Body** to the third party beneficiary.³²⁵

ARTICLE 6 — RIGHTS AND OBLIGATIONS OF THE RECIPIENT

6.1 The **Recipient** undertakes that the **Material** shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

6.2 The **Recipient** shall not claim any intellectual property or other rights that limit the facilitated access to the **Material** provided under **this Agreement**, or its genetic parts or components, in the form received from the **Multilateral System**.

6.3 In the case that the **Recipient** conserves the **Material** supplied, the **Recipient** shall make the **Material**, and the related information referred to in Article 5b, available to the **Multilateral System** using the Standard Material Transfer Agreement.

6.4 In the case that the **Recipient** transfers the **Material** supplied under **this Agreement** to another person or entity (hereinafter referred to as “the **subsequent recipient**”), the **Recipient** shall

- a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement; and
- b) notify the **Governing Body**, in accordance with Article 5e.

On compliance with the above, the **Recipient** shall have no further obligations regarding the actions of the **subsequent recipient**.

6.5 In the case that the **Recipient** transfers a **Plant Genetic Resource for Food and Agriculture under Development** to another person or entity, the **Recipient** shall:

- a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement, provided that Article 5a of the Standard Material Transfer Agreement shall not apply;

³²⁵ Note by the Secretariat: The Standard Material Transfer Agreement makes provision for information to be provided to the **Governing Body**, in the following Articles: 5e, 6.4b, 6.5c and 6.11h, as well as in Annex 2, paragraph 3, Annex 3, paragraph 4, and in Annex 4. Such information should be submitted to: The Secretary International Treaty on Plant Genetic Resources for Food and Agriculture Food and Agriculture Organization of the United Nations I-00100 Rome, Italy

- b) identify, in Annex 1 to the new material transfer agreement, the **Material** received from the **Multilateral System**, and specify that the **Plant Genetic Resources for Food and Agriculture under Development** being transferred are derived from the **Material**;
- c) notify the **Governing Body**, in accordance with Article 5e; and
- d) have no further obligations regarding the actions of any **subsequent recipient**.

6.6 Entering into a material transfer agreement under paragraph 6.5 shall be without prejudice to the right of the parties to attach additional conditions, relating to further product development, including, as appropriate, the payment of monetary consideration.

6.7 In the case that the **Recipient commercializes a Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement**, and where such **Product** is not **available without restriction** to others for further research and breeding, the **Recipient** shall pay a fixed percentage of the **Sales** of the **commercialized Product** into the mechanism established by the **Governing Body** for this purpose, in accordance with Annex 2 to **this Agreement**.

6.8 In the case that the **Recipient commercializes a Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of **this Agreement** and where that **Product** is **available without restriction** to others for further research and breeding, the **Recipient** is encouraged to make voluntary payments into the mechanism established by the **Governing Body** for this purpose in accordance with Annex 2 to **this Agreement**.

6.9 The **Recipient** shall make available to the **Multilateral System**, through the information system provided for in Article 17 of the **Treaty**, all non-confidential information that results from research and development carried out on the **Material**, and is encouraged to share through the **Multilateral System** non-monetary benefits expressly identified in Article 13.2 of the **Treaty** that result from such research and development. After the expiry or abandonment of the protection period of an intellectual property right on a **Product** that incorporates the **Material**, the **Recipient** is encouraged to place a sample of this **Product** into a collection that is part of the **Multilateral System**, for research and breeding.

6.10 A **Recipient** who obtains intellectual property rights on any **Products** developed from the **Material** or its components, obtained from the **Multilateral System**, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of **this Agreement** to that third party.

6.11 The **Recipient** may opt as per Annex 4, as an alternative to payments under Article 6.7, for the following system of payments:

- a) The **Recipient** shall make payments at a discounted rate during the period of validity of the option;
- b) The period of validity of the option shall be ten years renewable in accordance with Annex 3 to **this Agreement**;
- c) The payments shall be based on the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in Annex 1 to **this Agreement** belongs;
- d) The payments to be made are independent of whether or not the **Product** is **available without restriction**;
- e) The rates of payment and other terms and conditions applicable to this option, including the discounted rates are set out in Annex 3 to **this Agreement**;
- f) The **Recipient** shall be relieved of any obligation to make payments under Article 6.7 of **this Agreement** or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop;

- g) After the end of the period of validity of this option the **Recipient** shall make payments on any **Products** that incorporate **Material** received during the period in which this Article was in force, and where such **Products** are not **available without restriction**. These payments will be calculated at the same rate as in paragraph (a) above;
- h) The **Recipient** shall notify the **Governing Body** that he has opted for this modality of payment. If no notification is provided the alternative modality of payment specified in Article 6.7 will apply.

