

# UNU-IAS Report The Role of Registers and Databases in the Protection of Traditional Knowledge A Comparative Analysis



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## **UNU-IAS Report**

# The Role of Registers & Databases in the Protection of Traditional Knowledge

A Comparative Analysis

# Contents

| Foreword                                       |   | 5                                       |
|--|---|---|
| Executive Summary                              |   | 6                                       |
| Introduction                                   |   | 9                                       |
| <b>1</b><br>1.1<br>1.2<br>1.3                  | Underlying Concepts<br>What Is Meant By Traditional Knowledge?<br>What Is Meant By "Protection"?<br>Distinguishing Registers and Databases  | <b>10</b><br>10<br>11<br>11             |
| <b>2</b><br>2.1<br>2.2<br>2.3<br>2.4           | Case Studies of Registers and Databases Used to Record and<br>"Protect" Traditional Knowledge<br>Indigenous Peoples and Local Community Databases and Registers<br>Institutional Databases<br>NGO Co-operative Databases<br>Registers Established by Law  | <b>14</b><br>14<br>16<br>19<br>22       |
| <b>3</b><br>3.1<br>3.2<br>3.3<br>3.4           | Comparative Analysis of the Role of Databases and Registers<br>in the Protection of Traditional Knowledge<br>Objectives of Traditional Knowledge Registers<br>Information Included in a Traditional Knowledge Database or Register<br>Criteria for Incorporating Traditional Knowledge into a Database or Register<br>Scope and Institutional Management of Registers   | <b>26</b><br>26<br>26<br>26<br>27       |
| <b>4</b> .1<br>4.2<br>4.3<br>4.4<br>4.5<br>4.6 | The Role of Databases and Registers in the Legal Protection<br>of Traditional Knowledge<br>Defensive Protection<br>Positive Protection: The Role of Databases and Registers Protection Under Sui Generis Regimes<br>The Nature and Characteristics of Declarative Versus Constitutive Registers<br>Standardised Registration, Protection, or Erosion of Rights<br>Protection of the Contents of Databases and the Public Domain<br>Tradtional Knowledge Database Trusts | <b>29</b><br>30<br>32<br>33<br>34<br>36 |
| 5  | Conclusions and Recommendations   | 38                                      |
| Endnotes                                       |   | 41                                      |
| Bibliography                                   |   | 45                                      |

### Foreword

In the decade since the Convention on Biological Diversity (CBD) has come into force, increasing attention has been given to the development of measures to protect traditional knowledge (TK). This has led to action by indigenous peoples, research institutes, non-governmental organisations and states.

One measure which has received much attention from all actors has been the documentation of TK in databases and registers. This has resulted in the development of a range of databases and registers demonstrating a wide variety of objectives, scope, procedures and enforcement mechanisms, based upon diverse notions of traditional knowledge and what constitutes "protection". UNU-IAS has carried out a comparative study of a number of such experiences with a view to identifying their effectiveness, possibilities and limitations, and in order to contribute to a more informed and productive debate on this important topic in the development of international mechanisms for the protection of traditional knowledge.

Development of this report is part of the wider programme on access to genetic resources and benefit-sharing (ABS Programme) at the United Nations University Institute of Advanced Studies (UNU-IAS). UNU-IAS was established in 1996 as a research and training centre of UNU to undertake research and postgraduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral, and objective manner. A key purpose of the Institute is to promote interactions between the UN System and the academic community. UNU-IAS is currently focusing a significant amount of its efforts on research of international biodiversity policy, with a particular emphasis on ABS issues.

This work is designed to inform and facilitate global dialogue on the negotiation of an international regime on benefit–sharing, as called for in the Implementation Plan of the World Summit on Sustainable Development, and to inform the deliberations of the World Intellectual Property Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore.

A H Zakri Director, UNU-IAS January 2004

### **Executive Summary**

With the entry into force of the CBD the need for the protection of traditional knowledge (TK) has received increased attention. One mechanism with much potential as a tool for protection of traditional knowledge is its documentation in databases and registers. Within the World Intellectual Property Organization (WIPO), the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC), databases and registers have been discussed as mechanisms for both defensive and positive protection of TK.

This report provides a comparative analysis of a number of case studies of existing databases and registers and attempts to draw some conclusions and recommendations regarding their strengths and limitations for securing protection of TK.

# Case Studies of Traditional Knowledge Databases and Registers

UNU-IAS has prepared a comparative study of seven case studies, which have been considered within four categories. These are:

- indigenous registers and databases: database of the Inuit of Nunavik Canada
- institutional databases: BioZulua database in Venezuela and the Traditional Knowledge Digital Library (TKDL) in India
- NGO co-operative databases: the database of the Farmers Rights Information System (FRIS) and the Honey Bee Network database, both in India
- state registers: the holistic register in Panama and national and local registers of TK relating to biodiversity in Peru

These databases demonstrate the wide variety of objectives, scope, procedures, rights, benefits and enforcement mechanisms which have been employed by different actors in order to secure varying levels of protection of TK. The studies show a tendency for all databases and registers to play a role in the preservation of traditional knowledge. This may be primarily for the benefit of indigenous peoples themselves, as with the Inuit database, or for the benefit of both indigenous peoples and the scientific sector, as is the case with the TKDL database. They also provide examples of varying levels of defensive and positive protection.

The overall effectiveness of databases and registers as a means for protection of TK for the benefit of indigenous peoples will depend upon a number of different factors, including: the extent to which any database is linked to local and indigenous communities in a manner which respects and responds to the dynamic nature of TK and ensures that compilation and classification of data does not atrophy TK;<sup>2</sup> the capacity of a database to compile maintain and provide access to TK for local communities in a usable form; their capacity to control access to and use of TK by third parties, and the extent to which any database may serve as an effective means to secure recognition of community rights over TK and as a source of evidence of prior art.

#### **Defensive Protection**

Databases are an important source of information on prior art for authorities reviewing patent applications to determine whether they achieve the levels of novelty and inventiveness necessary for granting intellectual property protection. This has led to proposals for incorporating TK in the public domain into more accessible databases for the purpose of aiding patent authorities in searches of prior art—the argument being that this will act as a form of defensive protection for TK by preventing the granting of patents over it. However, defensive protection does not in fact amount to the recognition of rights of ownership over TK in favour of indigenous peoples. Despite the potential for defensive protection provided by compilation of TK into open access databases, there have been criticisms that such database will provide increased access to TK for the private sector, without in any way increasing indigenous peoples rights over their knowledge.

Desire to protect TK from unapproved use has led to the establishment of confidential registers. As a result important sources of prior art including local community registers, indigenous peoples and other confidential registers including the Inuit, BioZulua, and the confidential register under the Peruvian legislation, as well as the oral registers of TK maintained by elders and wise men and women, are effectively excluded from the remit of prior art investigations.

Requiring that TK be placed in the public domain as a condition for recognising it as prior art, is a double-edged sword. In effect this may be seen as requiring the renunciation by indigenous peoples of their rights to control their TK by placing it in the public domain in order to prevent weakness in IPR regimes being utilised as a means for its misappropriation. Strict application of the principle of the public domain to TK may therefore lead to inequities for indigenous peoples. To attempt to redress these inequities measures may be sought to provide some form of compensatory scheme for use of TK in the public domain. In Peru, for instance, legislation on collective knowledge requires payment of compensation for use of TK in the public domain. A proposed South Pacific model law on TK goes

even further and provides that the principle of the public domain should not apply to TK which entered the public domain as the result of a breach of confidence or misappropriation, or where its use would undermine the cultural integrity of indigenous peoples.

Requirements to disclose the origin of TK in patent applications would assist patent authorities in making directed searches of prior art in the country of origin. Incorporating local and indigenous peoples' registers within the framework of a national register of TK would extend the remit of potential sources of evidence of prior art for the purposes of defensive protection.

#### **Positive Protection**

Positive protection requires legal recognition of rights over traditional knowledge, either under existing IPR regimes or *sui generis* regimes. This study focuses on the latter, *sui generis* regimes, and identifies two types of systems for the recognition or granting of rights, that may utilise what have been termed declarative and constitutive registers, respectively.

Declaratory regimes, such as established in Peru, recognise that rights over TK derive from ancestral rights rather than any act of government. Rights over TK do not stem from inclusion in declarative registers. However registration may have the benefits of putting the authorities on notice of the existence of that knowledge for benefit–sharing purposes and for the purposes of challenging patents, etc.

In cases such as that of Panama, relevant legislation establishes a rights regime granting exclusive property rights over TK. A constitutive register is part of such a regime, and registration puts the public on notice of the existence of rights over TK.

Both Panama and Peru in their respective legislation on folklore and collective knowledge of biological diversity have recognised TK to be the cultural patrimony of indigenous peoples. Recognising TK to be cultural patrimony establishes obligations between the State and indigenous peoples, and creates a measure of protection against third parties where cultural patrimony is recognised as being inalienable and indefeasible.<sup>3</sup> The importance of recognising indigenous knowledge to be cultural patrimony is that it protects these rights not only between indigenous peoples and third parties, but also within indigenous societies themselves. As cultural patrimony it may not be alienated which means that it cannot be commercialised in a manner which would pass monopolistic rights to third parties. Furthermore, it requires that benefits received must be utilised by the recipient indigenous peoples in

order to strengthen and protect their knowledge base in a manner which secures equitable sharing both within and between generations.<sup>4</sup>

The Panamanian and Peruvian experiences make possible a potentially dynamic role for customary law and practice in defining the parameters of positive protection for TK. The case for recognition of customary law and practice as the basis for protection of TK is even stronger in cases where under treaty, national and constitutional law, indigenous peoples or local communities have rights to full or partial self–governance and/or control access to and use of their resources and TK.

The UNU-IAS study identifies the need for further analysis of the interface between customary law and practice, and national and international law, as a prelude to the development of international legal regimes relating to TK.

# Standardised Registration, Protection or Erosion of Rights

Development of international law for protection of TK is likely to require the definition of standardised minimum specification data for registration of traditional knowledge. However, the desire for harmonisation of standards may be in conflict with the diversity of TK and of relevant customary law and practice. In developing international law and policy on TK it will be important to be guided by the need for flexibility, sensitivity to local realities, and adaptability to changes in customary law and practice.

Developing standardised specification data, prior to defining the nature and scope of any international regime for sui generis protection of TK could pre-empt necessary debate on what form *sui generis* protection should take. Developing standards based upon criteria developed for IPR regimes would have the effect of progressively defining the modalities for protection of TK based upon IPR practices, thereby potentially limiting the scope of future options. The UNU-IAS study would suggest that the time is not yet ripe, nor the technical basis sufficiently clear for establishing a single set of classification standards at this time. To do so would effectively amount to adopting a technical response to an issue, which includes not only social, economic, cultural and environmental dimensions but also includes spiritual dimensions. However, the study notes that differences in the nature of TK from country to country may warrant the development of specification data for distinct types of knowledge with defined characteristics, such as, for instance, sources of traditional medicine, which are highly codified and widely documented.

# Sui Generis Protection of Databases and Database Trusts

Protection of TK through the development of sui generis regimes, based upon Article 39.3 of the WTO's Trade–Related Aspects of Intellectual Property Rights Agreement (TRIPS) may provide a certain level of protection for the content of databases. Such protection would, however, be given to the proprietor of any TK database or register rather than to indigenous peoples. Developing a form of TK database trust, as is in principal suggested by the case of the BioZulua database in Venezuela, may be a means for bringing greater equity to the management of databases. Creating opportunities for indigenous peoples and local communities to participate in the management of existing TK databases by establishing trusts to manage the access to and use of TK held in such databases may provide an interesting mechanism for securing the long-term control and management of TK for and on behalf of indigenous peoples.

#### **Conclusions and Recommendations**

Depending on the specific objectives of any regime, registers and databases may play a substantial role in protection of TK. They can amongst other things, serve to:

- promote documentation, preserve and maintain TK
- provide a means to assist patent search procedures and identify prior art
- identify communities which might be entitled to benefit-sharing, and assign exclusive rights
- provide the means for recording the existence of TK over which positive rights have been recognised under national or customary law
- serve as the mechanism for obtaining protection of TK through *sui generis* database protection

However, databases and registers alone do not provide a means for the effective protection of TK. Rather they must be seen as one element or mechanism in a wider system of TK governance including customary law and practice, national access and benefit—sharing legislation, and *sui generis* TK law and policy.

Development of any TK regime must be guided by the customary law and practice of indigenous peoples and local communities. Considering the number and diversity of indigenous peoples and local communities and consequently the diversity of their customary laws and practices, any international system for the protection of TK must be based upon flexibility, sensitivity to local realities and adaptability.

There is a need for the full participation of indigenous peoples in the development not only of registers

*per se* but also in the process for development of any regime, *sui generis* or otherwise, for the protection of TK.

