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Incorporating Traditional Knowledge in an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects

Gurdial Singh Nijar*

Abstract

The Seventh Meeting of the Conference of the Parties (2004) of the Convention on Biological Diversity established a mandate for the negotiation of an international regime on Access to Genetic Resources and Benefit Sharing arising from their utilization. Negotiations have been proceeding and have entered the final phase. Seven working group meetings have been held to date and there is expectation that an instrument will emerge by the final deadline – the Tenth Meeting of the Conference of the Parties in Nagoya, Japan in October 2010. A key component singled out for inclusion in the international regime relates to the recognition and protection of the rights of indigenous and local communities (ILCs) over their traditional knowledge (TK) associated with genetic resources. The Ninth Meeting of the Conference of the Parties (2008) established a Group of Technical and Legal Experts to assist the Working Group to deal with this issue. The Group met in India in June 2009 and has submitted a report. This article reflects on the key outcomes of this Expert Group report. In particular, it identifies the key issues that need to be considered and resolved for TK associated to genetic resources to form an integral and viable component of the proposed international regime.

* Professor, Law Faculty, University of Malaya, Kuala Lumpur, Malaysia. Email: director.ceblaw@um.edu.my

1 Introduction

Traditional knowledge of indigenous and local communities (ILCs) associated with genetic resources is at the centre of the current negotiations for an international regime on access and benefit-sharing (ABS) of these resources under the Convention on Biological Diversity (the Convention; CBD).¹ The Convention recognizes the crucial contribution of such knowledge to its conservation and development objectives, in particular the conservation and sustainable use of biodiversity;² and calls for the protection, preservation, and the enhancement of traditional knowledge (TK).³ It further exhorts its 190 contracting parties – the largest subscription thus far to an international environment treaty – to include indigenous and local communities (ILCs) in decisions involving access to their TK and encourages parties to share benefits arising from the utilization of such TK.⁴ In parallel with these negotiations, the Article 8(j) working group has been meeting to work towards the protection and preservation of TK in the establishment of the international regime as well as

national ABS laws; and that ILCs secure fair and equitable benefits from the use and application of their TK.⁵

It is widely acknowledged that it is the TK associated with genetic resources that is of value to industry. TK's contribution to modern medicine illustrates this rather vividly. It is estimated that three quarters of the plants that provided active ingredients for prescription drugs came to the attention of researchers because of their use in traditional medicine.⁶ Of the 120 active compounds currently isolated from the higher plants and widely used in medicine today, 74 per cent show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived.⁷ TK's role in increasing the efficiency of screening plants for medicinal properties is often highlighted, with various calculations – that it increases the efficiency by more than 400 per cent⁸ or that it enhances the probability of drug development at the lead discovery stage by as much as 0.5 or a 50 per cent chance of success.⁹ Shaman Pharmaceuticals of the

¹ COP 7 set up a mandate for the negotiation of an international regime on ABS. Negotiations have been proceeding and have entered the final phase. 7 working group meetings have been held to date and there is expectation that some instrument will emerge by the final deadline – fixed for the Conference of the Parties (COP) 10 meeting in Nagoya, Japan, in Oct. 2010.

² It is generally agreed that TK with regard to the use of biological and genetic resources continues to provide the integral foundation for the management, conservation, and improvement of a wide variety of resources.

³ Art. 8(j) CBD, available at: www.cbd.int/convention/convention.shtml.

⁴ *Ibid.*

⁵ See www.unutki.org/phprint/php (last visited 10 Sept. 2009).

⁶ Gray, 'Between the Spice of Life and the Melting Pot: Biodiversity Conservation and Its Impact on Indigenous Peoples', International Working Group for Indigenous Affairs (IWGIA), Doc 70 (1990).

⁷ Farnsworth *et al.*, 'Medicinal Plants in Therapy', 63 *Bull WHO* (1985) 965, at 966.

⁸ Balick, 'Ethnobotany and the Identification of Therapeutic Agents from the Rainforest', in D.J. Chadwick and J. Arsh (eds), *Bioactive Compounds from Plants* (1990).

⁹ Reyes, 'The Value of Sangre De Drago', *Seedling*, GRAIN (1996), available at: www.grain.org/seedling/?id=150# (last visited on 17 Sept. 2009).

US calculates its rate of scoring a marketable hit as one in every two plants studied with the use of TK. The comparable success rate for random bioprospecting in plants, animals, and microorganisms is one in 10,000 compounds.¹⁰ The current value of the world market for medicinal plants derived from such leads is estimated at US \$43 billion.¹¹

Modern biotechnology which creates products by modifying life forms has enhanced the value manifold yet further. A further boost has come from the extension of patent claims over such life forms, including biological and genetic resources, and of plant variety protection for new crop varieties.

In the 1970s, developing countries complained bitterly that genetic resources taken from them on the basis that these were the 'common heritage of mankind' were returned to them as a commodity with a price. These resources represented the innovations associated with the TK and practices of ILCs of developing countries. Through the Convention the South finally succeeded in rectifying the unequal and unfair exchange. The sovereign right of countries over their resources was recognized. This included the right to regulate access. The role of ILCs in preserving and enhancing biodiversity was explicitly acknowledged; as was the need to share benefits when their TK was utilized.

¹⁰ *Ibid.*

¹¹ Gray, 'Indigenous Peoples and the Marketing of the Rainforest', 20 *The Ecologist* (1991) 223; and Posey, 'Intellectual Property Rights and Just Compensation for Indigenous Knowledge', 6 *Anthropology Today* (1990).