ARTICLE 7 — APPLICABLE LAW

The applicable law shall be General Principles of Law, including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the **Treaty**, and, when necessary for interpretation, the decisions of the **Governing Body**.

ARTICLE 8 — DISPUTE SETTLEMENT

8.1 Dispute settlement may be initiated by the **Provider** or the **Recipient** or the (the entity designated by the **Governing Body**), acting on behalf of the **Governing Body** of the **Treaty** and its **Multilateral System**.

8.2 The parties to **this Agreement** agree that the (the entity designated by the **Governing Body**), representing the **Governing Body** and the **Multilateral System**, has the right, as a third party beneficiary, to initiate dispute settlement procedures regarding rights and obligations of the **Provider** and the **Recipient** under **this Agreement**.

8.3 The third party beneficiary has the right to request that the appropriate information, including samples as necessary, be made available by the **Provider** and the **Recipient**, regarding their obligations in the context of **this Agreement**. Any information or samples so requested shall be provided by the **Provider** and the **Recipient**, as the case may be.

8.4 Any dispute arising from **this Agreement** shall be resolved in the following manner:

- a) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.
- b) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.
- c) Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. Either party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the Governing Body may establish for this purpose; both parties, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

ARTICLE 9 — ADDITIONAL ITEMS

Warranty

9.1 The **Provider** makes no warranties as to the safety of or title to the **Material**, nor as to the accuracy or correctness of any passport or other data provided with the **Material**. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the **Material** being

furnished. The phytosanitary condition of the **Material** is warranted only as described in any attached phytosanitary certificate. The **Recipient** assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of **genetic material**.

Duration of Agreement

9.2 **This Agreement** shall remain in force so long as the **Treaty** remains in force.

ARTICLE 10 — SIGNATURE/ACCEPTANCE

The **Provider** and the **Recipient** may choose the method of acceptance unless either party requires **this Agreement** to be signed.

Option 1 –Signature*

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Provider** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....

Name of the **Provider**

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute **this Agreement** on behalf of the **Recipient** and acknowledge my institution's responsibility and obligation to abide by the provisions of **this Agreement**, both by letter and in principle, in order to promote the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture**.

Signature..... Date.....

Name of the **Recipient**.....

Option 2 – Shrink-wrap Standard Material Transfer Agreements*

The **Material** is provided conditional on acceptance of the terms of **this Agreement**. The provision of the **Material** by the **Provider** and the **Recipient's** acceptance and use of the **Material** constitutes acceptance of the terms of **this Agreement**.

Option 3 – Click-wrap Standard Material Transfer Agreement³²⁶

☐ I hereby agree to the above conditions.

³²⁶ Where the **Provider** chooses signature, only the wording in Option 1 will appear in the Standard Material Transfer Agreement. Similarly where the **Provider** chooses either shrink-wrap or click-wrap, only the wording in Option 2 or Option 3, as appropriate, will appear in the Standard Material Transfer Agreement. Where the "click-wrap" form is chosen, the **Material** should also be accompanied by a written copy of the Standard Material Transfer Agreement.

Annex 1

LIST OF MATERIALS PROVIDED

This Annex contains a list of the **Material** provided under **this Agreement**, including the associated information referred to in Article 5b.

This information is either provided below or can be obtained at the following website: (URL).

The following information is included for each **Material** listed: all available passport data and, subject to applicable law, any other associated, available, non-confidential descriptive information.