All reasonable efforts need to be made to ensure that prior informed consent is obtained from the relevant indigenous peoples for inclusion of their TK in databases or registers, whether TK is in the public domain or not. For information not already in the public domain, prior informed consent should be a mandatory condition of inclusion of information in any database for scientific or commercial use whether or not the relevant database is open or subject to restricted access.

Explicit institutional policies need to be developed by museums, botanical gardens, universities, companies and all entities working with biological materials and related TK. Acceptance of the rights of indigenous peoples over their TK should be a precondition for access to databases and registers. Database owners of existing databases holding TK should consider the development of a common code of conduct to govern the holding of TK. To this end, database owners should consider adopting a system establishing a fiduciary obligation to hold any TK in trust for the benefit of indigenous people. In the development of any such policies database owners should liaise closely with indigenous peoples.

Databases and registers provide a good opportunity for benefit-sharing with indigenous peoples and local communities through repatriation of information in user-friendly format and where possible in local languages.

National governments and international organisations should: review existing law and policy with a view to the development of more sensitive and directed prior art search procedures; consider possibilities for adopting interim measures which reduce pressure on indigenous peoples and their knowledge systems by creating obligations for users to demonstrate prior informed consent as a condition for scientific and commercial use of TK; give attention to the ongoing discussions on user measures within the framework of the Convention on Biological Diversity (CBD), and to proposals for the negotiation of an international regime on access to and benefitsharing of genetic resources (ABS); and ensure that intellectual property regimes are supportive of the CBD and human rights.

### Introduction

The entry into force of the Convention on Biological Diversity (CBD) and, in particular, Article 8(j) and related provisions<sup>5</sup> pertaining to the knowledge, innovations and practices of indigenous and local communities, has fuelled national and international efforts to design, adopt and implement legal and policy mechanisms that respect preserve and maintain the traditional knowledge (TK) of indigenous and local communities.

As the debate on the protection of traditional knowledge (TK) has grown the potential role of databases and registers as both a source of defensive and positive protection has been the subject of increased attention. To date, discussion has focused primarily on the possible role of databases to act as a form of defensive protection for the purposes of aiding patent authorities in the search for prior art relating to patent applications. More recently attention has shifted to the role of registers in securing positive protection for TK.

Although, databases and registers have very distinct legal status there has been a frequent tendency to use the terms as if interchangeable when describing existing experiences in documenting traditional knowledge. This may cause some confusion for those wishing to determine the relative merits of particular experiences in documenting TK and their capacity to provide protection to indigenous peoples and local communities over their knowledge.

Recognition of the need for further investigation on databases and registers may be seen from deliberations by member countries of the World Intellectual Property Organization's (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).<sup>6</sup> Documentation of TK in the form of databases and registers and technical issues surrounding them have been raised throughout the IGC sessions for various purposes, such as defensive protection, positive protection, protection from erosion<sup>7</sup> and for the purpose of recording rights.<sup>8</sup> For instance, regional groups including the Asian Group<sup>9</sup> and the African Group<sup>10</sup> provided their support for the development of TK databases as important tools for protecting TK. The African Group during the Third Session of the IGC requested that in order to establish databases WIPO's support was necessary. The Asian Group submitted a document entitled 'Technical Proposal on Databases and Registers of Traditional Knowledge and Biological/Genetic Resources',<sup>11</sup> at tshe Fourth Session of the IGC.. The document comprises content and resources, identification standards, technological standards and security standards related to TK databases and registries. Furthermore, a number of individual member countries gave their support for the creation of TK databases and registries,<sup>12</sup> and

have also requested WIPO to provide assistance when establishing their own databases.<sup>13</sup>

Furthermore, outside the discussions at WIPO, protection of TK for conservation and sustainable use purposes is deemed necessary as stipulated by Article 8 (j) of the CBD and, based on this provision, various other deliberations and initiatives to protect TK are taking place within different contexts and at different bodies at the international, regional, national, and local levels. Although databases and registers may not in themselves be sufficient mechanisms for protecting TK, it is worth considering to what extent, if any, they may serve to meet immediate short-term needs in the absence of concrete TK protection mechanisms.

This report seeks to help inform the debate regarding the potential and limitations of databases and registers for the protection of TK through the analysis of a number of case studies of existing registers established by indigenous peoples, states, nongovernmental organisations and research institutes.

Part I of the report discusses a number of underlying concepts regarding the nature of traditional knowledge; Part II presents case studies from Canada, India, Panama, Peru, and Venezuela; Part III provides a comparative analysis of the case studies focusing on objectives, scope, procedures and benefits; Part IV considers the role of databases and registers in defensive and positive protection of TK and their relationship to *sui generis* legal regimes, and the possibilities for interim protection of TK through use of *sui generis* database laws and database trusts; and Part V sets down a number of conclusions and recommendations for further study.

This study demonstrates a tension and interplay between three driving forces relating to the development of databases and registers for the protection of TK; these are intellectual property, access and benefit–sharing and cultural integrity. The following analysis hopes to help bring about greater awareness with regard to the need to find mechanisms which reduce the tensions between these forces in order to secure sensitive and appropriate governance of TK issues.

### 1 Underlying Concepts

# 1.1 What Is Meant By Traditional Knowledge?

There are numerous definitions used for the term "traditional knowledge". Definitions may illustrate the specific political, intellectual, social and/or economic context that the defining body places priority upon.

For instance, the World Intellectual Property Organization (WIPO) mandate includes intellectual property (IP) protection and its work has focused on IP forms of traditional knowledge protection. In its fact-finding mission (FFM) report, WIPO referred to TK as "...tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields".<sup>14</sup> This was specifically designed as a working definition for the FFM and is now being superseded by other definitions, WIPO having determined that use of the term tradition based rather than traditional is inappropriate.<sup>15</sup>

Many indigenous peoples on the other hand tend to define their knowledge in a much broader context<sup>16</sup> avoiding the term "traditional", which does not recognise the dynamic and adaptive nature of changing cultural patterns and a wide array of external influences upon such knowledge. The Inuit of Nunavut, Canada, for example, use the term "Inuit Qaujimajatuqangit", which is more properly defined as "the Inuit way of doing things: the past, present and future knowledge, experience and values of Inuit Society." This definition makes clear that it is the combining of the traditional knowledge, experience and values of Inuit society, along with the present Inuit knowledge, experience and values that prepare the way for future knowledge, experience and values.17

Similarly, the Coordinadora de las Organizaciones Indígenas de la Cuenca Amazónica (COICA) have stated:

Knowledge is sacred, renewed, permanent, exists, is born, grows, expands; if ill, it dies and is not renewed once again. Like a seed, if it dies, it cannot bear fruit. Everything is a permanent cycle, where the basic need is to know and to manage time, reciprocity, diversity, so that the land is always renewed and life flourishes. Traditional knowledge is life in harmony between the holder and the world that involves it.<sup>18</sup> Despite these widely differing definitions of TK, it is possible to identify a general tendency to characterise TK as being passed, orally or otherwise, among indigenous peoples from generation to generation, without necessarily being codified, and as being primarily collective in nature.

Although there is a tendency to recognise both tangible and intangible property of indigenous and local communities as collective property, closer observation shows that some traditional ownership systems can and do provide for certain types of individual ownership or custodianship rights over intangible property, including knowledge, whereby the individual or family group alone creates TK and can use, enjoy and dispose of it. Such is the case of Papua New Guinea where customary law of some communities may recognise a form of private ownership of intangible property such as knowledge related to healing practices, designs, songs and dances, which may be created and owned by individuals who can then use or exchange it in return for payments of some sort.<sup>19</sup> Such private ownership of TK can be found also in other Melanesian communities and in other parts of the world including the Shuar, the Miskito healers of Nicaragua and the Siona.<sup>20</sup>

Collective ownership of TK by indigenous and local communities may therefore be understood as a collective right to determine community and individuals' rights to use, enjoy, or dispose of the community's tangible or intangible property. Its legitimacy is derived from within the community and not from the state. In other words, it can be regarded as a private-community right or privategroup right.<sup>21</sup> Within the indigenous people or local community, the extent to which collective ownership may permit or restrict individual rights of ownership is a matter for customary law and practice. When documenting TK it will be important to make a distinction between collective and individual ownership of knowledge in order to avoid building conflicts within communities and indigenous peoples.

Definition of TK becomes even more complex if further distinctions such as that proposed between TK and what has been termed indigenous knowledge (IK) are taken into consideration. IK has been defined as knowledge that specifically belongs to indigenous peoples. On the other hand, TK is defined more broadly and includes the knowledge held by both indigenous peoples and non–indigenous peoples or local communities living within a geographical boundary or region.<sup>22</sup> Distinctions between the kinds and nature of information, such as IK and TK may be relevant to issues such as conferring rights, seeking prior informed consent (PIC) for use of TK, dealing with benefit–sharing arrangements and dealing with commercialisation and conservation activities. This may imply a need to establish a classification system of TK to distinguish IK or TK and other categories of information entered into any database or register.

#### 1.2 What Is Meant By "Protection"?

Since the CBD entered into force in 1993, TK related to land use technologies, medicinal plants, agricultural practices, among others, used and adapted by modern science and technology, have been widely acknowledged as important factors in the search for sustainable development, community progress and overall well-being.<sup>23</sup> There has also been extensive debate regarding misuse or the illegal or even unjust use of TK. This has especially been the case with regard to the use the pharmaceutical and agricultural industries have made of TK (and biological and genetic resources) in their research and development processes, most particularly when intellectual property rights (IPR) (patents and plant breeders rights) have been granted over the product of such research and development activities.<sup>24</sup> It is in this context, that the concept of "biopiracy" has been articulated as a means to portray concerns related to the acquisition of monopoly rights over TK and related genetic resources. These debates have in turn prompted international and national efforts to find appropriate legal mechanisms through which TK can be provided with recognition and protection.

To date the focus of international concern regarding protection of TK has focused primarily on the need to control the actions of the scientific and commercial sector and in particular the unapproved and uncompensated use of traditional knowledge. While this is of much importance, it is worth noting that indigenous peoples themselves have identified a much wider range of both internal and external causes for the loss and erosion of their traditional knowledge. These include loss of control over education and health, promotion of inappropriate agricultural and marine extension programs, adverse influence and frequent intolerance of organized religion, reluctance of elders to transmit TK to uninitiated youth, and disenchanted youth seeking solutions to their needs from foreign science in place of TK.<sup>25</sup> Strategies for protection of TK must therefore employ measures which not only secure control over use but also create incentives for preservation and maintenance of TK and removal of inappropriate national development policies, with a view to securing respect for the value and importance of pluri-cultural societies and diversity of knowledge bases. The role of documenting knowledge to meet such a challenge therefore takes on a much wider scope than merely identifying rights over specific elements of TK.

There are, therefore, numerous social, legal, cultural, political, economic reasons for the protection of TK, including:

- to support the maintenance and integrity of indigenous peoples' cultures
- to protect the pluri-cultural nature of global society
- to maintain the body of global knowledge necessary for the design and implementation of sustainable development strategies
- to secure the human rights of indigenous and local communities over their intellectual property
- to prevent illegal use and theft of traditional knowledge
- to ensure equity and justice
- to support poverty alleviation and economic development

Existing literature, laws, legislative drafts and a wide range of policy declarations demonstrate many different perceptions regarding the means available for securing the legal protection of indigenous peoples' traditional knowledge.<sup>26</sup> This diversity in perception highlights a need for flexibility in any international regime. Defining the objectives and nature of any regime for protection of TK must be carried out at the earliest possible time through a participatory process, which seeks to identify:

- the nature of TK and its role in indigenous and local community development
- internal and external threats to TK
- possible mechanisms for securing the protection, preservation and maintenance of TK, through both community initiatives and governmental action
- the effectiveness of existing national law and policy for securing such protection
- the role of customary law and practice for the protection of TK
- development of appropriate mechanisms for the protection of TK

# 1.3 Distinguishing Registers and Databases

A registry is not merely a list or database designed to provide information to users. It is a list or database into which people put information in order to gain legal rights relating to that information. "Registering" something in a registry "puts it on the record" and puts the public "on notice" that the registrant asserts a claim.<sup>27</sup>

As the above definition makes clear, registration of information in a register<sup>28</sup> is linked to the granting of rights. Although the registration serves to secure

the recognition of the relevant rights the register does not itself grant rights but rather records such rights. In other words where a party is entitled to a particular right, say, over land, registration confirms the existence of the right and failure to register may in some cases result in a loss of the right. Registers are generally open to public scrutiny as a record of the rights which have been registered.

