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The Protection of Traditional Knowledge Related to Genetic Resources: The case for a modified patent application procedure

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Abstract

This work assesses some of the ways in which TK related to genetic resources is protected. The first part addresses the use of patents and their shortcomings in protecting this type of knowledge. To compensate for these weaknesses, the second section of this work argues for the inclusion of sui generis elements into patent law. With regard to TK related to genetic resources, the introduction of procedural safeguards into the patent application procedure would provide an effective model of protection. The final part of this work will address the international dimension of TK protection.

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Introduction

Traditional knowledge in its numerous forms is an integral part of the indigenous and traditional communities¹ from which it originates. Traditional knowledge (TK) is often entwined in the culture and spirituality of these communities and can provide a form of self-identification. This intrinsic cultural and spiritual value has been supplemented by its potential value in non-traditional contexts, and indigenous communities have seen their heritage dispossessed and misappropriated. In introducing a variety of legislative, administrative and judicial means with which to protect traditional knowledge, policy-makers are faced with the challenge of protecting TK for its intrinsic value to indigenous communities as well for its value in a commercial context. The question of TK protection is also often part of a wider discourse surrounding indigenous peoples' minority rights. This work assesses some of the ways in which TK related to genetic resources is protected. The first part addresses the use of patents and their shortcomings in protecting this type of knowledge. To compensate for these weaknesses, the second section of this work argues for the inclusion of *sui generis* elements into patent law. With regard to TK related to genetic resources, the introduction of procedural safeguards into the patent application procedure would provide an effective model of protection. The final part of this work will address the international dimension of TK protection. Indeed, any approach taken needs to be international in application to provide global guarantees that TK will not misappropriated.

1. The trouble with patents

1.1 Indigenous communities and patents

The growing use and vast potential of TK related to genetic resources has led to an increase in the patenting of inventions based on genetic resources or information pertaining to them. Certain initial problems surround the patenting of TK, however, as in many cases TK has been passed down through several generations and at first sight might not meet the criteria of novelty and inventive step. This view misconstrues the true nature of TK, however, which should not be regarded simply as "old" knowledge² and although much of TK originates in the past, it is not static. There is usually no single act of discovery when creating TK³ but each new generation or individual which develops such knowledge contributes and adds to that knowledge base. These contemporary developments go some way to satisfy the double test.

Indigenous communities also face practical obstacles when patenting TK. Often they do not possess the requisite technical know-how needed to complete an application.⁴

¹ To avoid confusion related to terminology, the term indigenous community will be used throughout this work but should be considered interchangeable with the term traditional community.

² World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Review of Existing Intellectual Property Protection of Traditional Knowledge* (2002), WIPO/GRTKF/IC/3/7, at para. 33.

³ Dutfield, G., 'Protecting Traditional Knowledge and Folklore', in Grosheide, F.W., Brinkhof, J.J. (eds.), *Intellectual Property Law: Articles on The Legal Protection of Cultural Expressions and Indigenous Knowledge* (2002), pp. 63-86, at p. 79.

⁴ *Ibid.*, at p. 80.

A shaman will be aware of the medicinal qualities of certain plants, but may not be in a position to provide the chemical structure of the active compounds and the scientific specification required to satisfy a patent examiner. This problem may be overcome through raising the technical competence of indigenous communities and providing them with technical, scientific and legal support. This long term capacity-building within indigenous communities is central in empowering them, enabling them to retain control over their resources.

Before this level of technical development is achieved, this side of developing TK for wider use outside indigenous communities often lies with private companies or public institutions such as universities. This brings with it issues regarding joint-inventorship, which can be granted only if both parties contribute directly to the inventive concept.⁵ When genetic resources form the basis of a patent application, the input of indigenous communities can be limited to plant identification while product developers or public institutions identify, isolate and purify the active chemical compounds. One possible solution is the relaxing of the rules regarding joint-inventorship, as in Brazil, where IPRs granted on the basis of TK automatically grant co-proprietorship to the source community.⁶ Although guaranteeing protection for the source community at an early stage, this approach does not seem correct as it does not provide for the equitable recognition of the work completed. Although indigenous communities can play a crucial role in the development of new products, this does not compare with the time or resources expended on further R&D. Communities should still be recognized as the source of the original knowledge or genetic material and be compensated as such.

The cost of enforcing patents is one of the main shortcomings regarding their use by indigenous communities in protecting TK. In cases where indigenous communities are aware of the violation of their rights, they often struggle to meet the financial burden of applying for or challenging patents. Transaction costs for enforcement need to be reduced since at present they are prohibitively costly and complicated.⁷ Insight may be gained from the TRIPs regime applicable to designs which stipulates that

*requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection.*⁸

Besides financial aid, the need to build the technical and legal capacity of indigenous communities is again apparent as is the need for access to information and good legal

⁵ Blakeney, M., 'Ethnobiological Knowledge and the Intellectual Property Rights of Indigenous Peoples in Australia', in Blakeney, M. (ed.), *Perspectives on Intellectual Property: Intellectual Property Aspects of Ethnobiology* (1999), pp. 83-99, at p. 93.

⁶ Da Costa e Silva, E., 'The Protection of Intellectual Property for Local and Indigenous Communities', [1995] 11 EIPR 546, at p. 549.

⁷ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – An Overview* (2001), WIPO/GRTKF/IC/1/3, at para. 82.