2 Is ABS a Legal Imperative in Respect of TK?

A National Level

Is there an obligation for parties to require the prior informed consent of ILCs to access TK? The Convention, in recognition of the vital role of ILCs in preserving and enhancing biodiversity, exhorts parties to promote their wider application,¹² with the approval and involvement of ILCs. This implies that, where the TK of ILCs is involved, access applications require their prior informed consent. This has been consistently reiterated. The fifth meeting of the Conference of the Parties in 2000 established a general principle that access to TK of ILCs should be subject to the prior informed consent of its holders.¹³ The Bonn Guidelines¹⁴ require the state to respect the 'established legal rights of ILCs associated with the [resource]'.¹⁵

Article 15.7 of the Convention requires parties to legislate for the sharing of benefits arising from the utilization of genetic resources. This mandatory requirement

¹² Art. 8(j) CBD, *supra* note 3. The CBD also requires each party to protect and encourage customary use of biological resources in accordance with conservation or sustainable use requirements: Art. 10(c).

¹³ Decision V/16, Annex, in *From Policy to Implementation: Decisions from the Fifth Meeting of the Conference of Parties to the Convention on Biological Diversity* (2000), at 73.

¹⁴ Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (2002), at para. 26.

¹⁵ *Ibid.*, at para. 31.

would also apply to benefits where associated TK is accessed. This would translate the permissive requirement ('encourages' the sharing of benefits where TK is utilized) in Article 8(j) into a mandatory requirement for benefit-sharing under Article 15.7. The upshot is that there must be benefit-sharing where TK associated with genetic resources is accessed.

B International Level

Further, the requirement of prior informed consent of ILCs for access to TK associated with genetic resources may have evolved as part of international customary law.

First, various international instruments,¹⁶ albeit primarily soft law, provide a basis for this prior informed consent. These include instruments that deal with human rights. Thus rights inextricably integral to the enjoyment of these rights (which would include ILCs' rights over their land, genetic resources and associated TK) cannot be interfered with. Further, it implies that any abridgment of these rights must be with the consent of the rights' holders. By the UN Declaration on the Rights of Indigenous

Peoples (UNDRIP), in particular, the most recent of soft law on the subject, states have agreed to take measures to recognize and protect the exercise of rights of indigenous peoples that are enumerated in Article 31.¹⁷ These include their right to 'maintain, control, protect and develop', among others, their cultural heritage and TK as well as the manifestations of their sciences, technologies, and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of flora and fauna, and oral traditions. Indigenous peoples are also accorded similar rights in respect of their intellectual property over such cultural heritage, TK, and traditional cultural expressions. These rights flow from the recognition of the self-autonomous status of indigenous peoples. This accords the right to self-determination and, as a necessary concomitant, the right to exercise control over their resources and TK. This right to exercise control imports notions of prior informed consent for access to associated TK. The Technical and Legal Expert Group on TK Associated with Genetic Resources set up by the ABS Working Group negotiating the International regime on ABS¹⁸ concluded recently that these international instruments demonstrate a 'progressive trend towards international law mandating a requirement for the prior informed

¹⁶ The Universal Declaration of Human Rights, 1948; The International Covenant on Civil and Political Rights, 1966; The International Covenant on Economic, Social and Cultural Rights, 1966; ILO Convention No 169 on Indigenous and Tribal Peoples in Independent Countries, 1989, available at: www.ilo.org/ilolex/cgi-lex/convde.pl%3FC169; The Convention on Biological Diversity, 2001, *supra* note 3; The FAO Treaty on Plant Genetic Resources for Food and Agriculture, 2001, available at: www.planttreaty.org; The Bonn Guidelines, 2002, *supra* note 14; and The UN Declaration on the Rights of Indigenous Peoples, 2007, available at: www.un.org/esa/socdev/unpfii/en/drip.html.

¹⁷ The Declaration has been ratified overwhelmingly by all countries of the world, including Malaysia.

¹⁸ The Ninth Meeting of COP decided to establish 3 distinct groups of experts to provide legal and technical advice and input to assist the Working Group. The other expert groups deal with concepts and definitions; and compliance.

consent of indigenous peoples and local communities for TK associated to genetic resources. There is hence a clear trend that provides a basis in international law for the International Regime to require prior informed consent'.¹⁹

Secondly, prior informed consent may also have become part of customary international law by the practice of states. A growing preponderance of national and regional ABS laws requires the prior informed consent of ILCs in respect of access to TK associated with genetic resources.²⁰ Even in developed countries, there is a growing practice for commercial users to seek prior informed consent from ILCs as a matter of best practice.²¹ This establishes a clear and growing practice of states requiring prior informed consent. This has been confirmed by the current discussions on Article 8(j) and the international regime on ABS. For these reasons the Technical and Legal Expert Group on TK also further concluded that there is a clear basis in international law for requiring prior informed consent from

ILCs as a condition for granting access to TK associated with genetic resources and that this should be reflected in the international regime: paragraph 66.

3 TK and ABS: The International Context

The scope of the current negotiations for the international regime includes TK, innovations, and practices in accordance with Article 8(j) of the Convention. Two specific elements singled out for consideration are:

- the recognition and protection of the rights of ILCs over their TK associated with genetic resources; and
- the measures to ensure compliance with prior informed consent of ILCs holding TK associated with genetic resources, in accordance with Article 8(j).

The rest of this article reflects on the report of the Expert Group on TK which met in Hyderabad in June 2009.²² This report will inform the negotiations for an international regime when the TK component is discussed in the pending ABS working group meetings.²³

A Defining Traditional Knowledge

The Expert Group acknowledged that TK has diverse facets and represents an

¹⁹ Report of the Meeting of the Group of Technical and Legal Experts on TK Associated with Genetic Resources in the context of the International Regime on Access and Benefit Sharing, UNEP/CBD/WG-ABS/8/2, at para. 63.

²⁰ As examples: Nigeria, Philippines, South Africa, Kenya, Guyana, Australia, Bangladesh, Afghanistan, Bhutan, Ethiopia, Brazil, Bolivia, Costa Rica, Pakistan, Uganda, Hawaii. There are also similar requirements of regional groupings: Andean Decision 391, the Model law of the Organization of African Unity (OAU), and the proposed draft ASEAN Framework Agreement, all available at: www.cbd.int/abs/measures.