(List)

Annex 2

RATE AND MODALITIES OF PAYMENT UNDER ARTICLE 6.7 OF THIS AGREEMENT

1. If a **Recipient**, its affiliates, contractors, licensees, and lessees, **commercializes a Product or Products**, then the **Recipient** shall pay one point-one percent (1.1 %) of the **Sales** of the **Product or Products** less thirty percent (30%); except that no payment shall be due on any **Product or Products** that:

- (a) are **available without restriction** to others for further research and breeding in accordance with Article 2 of **this Agreement**;
- (b) have been purchased or otherwise obtained from another person or entity who either has already made payment on the **Product or Products** or is exempt from the obligation to make payment pursuant to subparagraph (a) above;
- (c) are sold or traded as a commodity.

2. Where a **Product** contains a **Plant Genetic Resource for Food and Agriculture** accessed from the **Multilateral System** under two or more material transfer agreements based on the Standard Material Transfer Agreement only one payment shall be required under paragraph 1 above.

3. The **Recipient** shall submit to the **Governing Body**, within sixty (60) days after each calendar year ending December 31st, an annual report setting forth:

- (a) the **Sales** of the **Product or Products** by the **Recipient**, its affiliates, contractors, licensees and lessees, for the twelve (12) month period ending on December 31st;
- (b) the amount of the payment due; and
- (c) information that allows for the identification of any restrictions that have given rise to the benefit-sharing payment.

4. Payment shall be due and payable upon submission of each annual report. All payments due to the **Governing Body** shall be payable in United States dollars (US\$)³²⁷ for the following account established by the **Governing Body** in accordance with Article 19.3f of the **Treaty**³²⁸:

**FAO Trust Fund (USD) GINC/INT/031/MUL,
IT-PGRFA (Benefit-sharing),
HSBC New York, 452 Fifth Ave., New York, NY, USA, 10018,
Swift/BIC: MRMDUS33, ABA/Bank Code: 021001088,
Account No. 000156426**

³²⁷ Note by the Treaty Secretariat: The Governing Body has not yet considered the question of currency of payment. Until it does so, Standard Material Transfer Agreements should specify United States dollars (US\$).

³²⁸ Note by the Treaty Secretariat: This is the Trust Account provided for in Article 6.3 of the Financial Rules, as approved by the Governing Body at its First Session (Appendix E to IT/GB-1/06/Report).

Annex 3

TERMS AND CONDITIONS OF THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

The discounted rate for payments made under Article 6.11 shall be zero point five percent (0.5 %) of the **Sales** of any **Products** and of the sales of any other products that are **Plant Genetic Resources for Food and Agriculture** belonging to the same crop, as set out in Annex 1 to the **Treaty**, to which the **Material** referred to in Annex 1 to **this Agreement** belong.

Payment shall be made in accordance with the banking instructions set out in paragraph 4 of Annex 2 to **this Agreement**.

When the **Recipient** transfers **Plant Genetic Resources for Food and Agriculture under Development**, the transfer shall be made on the condition that the **subsequent recipient** shall pay into the mechanism established by the **Governing Body** under Article 19.3f of the **Treaty** zero point five percent (0.5 %) of the **Sales** of any **Product** derived from such **Plant Genetic Resources for Food and Agriculture under Development**, whether the **Product** is **available or not without restriction**.

At least six months before the expiry of a period of ten years counted from the date of signature of **this Agreement** and, thereafter, six months before the expiry of subsequent periods of five years, the **Recipient** may notify the **Governing Body** of his decision to opt out from the application of this Article as of the end of any of those periods. In the case the **Recipient** has entered into other Standard Material Transfer Agreements, the ten years period will commence on the date of signature of the first Standard Material Transfer Agreement where an option for this Article has been made.

Where the **Recipient** has entered or enters in the future into other Standard Material Transfer Agreements in relation to material belonging to the same crop[s], the **Recipient** shall only pay into the referred mechanism the percentage of sales as determined in accordance with this Article or the same Article of any other Standard Material Transfer Agreement. No cumulative payments will be required.

Annex 4

OPTION FOR CROP-BASED PAYMENTS UNDER THE ALTERNATIVE PAYMENTS SCHEME UNDER ARTICLE 6.11 OF THIS AGREEMENT

I (full name of **Recipient** or **Recipient's** authorised official) declare to opt for payment in accordance with Article 6.11 of **this Agreement**.