⁸ Article 25.2, Agreement on Trade-Related Intellectual Property Rights (hereinafter TRIPs Agreement).

advice.⁹ In the short term, this role may be filled by specialist NGOs through information provision, fundraising, technical and research assistance, skill transfer or networking.¹⁰ Long term capacity-building projects need to be established as NGOs impose their own perspective on proceedings and reliance on them creates financial and other dependence for the indigenous communities in question.¹¹ The creation of an ombudsman or public defender has also been proposed.¹² This figure could provide legal assistance and have a mandate to investigate alleged infringements. In some countries there may be reluctance to instate such an ombudsman, however, as his or her remit could also include the investigation of other abuses directed against indigenous communities, perhaps by the hands of their own governments. As patents have proved insufficient in protecting TK related to genetic resources, other mechanisms have been used to compensate for these inadequacies. This work focuses on the use of contracts, voluntary codes of conduct and databases to supplement patents in the protection of TK related to genetic resources.

1.2 Helping hand

1.2.1 Contracts to ensure access and benefit-sharing

Regarding access to genetic resources and ensuing benefit-sharing, contracts have become 'the most common way of recording mutually agreed terms.'¹³ Examining the provisions of access contracts can provide insight into effective benefit-sharing regimes. Private entities such as pharmaceutical or cosmetic companies and public bodies such as universities have entered into contractual agreements with indigenous communities. These are collectively termed Material Transfer Agreements (MTA) or Information Transfer Agreements (ITA) and often set out mutually agreed terms.¹⁴ In Colombia, for example, this mechanism is compulsory and patent applications based on the use of genetic resources must include a copy of the contract of access.¹⁵ The EC has also felt that '[i]n accordance with the CBD [Convention on Biological Diversity], countries could incorporate in their national legislation requirements for the conclusion of such contracts.'¹⁶ As this contractual regime remains on a voluntary basis in many countries, the point of establishing minimum standards for access

⁹ Posey, D.A., Dutfield, G., *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities* (1996), at p. 76.

¹⁰ Kloppenburg, Jr., J., Gonzales, T., 'Between State and Capital: NGOs as Allies of Indigenous Peoples', in Greaves, T. (ed.), *Intellectual Property Rights for Indigenous Peoples: A Sourcebook* (1994), pp. 163-177, at pp. 168-170.

¹¹ *Ibid.*, pp. 170-172.

¹² Dutfield, G., *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties* (2000), at p. 81.

¹³ Convention on Biological Diversity, Conference of the Parties, *Addressing the Fair and Equitable Sharing of the Benefits Arising Out of Genetic Resources: Options for Assistance to Developing Country Parties to the Convention on Biological Diversity* (1998), UNEP/CBD/COP/4/22, at para. 32.

¹⁴ Article 15(4) of the Convention on Biological Diversity stipulates that access to genetic resources shall be on mutually agreed terms.

¹⁵ WIPO/GRTKF/IC/3/7, *supra* note 2, at para. 11.

¹⁶ Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made* (2002), WTO/IP/C/W/368, at para 21.

agreements has been raised.¹⁷ WIPO has gone some way to this end by drafting IP guidelines for access and benefit-sharing.¹⁸

MTAs and ITAs can deal with *in situ* as well as *ex situ* conservation, benefit-sharing, technology transfer, patent protection, confidentiality of publications, access to data and materials and capacity-building. Benefit-sharing can be negotiated as a combination of advance or milestone payments or on a long-term royalty basis. Immediate investments can thus be guaranteed while still providing for more equitable and just payment related to royalties. Technology transfer can be addressed by ensuring that the results of the ensuing research are shared with the relevant communities and that scientific collaboration with local scientists is offered.¹⁹ Technology transfer is a key element of benefit-sharing and, importantly, is also one of the objectives of the TRIPs Agreement.²⁰ Linked to technology transfer and to the long term development of indigenous communities, capacity-building has taken a central role in benefit-sharing regimes and should form the cornerstone of any access contract. Moreover, equitable benefit-sharing does not only have advantages for indigenous communities. The positive publicity surrounding equitable dealing with source communities can be used to boost consumer image and subsequent sales, as shown by the effect of the Merck-INBio agreement, for example.²¹

This oft-cited agreement raises an interesting issue relating to the parties to access contracts, however. Indigenous communities were excluded from the negotiations between Merck and the Costa Rican national biological sample collecting agency and were not made direct beneficiaries of the ensuing benefits. As Article 3 of the Biodiversity Convention safeguards national sovereignty over biological resources, national government are under no obligation to redistribute benefits to their own indigenous populations. Brush notes that 'nation-states may pass the benefits of appropriating biological resources as commodities on to other groups, but the record of abuse towards minorities and indigenous people should raise scepticism.'²² Parallel to the issue of improved protection for TK, indigenous communities may face a broader struggle for respect of their other rights. Here the idea of an ombudsman with a wider mandate becomes even more attractive. Within IP law, any system of protection must work to protect the rights of the indigenous communities concerned.

Access contracts are not a panacea, however, and cannot alone adequately protect indigenous communities interests. As noted by the African Group at the 7th Session of

¹⁷ Convention on Biological Diversity, Panel of Experts on Access and Benefit-sharing, *Options for Access and Benefit-Sharing Arrangements* (1998), UNEP/CBD/EP-ABS/2, at para. 39.

¹⁸ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, *Traditional Knowledge and Folklore, Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing* (2004), WIPO/GRTKF/IC/7/9.

¹⁹ Cragg, G.M. et al., 'Policies for International Collaboration and Compensation in Drug Discovery and Development at the United States National Cancer Institute, The NCI Letter of Collection', in Greaves, T. (ed.), *supra* note 10, pp. 83-98, at pp. 88-89.