Databases on the other hand need not necessarily be freely open to the public. Databases are systematised collections of information, developed for public or private use, that do not confer any legal right on the originator of the relevant information as a result of its inclusion in the database. Databases organise information in a specific manner. This organisational effort may be subject to legal recognition through intellectual property rights. Under the Trade–Related Aspects of Intellectual Property Rights Agreement (TRIPS), copyrightable databases are defined as "compilations of data or other material, whether in machine-readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations".<sup>29</sup> Copyright is sometimes used as a means to ensure moral and economic rights over databases.<sup>30</sup>

Under existing law, IP protection of databases does not generally confer legal rights over the information and data they contain but, rather, on the manner in which they are stored and organised. This may lead to concern as to the extent to which protecting databases through intellectual property rights might also be affecting the rights of indigenous peoples over their "stored and organised" TK. This concern is further fuelled by the fact that for most existing databases which collected TK in the pre–CBD era—information recorded was not necessarily obtained from indigenous peoples with their prior informed consent.

Recently, considerable attention has been drawn to the role databases might play with regards to defensive protection of TK. Organisations such as WIPO<sup>31</sup>, the International Peace Research Association<sup>32</sup> and the American Association for the Advancement of Science<sup>33</sup> have produced interesting—albeit still controversial—work regarding the use of TK databases as a means to protect indigenous people's interests. Most of these efforts call for a comprehensive systematisation of TK that would be widely available and propose its incorporation into the Internet through special databases.

Databases have also been employed with the declared aim of providing defensive protection to TK by making it readily available for prior art searches. Examples of such open access TK databases include the Traditional Knowledge Digital Library (TKDL) in India, discussed in greater detail below, and TEK\*PAD in the USA. There is much TK in the public domain which is available to researchers or companies for research purposes which is not readily available in an accessible fashion for patent offices carrying out prior art searches. Compilation of such information into databases will, in theory, enhance accessibility of TK for prior art searches, therefore helping to prevent the granting of what WIPO has termed "bad patents".<sup>34</sup> However, if information is made available through open access databases, it becomes a potential mine of information freely available to all visitors without any obligation to seek prior informed consent for its use. Both the TKDL database and TEK\*PAD have come under some criticism on the basis that they may facilitate increased commercial exploitation of TK.35 TEK\*PAD in particular has been criticised for promoting a system for defensive protection of TK based upon utilisation of the existing concept of the public domain, without adequate prior consultation with indigenous peoples.<sup>36</sup>

Clearly the ongoing trend to disseminate scientific and ethno-botanical knowledge and information (including TK) through the Internet should be carefully balanced with respect to indigenous peoples' interests in and rights over their TK, as well as of the rights of countries of origin. As some critics argue, this situation represents:

...the point at which conflicting trends of thought associated with the exchange of information converge. On the one hand, they reflect a global move towards the free flow and accessibility of information through electronic means [...] On the other hand biodiversity, economic botany, medicinal plants and other databases inadequately address the need to restrict access to information on genetic resources and TK in order to provide providers with greater control over their use.<sup>37</sup>

For some critics, the Precautionary Principle<sup>38</sup> offers one way to address the aforementioned problems. They argue that:

...publications present opportunities for uncontrolled appropriation and exploitation of TK and resources by third parties. Because third party users do not interact directly with providers of the knowledge, they rarely assume obligations to communities from where the knowledge originated, and are often unaware of negative impacts that may result from knowledge appropriation. Thus, a mechanism is needed that would require all users to seek consent through direct interaction with indigenous communities.<sup>39</sup>

This Precautionary Principle may facilitate the development of guidelines and principles for such a mechanism in the context of TK use in different fields, especially ethno–botany and related disciplines.<sup>40</sup>

An interesting distinction between databases and registers has been set down in a Position Paper submitted to the IGC by the Asian Group and China<sup>41</sup>

which stated *inter alia* that Member States may, "as appropriate, compile databases of TK which is in the public domain..." (paragraph 7 (b)(ii)) and may "establish registers of TK elements which are not in the public domain..." (paragraph 7 (b)(ii))—the distinction being made here with regard to the utility of databases and registers relates to whether or not TK is in the public domain, an interesting but not uncontroversial proposal, in particular for the potential implications regarding indigenous peoples and local communities' rights over TK in the public domain.

This leads to a number of provocative questions. First, to what extent do indigenous peoples wish to make their TK more readily available for use by third parties than it already is? Second to what extent may indigenous peoples wish to curtail access to and use of their traditional knowledge, including knowledge within the public domain? These are extremely complicated questions and highlight the importance of ensuring full, effective and empowered participation of indigenous peoples in any process for the development of equitable mechanisms for protection of their rights. The answers to these questions must also be deliberated at the community level and indigenous nation level as it is there that the distinct customary laws and practices and values associated with the collection and dissemination of knowledge can be identified and injected into the wider national and international debate.

In developing regimes based upon customary law and practice it is necessary to ensure consistency with new and emerging human rights law and policy including the draft UN declaration on indigenous peoples, the UN Human Rights Covenants and other relevant sources of human rights.

## 2 Case Studies of Registers and Databases Used to Record and "Protect" Traditional Knowledge

#### 2.1 Indigenous Peoples and Local Community Databases and Registers

Indigenous peoples and local communities have maintained virtual databases or registers of TK for centuries, most frequently storing and passing it on through oral traditions, without which their knowledge would have disappeared.

More recently some indigenous peoples have employed more formal and technological solutions involving documentation and recording of TK for a variety of reasons including disputed lands or as part of forward-looking processes to protect rapidly changing societies from the loss of their traditional knowledge. In some cases, national institutions such as the Australian Institute of Aboriginal and Torres Straits Islanders Studies (AIATSIS)<sup>42</sup> and the Vanuatu Cultural Centre actively assist indigenous peoples to collect and protect traditional knowledge, holding the information in trust, and in certain cases, subject to conditions of confidentiality on behalf of indigenous peoples. Indigenous peoples and local communities are also experimenting with the creation of databases of knowledge. These range from efforts of individual local communities in the creation of local traditional plant herbariums, actions by groupings of local communities to collate local knowledge in video and tape recordings, to more ambitious efforts to store the knowledge of indigenous people such as the Storybase database of the Tulalip people.<sup>43</sup>

Although there has been increased attention to such experiences since the adoption of the CBD, many of these systems pre-date the Convention and many may be seen as merely a logical application of information documentation technologies to support traditional systems for passing information orally from generation to generation. This is particularly the case in societies where the opportunities for sustaining traditional learning, training, and information transfer have been affected by cultural, economic, social and environmental change. Concerns have been voiced that the act of documentation and codification of TK may change its very nature and should therefore only be adopted as a last resort.44 There are also dangers that the act of documenting traditional knowledge may serve to freeze it in its present form and interpretation. Such dangers have led some indigenous leaders to actively oppose the codification of traditional knowledge, including customary law and practice arguing that this is the first step towards the eventual exhaustion of rights under national law and policy.45

One of the most ambitious experiences by an indigenous people to establish databases is that of Inuit who have established a comprehensive system of registers as a means to document their land and resource use strategies and rights as part of their efforts to secure land rights.

2.1.1 Traditional Knowledge Databases of Inuit of Nunavik, Canada

Our objective is to create a dialogue based on respect and equality, not to create a catalogue and make it available to the real scientists. It is not a question of recovery and recording, it is one of respect, recognition and sharing.<sup>46</sup>

#### Background

There are approximately 46,000 Inuit in Canada, living in four distinct regions: Inuvialuit or Western Arctic; Nunavut; Nunavik or Arctic Quebec; and Labrador.<sup>47</sup> In 1975, the Inuit of Nunavik and the Governments of Quebec and Canada concluded modern day treaty negotiations with the signing of the James Bay and Northern Quebec Land Claims Agreement (JBNQA).<sup>48</sup> One of the consequences of the JBNQA was the establishment by Inuit of Nunavik of a corporation called the Makivik Corporation ("Makivik") which would, among other objectives, guide their political and economic development.

Of particular importance, Makivik set up and funded a Research Department to "develop a database and expertise within Makivik Corporation which could be used to inform decision makers, help in the formulation of policies and programmes, and assist Inuit communities and their organisations." The overarching purpose was to develop a database on Inuit ecological and environmental knowledge, along with a long-term programme to apply it to resource management, planning, environmental impact assessment and economic development.<sup>49</sup>

#### Scope

Implementation of the JBNQA resulted in the transfer of tremendous responsibilities to the Nunavik region that catalysed the creation of new institutions controlled by Inuit with powers over the management, conservation and development of their territory and resources. Initially, Inuit in Nunavik accessed "scientific and other types of western-based information that was available about their territory and Arctic ecosystems". However, it became abundantly clear that this information was inadequate to address many of the critical social, economical, political, and environmental and education issues confronting Inuit society. The problem was not the simple accumulation of western-based information, but rather of acquiring an entirely new type of information base and perspective, and to do this in a way that was of direct use to Inuit.<sup>50</sup> The solution to the problem designed by Inuit was to develop a

research programme that brought together Inuit and non–Inuit researchers.

The scope of the research and data collected for the last twenty–five years has been in four main areas: Inuit land use and planning; Inuit knowledge about the environment, ecology and resources of Nunavik; long–term information gathering; and planning, and social and environmental impact assessment.<sup>51</sup> For the purpose of brevity, we will focus the following discussion on the Inuit land use and planning database project specifically.<sup>52</sup>

From its onset, the project was not designed to make Inuit traditional knowledge publicly available. It was designed to inform particular governmental decision making processes and the data is generally considered to be confidential between Nunavik and accessing government parties. As a "closed" system with limited access, the database has primarily a promotion, preservation and maintenance role within the particular Inuit communities.

#### **Procedures and Administration**

The project advanced in three stages. Stage One was the collection of all land use and ecological knowledge data for the entire region. This information was derived from interviews with Inuit in each of the fourteen communities of Nunavik. Stage Two was to review this data through a process of community verification. Stage Three is still in progress and includes the continual updating of the information as required for special projects or to meet specific needs of Nunavik communities and organisations.<sup>53</sup>

Inuit control over the activities of researchers has been consolidated through the Makivik Research Department, which has resulted in confidence among Inuit in their ability to carry out or participate in various levels of the studies or projects. Data, gathered by thousands of hours of interviews and from thousands of field maps, have been entered into a geographic information system. All of the information on land use/environmental knowledge has now been organized within a computerized database. Map analysis and presentation is carried out by GIS which has been designed by the Nunavik database.<sup>54</sup>

The methodology for this project covers both data collection and data processing. The collection of all information for both Inuit land use and about Inuit ecological and environmental knowledge was based on interviews. Land use data was collected through individual interviews, whereas data on Inuit knowledge was based on group interviews. Maps were the essential tools for recording the information for both types of interviews. Mapped information was supported by a written text and each interview was transcribed on tape in order to maintain an exact record. Both types of interviews were guided by a detailed field research manual that was developed through community consultation.<sup>55</sup>

The data processing utilised a computer mapping system using an Oracle database and a MicroStation GIS/CAD program. The system which is now operating allows for plotting large–scale maps based on the GIS and for producing finished maps using computer cartography software.

To date, the database is not readily accessible to the public and there are no prescribed procedures to obtain access. Certain data has been integrated into land use planning processes but the database generally serves the purpose of promotion and preservation of Inuit ecological and environmental knowledge. Inuit in Nunavik are still in the process of creating an appropriate model for benefit–sharing arrangements and, thus far, have not formally entered into bioprospecting agreements for the use of genetic resources or TK.

#### **Rights and Enforcement**

The database may have many different applications and uses. The most important practical rights that have arisen to date are within planning and impact assessment in the region. Inuit expect their data and perspectives to greatly influence the review process in a way that will reflect and respond to their needs, priorities and visions of the future. They have created a code of ethics that provides rules regarding the manner that scientists, academics, government and other private parties must interact with Inuit. But they do not have a structure for changing fundamental control over the research process nor for providing access to knowledge collected.

As set out above, the database remains a closed system and has been limited to a promotion and preservation role. One reason for ensuring the closed status of the database is the lack of protective mechanisms within the existing Canadian intellectual property regime. That is, the database does not create any intellectual property rights over the TK it contains under current Canada's IPR regimes, as the content of the database is not considered to be "original" under existing law. On the other hand the database itself may be considered original for the purposes of copyright protection. Therefore, while there may not be any protection for the information and knowledge contained in the database, the database itself may probably be protected under copyright.<sup>56</sup>

The long-term focus of Inuit of Nunavik is to secure legislative reform leading to recognition of self-governing jurisdiction, supported by constitutional recognition of such rights. In the pursuit of this objective, the Nunavik Commission, a body created under the JBNQA, recommended that the "Nunavik Assembly be empowered to enact laws in relation to the promotion and protection of traditional spirituality and cultural values, beliefs and practices, and the protection of Inuit culture and language, including: the preparation of a Charter of Inuit language and culture; the management of archaeological resources; the repatriation and conservation of artefacts and art collections."<sup>57</sup>

The prospect of indigenous laws creating protective mechanisms for traditional knowledge, including TK databases or registries, creates an intriguing legal situation in the Canadian context. Such a situation could lead to potential conflicts between regimes for the protection of TK established under customary law and practice of indigenous peoples and the exclusive jurisdiction of the Canadian government to regulate intellectual property. However, it should be noted that many elements of traditional knowledge do not fall within the scope of existing intellectual property rights regimes and are not therefore issues which intellectual property can or is meant to address.58 This may provide some scope for the development of sui generis systems of protection based upon customary law and practice.