²¹ Ministry of Economy, Trade and Industry, Japan, and Japan Bioindustry Association, *Guidelines on Access to Genetic Resources for Users in Japan* (2006), at 11, item 2(iii).

²² Final report: UNEP/CBD/WG-ABS/8/2, available at: www.cbd.int/meetings (last visited on 22 Mar. 2010).

²³ The next (Eighth) meeting of the working group is scheduled for Nov. 2009 at Montreal. It will be preceded by a Working Group meeting on Art. 8(j), *supra* note 3.

evolutionary and dynamic body of learning which is of contemporary relevance. The Expert Group thus opted to describe TK by reference to its several peculiar core characteristics, eschewing reference to details which are often place-specific. These include its holistic, communal, and inalienable nature. Further, TK reflects a system of self-management governing resource use which is embedded in the social and cultural practices of the community. It is usually transmitted through oral tradition and first hand observation.

There are also different types of activities for TK associated with genetic resources such as:²⁴

- Uses, preparation, processing, and formulations of useful species/varieties; (for example, for medicinal purposes);
- Agricultural management techniques: Planting methods, care, selection criteria, or storage of species (for example, seed treatment and storage methods which result in new resilient plant varieties);
- Ecosystem/biodiversity conservation (for example, preserve and use principle – resources taken only to the extent needed, manual collection of forest produce, hunting for subsistence purposes using methods which are specific to the purpose), often inextricably linked to cultural landscapes (for example, sacred sites, practices) and
- Systems of knowledge classification such as traditional plant taxonomies.

B *The Relationship between TK Use and Access*

An ABS regime may be general in nature – knowledge relating to the ecosystem which makes the resource available for access – or highly specific – that relating to the use value or properties of a genetic resource or a biological resource.

The TK, innovations, and practices of ILCs nurture the ecosystem as ILCs co-evolve with the environment they inhabit. Without the sustained nurturing of the ecosystem, the resource could well have disappeared. This is the ‘ecosystem-nurturing’ TK. Its value is reflected in the key two objectives of the Convention – conservation of biodiversity and the sustainable use of its components. Hence the TK of ILCs is recognized as crucial to the attainment of these objectives.

The ‘specific use’ TK often provides the lead to the investigation of a resource for its potential properties. The lead time has a commercially quantifiable value. TK may help to identify a plant with useful properties from the thousands of species. Thus the use of the *Hoodia* species of plant as a food and water substitute by the indigenous *San* peoples of Southern Africa led directly to a commercial product. The use of the berries of a plant to overcome fatigue by the *Kaani* community of the State of Kerala in India led to a lucrative byproduct for the plant.

This direct co-relationship between access to and the use made of the TK plainly attracts the regulatory access requirements, such as the prior informed consent of ILCs.

C *Linking Benefit Sharing to Use of Genetic Resources and TK*

The commercial and other utilization triggers the benefit-sharing obligations

²⁴ D.A. Posey and G. Dutfield, *Beyond Intellectual Property Rights: Towards Transitional Resource Rights for Indigenous Peoples and Local Communities* (1996).

of the user. Hence *benefit-sharing should be linked to the use of the genetic resources and associated TK – not to access*. This is to be negotiated through mutually agreed terms. This is distinct from the prior informed consent of the ILCs required for access. This benefit-sharing–use link makes practical sense. The applicant for access may be required to furnish information on whether commercial use is contemplated.²⁵ In practice, however, it may be difficult to supply any of this information at the time of an access negotiation. The genetic resources may yet not be collected, an end product yet to be determined, or a final user (and there could be many) yet not evident.²⁶ Access contracts are routinely negotiated when the actual value is not known and even difficult to predict. Hence the requirement in most ABS laws for benefit-sharing terms to be negotiated at the outset as a condition for the grant of access²⁷ may not result in fair and equitable benefit-sharing terms being obtained. Further, it may be difficult to monitor and track the development of the product from the TK accessed. A requirement in the ABS national law or in an agreement that the provider be informed when value is realized and a fresh contract negotiated at every such stage, or when there

is a different use of the resource,²⁸ may not overcome the problem. It is difficult to track the resource from access until a product is realized, especially where there is a long time lag. Developing countries often lack the capacity to ascertain the potential value of the benefits, as well as to track and monitor the research and development activity.

Nonetheless there can be more realistic negotiations once the result is obtained (or is imminent). Both parties are better positioned to conclude benefit-sharing terms. The contribution of the TK to the end product will also be easier to establish. Where access is for commercial purposes, the benefit sharing may vary depending on the way in which the TK is commercially utilized such as:²⁹

- in its original form;
- from ethno-botanical knowledge in databases and published literature;
- as a natural by-product;
- as a synthetic by-product of a genetic resource;
- as a by-product which is analogous to the original molecule isolated;
- to develop a research product with the same uses as the TK (direct/unmodified use);

²⁵ As in the ABS related laws of Afghanistan, Brazil, Ethiopia, Pakistan, Queensland (Australia), and Vanuatu.

²⁶ L. Glowka *et al.*, *A Guide to the Convention on Biological Diversity* (1994), at 83.

²⁷ See the ABS related laws of Afghanistan, Australia, Bhutan, Bulgaria, Guyana, India, Malawi, Pakistan, Philippines, and South Africa.

²⁸ Costa Rica, Brazil, India, and Uganda. Bhutan and Hawaii; require a fresh application to be submitted for every new use. The Bonn Guidelines, *supra* note 14, impose a duty on the users to obtain a new prior informed consent and enter into fresh mutually agreed terms if they use genetic resources for purposes other than those for which they were acquired, or where there is any change of use: Art. 16(b)(v) read together with Art. 34.

²⁹ M.S. Suneetha and P. Balakrishnan, *Benefit Sharing in ABS: Options and Elaborations* (2009), at 16–17.