²⁰ Article 7, TRIPs Agreement.

²¹ Asebey, E.J., Kempenaar, J.D., 'Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention', 28 *Vanderbilt Journal of Transnational Law* 703, at p. 728. Asebey and Kempenaar provide a detailed account of the Merck-INBio Agreement at pp. 725-730.

²² Brush, S.B., 'Is Common Heritage Outmoded?', in Brush, S.B., Stabinsky, D. (eds.), *Valuing Local Knowledge: Indigenous People and Intellectual Property Rights* (1996), pp. 143-164, at p. 160.

WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), a central problem with the use of contracts is the unequal bargaining power of the parties.²³ With little experience in negotiating or defending access agreements and few administrative or legal resources, indigenous communities often find themselves at the losing end of such bargains. Growing awareness within indigenous communities and the involvement of local and international NGOs has improved the situation but assistance and training for traditional knowledge holders is still a priority area.²⁴ Here again the importance of capacity-building is highlighted and should form part of any benefit-sharing system. Access contracts have inherent weaknesses, however, and problems include implementing and enforcing them. Moreover, there are often no guarantees that such contracts will be entered into in the first place. Indeed, the use of contracts has been heavily criticised as countries have argued that contracts do not provide the necessary guarantees to sufficiently protect TK. At the 7th IGC India emphatically stated that '[h]owever carefully any model contract is drafted, however ardently such contracts try to correct the huge imbalance between the provider and the user, such an approach simply cannot lead to anything even remotely resembling a fair and equitable regime.'²⁵ This view received the support of Brazil, which felt that too much time was being expended in developing contractual guidelines while the real issue to be tackled lay elsewhere. The Brazilian delegation also disapproved of making the disclosure of origin requirement dependant on a contractual regime which ultimately remains of a voluntary nature.²⁶ A system of safeguards in a universally binding instrument is therefore needed, which guarantees that TK which forms the basis of an invention or innovation has been legitimately obtained. Introducing *sui generis* elements into the patent application procedure is a possible solution.

1.2.2 Voluntary guidelines and codes of conduct

The growing number of private codes of conduct is evidence of the favour which this mechanism has found with industry.²⁷ A case study submitted to the CBD Secretariat by Switzerland

*shows a survey in which companies and institutions that are the users of genetic resources consider a voluntary code of conduct as the most promising instrument to implement incentives to further cooperation between providers and users of genetic resources and conclude that such a code constitutes the most practical approach.*²⁸

²³ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Draft Report of the Seventh Session* (2004), WIPO/GRTKF/IC/7/15 Prov. 2, at para. 187.

²⁴ WIPO/GRTKF/IC/1/3, *supra* note 7, at para 84.

²⁵ WIPO/GRTKF/IC/7/15 Prov. 2, *supra* note 23, at para. 175. See also para. 183 for Ecuador's contribution on this point.

²⁶ *Ibid.*, at para. 183.

²⁷ Abesey, E.J, Kempenaar, J.D, *supra* note 21, at pp. 742-743. The voluntary internal policies of Glaxo Welcome (now Glaxo SmithKline) and Novo Nordisk are noted in Convention on Biological Diversity, Conference of the Parties, *Review of National, Regional and Sectoral Measures and Guidelines for the Implementation of Article 15* (1998), UNEP/CBD/COP/4/23, at para. 57.

²⁸ UNEP/CBD/EP-ABS/2, *supra* note 17, at para. 15.

However, as Asebey and Kempenaar point out, 'even the most conscientious corporations almost never adhere to their codes of conduct in relations with developing countries.'²⁹ Additional measures are needed and international instruments have been developed in parallel to these private codes.

These include the FAO International Code of Conduct for Plant Germplasm Collection and Transfer, which deals with agricultural uses of genetic resources, recognises the impact of actors other than plant collectors, such as donors, sponsors, users and curators,³⁰ and encourages the use of material transfer agreements and benefit-sharing.³¹ Although the voluntary nature of the Code permitted drafters to include elements of benefit-sharing and enlarged responsibility for a wider range of actors, at a relatively early stage in the TK protection discourse, it is also its largest weakness. Although used by at least one country to establish national legislation,³² the application of the guidelines cannot be legally enforced.

Under the aegis of the Biodiversity Convention, the Bonn Guidelines were adopted to specifically deal with issues relating to access and benefit-sharing relating to genetic resources. States Parties are invited to designate a national focal point³³ to provide external actors with the possibility to easily identify the relevant parties to be consulted. The Guidelines also address issues such as increasing indigenous community participation and capacity to participate,³⁴ prior informed consent,³⁵ and mutually agreed terms.³⁶ The Bonn Guidelines also call for benefit-sharing to be instituted for derivatives of genetic products.³⁷ The aim of this provision is of course to avoid the problems related to synthesized genetic resources or derivative materials or products which may lead to by-passing the need to provide anything but initial compensation. One solution for protecting derived products may be to apply provisions similar to those found in software licensing agreements.³⁸ Licensees of TK relating to genetic resources could be allowed to modify those resources but source communities would retain ownership rights in the modified products. Although detailed in the issues relating to genetic resources, the Bonn Guidelines also remain voluntary. The WIPO IGC has also developed guidelines in the form of the draft IP guidelines for access and benefit-sharing.³⁹ As with any other guidelines, strict

²⁹ Abesey, E.J., Kempenaar, J.D, *supra* note 21, at p. 743.