To date, Canadian courts have not directly addressed the scope of indigenous peoples' right to protect traditional knowledge. However, the Supreme Court of Canada has stated that "to ensure the continuity of aboriginal practices, customs and traditions, a substantive aboriginal right will normally include the incidental right to teach such a practice, custom and tradition to a younger generation."<sup>59</sup> While not conclusive, this statement does create the basis of a position that Indigenous groups in Canada may have a constitutionally protected right to protect their TK to ensure the continuity of that knowledge.

#### 2.2 Institutional Databases

There are currently hundreds of millions of pages of published texts available on open access databases which include TK references. *Natural Products Alert*, better known as NAPRALERT at the University of Illinois, and MEDLINE are two of the best known examples of "academic" databases that serve as important tools for information exchange associated with genetic resources and TK. Likewise, the CABI Medicinal Plant Database in Wallingford, UK, holds over three million entries on scientific studies on medicinal plants.<sup>60</sup>

NAPRALERT is a database compiled from ethno-medical literature scanned and processed since 1975 from over 125,000 journal articles, publications, books, scientific abstracts and patent documents. It is an extensive source of information and data on the chemistry, pharmacology, biological activity, taxonomic and geographical distribution and ethno-botanical uses of around 110,000 natural products and 120,000 organisms. Information from about 600 new articles is scanned monthly.<sup>61</sup> This database is freely available for research purposes.

From a strictly scientific point of view, NAPRALERT offers an invaluable source of information. However, from a policy point of view, this type of database may raise concerns regarding their impact upon the realisation of the CBD's objectives on access and benefit—sharing and TK, especially when making TK freely available.

Besides the possibilities of commercial exploitation of TK obtained from databases, there is also the problem that disclosure may have the effect of placing TK in the public domain without the consent of relevant communities or indigenous people.

One potential alternative to such open databases has been promoted by BioZulua in Venezuela which has established a register which, it is claimed, offers possibilities for information to held in confidence on behalf of indigenous peoples.

#### 2.2.1 BioZulua Database in Venzuela

#### Scope

The BioZulua database was established by the Fundación para el Desarrollo de las Ciencias Físicas y Naturales (Fudeci) from Venezuela. It is an academic, scientific database which contains information and data of indigenous communities of Venezuela related to traditional medicine, ancestral technologies and TK pertaining to agriculture and nutrition. It is held by Fudeci at the National Academy of Science in Caracas, Venezuela. Users of the BioZulua database can search by species, geographic location, ethnic group, or even by ailment. The database includes video footage of shamans collecting and preparing medicinal plants, as well as images of how patients respond to treatment. It provides genetic profiles of every plant entry and the global positioning system coordinates of exactly where it grows.

Information includes taxonomic data on collected species, including indigenous and Creole names and nomenclature, main phenotypic characteristics of collected biological samples and compounds as well as their local traditional use. Scientific bibliographies are also part of the database. The database entries are complemented by geographical references, based on satellite localisation of areas where materials have been collected. Videos, photographs and digital images also form part of the database.<sup>62</sup>

One of the principal stated objectives of BioZulua is to preserve TK which is at risk of disappearing or being eroded. At the same time, Fudeci hopes to provide access to medicinal plants to outside researchers in the hope of promoting development of new pharmaceuticals.

Fudeci signed an Access Contract with the Ministry of the Environment and Natural Resources in 2000,

in conformance with obligations under Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources for the collection of genetic resources in Venezuela.

#### **Procedures and Administration**

The database is of a confidential nature and Fudeci allows its use on a case–by–case basis for scientific research mainly. Given the value of TK and the need to safeguard indigenous peoples' interests, as well as the commercial value of the information stored, Fudeci is in the process of developing confidentiality agreements with those involved in the collection, compilation and systematisation of the BioZulua database information.

According to Fudeci, the advantages provided by this database include maintenance and safeguarding sensitive information (TK), adding value to TK through its organisation and systemizing, and an opportunity for biotrade and biobusinesses. However, Fudeci also recognises its limitations, including potential biopiracy, difficult access to preserved information by communities, and lack of protection of the information and data held.

#### Rights

The BioZulua database cannot assign any rights over TK in favour of indigenous peoples or local communities. However, according to Fudeci officials, TK which has not previously entered into the public domain will be kept confidential until a positive *sui generis* system of protection is devised in order to ensure effective protection of TK. This treatment of TK by Biozulua recognises the possibilities for protecting TK as a form of trade secret.<sup>63</sup>

There remain a number of controversial aspects with regard to the BioZulua database. First, there is a lack of clarity over the extent to which PIC has been sought as a condition for collecting TK from communities prior to its incorporation into the database, an obligation according to Article 43 of Law 5468 of May 2000 (Biological Diversity Law). Law 5468 establishes that indigenous communities have the right to say "no" to the use of their TK and genetic resources in their territories.

Second, there are questions surrounding the implications of the grant of copyright protection for the BioZulua database. The Government of Venezuela, through the Ministry of Science and Technology, has sought to provide reassurance that this implies the database as such is protected, not the information it contains. This situation nevertheless raises questions regarding the extent to which indigenous peoples property and intellectual rights over the TK incorporated into the database might be affected.

Indigenous organisations in Venezuela have called for a halt to collection activity and for the database to be held by indigenous peoples.<sup>64</sup> In response, Fudeci's lawyer has stated that two things are clear: "the title to the database vests in the State, and the knowledge contained in the database belongs to the indigenous communities."<sup>65</sup>

The BioZulua experience would appear to suggest a possibility that the database may take on the characteristics of some form of database trust, wherein the State controls and manages the database to the benefit of indigenous people. If this is indeed the intention, it would be interesting to consider the extent to which indigenous peoples should have a say over institutional policy of the database and be empowered to make determinations regarding the granting or denial of rights to access.

# 2.2.2 Traditional Knowledge Digital Library (TKDL)<sup>66</sup>

TKDL is a collaborative project between the National Institute of Science Communication and Information Resources (NISCAIR, erstwhile NISCOM) the Department of Indian System of Medicine and Homoeopathy (ISM&H), and the Ministry of Health and Family Welfare. The TKDL, which is based at NISCAIR, was created by an inter–disciplinary team of thirty Ayurveda experts, two patent examiners, five information technology experts, two NISCAIR scientists, and three technical officers.

#### Background

The rationale for the TKDL may be drawn from the experience of India in seeking to overturn two patents granted over products based upon traditional knowledge in the US and Europe. In the first case the Council of Scientific and Industrial Research (CSIR) called for a re-examination of US patent No. 5,401,504, which was granted for the wound healing properties of turmeric, filed by two US-based Indian nationals. In a landmark decision, the United States Patent and Trademark Office (US PTO) revoked this patent after ascertaining that there was no novelty, the innovation having been used in India for centuries.<sup>67</sup> In the second case the European Patent Office revoked a patent granted to W R Grace & Company and US Department of Agriculture on Neem (EPO patent No. 436257) on the grounds of its use having been known in India.<sup>68</sup>

More than a dozen organisations from around the world got together to oppose the EPO Neem patent and the entire process took five years. Overturning the patents was extremely expensive and time-consuming, making it preferable to establish mechanisms to prevent the granting of inappropriate patents, rather than to rely on expensive and lengthy challenges to patents once granted.

A TKDL task force has studied 762 randomly selected US patents, which were granted under A61K35/78 and other International Patent Classification (IPC) classes, having a direct relationship with medicinal plants. Out of these 762 patents, 374 (49 per cent) patents were found to be based on traditional knowledge.<sup>69</sup> This demonstrates the high proportion of patent applications for which evidence of traditional knowledge as prior art is relevant.

#### **Objectives of the TKDL Project**

TKDL has a dual objective. In the first place it seeks to prevent the granting of patents over products developed utilising TK where there has been little, if any, inventive step. Second, it seeks to act as a bridge between modern science and TK, and can be used for catalysing advanced research based on information on TK for developing novel drugs.

#### Scope of the Project

TKDL is being created based upon the codified traditional knowledge on Indian Systems of medicine. In its first phase the TKDL is compiling information present in fourteen Ayurvedic texts listed in the Indian Drugs and Cosmetics Act of 1940.<sup>70</sup> To date, about 36,000 formulations have been transcribed in patent application format. The images from the original texts that have been transcribed will also be incorporated into the database. For the creation of the TKDL, an innovative traditional knowledge resource classification system has been developed.

#### Traditional Knowledge Resource Classification (TKRC)

Under existing intellectual property rights regimes, documentation of traditional knowledge lacked a distinct classification system. In response to this lack, a modern system of TK classification is being developed based on the structure of the International Patent Classification (IPC) system. Development of the TKRC system began with work on Ayurveda.

TKRC is an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval which identifies about 5,000 sub–groups of TK against one group in international patent classification (IPC), i.e. AK61K35/ 78 related to medicinal plants. The information is being structured under section, class, sub–class, group and sub–group as per the International Patent Classification (IPC) for the convenience of its use by the international patent examiners. Information from about 36,000 Slokas (Verses & Prose) describing Ayurvedic medicine will be put in the database during the first stage of the TKDL's development.

Each Sloka is read and converted into structured language using the TKRC by Ayurveda experts. TKDL software then converts Sanskrit Slokas into English, German, French, Japanese and Spanish. The software does not do transliteration; rather, it does smart translation, where data abstracted once is converted into several languages by using Unicode metadata. Software also converts traditional terminology into modern terminology, e.g., kumari to aloe vera, mussorika to small pox, etc.

The progress of the work so far has been that 36,000 Slokas have been identified and transcribed from the

Ayurvedic texts for inclusion in the database. Of these 29,000 formulations have been verified and validated by the eminent Ayurveda experts. The decodified format of the formulation is readable and understood by a layperson. About 35,000 Slokas have been scanned and are available for establishing prior art. The translation of TKRC in Spanish, German, French and Japanese has been completed.

The TKDL database is intended to act as a bridge between ancient Sanskrit Slokas and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners. It is expected that the gap on lack of prior art knowledge shall be minimised. The database will have sufficient details on definitions, principles, and concepts to minimise the possibility of patenting "inventions" for minor/insignificant modifications.

#### Incorporating TKRC into the International Patent Classification System

In order to secure international recognition for the TKRC system links were established with the IPC Union at WIPO. The IPC Union established a Task Force to study the possibility of linking and/or integrating the TKRC with the IPC.<sup>71</sup> The Task Force consisted of representatives of the United States Patent Office, the European Patent Office, China, Japan and India. During its deliberations the Task Force recognised the need for more detailed levels of classification for medicinal plants. This led to the preparation of a draft recommendation according to which up to 250 sub-groups may be identified for purposes of IPC instead of just a single sub-group on medicinal plants.<sup>72</sup> The Task Force has also recommended the linking of TKRC developed by India with the IPC.<sup>73</sup> Such a system would be likely to enhance the system of search and examination of TK in prior art searches, and therefore the possibilities that the granting of bad patents may be significantly reduced.

#### **Access Policy**

The Department of the Indian System of Medicine and Homoeopathy has set up an Inter–Ministerial Access Policy Committee which is currently developing a system to control access to the TKDL with a view to providing adequate safeguards against the misuse of data, while giving access to global patent examiners and others at national and international level. It is proposed that the database will be made available to patent examiners throughout the world under a non–disclosure agreement and it is also likely that the database would be available via the internet on a secure access basis.

#### Distinguishing Ayudervic Knowledge

The knowledge currently being incorporated into the TKDL is based upon Ayudervic texts which codify traditional knowledge in widely published volumes freely available in many Indian libraries and universities. This has been argued as creating a distinction between the types of knowledge being incorporated in the TKDL from other less readily accessible sources of TK.<sup>74</sup> This distinction may be seen as being based upon three fundamental features: first, the extent of codification of traditional knowledge; second, the extent of publication; and third, the level of availability or freedom of access to published texts in the public domain.

If valid, such a distinction will be important for a number of reasons. First, it identifies the need to design systems for the protection of TK in a manner which is appropriate for the type of knowledge system involved, including, as appropriate, the development and use of databases. Second, it signifies the fact that a system for the classification of traditional knowledge must be sensitive to the differences in knowledge systems. Finally, it signals a need to ensure that the international debate on the protection of traditional knowledge is cognisant of the differences in traditional knowledge systems and does not seek to promote a one–size–fits–all solution.