- to develop a product based on modifying the traditional use of the TK information (direct/modified use);
- to develop a non-commercialized research product with different uses from the TK information (indirect/modified non-commercial use);
- to develop and commercialize a research product with different uses from the TK information (indirect/modified commercial use).

The benefit sharing would also depend upon whether the development is simple and linear or involves highly sophisticated technological processes; and the distance of the use of the TK component from the commercial market capitalization. Milestone payments may be made if values are realized as genetic resources go through a continuous process of research and development. This provides the rationale for 'phased agreements'. Crucially, there would be an obligation to enter into a benefit-sharing contract once the research and development yields a product.

Users may be placed in the invidious position of having to agree to the imposition of onerous terms to save their investment. However, industry may well prefer this option as it provides a sounder basis for ascertaining the likely benefits. Even intellectual property rights (IPRs) are often claimed well in advance of commercialization. And they may thus more likely avoid any suggestion that the benefits are inequitable.³⁰

Indeed, bioprospecting partnerships seldom involve a single framework

agreement. Instead there is an interlocking web of agreements. A single umbrella agreement may encompass several different interrelated agreements, as in the case of the University of Illinois-Chicago Vietnam Laos programme.³¹ A CBD study notes that phased agreements are prevalent in several sectors and are preferred in sectors where there are wide differences in the financial profile and activities undertaken during discovery, development, and commercialization (for example, the pharmaceutical sector). The study notes that in the seed sector there is a research agreement to allow the material accessed to be examined for its suitability and the information assessed. Then, nearer commercialization, a Material Transfer Agreement is signed for capacity building and knowledge, and technology transfer. Finally licensing and commercialization agreements are signed.³²

Although the illustrative scenarios distinguish between research for commercial and non-commercial purposes, the line between these kinds of research is often blurred. Often, research for non-commercial purposes (publications, taxonomic) opens up commercial opportunities and is harnessed for commercial ends. A complex web of relationships links such research to commercial objectives: through partnerships, joint ventures, funding,³³ and sometimes buy

³⁰ The preference may then be for a research and commercialization agreement rolled into a single agreement, specifying the royalty rates and technology transfer.

³¹ S. Laird and R. Wynberg, *Access and Benefit Sharing in Practice: Trends in Partnerships across Sectors* (2008), at 27–28.

³² *Ibid.*, at 28.

³³ Swiderska, 'Traditional Knowledge Protection and Recognition of Customary Law: Policy Issues and Challenges', available at: www.iied.org/NR/agbioliv/bio_liv_projects/documents/TKWorkshopMay04.pdf, at 10.

up of what starts off as non-commercial publicly or privately funded research. The documented use of the *Hoodia* species in colonial botanical accounts led a research institute to investigate its properties. A publication in 1962 on medicinal and poisonous plants also inspired the research project.³⁴

D Ownership of the Resource

Determining the benefits for TK holders may also be complicated by issues of ownership of the resource. A distinction is sometimes drawn between the resource and its genetic make-up. While the former may be tied to land and evidenced by a title deed, the genetic makeup of a resource (which could include the associated TK information) is a new and complex juridical concept. Some states claim an overriding ownership right to the genetic resources, referring to it as ‘the patrimony of the State’.³⁵ Then, the state decides on approvals and the terms of access, although the specific landowner or TK holder will have limited rights – for example, to give prior informed consent (which may or may not amount to the right to say ‘no’) and a right to share in the benefits, with perhaps an ancillary right to negotiate the terms. Some propose the following limitation of the rights of landowners to take account of the special legal status of genetic resources:³⁶

- Proprietary rights to biological material imply only a non-exclusive right to use the genetic resources;
- Proprietary rights to biological material imply only non-exclusive rights to such material;
- Rights to genetic resources are separate from ownership of biological resources and such rights can be exercised only through the use of IPRs. The right to biological material will still be respected, but granting rights to genetic resources is left to national legislation. If access to genetic resources is left unregulated, the holders of biological resources cannot exercise any control over genetic resources.

It follows that the right to obtain benefits may vary according to the legal status of the genetic resources and associated TK in national law. A requirement in a national law that the prior informed consent of TK holders must first be obtained when their resources or associated knowledge is sought for the access application to be considered³⁷ may not, by itself, give the TK holders the right to negotiate and conclude benefit-sharing terms. This will also be the case where national laws approve the application for access but then require the prior informed consent of the TK holders for any access activity (for example, the collection of samples) to commence. The prior informed consent of the TK holders may be one among many other conditions

³⁴ R. Wynberg, D. Schroeder, and R. Chennells, *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case* (2009), at Chap. 6.

³⁵ Andean Decision 391.

³⁶ *Access and Rights to Genetic Resources: A Nordic Approach*, Nord 2003: 16, Nordic Council of Ministers, Copenhagen (2003) at 116–117.

³⁷ Bangladesh, Andean Decision 391, Bolivia, Brazil, Costa Rica, Uganda, Vanuatu, Nigeria, Philippines, Seychelles, Afghanistan, Northern territory, South Africa, and Pakistan.

to be satisfied. The breach of any condition may be penalized.³⁸ Where access approval allows the activity to proceed, it depends upon the nature of the penalty whether this amounts to a negation of the approval process. A few countries eschew all reference to the prior informed consent of ILCs.³⁹ It is conceivable that some countries may provide for the state to represent the national interest,⁴⁰ which presumably includes the interest of local communities. This finds expression in some national laws which allow only for consultation with the ILCs, with final authority for the grant of approval for access residing entirely with the national competent authority.⁴¹ Some countries explicitly state that the ILCs have the right to grant or to refuse access to their TK with no authority in the state to override their decision;⁴² while yet others provide for this veto power.⁴³ However in most countries there is recognition that ILCs are entitled to benefit-sharing where their genetic resources and associated TK are accessed⁴⁴ and a distinct process established for determining the benefit-sharing. Industry players,

too, recognize the entitlement, although some shun actual involvement in the negotiation of the benefit-sharing terms, preferring to leave this task to national governments.⁴⁵ These diverse provisions in national laws make clear that there is no link *per se* between the prior informed consent of ILCs and the right to determine benefit-sharing terms. The link is established by an affirmative provision in national law.

