

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	features might only be of value as a ceremonial element - TK as such is not protected - limited temporal protection
• industrial design	• need not to be new but must exhibit new esthetical features • protection spans over 15 years	a) from an IPR perspective - no specific limitations b) from a TK perspective - 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	• 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	a) from an IPR perspective - some marks are already well known - must fit into existing system of classification of goods or services b) from a TK perspective - TK as such is not protected - difficulties in managing GI or collective trademark systems
Rights over plant varieties		
• plant breeders' rights	• the plant's geno- and phenotype needs to be new, stable, distinct and uniform • protection spans over 15 - 25 years	a) from an IPR perspective - 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> b) from a TK perspective - TK associated with the plant as such is not protected - limited temporal protection
Copyrights and related rights		
• copyright	• religious text or prayer needs to contain original expressions of intellectual creations • religious text or prayer	a) from an IPR perspective - the author cannot be determined in many cases b) from a TK perspective

	<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.tkdl.res.in/tkdl/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.