³⁰ WIPO/GRTKF/IC/1/3, *supra* note 7, at para. 39.

³¹ Article 13(3), FAO International Code of Conduct for Plant Germplasm Collection and Transfer.

³² Botswana. See <http://www.un.org/esa/agenda21/natlinfo/countr/botswana/natur.htm> (visited August 2004).

³³ Article 13, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (hereinafter Bonn Guidelines).

³⁴ Article 16(a)(vi)-(vii), Bonn Guidelines.

³⁵ Article 16(d) and Articles 24-40, Bonn Guidelines.

³⁶ Article 16(b) and Articles 41-50, Bonn Guidelines.

³⁷ Article 44(i), Bonn Guidelines.

³⁸ Posey, D.A., Dutfield, G., *supra* note 9, at pp. 69-70.

³⁹ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Genetic Resources: Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts* (2004), WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9, *supra* note 18.

adherence cannot be guaranteed, and none of the above measures may ultimately prove to guarantee sufficient protection of TK.

1.2.3 Databases and community registers

The use of databases and community registers to protect TK has also been advocated. Defensive publication is used to block the grant of a patent by entering information held by indigenous communities into the public domain. This in turn makes the TK in question part of the prior art whereby a patent application based on it would no longer satisfy the novelty test.⁴⁰ However, patent examiners in certain jurisdictions, most notably the USA, do not extend their search to other countries. To rectify this, all national patent regulations should stipulate an international search of prior art. However, an immediate drawback of placing information in the public domain is that it becomes very difficult to control.⁴¹ Although no longer in a position to patent the knowledge in question, non-indigenous actors could still use that TK to develop new products. By voluntarily placing information in community registers indigenous communities also forgo the possibility of receiving compensation for that knowledge. Open-access databases should only be used for TK which is already in the public domain or for which prior informed consent has been obtained.⁴² Insight as to how to obtain compensation for TK in the public domain may be gained from systems of *domaine public payant* whereby royalties are paid for the use of artistic or musical works in the public domain.⁴³ To avoid this issue of non-compensation, confidential registers have been proposed.

Information contained in limited access databases cannot be used without compensation. Indeed, the aim of these registers and databases is not only to document TK but also to encourage technology transfer and equitable business relationships between indigenous communities and non-indigenous users of TK.⁴⁴ As envisaged by the Biodiversity Convention clearing-house mechanism, such registers place interested parties in contact with each other. Indigenous communities can place information on confidential registers outlining the content and use of their TK without revealing commercially valuable details. Interested companies are then able to approach these communities through the appropriate body and establish proper commercial links. This mechanism is not problems free, however, as some indigenous communities have lacked confidence and trust in such a system and have preferred not to divulge TK at all. Although this in part may be as a result of mistrust towards prospective partners, confidence-building measures aimed at bridging the gap

⁴⁰ Posey, D.A., Dutfield, G., *supra* note 9, at p. 36 and p. 80.

⁴¹ Posey, D.A., *Traditional Resource Rights: International Instruments for Protection and Compensation for Indigenous Peoples and Local Communities* (1996), at p. 46.

⁴² World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *The Protection of Traditional Knowledge and Folklore: Summary of Issues Raised and Points Made* (2002), WTO/IP/C/W/370, at para. 16.

⁴³ WIPO/GRTKF/IC/1/3, *supra* note 7, at para. 73(iv).

⁴⁴ Examples include the People's Biodiversity Register and the local innovation databases of the Society for Research and Initiatives for Sustainable Technologies and Institutions, both in India. See Dutfield, G., 'Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India', in Blakeney, M. (ed.), *Perspectives on Intellectual Property*, *supra* note 5, pp. 101-122, at pp. 117-121.

between indigenous and non-indigenous users may be introduced leading to a rapprochement between the various parties.

The creation of a global bio-collecting society (GBS) has been proposed to deal with these issues on a global scale.⁴⁵ Any information provided by indigenous communities would be strictly confidential and the GBS – while also serving to assist in contractual negotiations and monitoring the use of TK – would serve as a point of contact for interested parties.⁴⁶ As information on these registers is not in the public domain, complete confidentiality within the GBS, but also within the indigenous communities in question, must be guaranteed. Any such strategy will otherwise fail as information obtained in ignorance as to the real source of information, or by less scrupulous means, can lead to the granting of a patent and undermining of the system. To ensure this confidentiality the coupling of digital rights management with TK has been proposed.⁴⁷ Nevertheless, the use of patents, even when supplemented by additional private law mechanisms, has not always proved adequate to protect TK related to genetic resources.

2. A modified patent application procedure

2.1 An IPR led approach

It is clear that a pragmatic and enforceable system of protection is needed. Despite the shortcomings of the patent regime, the use of patents to protect TK related to genetic resource should not be dismissed out of hand.⁴⁸ Patent law can be modified and by adding *sui generis* elements sufficient protection of indigenous communities' rights can be achieved. It is submitted that this is best achieved by introducing procedural safeguards into the patent application procedure. Concentrating protection efforts on the relevant subject-matter renders it easier to define rights and administer and enforce them.⁴⁹ A system introducing *sui generis* elements into existing conventional IPRs will also prove conceptually easier to adopt in many countries than other, such as rights-based, approaches. Using the well-established patent paradigm will enable effective interpretation and application by patent offices which deal with applications. To minimize alienating critical industry acceptance of this proposal, these safeguards are of a procedural nature and limit the additional burden placed on applicants. The introduction of three procedural safeguards within patents is proposed.

⁴⁵ See Drahos, P., 'Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?', [2000] EIPR 245.