#### 2.3 NGO Co-operative Databases

India has been one of the most important testing grounds for registers of traditional knowledge. These have included a range of experiences including the highly renowned Peoples Biodiversity **Registers, the Traditional Knowledge Digital Library** (discussed previously), the Honey Bee Database and National Innovation Fund, and the Farmers Rights Information System (FRIS). The scope of knowledge recorded in databases in India is very broad and includes knowledge on conservation and use of biodiversity, agricultural and farm practices, livestock management practices, water management practices, herbal medicine and human health practices, rural craft and innovations in general. The registered knowledge has economic, socio-cultural, ecological ethical and spiritual values. The databases display a wide diversity of objectives and have developed distinct operating practices which in turn have provided a wider range of experiences from which to inform national debates on the development of legislation-based TK databases.

One of the most interesting questions regarding the Indian experiences relates to the role of non-governmental organisations in seeking to develop mechanisms to provide protection for TK in the absence of national laws governing the collection and use of such information. This report will look at two distinct cases: that of FRIS, which has collected information primarily for conservation purposes, and the Honey Bee database, which seeks to bring commercial benefits to local community innovators in return for disclosure of their innovations for wider global use by local communities.

#### 2.3.1 Farmers Rights Information System (FRIS)

The Farmers Rights Information System database is part of the collection of the Scarascia Mugnozza Genetic Resources Centre of the MS Swaminathan Research Foundation–MSSRF, an NGO in Chennai. FRIS is essentially a holistic database linked to the Community Gene Bank(CGB)<sup>75</sup> which holds seed samples of farmers' varieties of different crops from Tamil Nadu, Kerala and Orissa, where the Foundation is involved in livelihood-linked conservation. The objective of the gene bank to collect and document biological materials, predominantly seed varieties of the regions mentioned above as well as fruit, inflorescence, roots, tubers, rhizomes, sucker, live plants and dried plants, and to regenerate these plants using genetic techniques in the case of extinction, alarmingly low count of the species, or for propagating and sustaining agrobiodiversity.

#### Scope

The CBD and FRIS are parts of a larger comprehensive system for the conservation of agro-biodiversity as an aid to local development, coordinated by the Foundation. The underlying impetus behind the establishment of FRIS is that local communities who play a big role in conservation should derive economic benefit from it. To that end, the system seeks to put community conservationists in contact with relevant traders.<sup>76</sup> The components of this project include the documentation and promotion of agricultural and farm conservation practices in Tamilnadu, Kerela, Andhra–Pradesh and Orissa. In these regions, the Foundation undertakes conservation-based project activities involving collection and depositing of traditional varieties in the CGB, conducting farmers' forums at villages, establishing farmer-participatory village seed banks, educating farmers on seed selection, variety purification, plant breeding, and new techniques developed through research, as well as linking farmers to traders by excluding intermediaries. FRIS seeks to promote the traditional role of farmers in the conservation and enhancement of genetic resources and to establish legal entitlement for tribal and rural farming communities.<sup>77</sup> Through this system, FRIS aims to get recognition and reward for tribal and rural families for their contribution to genetic resources conservation and enhancement.

#### Procedures

*Gathering and Recording of Material and Information* There are three components to the gene bank:

- 1. A repository for small quantities of biological material and seeds
- Collection forms for seeds which record passport data about seeds<sup>78</sup> and herbarium specimens, in some cases
- A database which includes detailed morphological descriptors, associated traditional knowledge and ethno–botanical information,<sup>79</sup> in manual and electronic format

The members of the Foundation's field staff responsible for collection of seed samples directly from farmers record data in two forms: a farmer identity form and a passport data form. Where possible a photo of the farmers making seed deposit is also made.<sup>80</sup> The seed samples, photos and the collection forms are forwarded to the gene bank manager at Chennai. The seeds are suitably cleaned and dried and then sealed into air-tight aluminium foil bags specially made for the purpose. The seed samples are then labelled with an assigned accession number and stored in a medium range storage facility at the foundation.

Passport data collection forms include information on:

- Collection date
- Collection number<sup>81</sup>
- Accession number<sup>82</sup>
- Nomenclature data
- Source
- Status (botanical, topographical, pedological, habitat, season, phytopathological details, etc)
- Photograph of the collection: b/w, colour
- Farmers attribute
- Farmer's name/donor's name
- Ethnic group
- Full address
- Collector's name
- Collector's address
- Collection given to gene bank manager

In 2001, a new farmers' identity data collection form was adopted with the following information in it:

- The photograph of the farmer
- Name of the Farmer
- Sex
- Spouse name
- Ethnic group/tribe/caste/any other
- Status in village panchayat
- Block/village
- District/state
- Botanical name
- Identity of the collection
- Major identifying feature
- Collection number
- Collection date
- Signature/Thumb Impression of the Farmer
- Signature of CBG manager
- Disclaimer of rights in favour of community rights

The decision to change the collection form was influenced by a number of factors including the Convention on Biological Diversity, the national and international debate on issues of prior informed consent, the national biodiversity strategy, and the development of the plant varieties act. The original form contained more information on botanical and other related details and caters more for scientific and research purposes, whereas the modified form has a more administrative/legal format. Details relating to the farmer are recorded more precisely, including: the status of the farmer in the village panchayat; the addition of the spouse's name for the purposes of benefit—sharing; and where the need arises, identification of community rights, the information about the ethnic group, tribe and caste will also prove helpful.

The larger FRIS system itself documents the history, customs and practices of the communities. Therefore, identification of community rights can be more easily done through this system. This may be one of the advantages of having a database embedded in a more comprehensive system. The addition of the photograph of the farmer helps overcome any confusion about the identity of the farmer and the community he/she belongs to. The details in the present collection form are more precise and concise than the earlier format and there are inherent advantages in having a simple form in terms of maintaining records. This simpler form with more precise details may prove more efficient and cost effective. But at the same time, collecting farmer's photographs, and obtaining signatures of prior informed consent from farmers may prove time consuming as well. Maintenance of the CGB with its data system and periodic regeneration of accessions is a cost intensive process. Without dedicated sources of funding, the sustainability of the FRIS and CGB is being threatened.<sup>83</sup> For one thing, the funding for the gene bank is dwindling and there is an acute shortage of dedicated personnel, and a backlog in the record keeping.<sup>84</sup>

#### **Disclaimer of Rights**

From 2001 onwards, a disclaimer was sought of the farmer providing seed, to the effect that where the variety is owned by the community, the farmer whose name is identified in the collection FID form shall be deemed to hold collective ownership of the variety along with the community and not individually.

The decision to insert the disclaimer was in recognition of community involvement in the development and conservation of many of the traditional varieties and to exclude possible legal complications that could arise by the farmer claiming sole ownership of a community variety, on the strength of the FID sheet issued by the Foundation.<sup>85</sup> The Foundation takes the position that it holds seeds of farmer's varieties and the information in its database as a custodian of the genetic resources which continue to be owned by farming and tribal communities. Access to collections is not at the discretion of the foundation but requires the prior informed consent of farmers and is subject to the agreement of mutually agreed terms, as facilitated by the foundation.<sup>86</sup> This may be likened to a form of trust arrangement with the foundation assuming a fiduciary obligation to protect the interests of farming communities.

#### 2.3.2 Honey Bee Network

The Honey Bee Network established fifteen years ago is an initiative of the Society for Research Initiatives for Sustainable Technologies (SRISTI), an Indian non-governmental organisation (NGO). It is comprised of a number of NGOs, collaborators and members, which include innovators, academics, scientists, researchers, students and homemakers from within and outside India.<sup>87</sup>These include the National Innovation Foundation (NIF), established in 2000 by the Department of Science and Technology of India to promote database management, research and development and IPR management,<sup>88</sup> and the Gujarat Grassroots Innovations Augmentation Network (GIAN), established in 1997 for linking innovators with modern science and technology, market research, design institutions and funding organisations.<sup>89</sup>

The Honey Bee Network is an informal association which pools TK and community innovations in a common database now being managed by the National Innovation Foundation (NIF), with each collaborating institution maintaining separate registers in different regions of India and some outside India.

#### Scope

The network has been gathering and documenting grassroots innovations and TK to prevent abuse by outsiders, to share TK and stimulate innovation and to promote the use of innovations and TK for poverty alleviation. Some of the subject matter documented in the Honey Bee database includes information on conservation and use of biodiversity, agricultural and farm practices, livestock management practices, water management practices, herbal medicine and human health practices, rural craft and innovations.

The main objectives of the Network are: to forge lateral linkage among knowledge providers and innovators in the spirit of mutual help and cooperation; overcome anonymity (that is, every knowledge provider as well as collectors are acknowledged); and ensure fair distribution of benefits among all stakeholders including communities.<sup>90</sup>

#### Procedures

In the Honey Bee case study, students and teachers, grassroots functionaries and rural youths gather information through field trips and surveys.<sup>91</sup> The network's collaborators and members also send in innovations and TK. What is gathered and received is then translated into a number of languages including English and registered in the database or published in the Honey Bee newsletter. The translation effort eases the language barrier that could be faced by foreign patent offices when conducting prior art searches and allows other innovators and TK.

The NIF of India, a collaborator of the Honey Bee, has developed a PIC system primarily to seek the consent of the innovators and TK holders for documenting and adding value to the information. The PIC system comprises a number of elements including a statement of names and addresses of innovators and TK holders, which may include, as appropriate, the community and or communities which hold the relevant information, the sharing of innovations and TK with third parties through various forms of publication, benefit–sharing arrangements for commercial use of the innovations and TK and the assignment of technology to NIF.<sup>92</sup>

Under this PIC system, NIF can mediate and negotiate on behalf of the innovators and TK holders with potential entrepreneurs and investors. Also, in the event that disputes arise with regard to the transfer of technology to third parties, NIF will provide legal support.

Information included in the Honey Bee Network database may include TK of both local communities and indigenous peoples. One potential concern with this form of registration is that by placing traditional knowledge in the database, communities may be deemed to be placing it in the public domain, and thereby may lose any rights over such information.

#### **Rights and Benefit–Sharing Arrangements**

Registration in the Honey Bee database does not lead to the award of a legally defensible right. However, discussions with the national government have been sought to promote the development of some form of certificate of assurance to protect innovators' rights.<sup>93</sup>Innovators are advised in the PIC form that, if they indicate their wish to do so, their information will be kept confidential.

The Honey Bee database is intended for sharing the innovations, ideas, and TK with other third parties including innovators and TK holders throughout the world. However, if the innovations, ideas ,and TK are intended for commercial use by third parties, then rights holders should share in either monetary or non-monetary benefits.

Clause 21 of the Indian Biological Diversity Act 2002 now provides for the determination of equitable sharing of benefits arising from the use of biodiversity and its related knowledge. The following benefit—sharing scheme has been suggested by the NIF: innovators 35 per cent, innovator's community/village 15 per cent, innovation promotion fund 20 per cent, researchers 15 per cent, and institutional overheads 15 per cent. This arrangement is, however, negotiable.

To date, GIAN has filed a number of patents on behalf of innovators, licensed technologies to companies in India and the USA, and shared all the benefits with innovators.<sup>94</sup> When dealing with foreign nationals who have submitted TK or innovations to the Honey Bee database but reside outside India, the question arises as to the status of such knowledge. It appears that any access and benefit–sharing arrangements would fall within the scope of the Biological Diversity Act 2002 implying the need for a mechanism for benefit–sharing with foreign nationals that have their TK or innovations registered in the Honey Bee database.

There is much to learn from the Honey Bee database as one of the oldest TK and innovation databases. By documenting TK and innovations, it is working toward the achievement of some of its goals, such as preventing TK from erosion and attempting to add value to the TK and innovations and commercialising them, which in turn is intended to alleviate poverty. However, there are practical difficulties such as attracting public and private investment for innovations which may not generate high returns. To date commercialisation of innovations has not yet generated much success.95 This may be seen as arising from the lack of support structures required to secure recognition for the value of community innovations and TK and their potential role for local and national development. The Honey Bee Network may, to some extent, be seen as a reaction to this lack of formal support for community innovation and TK which might more properly be expected of development planners, international aid agencies, and science and technology research institutions.<sup>96</sup>

While the PIC system developed by NIF is a progressive step in the documentation exercise, it may be time consuming and costly. There may also be a need for a review of the database to bring it within the framework of the Biological Diversity Act 2002.<sup>97</sup>

There have also been proposals to promote the establishment of a Global Innovation Foundation, based on the Honey Bee Network model, to protect innovators' rights in a manner similar to performers' rights.<sup>98</sup> This may be seen as the promotion of a form of database trust for innovators.

Legislative Recognition of Registers in India Various other agencies and institutions in India have also experimented with databases for various purposes including, most notably, the Peoples Biodiversity Registers (PBR) and the Traditional Knowledge Digital Library (TKDL). Together with the case study experiences discussed previously, these have influenced the development of national legislation; namely, the Biological Diversity Act 2002 and Protection of Plant Varieties and Farmer's Rights Act 2001, both of which provide for registers, which will include components of TK.