E Addressing TK in the International Regime

The nature of the TK that needs to be included within the scope of the international regime needs to be addressed. In particular, should the TK be associated only with genetic resources or with biological resources as well? Commercial by-products are made from biological resources based directly on TK. The TK invariably relates to the intrinsic qualities of the biological resource, which appears to be inextricably linked to the genetic component, although traditional communities neither couch it in these terms nor distinguish between these two facets in the same way as modern science does. It would then be fundamentally unfair to allow the use of TK without the concomitant benefits, especially since the underlying impetus for the development of an international regime is to right a historic wrong.

Secondly, the ownership status of the associated TK needs to be clarified. Is the TK holder-community the sole owner of the resource? Or is the community the co-owner together with the state?

³⁸ E.g., Bhutan.

³⁹ India, Malaysian State of Sabah and Sarawak, Bulgaria, Queensland (Australia).

⁴⁰ E.g., Bhutan.

⁴¹ E.g., India; Guyana.

⁴² Costa Rica, Pakistan, South Africa.

⁴³ Brazil, Bhutan.

⁴⁴ E.g., Bolivia; Brazil; India; Pakistan; Uganda; Sabah; South Africa; Philippines; Ethiopia; Bangladesh; Australia; Vanuatu. In developed countries as well, there seems to be an assumption that MATs relating to benefit-sharing must be directly negotiated with the ILCs when their TK is accessed: see *supra* note 32, Japan Bio Industry, *Guidelines for Users in Japan* (undated), at 18. See also Swiss Academy of Sciences, *Access and Benefit Sharing: Good Practice for Academic Research on Genetic Resources* (2006), at 15, 29.

⁴⁵ See Laird, *supra* note 31, at 26.

This, as discussed earlier, depends upon national law. Ownership carries with it the right to refuse access. Would according such extensive rights to a community undermine the provisions of the Convention which mandates access to be facilitated by the Contracting Party? Then again there is a clear requirement in the Convention for states to protect the rights of ILCs relating to the objectives of the Convention – including for the conservation and sustainable use of biodiversity. This, as argued earlier, requires the prior informed consent of ILCs. This implies that ILCs have the right to refuse access in appropriate circumstances. As noted earlier, most national ABS laws, in any event, provide for the prior informed consent of ILCs as a precondition for approving access. This seems to bestow on the TK of ILCs attributes akin to ownership rights over the TK associated with the genetic resources. However, some countries assert an overriding right ('patrimonial rights') over genetic resources within the country. They reserve their final right to determine access to genetic resources. Brazil, for example, has proposed a constitutional amendment to make all genetic resources part of the national heritage. This reasserts the sovereign right of the state over the claim by communities to qualify this right.⁴⁶ This conflicts with any mandatory prior informed consent requirement of the ILCs. It also conflicts with the commitment made by countries which have ratified the UNDRIP to recognize the rights of indigenous peoples

over their TK. A further complication arises where countries dispense with the need to obtain the prior informed consent of the state altogether. This is permitted by the Convention (Article 15.3). Will the prior informed consent of ILCs be required then when seeking access to associated TK? The challenge for the negotiation of the international regime is to reconcile these seemingly irreconcilable positions. The crucial question is whether, and if so to what extent, states should be allowed flexibility to dispense with the prior informed consent of ILCs; or substitute this with mere prior consultation; or subsume the interest of the ILCs with the interest of the state? Such provisions exist in some, albeit a small number of, national laws.

A difficult issue arises with regard to information of associated TK that resides *ex situ*, for example in databases, libraries, or gene banks. Should access to these attract the prior informed consent and/or benefit-sharing requirements? Seed companies – perhaps to avoid any problems of legal uncertainty – commonly obtain landraces directly from the Consultative Group on International Agricultural Research or national gene banks.⁴⁷ There may be practical difficulties in implementing an obligation for access to such *ex situ* collections. First, the TK holder may not be identifiable; or there may be multiple holders. A similar problem existed for the *ex situ* genetic resources in the context of the FAO. The solution that emerged was to bring designated plant genetic resources which were in the international centres within the multilateral system of

⁴⁶ Firestone, 'You Say Yes, I Say No: Defining Community Prior Informed Consent under the CBD', 16 *Georgetown Int'l Environmental L Rev* (2003) 1; ABL/INFORM Global, at 171.

⁴⁷ See Laird, *supra* note 31, at 26.

the International Treaty on Plant Genetic Resources for Food and Agriculture. The system presumes that prior informed consent is given when a resource is accessed. Where the product created out of the TK is restricted (for example by claiming patents), then mandatory payments must be made to a fund along a prescribed formula (1.1 per cent of the sales of the product less 30 per cent). Where the product is available without restriction, the recipient is encouraged to make voluntary payments. This system could be adapted to products made from the associated TK *ex situ* data. Disbursements from the fund could be managed by a body created by the Convention either directly or as part of the proposed international regime.

In other cases, where it is clear that TK is involved but it remains difficult to link the TK with an identifiable holder, prior informed consent may be sought from a national authority. The benefits could be negotiated with the authority and the benefits paid to a national body in trust for the TK holders.