⁴⁶ *Ibid.*, at p. 248.

⁴⁷ See Owens, R., 'Digital Rights Management and Documentation of Traditional Knowledge: Strange Bedfellows?', in Grosheide, F.W., Brinkhof, J.J. (eds.), *supra* note 3, pp. 201-218.

⁴⁸ Dutfield, G., *supra* n. 44, at p. 115.

⁴⁹ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Traditional Knowledge: Policy and Legal Options* (2003), WIPO/GRTKF/IC/6/4, at para. 54.

2.2 A new patent application procedure

2.2.1 Disclosure of origin

When applying for a patent for an invention which is based on TK related to genetic resources or information pertaining to these resources, an applicant should be under an obligation to disclose the origin of the material used. This could come under the form of a certificate of origin indicating where the resource or information was obtained from. Besides the legal support this would give indigenous communities in their own countries, on an international level this would provide patent examiners from third countries with a starting point for prior art searches and would give them the possibility of liaising more effectively with the focal points in the country of origin of the TK. Identifying these focal points will facilitate third country patent examiners in confirming that the requirements of local access regulations had been met. It should be noted that an attempt to introduce the disclosure of origin requirement for plant and animal genetic resources has been made at the European level.⁵⁰

When negotiating the Biotech Directive the European Parliament called for the adoption of a separate amending article, the first part of which ‘stipulates that patents relating to such material [biological material originating from plants or animals] will only be granted if the geographical place of origin of the material is mentioned and if the patent applicant provides evidence (to the patent office) to the effect that the material was used in accordance with the regulations regarding access and export in force in the place of origin of the material.’⁵¹ This amendment was rejected by the Commission. A watered-down version of this provision found its way into the final version of the Biotech Directive as Recital 27 which reads:

Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents

Placed in the Directive’s Preamble the provision lacks legally binding effect. More importantly, the requirement itself is largely ineffective as the origin of the material need only be provided if it is known. Applicants are under no obligation to ascertain what the origin is, a problem which is magnified as much bio-prospecting is outsourced and carried out by intermediaries.⁵² In any case, indicating the origin of the material has no legal effect on patent applications filed or on the rights granted

⁵⁰ For the full text of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter Biotech Directive) see http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf (visited July 2004). For a more detailed analysis of the provision’s passage into the Biotech Directive see Sterckx, S., ‘Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions’, [1998] EIPR 123.

⁵¹ Ibid., at p. 125 (footnote omitted).

⁵² ten Kate, K., Laird, S.A., *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (1999), at p. 302.

under such patents. Further legislative attempts must be undertaken and an effective provision requiring the disclosure of origin should be introduced. Reform will be difficult to achieve, however, as it will encounter fierce resistance from the private sector, which favours the use of contractual models discussed above. For example, it has been argued that introducing the disclosure requirement into the patent application procedure would not reflect the features and conditions of the Biodiversity Convention and would not take into effect the practical impact of the measures.⁵³ Introducing a disclosure requirement into the patent application procedure would bring with it additional costs but these should not prove to be inhibitive.

2.2.2 *Prior Informed Consent*

Having identified the origin of the material through certification provided with a patent application, it is easier for a patent examiner to confirm whether an applicant has complied with the requirement of prior informed consent (PIC). Posey and Dutfield propose the following definition:

*Prior informed consent is consent to an activity that is given after receiving full disclosure regarding the reasons for the activity, the specific procedures the activity would entail, the potential risks involved, and the full implications that can realistically be foreseen. Prior informed consent implies the right to stop the activity from proceeding, and for it to be halted if it is already underway.*⁵⁴

The key element here is the issue of control. Enabling indigenous communities to retain control over their animal or plant resources will be facilitated by introducing the requirement of PIC at the patent application stage. To enable PIC to be obtained as easily and as quickly as possible, a system of clearly established legislative, administrative and policy measures needs to be put into place in countries with indigenous communities.⁵⁵ This may again come in the form of national focal points designated to deal with such issues. In order to avoid disincentives for potential private-sector partners, time-frames also need to be established for the grant or denial of PIC.⁵⁶

Legislative efforts regarding PIC have been made in Europe. Recital 26 of the Biotech Directive calls for consent to be obtained where the patent application is based on biological material of human origin or if it uses such material. This provision should be further developed, however, and free and informed consent should be obtained from the owners or holders of plant or animal genetic resources as well. Moreover, the provision should be made legally-binding. Insight may be gained from Belgian patent

⁵³ WIPO/GRTKF/IC/7/15 Prov. 2, supra note 23, at para. 198.

⁵⁴ Posey, D.A., Dutfield, G., supra note 9, at p. 47.

⁵⁵ UNEP/CBD/EP-ABS/2, supra note 17, at para. 3(b).

⁵⁶ Convention on Biological Diversity, Conference of the Parties, *Review of National, Regional and Sectoral Measures and Guidelines for the Implementation of Article 15* (1998), UNEP/CBD/COP/4/23, at para. 43.

law which holds that a patent is against the *ordre public* if it is done in violation, inter alia, of CBD Article 15 which includes the PIC requirement.⁵⁷

2.2.3 Benefit-sharing with a focus on capacity-building

When applying for a patent, applicants should be under a procedural obligation to enter into benefit-sharing negotiations with TK source communities. Similar to the obligation to carry out an environmental impact assessment, parties should not be bound as to the result of the negotiations, but would need to address certain key issues. At the least these would include negotiations relating to monetary benefits including access fees, up-front, milestone and royalty payments, licence fees, and research funding. Negotiations relating to non-monetary benefits should cover the sharing of research results, collaboration, co-operation and contribution in the provider country or community, participation in product development and education and training.⁵⁸ Capacity-building should be the focus of any benefit-sharing model. The indigenous community which is the source of TK should be left with long-term benefits such as research and development infrastructure and the capacity to add value domestically.⁵⁹ This would further empower indigenous groups. Moreover, including the negotiation of capacity-building measures, such as technology transfer, as a procedural obligation of a patent application would shift the onus of technology transfer from States, as provided for in the CBD and TRIPs, onto the private businesses and public institutions which in fact own this technology.