The Biological Diversity Act 2002, under clause 36(5), states that one of the methods to respect and protect the knowledge of local people relating to biological

diversity is through registration of such knowledge at the local, state, or national levels, and allows for other measures for protection, including sui generis system. The Protection of Plant Varieties and Farmer's Rights Act 2001 goes a step further and embodies a set of rules in Sections 12 to 38 to establish a registry, and obtain certificates of registration, etc. According to Section 28 of the Act, registration confers an exclusive right on the breeder or their successor, their agent or licensee, to produce, sell, market, distribute, import or export the variety. In establishing the national systems of registers, one challenge will be to decide how to incorporate information already included in databases like FRIS and Honey Bee, as well as the PBR and TKDL. It will also be necessary to determine whether information collected prior to the entry into force of the Act is to be considered to be in the public domain. Alternatively, these various databases may in some cases be considered to have been holding data in trust for communities until such time as the national system for registration of TK is established and functioning.

#### 2.4 Registers Established by Law

National law in a number of countries has established registers for the protection of traditional knowledge. This has included the adoption of administrative, legislative and policy measures in many countries including the Indian Biodiversity Act 2002 (discussed above), Brazil's interim regime (medida provisoria No. 2.126-8) on ABS, Kenya's register of traditional healers, Panama's law on folklore, Peru's collective regime on traditional knowledge, Portugal's TK law, and Thailand's register of traditional medicine, as well as measures within the Andean Community, the Organization of African Unity and the South Pacific Forum providing for the registration of traditional knowledge.<sup>99</sup>

Despite these efforts, the majority of these instruments are not yet operational and discussion of their relative merits and limitations is therefore restricted by lack of firm experience upon which to base an analysis. In the hope of demonstrating the diversity of potential legal regimes, two examples have been considered to show the distinction between what are termed declaratory and constitutive registers. These are the Panamanian regime, which focuses both on folklore and TK relating to the environment, and on the Peruvian regime for the protection of collective knowledge relating to biodiversity.

#### 2.4.1 Panama

Law No. 20 of 26 June 2000 of Panama creates the Special Regime for Intellectual Property over Collective Knowledge of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge. Executive Decree No. 12 of 20 March 2001 establishes the implementing regulation to this law. Both the law and the executive decree focus primarily on the protection of expressions of culture rather than on TK relating to biological diversity. However, reference is made to knowledge relating to resources and traditional medicines in the Executive Decree. Analysis of the existing registers for protection of expressions of culture may provide some insights into the format for any register to provide for positive protection of TK related to biodiversity which may in the future be adopted in Panama.

#### Scope

This legal regime seeks to protect collective intellectual property rights and TK of indigenous peoples over creations such as inventions, models, drawings and designs, innovations contained in images, symbols, graphics and others; and cultural elements of their history, music, art, traditional artistic expressions, all of which might be susceptible to commercial use through a special system of registers and the promotion and commercialisation of their creations and products.

The regime identifies elements of indigenous cultural patrimony such as customs, traditions, beliefs, cosmovision, religion, folklore expressions, artistic manifestations, TK and any other traditional expression of indigenous peoples. These cannot be subject to applications for exclusive rights under the intellectual property system such as copyrights, industrial models, trademarks, indications of geographical origins by non–authorised third parties.<sup>100</sup>

Indigenous collective rights are defined as intellectual and cultural rights of indigenous peoples which refer to art; music; literature; biological, ecological, medical knowledge and other aspects and expressions, with no known author nor owner, nor date of creation and which are part of the patrimony of an indigenous group (pueblo indígena). Law No. 20 recognises rights over traditional dress and garments, musical instruments, music, dance, written or oral expressions, techniques for their creation and, in general, any and all manifestation of a traditional nature. These can be registered in order to preserve their originality and authenticity. To be protected, the objects need to comply with certain criteria: "cultural identification" (an intrinsic bond between the community and tradition) and susceptibility to commercial use (this condition is critical for the protection of the collective right).

#### Procedures

In terms of procedure, an application is presented to the national authority and is reviewed within thirty days. If information is missing, it will be requested of the applicant (and must be provided within a maximum of six months). If this is not satisfied, the application is abandoned. If the application is fully completed and conditions met, the Collective Right is registered, recognising the indigenous group or community who created and possess the TK or folklore expression as the owner.

#### **Rights and Administration**

The Collective Register for Intellectual Property is part of a sui generis regime for the protection of TK (which offers positive protection) by granting rights over registered traditional knowledge. The State confers an exclusive right to indigenous peoples to exclude third parties from the exploitation of the collective right which is based on the registered TK or expression of folklore. The application can be presented to: the Dirección Nacional de Derechos de Autor del Ministerio de Educación (the copyright office), or the newly created Departamento de Derechos Colectivos y Expresiones Folclóricas de la Dirección General del Registro de la Propiedad Industrial del Ministerio de Comercio e Industrias (Department of Collective Rights and Expressions of Folklore of the Industrial Property Office). The register application must be presented by the general national congresses or indigenous peoples' traditional authorities in order to protect their dress, art, music or any other traditional right susceptible of protection. The congress or authorities will also appoint a formal representative.

In terms of content, the application for protection (which is in a standardised format) must include: an indication that it refers to a collective right; that it pertains to national indigenous people; the technique used (if it refers to an object); brief description of the tradition involved; and, an official act which formalises the request for an application. Information in the registration includes: the indigenous people group(s) which request(s) the registering of the TK or object, the general congress or indigenous peoples authority, the indigenous collective right which it is sought register (using indigenous language and the official language), use or uses of indigenous TK or object, history of the collective right, dependent communities or beneficiaries, and a sample of the object which is to be registered.

Access to the register is open to the public except in the case of experiments and "cognitive processes", meaning knowledge acquired over time through observation of and experimentation with the environment in which humans conduct their existence, which may be seen as biodiversity– related TK.<sup>101</sup>

Registration of the right is for an undetermined period. The rights cannot be used to prevent other indigenous peoples from using their traditional knowledge.

The right provided by the register allows the holder of the collective right to impede third parties from the use and commercialisation of the object or knowledge without the consent of the relevant indigenous traditional authorities. The holder can impede the reproduction, serigraphy, and printing of the cultural object or feature. The register may therefore be termed a constitutive register as rights stem from the act of registration. The law recognises a specific role for customary law and practice stating that the rights of use and commercialisation of the art, crafts and other cultural expressions based on the tradition of the indigenous community, must be governed by the regulation of each indigenous communities, approved and registered at the office of the Director–General of Intellectual Property (DIGERPI) or in the National Copyright Office of the Ministry of Education, according to the case.<sup>102</sup>

The law proposes a system of reciprocity with regard to protection of TK from other countries, perhaps showing the way towards the progressive development of an international system for positive protection of TK.

#### 2.4.2 Peru

Law 27811 of 24 July 2002 established the Regime for the Protection of Collective Knowledge of Indigenous People Related to Biodiversity. This is the first comprehensive effort by a developing country with a large indigenous population to establish a *sui generis* regime for the protection of rights over traditional ecological knowledge. The law was the product of a protracted development process spanning almost six years which adopted a range of strategies to engage indigenous peoples,<sup>103</sup> and incorporated the participation of national and international experts in its preparation.

#### Objectives

The objectives of the Peruvian regime are very ambitious:

- To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples
- To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge
- To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general
- To ensure that the use of the knowledge takes place with the prior informed consent of indigenous peoples
- To promote the strengthening and development of the potential of indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime
- To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of such inventions

#### **Scope and Rights**

This legal regime focuses on the protection of TK as it specifically relates to the characteristics, uses and properties of biodiversity. Unlike the CBD and regional legislation relating to access to genetic resources and TK, as well as national law in this area the regime does not specifically address the issue of protection of the innovations and practices of indigenous peoples relating to biological diversity.

As a basic principle, any interested party who seeks to use TK for scientific, commercial or industrial purposes needs the prior informed consent of the representative organisation of indigenous peoples (Article 6). TK will be protected through a series of inter–related instruments: contracts (licences for the use of TK for commercial or industrial ends), trade secrets, registers and unfair competition administrative regulations.

The law provides two kinds of protection for TK. Defensive protection—basically through registers and positive protection by recognising that TK is the cultural patrimony of indigenous peoples (Article 6) and, in the case of TK not in the public domain access or use for commercial purposes, requires the prior consent of indigenous communities (Article 42). Furthermore, the law provides for action to prevent the disclosure or publication of TK, using principles of trade secrets as a basis for protection.

The law establishes an important precedent recognising rights of indigenous peoples to share in the benefits derived from the use of TK in the public domain. This right is limited in two aspects, first it relates only to TK which entered into the public domain in the last twenty years, and second, it only allows for a right to compensation and not to restrict or otherwise control access to or use of such TK.

#### **Administration and Procedures**

The Peruvian Law provides for three types of TK registers: a national public register, a national confidential register and local registers. The national registers will be administered by the Instituto Nacional de Defensa de la Competencia y la Propiedad Intelectual (INDECOPI), the national authority for consumer affairs, unfair trade law and IPR. The local register will be developed and administered by communities themselves (Article 15). These registers are created basically to preserve TK and safeguard existing rights of communities over them, and provide INDECOPI with information which might allow them to defend indigenous peoples' interests over their TK (Article 16).

The national public register will incorporate TK which is in the public domain (Article 15). It will basically serve to assist in providing centralised and organised information relevant for patent prior art searches and to challenge patents and other IPR's granted in conflict with rights over TK. The public register will be open and available to interested parties. INDECOPI will be primarily responsible for this.<sup>104</sup> A confidential TK register will also be maintained by INDECOPI. The exact role of a confidential TK register, administered by the national authority, is still unclear. Although during the consultation process of the law, indigenous peoples groups manifested themselves in favour of this type or modality or register, its practical objective is difficult to envision as is the incentives indigenous peoples would have to register TK under confidentiality. Arguably, if there is secret or valuable TK which is not in the public domain and for which registration is required, a local register might be the best and safest instrument.

Indigenous peoples, through their representative organisation will register their TK in the public or confidential register administered by INDECOPI. Applications for registering TK will include: identification of indigenous peoples, identification of representatives, indication of the biological resource to which TK is related, uses of biological resource, clear description of TK subject to registration, formal agreement (an act) where indigenous people agree to register their TK. The application could include a sample of the relevant biological resource or, if this is not possible in practice, photographs which enable INDECOPI to identify the resource under consideration and submit it to taxonomical analysis (Article 20).

In terms of procedure, the application should be registered within ten days of its reception. If a requisite is missing, indigenous peoples are given up to six months to complete the application after which it will be declared abandoned (Article 21). To further promote the registration of TK, INDECOPI will send officials to the field to register TK (Article 22).<sup>105</sup>

It is the obligation of INDECOPI to ensure that information which is recorded in the public TK register is brought to the attention of relevant IPR authorities worldwide in order to ensure it is taken into account in the case of intellectual property applications involving TK (Article 23).

Registration in either the public or confidential register may be cancelled by INDECOPI if it does not comply with the overall provisions of the Law or if the information and data included are proved to be false or inexact (Article 34).

In the case of local registers, the Law simply states that these can be organised and designed according to indigenous peoples' traditional uses and practices. The law states that INDECOPI may provide technical assistance, if required, to assist with design, development, and implementation of these registers. The law makes no specific provisions for the recognition of local registers as sources of prior art and it is unclear what exactly the relationship, if any, will be between the local and national registers. The law establishes an indigenous fund to be managed by indigenous peoples. The fund will capture a percentage of all transactions involving TK. The purpose of the fund is to promote more equitable sharing of benefits amongst the nation's indigenous peoples. The mechanism for this fund has not been finalised but it may conceivably be established as a form of trust fund with a majority of indigenous peoples on its board.

The law also recognises a potential role for customary law in the resolution of disputes. This appears to be limited to resolving disputes between communities.

The existing law has been recognised as being merely the first step in the adoption of an effective regime for protection of traditional knowledge. In November 2002, the then President of the National Commission on Andean, Amazonian, and Afroperuvian peoples (CONAPA) stated that the process for development and adoption of implementing regulations will include a national consultative process.<sup>106</sup>

Indigenous peoples have already proposed a series of modifications to the law, including calls to broaden its scope to include not only knowledge, but also their innovations and practices relating to biodiversity, and for increased protection over TK in the public domain.<sup>107</sup> One of their principal concerns has been to promote a national dialogue on the protection of TK in its widest sense. A group of indigenous organisations representing Andean, Amazonian, and Afroperuvian indigenous peoples and local communities have taken the initiative to promote a national indigenous workshop to develop a proposal for a participatory national dialogue on TK.

## 3 Comparative Analysis of the Role of Databases and Registers in the Protection of Traditional Knowledge

The case studies discussed in the previous section demonstrate the existence of a wide range of possible objectives, criteria and administrative procedures for databases and registers. Although it is not intended to set out a checklist of these elements, it is worth briefly setting out the general options which can be discerned from these experiences.