There is yet another problem when TK associated with genetic resources is in the public domain. It is then publicly available and can be readily accessed. There seems to be a misconception that this allows its free use for commercialization. The public domain concept does no more than defeat a claim for lack of inventiveness or prior art in a claim for a patent. It does not permit the overriding and usurping of the rights of its holder. More particularly it does not mean that benefits should not be shared with the TK owner. A parallel may be drawn with copyright law. Intellectual creations of works are entitled to copyright protection. Yet they are freely available. For their commercial use permission must

usually be obtained and can be made subject to terms. Similarly TK that is in the public domain can be made subject to ABS requirements. The *Hoodia* case described earlier illustrates this. The TK of the *San* was widely known, having been in the public domain for a long time. Yet a benefit-sharing agreement was entered into *after* it became known that the patent and the product being developed were based on the TK of the community. Similarly, a market association in Brazil – *Ver-as-Ervas* – succeeded in securing benefit-sharing terms from a company which had used TK in developing natural care and cosmetic products even though the TK was widely known.⁴⁸

F TK Across Communities and Transboundary Issues

The associated TK may be spread across several communities within the country. Or the genetic resources may exist in one country and associated TK in another. Or the TK in relation to the resource may transcend boundaries. Whose prior informed consent should be sought? With whom should the negotiations for benefit-sharing be done? And with whom should benefits be shared, especially if the prior informed consent was not obtained from, and the negotiations for an agreement not done with, all the communities?

Some particular difficulties may be highlighted. First, where the TK is widely dispersed geographically and with a multiplicity of holders, it may not be possible to identify any, or all, the possible TK holders. There seems to be no systematized information regarding how much,

⁴⁸ *Ibid.*, at 26–27. Expert Group report, *supra* note 19, at para. 120.

and the extent to which, TK exists widely within a country or across boundaries.⁴⁹ Secondly, the TK holders may make themselves known only after the prior informed consent has been secured and the MATs negotiated with other TK holders or the state. Thirdly, the TK may have diffused into the public domain widely through various forms – publications, the media, electronically, and such like – without the consent or knowledge of the holders.

Each of these scenarios needs to be addressed differently. Where the TK is spread widely within the country with numerous known potential communities who can lay claim to the TK, the prior informed consent could be sought from the actual providers of the resource and associated TK who are entitled to negotiate benefits. Other holders of the same TK would be entitled to receive benefits through a public fund.⁵⁰ The new Brazilian draft law takes this approach. A more challenging situation arises where the resource and associated TK are shared by communities across boundaries.

In the *Hoodia* case the resource and the TK were spread among indigenous *San* communities residing in Namibia, South Africa, and Botswana. Such situations require regional strategies to ensure a participatory process among all TK holders to secure benefits. This would also safeguard against users seeking out the weakest link to obtain access on terms which may prejudice the other communities. The proposed ASEAN Draft ABS Framework Agreement⁵¹ is instructive. It requires member countries to be informed of any access application approval or denial, possibly through a clearing house mechanism.⁵² It also provides for member countries to discuss benefit sharing where resources exist in more than one member country.⁵³

Solutions for the second and third case scenarios are also reflected in the *Hoodia* case. The commercialization of the *Hoodia* drug proceeded for many years without the prior informed consent or acknowledgement of the contribution of the *San* community, the original holders of its knowledge. The associated TK was widely known. The developers – South African Council for Scientific and Industrial Research (CSIR) – patented the product and entered into agreements with private companies. Eventually – after media publicity that juxtaposed images of emaciated African tribes against ‘biopirating’ western pharmaceutical companies – benefit-sharing arrangements were entered into between the *San*

⁴⁹ M.R. Muller, *The Protection of Traditional Knowledge: Policy and Legal Advances in Latin America*, IUCN-SPDA-BMZ (2006), at 171. Some notable exceptions are emerging. India has digitally documented its TK in relation to traditional medicine extensively primarily to establish prior art to defeat any claims of novelty in IPR claims. It has entered into an agreement with the EPO. This has reduced patent claims based on Indian TK substantially. A similar agreement exists with the USPTO: Gupta, ‘TK Digital Library & ABS Policy and Legislation in India’, Workshop on Benefit Sharing of TK and associated Biological Resources, Beijing, 4–5 Sept. 2009.

⁵⁰ E. Kamau, B. Tobin, and G. Winter, *Undoing the Knot in ABS Transaction: In Search of Amicable Solutions*, Summary of Debate of Bremen Workshop, 15–16 Feb. 2008, at 9.

⁵¹ Adopted by the ASEAN ministers for the environment in 2005. It has yet to be signed by the countries.

⁵² *Ibid.*, Art. 5(c) and (d).

⁵³ *Ibid.*, Art. 7.4.

and the developers. The *San* were assisted by *San*-community-based organizations as well as by an NGO. The *San*, organized as *San* Councils in each of their states – after initially anguishing over whether to challenge the patent on legal (lacking novelty) and ethical grounds – ultimately agreed to a pragmatic solution to enforce their communities' collective intellectual property. The benefit-sharing deal negotiated, however, vested the patent in the developers. The South African *San* Council and the developers were the two primary parties to the agreement. While this allayed concerns about the difficulty of identifying genuine TK holders of the plant, it excluded non-*San* traditional groups which historically occupied the areas where the plant grows and which also used the plant based on their TK.⁵⁴ The *San* communities across the borders organized themselves into a *San* Council and developed procedures to resolve the shared TK issue. A common trust fund was established to ensure equal benefit-sharing among all the *San* communities in the region.⁵⁵

Drawing upon these varied experiences, the difficulties relating to shared transboundary TK associated with genetic resources could be resolved by the inclusion of the following requirements in the international regime. A state would be obliged to disseminate widely the information of the application for access to a resource and associated TK which exists

(or may exist) across national boundaries. TK holders wherever located could inform the authority considering the application of their views (prior informed consent) as well as on benefit-sharing. The prior informed consent of the actual provider of the resource must be obtained, but the benefit-sharing can be with all the other (known) communities which hold the same TK. A fund could be established to distribute the monetary benefits equally on the common law equitable principle of 'equity is equality'. If the access has occurred without the involvement of the TK holders other than the providers, at least if this was done in good faith (for example, if there was no knowledge that TK was involved or there was no knowledge of the existence of TK holders or the TK holders across boundaries did not respond after the information about the access application was disseminated), the user could be required to negotiate benefit-sharing arrangements with these other communities. The benefits already agreed upon could be used as a basis for the negotiations. For example, benefits could be limited to the aggregate amount already agreed, with the proviso that they be shared amongst the communities. If there has been access and the communities, though known, were bypassed, then the access may be annulled and the user made to account for any profits obtained. Alternatively, the communities concerned could be given the option of agreeing to accept benefits, in which case a new agreement must be negotiated.