2.3 Intellectual property law: forum non conveniens?

It has been argued that the purpose of patent law is neither to regulate access and use of genetic resources nor to regulate the terms and conditions of bio-prospecting or any resulting commercialization of patent-protected inventions.⁶⁰ Instead, these should be regulated either through private law mechanisms such as contracts, specific access legislation, or *sui generis* systems of protection. Although such models may work in some instances, they have not proven to be effective in all cases. As contracts can be hard to implement and enforce patents can provide a further safety net to protect the rights of indigenous communities. Although the rationale underlying IPRs is not to act as access legislation, in practice patents can be and are used as tools to this end. Patents provide an exclusionary property right and effectively control access to an invention. WIPO notes that '[t]he idea to be retained is that IP is the right to say "no" to third parties (and consequently, the right to say "yes" to a person who requests

⁵⁷ Owens, R., supra note 47, at p. 258. A patent in Belgium is also against *ordre public* if it does not meet the requirements of Biodiversity Convention Article 3 relating to national sovereignty, Article 8(j) relating to indigenous community rights, and Article 16 relating to technology transfer.

⁵⁸ For a more complete list of monetary and non-monetary benefits to be addressed, see for example Appendix II of the Bonn Guidelines or Appendix I of the Annex to WIPO/GRTKF/IC/6/5, supra note 39.

⁵⁹ Grifo, F.T., Downes, D.R., 'Agreements to Collect Biodiversity for Pharmaceutical Research: Major Issues and Proposed Principles', in Brush and Stabinsky (eds.), supra note 22, pp. 281-304, at p. 282.

⁶⁰ Opinion of the EC in WTO document IP/C/W/254, cited in WTO/IP/C/W/368, supra note 16, at para. 21.

permission to reproduce and/or fix and/or use the protected subject matter).⁶¹ A patent permits the right holder to exclude all third parties from the use of, in other words control access to, the product or process which it protects. When an invention is based on a genetic resource, the use of that resource can consequently also be limited.

Moreover, it is legitimate to include the requirement to enter into benefit-sharing negotiations in patent law. Traditional licensing agreements deal with benefit-sharing, as licensees provide compensation to the owners of a patent in return for use of the latter's invention. Although the terms of licensing agreements are not pre-determined in legislation, negotiation in good faith between the parties is implied. With respect to TK, parties should be under a duty to enter into negotiations regarding benefit-sharing, without being bound as to the result. This procedural safeguard would provide indigenous communities with the guarantee that partner companies and institutions adequately address issues relating to benefit-sharing. It would not, however, tie the hands of the commercial users of these resources as to the result of such negotiations. Furthermore, applicants would be under an obligation to prove that such negotiations had taken place, but would not need to jeopardise the commercial confidentiality of the ensuing agreements.

3. The need for internationally enforceable minimum standards

3.1 An international regime

Intellectual property protection is far from a purely national issue. Suthersanen notes that

*The benefits and harm which may entail in relation to extracting or using organic or informational resources effect [sic.] are not merely national matters, to be regulated by national governments, but have a trans-border impact effecting manufacturing, distribution, and consumer trends in other regions.*⁶²

In this context it is interesting to note Latvia's contribution to WIPO's study of measures used to protect TK.⁶³ With no indigenous populations of its own, Latvia held that it had no need to introduce legislation to protect TK. This view ignores the vital issue of protecting TK which originates in a third country and to provide a comprehensive system of protection, TK must be protected also outside its country of origin. A concerted, global approach incorporating internationally enforceable minimum standards is needed.

Non-customary users of TK would also benefit from an international regime. The disclosure requirement, for example, has been justified by the added certainty and predictability for governments, investors and researchers; it would improve R&D

⁶¹ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Elements of a Sui Generis System of Protection of Traditional Knowledge* (2002), WIPO/GRTKF/IC/4/8, at para. 35.

⁶² Suthersanen, U., 'Legal and Economic Considerations of Bioprospecting', in Blakeney, M. (ed.), *supra* note 5, at p. 79.

⁶³ WIPO/GRTKF/IC/3/7, *supra* note 2, at para. 30.

investment in developing countries and facilitate the conclusion of contracts such as MTAs and ITAs.⁶⁴ If rules and procedures are clearly defined, and all the relevant national actors are identified, it is more likely that agreements with indigenous communities and source countries will be entered into.⁶⁵ It is often the lack of transparency which makes prospective partners reluctant to acquire TK. Apart from this economic argument, the WTO identifies food security, development and the protection of culture and the environment as reasons for an international regime of TK protection.⁶⁶

The following paradox also justifies internationally enforceable minimum standards. In today's technology and information led economies, developed countries aim to encourage investment, both domestic and foreign, by improving the scope and terms of IP protection.⁶⁷ The opposite holds true with regard to TK. Where two countries have similar genetic resources, interested parties from third countries will choose the country with the lowest standards of protection and the lowest benefit-sharing requirements.⁶⁸ In a survey of companies using plant genetic resources, ten Kate notes that '[s]everal said they would avoid working in countries that have adopted stringent access regimes.'⁶⁹ A strategy of providing freer access often proves to have only short-term advantages, however, as investment in long-term projects and capacity-building is sidelined. Internationally enforceable minimum standards would guarantee global protection for TK and the safeguards introduced would go some way in guaranteeing that the indigenous communities in question are dealt with equitably.