# 3.1 Objectives of Traditional Knowledge Registers and Databases

An important question to be asked—in the context of a policy and regulatory process—is what exactly can registers and databses achieve? The objectives for establishing a database or register will define their characteristics and become a key aspect of their development. Similar to the objectives a TK protection regime might pursue, databases and registers could, on differing levels:

- identify TK rights holders
- serve as a mechanism and tool to promote, protect and either claim rights over or prevent appropriation of TK<sup>108</sup>
- enable the transmission of TK (to future generations of indigenous peoples and interested third parties)
- identify TK holders who might be entitled to benefit-sharing
- identify TK holders who might be interested in entering into research and development endeavours with universities or companies
- provide evidence of the granting of property rights over TK to indigenous peoples, and their assignees, where appropriate
- serve for specific, locally identified educational, social, cultural, religious or other purposes

As the case studies demonstrate, TK registers and databases can actually operate within an existing legal context of specific legal rules and regulations, which will establish scope, nature and procedural aspects of the register and the protection system within which it is embedded (i.e. Peru), or in isolation, as part of specific community or private efforts (as is the case in Canada and Venezuela) without the formal recognition of legislation nor a specific TK protection framework. In some cases, such as the Honey Bee case study, opportunities for databases to play a more proactive role in defense of indigenous interests may occur through securing opportunities for negotiating contracts for the use of material incorporated within the database. 3.2 Information Included in a Traditional Knowledge Database or Register

In terms of the type of TK information which might be registered, a preliminary list could include:

- information regarding uses, characteristics, effects of medicinal plants, and methods for the preparation of medicinal compounds
- information regarding uses of agro-biodiversity components (crops, insects, soils, etc.)
- descriptions of nature/sacred rites and religious practices
- descriptions of myth, legends and historical passages
- information regarding specific features and characteristics of ecosystems
- information regarding different uses of biodiversity and natural resources in general

This information would, of course, depend on the exact scope given to the database or register and what it exactly seeks to incorporate and maintain. Current policy and legal efforts and interests are mostly focused on the first, second, and last points above.

Interestingly, in the case of Peru, the national register authority requires that, under certain circumstances, a sample or photograph of the biological resource to which TK relates is included or attached to the TK register application for identification or taxonomic purposes.

# 3.3 Criteria for Incorporating Traditional Knowlege into a Database or Register

In order to incorporate TK into a database or register, certain criteria would need to be met. Some of these criteria could include:

- identification of the community, nation, indigenous group, tribe, etc, (or its duly authorised representative) whose TK is to be incorporated in a database or which applies for registration of TK<sup>109</sup>
- a description of the relevant TK (this could imply translations, standardised and common formats and the provision of additional taxonomic information of resources to which TK relate)<sup>110</sup>
- written evidence of the Prior Informed Consent (PIC) of the applicable indigenous or local community regarding the incorporation of their TK into a database or register

An important aspect of the discussion on databases and registers is the public disclosure of information that may be of a confidential/semi-confidential or of a privileged nature. Establishing a register in which all of the information is maintained as confidential and third parties (who are not indigenous) are denied access would seem to run counter to the very principle of registers which is to put the public on notice of the existence of a right. However, in particular circumstances, as will be discussed more fully below, this may be a valid option for indigenous peoples seeking to protect and preserve their TK. A register which has varied levels of access and disclosure of information, may offer the flexibility required to make the register operational. Rules and procedures setting out the particular type of information and conditions of access and confidentiality would need to be clearly specified.

Establishing confidential databases as a means to collate and protect traditional knowledge for the use of local communities or closed research groups approved by indigenous peoples may offer interesting opportunities for protection of TK. However, if the purpose of the register or database is to promote defensive protection, then this can at present only be achieved by making it public.

Establishing different levels of access to a register (and to databases) is one way to ensure a degree of control over the TK information. For example, one means to limit access is to maintain the physical equipment (i.e. the computer hard drive) in a restricted area (this would be the case of registers or databases which are not connected to the Internet); another means to limit access are special passwords for the use of the computer; restrictions to the actual use of the program are yet another level; restricting access to the specific file or archive of the relevant program acts as another level to limit access to the information; access could be limited in terms of who is operating the program: the administrator; the database manager; the general public.<sup>111</sup>

An often overlooked issue, which is central to these discussions, is the general motivation and incentives that might encourage indigenous peoples (at the individual, communal, or political organisation level) to document their TK, whether in a database or register. The incentives and general purposes for doing so need to be clearly specified in any regime, and fully understood by indigenous peoples if any TK database or register is to be successful in protecting TK. Such incentives might include: direct monetary and non-monetary compensation, recognition of intellectual property rights, exclusive rights to use of TK, mechanisms to secure the material existence of TK. The establishment and clarification of measurable benefits arising from registration will be instrumental to the development of TK registers and databases.

Arguments regarding "the need to preserve TK" may not be sufficient incentive to ensure proactive registering of TK by indigenous peoples; in particular, where there are concerns regarding the potential for unapproved use of their knowledge. Indigenous peoples will want to see effective systems for recognition and protection of their rights over their TK; most probably through the development of *sui generis* regimes.

Finally, institutional aspects related to who can establish a register and how are registers administered pose interesting challenges regarding capacities to manage these registers, participation in their design, how information and data might be processed, etc. Technical and technological aspects of registers and database management will play a key role in determining possibilities for the effective management and protection of their content.

# 3.4 Scope and Institutional Management of Registers

With respect to their scope, registers may have a local, national, regional or even international dimension. If an international database or register is to be established, it will be important to ensure indigenous peoples participation and involvement in its design, maintenance and management. In reality, what is more viable than an international consolidated database or register may be a network which creates linkages among registers in order to strengthen their overall roles at the local, national and international levels.

#### **3.4.1 Local Databases and Registers**

Local registers are particularly interesting. Where TK is being eroded and lost, documenting and recording that knowledge and its different manifestations (knowledge per se, innovations and practices) at the local level may be an integral component for a strategy designed to maintain and preserve TK. Establishment of local databases and registers in the form of handwritten or electronic databases, information booklets, video or audio recordings or more sophisticated methods offer communities an alternative to maintaining TK solely on the basis of oral tradition, and may be important for ensuring its transmission to future generations. Local databases and registers can help to develop new approaches to teaching and understanding TK within communities,<sup>112</sup> and in as much as they can identify individual innovators, they can also act as an additional incentive for promoting continued traditional innovation processes at the community level. It should be noted that preserving TK in written, digitised, photographic, taped or other such formats may have the effect of modifying the content and

nature of TK and may have a potentially negative cultural impact in some circumstances. There is always a danger of consolidating one source or type of knowledge, it may have the unintentional effect of creating a static form of that knowledge. For instance, a particular indigenous community might have a traditional story related to a particular land use this story would likely be dynamic and held by multiple TK holders in the community. The act of having a single interview recorded on video to pass on from one generation to the next might actually lock the story in static form. A solution might include revisiting the interpretation to ensure that there is an evolving interpretation of that TK in the relevant database.

Local databases and registers may be directly designed, developed, constructed and managed by indigenous communities. Rules for access and use of TK in registers could be defined by indigenous communities based on their customary and traditional practices, and/or community protocols. Reflecting these customary and traditional practices in national laws and regulations will play a key role in building indigenous peoples' engagement and confidence with the system in order to enable effective implementation of any local and national system of registers and databases. At a minimum, national laws and regulations might affirm that indigenous peoples through their customary laws and practices shall have ownership of their TK and recognise indigenous jurisdiction to legislate, contract and otherwise control their TK. National laws may be able to act as enabling laws in order to establish substantive recognition of indigenous rights.

The possibilities for local databases and registers to play a proactive role in securing legal protection of TK is at present limited and mainly restricted to defining rights within the jurisdiction of relevant customary law. The manner in which national law incorporates local databases and registers into national efforts to protect TK will play an important part in securing community rights both nationally and internationally. Local registers could serve a role as evidence of prior art if incorporated into a national network including both local registers and the national (public and confidential) registers. Establishment of standard minimum criteria for classification of information in local registers may be necessary to facilitate their inclusion in a national system of registers.

#### 3.4.2 National Registers

National registers might serve to either grant legal rights over TK or to recognise the existence of ancestral rights over TK for indigenous communities that decide to register. A key role of a national register might be to ensure that the registered TK holder(s) are able to participate in the benefits generated from the use of their TK. Responsibility to ensure equitable sharing of benefits could be assisted through registration where various communities share similar TK which is generating different types of commercial or non commercial benefits. Registration may also offer an advantage to indigenous peoples where this serves to promote increased access to conservation and development funds based upon their knowledge of the biodiversity of a region. Finally, a national register could also help to identify communities which are willing and committed to establishing research, and development partnerships with universities, companies or other entities. An important issue will be to determine the particular custodian or manager of a national register(s). This will likely depend on the nature of the actual register. A national register might be managed and administered by a national centralised authority which has the capacity and mandate to ensure indigenous peoples participation in its establishment maintenance and management. An existing public authority such as the national IPR office, a national authority responsible for indigenous affairs or a similar body may be a suitable manager and administrator. A progressive model might be to design and create a central authority that was co-managed by representatives from existing intellectual property offices and indigenous experts on traditional knowledge, including TK holders. This authority would be responsible for:

- processing TK registration applications
- systematising and classifying the TK related information in the application
- overseeing the overall registration procedure
- granting or denying applications
- solving administrative disputes (similar applications, overlapping TK)
- providing foreign IPR offices with relevant information (in order to promote thorough prior art searches)
- overseeing who accesses the register and under what conditions or limitations
- developing protocols governing access and use of TK information, among other possible functions

## 4 The Role of Databases and Registers in the Legal Protection of Traditional Knowledge

#### 4.1 Defensive Protection

Defensive protection of TK basically entails ensuring the IPR system (and patent application processes in particular) takes into account TK during the process of evaluating applications for IPR in order to determine the level of novelty and inventiveness.<sup>113</sup> At present this requires ensuring that IPR authorities have free access to all available and relevant information on which to base their decisions regarding the granting of a patent over an invention. Providing access to documented TK—in journals, books, databases, and registers—is one of the mechanisms through which IPR authorities analyse prior art in order to verify essential and substantial characteristics of inventions and determine whether they are worthy of being granted protection.

Legislation in the Andean Community (Venezuela, Colombia, Ecuador, Peru, and Bolivia) has established measures providing for defensive protection of TK (Decisions 391 and 486); Brazil (Medida Provisoria No. 2.186-16 of 23 August 2001), Costa Rica (Ley 7788), and Peru (Ley 27811) have done likewise. What these legal instruments basically require is that prior to the processing and granting of patent rights, evidence must be provided by applicants regarding the legal origin of biological materials and TK incorporated in or utilised to develop the invention (usually in the biotechnological field). These measures are designed to support national legislation which establishes rules on access to genetic resources and TK.

Efforts to compile TK in the public domain into accessible databases as means for defensive protection has been undertaken in a number of countries, most notably in India with the TKDL database. Similarly, legislation in Peru provides for the establishment of a national register for the purpose of defensive protection of TK. As noted above, the development of open access databases in developing countries as a means to enhance defensive protection has been criticised as providing a more readily accessible source of TK for commercial use without securing any recognition of rights over such knowledge. Notwithstanding the merits behind such concerns, where there is TK which has been freely and knowingly placed in the public domain, or over which indigenous or local communities have waived any claim, the compilation of such knowledge into public databases or registers for the purpose of defensive protection may help prevent the granting of patents over elements of TK or products developed without an inventive step.

While a number of the databases and registers analysed in the case studies may have a role to play for the purposes of defensive protection, a high percentage would not serve as sources of prior art for patent searches as they are not publicly available. This is the case with the Inuit database, confidential elements of the BioZulua database, the Peruvian confidential register, and any registration of "cognitive processes" in Panama. These four examples demonstrate one of the contradictions relating to the development of databases and registers of TK as a means for securing defensive protection of indigenous rights; that is, that in order to protect against expropriation by third parties, indigenous peoples may need to place their knowledge into the public domain, thereby losing control over access to and use of such knowledge.

#### 4.1.1 Confidentiality and Defensive Protection: Conflicts and Opportunities

TK is not merely a collection of facts and figures; it is a complete knowledge system bound by codes of conduct and customary law regarding rights of transmission, and frequently including initiation rites as a prerequisite for receiving information. Requiring documentation of TK as a prerequisite for accepting evidence of TK for defensive protection purposes may run counter to these cultural practices. Faced with cultural restrictions and concerns regarding the disclosure of knowledge into the public domain or its sharing with uninitiated people the challenge to the IP system is to design mechanisms through which the existence of prior art maybe identified without jeapordising the knowledge system and cultural integrity of the holders of such knowledge.