Signature..... Date.....^{*}

^{*} In accordance with Article 6.11h of the Standard Material Transfer Agreement, the option for this modality of payment will become operative only once notification has been provided by the **Recipient** to the **Governing Body**. The signed declaration opting for this modality of payment must be sent by the **Recipient** to the **Governing Body** at the following address, whichever method of acceptance of **this Agreement** (signature, shrink-wrap or click-wrap) has been chosen by the parties to **this Agreement**, and whether or not the **Recipient** has already indicated his acceptance of this option in accepting **this Agreement** itself:

The Secretary,
International Treaty on Plant Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
I-00100 Rome, Italy

The signed declaration must be accompanied by the following:

- The date on which **this Agreement** was entered into;
- The name and address of the **Recipient** and of the **Provider**;
- A copy of Annex 1 to **this Agreement**.

Annex IV: Programme



United Nations Conference on Trade and Development

Ad Hoc Expert Group Meeting on the Development Dimensions of Intellectual Property: Biological Diversity and Access and Benefit Sharing (ABS)

Programme

16-17 April 2013
Room IX, Palais des Nations
Geneva, Switzerland

Day 1, Tuesday, 16 April 2013

- 10:00 **Welcome Remarks**
Kiyoshi Adachi
Chief, Intellectual Property Unit
Division on Investment and Enterprise, UNCTAD
- 10:15 **Making Investments in R&D Using Genetic Resources – the Role of ABS**
1) The Convention on Biological Diversity and the Nagoya Protocol
Beatriz Gomez
Associate Programme Officer, Social, Economic and Legal Matters
Secretariat of the Convention on Biological Diversity, UNEP
- 2) Vaccine Research and the WHO Standard Material Transfer Agreements*
Steven Solomon
Principal Legal Officer, WHO
Anne Huvos
Team Leader
PIP Framework Secretariat, Pandemic and Epidemic Diseases Department, WHO
- 11:15 Coffee Break
- 11:30 *3) Perspectives of the Pharmaceutical, Health Products and Cosmetics Industries*
Andrew Jenner
Director, Innovation, Intellectual Property and Trade
International Federation of Pharmaceutical Manufacturers' Associations
- Maria Julia Oliva
Senior Advisor on ABS
Union for Ethical Biobanking
- Discussion
- 12:30 Lunch Break
- 14:30 **Trends in Genetic Resources R&D, IP and ABS**
1) Open Science and the Freedom to Operate
Padmashree Gehl Sampath
Chief, Science and Technology Section

Division on Technology and Logistics, UNCTAD

2) Patenting the Fruits of University Research

Yumiko Hamano

Senior Program Officer

WIPO University Initiative Program, WIPO

15:30 Coffee Break

3) Misappropriation and its Prevention

Johanna von Braun (via Skype)

Natural Justice

Discussion

17:00 Close of Day 1

Day 2, Wednesday, 17 April 2013

Peer Review: Handbook on the interface between Global ABS Rules and IP

09:30 *Presentation of the Handbook*
Kiyoshi Adachi
Chief, Intellectual Property Unit
Division on Investment and Enterprise, UNCTAD

David Vivas-Eugui
Vivas Consulting

Hartmut Meyer
Independent Consultant

10:15 *Participants' and Tutors' Perspective*
Kongchay Phimmakong
Deputy Director, Biotechnology and Ecology Institute
Ministry of Science and Technology, Lao PDR

Viviana Munoz-Tellez
Programme Manager, Innovation and Access to Knowledge
South Centre

Christoph Spennemann
Legal Expert
Intellectual Property Unit, UNCTAD

10:45 Coffee Break

11:00 *Peer Reviewers' Comments and Free Discussion*³²⁹
Suneetha Subramanian
Research Fellow
United Nations University Institute of Advanced Studies

Jayashree Watal

³²⁹ Written comments also provided by Ms. Katrin Antonow, Lawyer and GIZ Consultant.

Counsellor
Intellectual Property Division
World Trade Organization

Maria Julia Oliva
Senior Advisor on ABS
Union for Ethical Biobanking

Pedro Roffe
Senior Associate
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Discussion

12:40 **Concluding Remarks**

12:45 *End*