3.2 International enforcement: the role of the WTO

With regard to enforcing the protection of TK in an international context and specifically relating to the use of patents to protect genetic resources, several international fora may be available. At first glance, Article 8(j) and 15 of the Biodiversity Convention seem to provide a suitable normative framework for the protection of genetic resources and indigenous communities' interests. The inherent disadvantage of the CBD is that it only offers a non-binding dispute settlement mechanism.⁷⁰ If Parties to the Convention cannot settle their dispute through negotiation,⁷¹ 'they *may* jointly seek the good offices of, or request mediation by, a third party.'⁷² Moreover, it is up to the discretion of the Parties to accept one of two compulsory dispute settlement mechanisms, viz. arbitration or submission to the

⁶⁴ Opinions of Brazil and India cited in WTO/IP/C/W/368, *supra* note 16, at para. 25.

⁶⁵ Gibson notes the Australian government's efforts to encourage investment by guaranteeing legal certainty in Gibson, J., 'Traditional Knowledge and the International Context for Protection', (2004) 1:1 *SCRIPT-ed*, at p. 3.

⁶⁶ WTO/IP/C/W/370, *supra* note 42, at para. 8.

⁶⁷ Drahos addresses this trend in Drahos, P., 'Biotechnology Patents, Markets and Morality', [1999] *EIPR* 441, at pp. 445-446.

⁶⁸ UNEP/CBD/COP/4/23, *supra* note 56., at para. 17(d).

⁶⁹ ten Kate, K, Laird, S.A., *supra* note 52, at p. 301.

⁷⁰ Article 27, Biodiversity Convention.

⁷¹ Article 27(1), Biodiversity Convention.

⁷² Article 27(2), Biodiversity Convention (emphasis added).

International Court of Justice. It is unlikely that either of these mechanisms will be used. Bengwayan notes that '[o]verall, the Convention lacks teeth: it has no mechanisms to control outsiders' access to indigenous bio-resources [...] and no mechanisms to determine the equitable sharing of benefits.'⁷³ Some moves within the Biodiversity Convention towards are being made, however. With the negotiation of an international regime on access and benefit-sharing, a distinct dispute settlement mechanism may be created.⁷⁴ Nevertheless, there is still some way to go before an agreement on such an international regime is reached.

Although WIPO has undertaken vital research and administrative work related to the protection of TK, it is not an international enforcement organization and can only make recommendations to States regarding the introduction of IP-related legislation. It should be noted that although WIPO has a fully functioning Arbitration and Mediation Centre, as its name suggests, this organ only has limited competence. Although WIPO has been requested to facilitate discussions relating to international standards of TK protection,⁷⁵ it cannot offer a binding dispute settlement mechanism. Furthermore, as it would have required a separate policy decision, the IGC at its 7th Session did not develop further the idea of a specialized tribunal in this area.⁷⁶ It was largely due to the lack of an enforcement mechanism that the Uruguay Round of international trade talks incorporated matters dealing with intellectual property, as many industrialized countries, led by the US, pushed for a compulsory and enforceable regime of global intellectual property protection.⁷⁷ The resulting TRIPs Agreement and associated WTO dispute settlement mechanism provide the best forum for enforcing IPRs internationally.⁷⁸

Some commentators view that '[o]n a juridical level, international economic law may be the only recourse left for the question of bio-prospecting activities in relation to organic or informational sources.'⁷⁹ The idea of introducing the provisions of the CBD into TRIPs was in fact tabled by the African group during the failed Seattle round of talks.⁸⁰ As the Agreement stands, therefore, TK related to genetic resources is protected merely through conventional IPRs. To provide adequate protection for indigenous communities, new aspects of the Agreement must be negotiated. Although it has been argued that 'the WTO is not the right place to negotiate a fully fledged system of protection for a complex, new, and as yet undefined, subject-matter like traditional knowledge or folklore'⁸¹ such technical work could be carried out – and to

⁷³ Bengwayan, M.A., *Intellectual and Cultural Property Rights of Indigenous and Tribal Peoples in Asia* (2003), p. 14.

⁷⁴ WIPO/GRTKF/IC/7/15 Prov. 2, supra note 18, at para. 183

⁷⁵ WIPO/GRTKF/IC/1/3, supra note 2, at para. 76.

⁷⁶ WIPO/GRTKF/IC/7/9, supra note 23, at para. 42.

⁷⁷ Gibson, J., supra note 65, at p. 11.

⁷⁸ For a full discussion of the use of Article 64 of the TRIPs Agreement applying Articles XXII and XXIII of GATT relating to dispute settlement, see Blakeney, M., *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement* (1996), at pp.123-132.

⁷⁹ Suthersanen, U., supra note 62, at p. 79.

⁸⁰ Blakeney, M., 'The Protection of Traditional Knowledge under Intellectual Property Law', [2000] EIPR 251, at p. 261.