It is possible that some time in the future conflicts may well arise where communities across jurisdictions feel that their prior informed consent for access or for the agreement should have been, but was not, secured; or who are unhappy

⁵⁴ See Wynberg, *supra* note 34, at Chap. 6.

⁵⁵ See also Report of the Meeting of the Group of Technical and Legal Experts on TK Associated with Genetic Resources in the context of the International Regime on Access and Benefit Sharing, UNEP/CBD/WG-ABS/8/2, at para. 87.

with the quantum, or nature, of benefits. A dispute-resolving mechanism may need to be established. An ombudsperson under the proposed international regime has been suggested by the Expert Group as fulfilling that purpose.⁵⁶

G Prior Informed Consent Procedures for Traditional Knowledge

As argued earlier, prior informed consent of ILCs may be mandatory under the Convention. Most national ABS related laws make this a mandatory requirement. However, most of these laws are singularly lacking in clear procedures for securing the prior informed consent.⁵⁷

Where procedures are prescribed they vary considerably. Poorly defined procedures create legal uncertainty for both users and providers. Similarly, any arbitrarily prescribed procedures remove the flexibility essential to reflect the unique characteristics of a particular community. A single procedure for all situations ('one-size-fits-all') is particularly ill-suited as, often, there exist unique community-specific procedures, grounded in customary laws, practices, and community protocols. This diversity of local governance processes ought to be preserved in the international regime.

In many parts of Africa, Asia, Latin America, and the Pacific region, constitutional and national law recognize a role

for customary law in issues regarding natural resource management and land and marine tenure. In the Pacific region, upwards of 80 per cent of land and a significant portion of coastal and marine areas are subject to traditional tenure rights. And rights over both biological and genetic resources are subject to customary law rights.⁵⁸ Internationally, Agenda 21, established in 1993, recognizes the value of preserving the administrative customary systems and practices in protecting indigenous intellectual and cultural property.⁵⁹ The recent UNDRIP reiterates the right of indigenous peoples to maintain their institutional structures, customs, procedures, and practices, including juridical systems.⁶⁰ Similar provisions exist in many other 'soft law' documents.⁶¹ The procedures in the customary laws vary vastly from community to community. Some are elaborate, replete with detailed provisions; others are scanty in detail. Yet others depend upon the oral pronouncement of a village or community elder. Where they are sufficiently detailed and provide adequate safeguards, these procedures may be incorporated into the international regime, either directly by reproducing them in the regime or by a general reference that the prior informed consent should accord with the customary laws and established practices of the community. This has the support of the

⁵⁶ See also *ibid.*, at para. 95.

⁵⁷ The Philippines law is an exception and provides detailed procedures for prior informed consent and benefit-sharing: see sects 13.2 and 14 of the Guidelines for Bioprospecting Activities established under the Joint DENR-DA-PCSD-NCIP, Administrative Order No. 1 of 2005, available at: www.cbd.int/abs/measures.

⁵⁸ B. Tobin, *Customary Law as the Basis for prior informed consent of Local and Indigenous Communities* (undated).

⁵⁹ Agenda 21, Art. 26.4.b. Bonn Guidelines, *supra* note 14.

⁶⁰ *Supra* note 16, Art. 34.

⁶¹ E.g., the Draft American Declaration on the Rights of Indigenous Peoples, Art. XXI, in particular items 1 and 2, available at: www.indianlaw.org/en/projects/ihr/oas/draft.

Contracting Parties to the Convention. One of the potential elements it has highlighted for consideration in the development of systems for the protection of TK, innovations, and practices of ILCs is ‘customary procedures which govern access and consent to make use of TK and biological and genetic resources’ and ‘a process and set of requirements governing prior informed consent’.⁶²

Securing compliance with these procedures may be best left to national competent authorities. In any event there may be a need for capacity building so that ILCs are better able to participate in the prior informed consent procedures on a level playing field. Again the international regime should build upon existing customary laws and practices of communities to reinforce such capacity.

1 Adapting the Procedures for Prior Informed Consent

The procedures for securing prior informed consent under Article 15 of the Convention elaborated in the Bonn Guidelines are confined to those from a Contracting Party. To what extent can these procedures be adapted to the prior informed consent from TK holders when associated TK is being accessed? In addition to the proposal for the incorporation – directly or indirectly – of procedures established by customary law, the international regime could establish fundamental elements which should be adopted as the ‘minimum’ procedures for obtaining prior informed consent from ILCs.⁶³

These would be particularly useful where the procedures are unclear or are inadequate to protect the rights of ILCs. There is of course the danger that reducing that which may not be reducible – the rich jurisprudential community or contextual-based diversity which exists across the tapestry of indigenous peoples and communities spread throughout the world – could undermine the fundamental construct of customary laws and practices. Homogenized and mono-culturalized TK is antithetical to its conceptual underpinning and a contradiction in terms. What is being suggested, however, is a set of ‘core principles’ gleaned from across this rich universal diversity of extant TK. As was lucidly stated:

The diversity of the very subject of TK and its customary modes of protection may require instead, a *suorum genorum* framework – a heterogeneous network of mutual recognition that does not confine TK into one distinct genus, but recognizes that divergent knowledge traditions, integrated with customary law, warrant recognition as distinct genera, under the aegis of a general set of core principles.⁶⁴

The Bonn Guidelines list both principles and elements of a prior informed consent system. One of the principles includes the consent of ILCs ‘as appropriate to the circumstances and subject to domestic law’. A key element is the establishment of a national competent authority for granting, or providing evidence of, prior

⁶² Decision VII/16H, Annex, items 4 and 5, available at: www.cbd.int/decisions/cop/?m=cop-07.