⁸¹ Opinions of the EC, Japan and Singapore, in WTO/IP/C/W/370, supra note 42, at para. 10.

a certain extent has already been completed – under the aegis of WIPO and the CBD. Proposals and conclusions reached through this work with national delegations, for example, could be presented to the WTO. Indeed, the WTO itself has noted that ‘once WIPO has completed work on model national legislation, attention could be focussed on how and to what extent the protection of traditional knowledge can be included in the TRIPs Agreement.’⁸² The TRIPs Agreement offers opportunities but reform is needed.⁸³

3.3 A question of reform

Reform of the TRIPs Agreement must bridge the gap between those parties calling for the introduction of *sui generis* systems of protecting TK and those parties content with the current system of protecting TK through conventional IPRs. Adopting the TRIPs Agreement as a forum for enforcement brings with it certain limitations as this approach would a priori imply that any proposed reform would need to work within the conventional IPRs already protected under TRIPs. A compromise solution of inserting *sui generis* elements into conventional IPRs may prove acceptable to both sides of the debate. The elements to be introduced into patent law could be the procedural safeguards discussed above: disclosure of origin, prior informed consent and the obligation to enter into benefit-sharing negotiations. As we have seen, this proposal would already have the support of the African group as well as, importantly, India and Brazil, who have both called for the introduction of the Biodiversity Conventions provisions into the TRIPs Agreement.⁸⁴ Despite the support given to this proposal by some states, note should be made of the fact the WTO and its dispute settlement mechanism is only available to States Parties. As an inter-state body, indigenous communities do not have standing to bring matters before the WTO and as we have seen, problems may therefore arise when a state’s interests do not coincide with the interests and rights of their own indigenous communities.

There is also uncertainty as to what is required in introducing such safeguards. Dutfield notes that as the TRIPs Agreement stands, it allows for certain administrative requirements – including certification of origin – to be introduced.⁸⁵ This is nuanced by the opinion that the disclosure of origin and PIC are inconsistent with the Agreement although they could be made into conditions for enforcement of patent rights.⁸⁶ Introducing any such obligations may ultimately ‘modify the balance of rights and obligations found in the TRIPs Agreement’⁸⁷ requiring an amendment to the Agreement. This could be done by amending either Article 27(3)⁸⁸ which deals

⁸² Opinion of the EC, *ibid.*, at para. 27.

⁸³ Dutfield, G., *supra* n. 3, at p. 84.

⁸⁴ Opinions of India and Brazil cited in WTO/IP/C/W/368, *supra* note 16, at para. 13.

⁸⁵ Dutfield, G., *supra* n. 12, at p. 75.

⁸⁶ De Carvalho, N.P., *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and the Solution*, cited in McManis, C.R., ‘Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally’, in Grosheide, F.W., Brinkhof, D. (eds.), *supra* note 3, pp.221-247, at p. 235.

⁸⁷ WTO/IP/C/W/368, *supra* note 16, at para 26.

⁸⁸ Opinion of Brazil, *ibid.* at para. 20.

with exclusions to patentability and *sui generis* systems for plant varieties. Alternatively, Article 29 may be amended to incorporate the new requirements.⁸⁹ As this latter article deals with disclosure requirements, it would seem more logical to choose this option for reform. Through a reform of Article 29, an applicant could be placed under a requirement to disclose the origin of any genetic resources forming the basis of an invention and show evidence of PIC and of having entered into benefit-sharing negotiations.

Amending the TRIPs Agreement will certainly encounter protests, however. Japan and Korea have stated that introducing procedural safeguards would be overly burdensome and would thereby contravene TRIPs Article 62(1) which calls for the use of 'reasonable procedures and formalities.'⁹⁰ It is submitted that the proposed procedural requirements would not prove such a burden as under the Biodiversity Convention applicants, or the intermediaries carrying out bio-prospecting, are already under an obligation to comply with similar provisions. Such a system would in fact support one of the main objectives of the TRIPs Agreement as stated in Article 7. Intellectual property rights should contribute to the promotion, transfer and dissemination of technology and this to the mutual advantage of producers and users of technical knowledge. As discussed above, technology transfer as part of capacity-building should form a central part of any benefit-sharing regime. As stipulated by Article 1 of the TRIPs Agreement, more far reaching protection of TK would continue to be permitted in domestic law. This would enable the introduction and continued use of *sui generis* systems already in place in some countries. Furthermore, countries such as those in the Andean Pact with similarly strong TK legislation would still be permitted to enter into this new kind of TRIPs-plus agreement with each other.

4. Conclusion

The focus of this work has been on improving the current protection of traditional knowledge, specifically related to genetic resources. Patents have proven largely inadequate in upholding indigenous communities' rights over their TK. The introduction of *sui generis* elements as procedural safeguards, incorporated into the existing patent law structure, was put forward as an effective alternative. Internationally enforceable minimum standards providing for a globally harmonized approach to TK protection are also needed. Having put forward a regime of intellectual property protection, the importance of alternative approaches to protect TK should not be overlooked. Efforts based on human rights and indigenous peoples' rights should be encouraged as should any model which incorporates the customary laws of indigenous peoples. Equal rights for indigenous peoples are not limited to the use of their resources and it is beyond the scope of intellectual property law to answer wider questions relating to indigenous peoples' self-determination. The diverse models of protection are not mutually exclusive, however, and instead of a fragmented approach a paradigm exploring synergies between these disciplines should be encouraged. The various parties with an interest in traditional knowledge should attempt to work together as partners towards the same end rather than as rivals fighting over limited resources.

⁸⁹ Opinion of India, *ibid.*

⁹⁰ Opinions of Japan and Korea, *ibid.*, at para. 26.