⁶³ The customary protocol developed by the *Talaandig* community includes elements from the Philippines Indigenous Peoples Rights Act: Krystyna, *supra* note 33, at 25.

⁶⁴ Tauban, ‘Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge’, in M. Alexander, P. Hardison, and M. Ahren, *Study on Compliance in Relation to the Customary Law of ILCs, National Law, Across Jurisdictions, and International Law: A Consultancy Paper* (2009), at 20.

informed consent. The TK Expert Group emphasized the need for legal recognition of a competent authority *at the community level* with a statutory mandate – an ‘ILC competent authority’. Otherwise there could be a risk that customary law would be replaced by local government regulations. The TK Expert Group also added to, and elaborated upon, the elements referred to in the Bonn Guidelines. For example, the ‘process’ element was fleshed out to include: a written application; wide notification of applications; applications to be widely accessible; adequate timing and deadlines; and specification of use with a clause to address change of use and transfer to third parties.⁶⁵ The essence of establishing these elements, or requiring their adherence, is to ensure the legitimacy of the prior informed consent process and decision-making from the perspective of the ILCs. In other words the process must be culturally appropriate, in accordance with the established customary laws, practices, and protocols, and be fair and comprehensive.

2 Best Practices

Several ILCs have instituted community protocols which are related to access to associated TK. These protocols have built upon, and even revitalized, the customary laws and practices. Some communities have established an entire functioning management regime based on customary law. An example is the project in the Peruvian Andes being developed to design models to access and distribute benefits

based on a revitalized customary law of *Quechua* communities from the ‘Potato Park’ – which encompasses 8,661 hectares owned by some 8,000 villagers from six communities in the Sacred Valley of the Incas.⁶⁶ The indigenous peoples of Peru and Ecuador have also recommended the development of a set of common protocols based on common customary law for regulating access to TK and to require that compliance with these should be required in national ABS laws.⁶⁷ In the southern Philippines, a *Talaandig* community has formulated and implemented its community protocol to govern access to biological resources in an area which is part of its ancestral domain. This is pursuant to a law which requires that prior informed consent must be ‘obtained in accordance with customary laws of the concerned community’.⁶⁸ The recognition of community protocols and practices by national law would formally strengthen their legitimacy by obliging adherence, especially if accompanied by sanctions.

A unique opportunity now presents itself for an international regime to integrate customary laws and practices into the prior informed consent procedures and processes. These should be community specific to take into account the diversity of such laws and practices in multi-cultural communities. Where no such laws or practices exist, or they are

⁶⁵ Other desirable elements suggested for inclusion are prior informed consent on the basis of MATs, a consultation process with ILCs, and procedures consistent with customary practices.

⁶⁶ Colchester, ‘Peru: Visit to a “Potato Park”’, 73 *World Rainforest Movement Bull* (2003), available at: www.wrm.org.uy/bulletin/73/Peru.html.

⁶⁷ Alexander, Hardinson, and Ahren, *supra* note 64, at 9.

⁶⁸ S.35, The Philippines Indigenous Peoples Rights Act 1997, available at: www.glin.gov/view.action?glinID=61555.

weak, then core prior informed consent procedures may be developed with the involvement and consent of ILCs. Where even this is not possible or feasible, then the fundamental common elements of such laws and practices should be used as the basis for the procedure for prior informed consent. The international regime negotiations offer this opening – a tide to be taken at the flood.⁶⁹

H Tracking and Monitoring Use of Traditional Knowledge

Where TK is properly accessed there is still the issue of the subsequent use of the TK. First, it must be in accordance with the basis on which the access was granted and the benefit-sharing terms agreed upon. The user would have to disclose the specific utilization of the TK in the access application; and access be granted for this use. The value of the resource, and the benefit-sharing terms, will be based on this use. Secondly where the associated TK is transferred to a third party, the same conditions as in the original agreement should continue to apply. It may be difficult to monitor and track compliance with these conditions. One solution is to require disclosure of compliance with the prior informed consent requirement of ILCs and other access conditions at various checkpoints – such as at the point of product registration or patent application. This could help track adherence to the original access terms. In particular, it could help prevent leakage of the agreed

benefits. The Expert Group highlighted the value of a certificate of compliance issued by the provider. The components of the certificate could include: whether or not there is associated TK involved; the holders of the TK; and whether or not the user has complied with indigenous customary law, community protocols, and other consent or decision-making processes; and whether there has been a change of use or transfer to a third party. Although this helps tracking and monitoring, there could still be serious jurisdictional issues in enforcing the obligations. More crucially, severe tracking difficulties could arise from the physical and informational nature of genetic resources and the dynamics of technologies which make use of them at different stages of the research and development process.⁷⁰ This could be particularly true in the case of genetic resources which are, in essence, coded information.⁷¹

4 Conclusion

This article has outlined the problems and prospects in incorporating associated TK into a prospective international regime. With the road map charted by the TK Expert Group the negotiators now have a clear direction on this complex component of an international regime. Expert group reports have varying degrees of

⁶⁹ Adaptation from William Shakespeare, *Julius Caesar* (1599–1600), 4.3.218: ‘There is a tide in the affairs of men which taken at the flood leads on to fortune.’

⁷⁰ M.R. Muller and I. Lapena (eds), *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows* (2007), at 118.

⁷¹ *Ibid.*, at 118, citing Report from the Regional Biopiracy Prevention Workshop, Bogota, 2005, available at: www.biopirateria.org.

influence on the final outcome of negotiations. Often political choices decide the impact of such an input. Nonetheless, as the report of the Expert group – and this

article – makes clear, there are practical solutions to overcoming the intricate issues posed by the interface between TK and an international ABS regime.