An example of how this may be achieved can be seen from the case of the Inuit who maintain a very high level of secrecy over the content of their registers. On occasion access has been provided to information in the registers for government officials on a confidential basis, as necessary; for example, to substantiate a land claim. Another example relates to an action to seek revision of a patent over Ayahuasca. As part of this action a shaman from the Amazon offered to give oral evidence of TK. However the relevant US patent regulations treated such oral evidence of prior art as inadmissible.

These experiences suggest a number of opportunities for broadening the scope for defensive protection of TK in a more culturally sensitive manner. This would include allowing for oral evidence of prior art, establishing means for such evidence to be given in a confidential manner, and providing for limited and restricted access to confidential databases. Where a system of local community and indigenous peoples databases and registers is linked into the national system of registers of traditional knowledge, these registers may also become a source of evidence of prior art. Existing requirements for declaring prior art in patent applications may bring to light the existence of TK. In such cases the patent authorities may carry out a directed search in the source country contacting national patent authorities and registers of TK for information on relevant prior art. In cases where an application identifies the use of genetic resources a patent authority may also seek to identify the country of source of such genetic resources and request information regarding the existence of relevant traditional knowledge relating to these resources.

Tracing the source of TK is more difficult for patent authorities where there is no clear information regarding the source of TK or of genetic resources in the patent application.

#### 4.1.2 Disclosure of Origin and Defensive Protection

Requirements for the disclosure of the source, origin, or legal provenance of genetic resources and/or TK in patent applications have already been incorporated into legislation in a number of countries, including Costa Rica, Denmark, Egypt, Norway, and Peru, as well as in the legislation of the Andean community, while Brazil, on behalf of a group of developing countries, has proposed inclusion of such requirements within TRIPS.<sup>114</sup> More recently a submission made by Switzerland to the WTO Council for TRIPS, in May 2003, proposes amendment to Regulations under the Patent Cooperation Treaty, to enable Contracting Parties to require patent applicants to disclose the source of genetic resources and/or traditional knowledge, if an invention is based on or uses such resource or knowledge.<sup>115</sup> As regards the compatibility of such disclosure requirements with international law, WIPO has prepared a recent study which noted that there is a range of methods that are consistent with the essential elements of patent law and key aspects of WIPO Treaties.<sup>116</sup>

Requiring disclosure of origin of genetic resources and TK in patent applications would provide patent authorities with more specific detail upon which to direct their search for prior art. A request for information might then be sent by a patent authority to the national authorities in the country from which TK has been sourced, who in turn can inform indigenous people of the request for information. In such a case, indigenous peoples or local communities could refer to their local register or source of oral evidence of prior art. A system could be developed to assist the flow of information from the relevant indigenous people to the patent authority reviewing the patent application.

Where relevant evidence of prior art is held in a confidential register, measures may be taken to provide limited access to the extent necessary to disclaim or prove the existence of novelty. Mechanisms might be established to enable this information to be given in confidence, orally or otherwise. Where this would require disclosure of confidential information, a requirement could be established for IP offices to take all possible measures to protect this information against unfair or unapproved use of TK. Such a system may, in the long run, prove a cost–effective mechanism for preventing escalating costs of patent revision as increasing attention is drawn to cases of biopiracy.

# 4.2 Positive Protection: The Role of Databases and Registers Protection Under Sui Generis Regimes

While a register or database can act as an instrument for defensive protection through little more than the collation and maintenance of information in a manner which is accessible and complete for the purposes of patent searches, positive protection requires a legislative basis for the recognition or granting of rights over knowledge. This may arise through extension of existing intellectual property rights regimes or the establishment of sui generis regimes. The potential and limitations of providing protection to TK through existing intellectual property regimes have been widely discussed elsewhere and analysis of the merits or otherwise of such regimes is beyond the scope of the present study. Instead this part of the report focuses on the role a register may play within the framework of a sui generis regime for the protection of traditional knowledge.

Positive protection may also be granted by customary law and practice or the legal enactments of indigenous peoples where their rights to regulate their cultural patrimony, whether tangible or intangible are recognised by national law and policy.

Creating an obligation for the registration of TK as a precondition for recognition of rights over it would place indigenous peoples under a heavier burden for recognition of rights than is generally required by existing intellectual property rights regimes which do not require prior documentation of intangible property as a condition for its protection.<sup>117</sup>

#### 4.2.1 Sui Generis Regimes for the Protection of Traditional Knowledge

A sui generis regime for the protection of TK will set out the legal rules and procedures applicable to TK and will define what purpose or role a register will play in the regime.

Existing conceptual frameworks, draft laws or legislation differ considerably with regard to the role registers can play in positive protection. In the case of Peru's Law 27811 for the protection of collective knowledge, local registers have no defined role in legal protection of TK, while national registers play a dual role, seeking to maintain and preserve TK as well as to enable the national authority (INDECOPI) to take action to prevent unapproved use of TK. In the case of Panama, registers assign specific rights to indigenous peoples to impede the commercial use of certain TK and cultural objects. In India, through Clause 36 (5) of the Biological Diversity Act 2002 the central government endeavours to respect and protect the knowledge of local people relating to biological diversity through measures which may include registration of knowledge at the local, state or national levels and other measures for protection including development of a *sui generis* system.

If a special or *sui generis* regime for the protection of TK is developed at the national or international level, registers will likely serve as one of the various tools required to make such a regime functional. Trade secrets, patents, copyright, collective marks, access and benefit–sharing law and policy, compensation funds, contracts, registers, among other instruments, could all play a role in the context of a regime or system to protect TK. Depending on the exact meaning given to the concept of protection and its ultimate objective, these (and other) different tools and instruments could be incorporated into a *sui generis* regime established to protect TK which might include the following components:

- establishment of laws to recognize exclusive rights for indigenous peoples over their TK (i.e. in a way similar to that of "traditional" IPR)
- registries and/or databases that promote the documentation, maintenance and preservation of TK
- mechanisms for the monetary and non-monetary compensation of indigenous peoples for the use of their TK
- procedures ensuring that TK is not utilised without the Prior Informed Consent (PIC) of indigenous peoples, including disclosure of origin requirements in patent application procedures
- utilisation or amendment of existing intellectual property instruments, including copyright, patents, trade secrets, plant breeders rights, and unfair competition laws in order to secure indigenous peoples' interests over the product of their intellectual efforts<sup>118</sup>
- mechanisms establishing a duty to negotiate in good faith
- measures for resolving conflicts arising from access to and use of TK
- investigation and enforcement powers
- recognition of the role and importance of customary law and practice in the definition of rules for access and use of TK, benefit–sharing and resolution of disputes

*Sui generis* regimes may be adopted both in countries in which the original custodians of TK reside and those countries in which it is used, now commonly known as "user countries". Under the Bonn Guidelines on Access and Benefit–Sharing (ABS), international ABS governance, and by implication, international governance of TK issues, requires adoption of administrative, legislative and/or policy measures by both source countries and countries where resources are used.

#### 4.2.2 Customary Law and Positive Protection

Consideration of the cases studies examined previously suggests that customary laws and practices of indigenous peoples may play a dynamic and decisive role in establishing the parameters of positive protection, and in defining the objectives, scope, procedures and enforcement of rights over TK. This may occur in a number of different ways.

First, there are those cases in which national law recognises TK to be the cultural patrimony of indigenous peoples, such as is the case under the Peruvian and Panamanian laws TK laws. The concept of cultural patrimony brings with it the notion of cultural integrity and the right of indigenous peoples to define mechanisms for protection of their knowledge in accordance with customary law and practice. It also presumes an obligation on the part of the state not to take any action which will undermine the integrity of such patrimony.

Second, there are those cases where national law and policy specifically grants to indigenous peoples or local communities rights to exercise control over biological resources on their traditional territories and/or their TK through the application of customary law and practice. This is the case to a lesser or greater degree in many South Pacific Island States, as well as in numerous countries of Africa, Asia and South America.

Third, there are cases where national authorities are bound by treaty not to take any action which will affect the rights of indigenous peoples over their natural resources or TK without first entering into consultation with them. This is the case, for example, with the Treaty of Waitangi in New Zealand.<sup>119</sup> In such situations, although indigenous peoples may not be empowered to exercise full self governance, national authorities may be required to give effect to treaty obligations through the provision of appropriate protection for rights over traditional knowledge.

Finally, there are instances where indigenous rights to self–governance have been recognised by treaty or under national law, and indigenous peoples have the opportunity to define their own internal regulations regarding access to and use of their knowledge. A number of Canadian First Nations, for example, have obtained legal recognition of extensive rights of self–governance. It remains to be seen to what extent they may exercise such rights in order to develop their own TK regimes and, where appropriate, to grant positive rights over TK. The case studies have shown a tendency to avoid the definition of detailed provisions regarding the scope of cultural rights (Panama and Peru), to regulate access to and use of TK, and to leave it to indigenous peoples to define their own sets of rules (Panama), or to apply customary law to resolution of disputes (Panama and Peru). This trend tends to demonstrate the need for full and effective interaction with indigenous peoples and local communities when defining national and international law and policy in this area in order to ensure the development of a flexible but integrated system to provide functional protection for TK.

It is necessary to remember that even if customary law is given due recognition, there are as many customary law systems as there are indigenous peoples. This poses a major challenge which cannot be overlooked in developing international and national law in this area.

# 4.3 The Nature and Characteristics of Declarative Versus Constitutive Registers

Registers can be analysed from many different perspectives. According to their legal nature, registers can be termed either declarative or constitutive, depending upon the system under which they are established.

#### 4.3.1 Declarative Registers

A declaratory regime relating to TK recognises that the rights over TK do not arise due to any act of government but rather are based upon pre-existing rights, including ancestral, customary, moral and human rights. As a result, a declaratory regime may in effect be seen as recognising the existence of positive rights over traditional knowledge, as may be defined by the customary laws and practices of indigenous peoples and local communities.

In the case of declarative registers, although registration does not affect the existence of such rights, it may be used to assist patent officials in analysing prior art, and to support challenges to patents granted which may have directly or indirectly made use of TK. In circumstances where these registers are organised in an electronic form and available through the Internet, it is important to establish a mechanism that ensures that entry dates of TK are valid when carrying out searches related to novelty and inventiveness. A third function that these registers may have is to facilitate benefit–sharing between users and providers.<sup>120</sup>

The Peruvian TK regime, for instance, is declaratory in nature, recognising that the collective knowledge of indigenous peoples is part of their cultural patrimony. Although the regime does not link any positive rights to registration of TK under this regime, it does recognise an obligation upon the national authority to seek to defend the rights of indigenous peoples over the knowledge in the registers. The law also recognises a right of indigenous peoples to share in the benefits derived from use of their knowledge within the public domain. Furthermore, the law requires PIC for use of TK which is not in the public domain. Most importantly, as the law recognises TK to be cultural patrimony this would appear to imply an obligation upon the state to be guided in its governance of TK by customary law and practice.

#### 4.3.2 Constitutive Registers

Constitutive registers form part of a legal regime which seeks to grant rights over traditional knowledge. Constitutive registers will record the granting of rights (i.e. exclusive property rights) to the TK holder as a means to ensure their moral, economic and legal interests are protected and recognised. Most model constitutive registers are conceived as public in nature, run by a national entity and under a law or regulation which clearly determines how valid registration of TK can take place and be formally recognised and accepted.. As such they may be more controversial and difficult to design and face some critical challenges and questions in moving from concept to practice.

One of the principal questions to be answered in establishing a system of positive protection relates to who is legitimately entitled to register TK. Is it an indigenous nation through its leader, a representative political organisation at the national, regional, or local level, or is it an individual shaman or healer? The answer in any particular case will depend upon relevant customary law and practice, the local realities of communities and indigenous peoples and their existing governance structure. For this reason, national and international law should be guided by the need to maintain a flexible interface with customary legal regimes.

Besides the internal question of representation there is the issue of ownership of TK shared between or among several indigenous peoples. What should happen, for instance, where an indigenous people or local community legitimately registers TK and exclusive property rights over the registered TK are granted, but other indigenous peoples within the same country, region or otherwise share similar or even the same knowledge? A simple "first to register" system, as most traditional IP regimes maintain may prove inequitable in these circumstances, as granting rights to a single indigenous group, may result in depriving another of its rights over its own TK.

Current research suggests that many indigenous peoples groups within any given country or even a region tend to share similar TK and understandings about biodiversity which surrounds them. For example, even though native names for plants and procedures to obtain a traditional medicine might vary (variations in the cultural and religious context), closer analysis often shows similar use and preparations for similar plants. This has an immediate effect on who could or should be granted an exclusive or even non–exclusive (i.e. use) right.

A possible solution might be to allow multiple parties to be given a collective and exclusive right. For instance, if indigenous group A applied to register TK that was shared equally by indigenous groups B and C, instead of a simple attack on the application, sui generis legislation might be able to recognise and validate multiple claims to the same TK. In that circumstance, the system could recognise the shared and collective nature of TK and still protect and provide a mechanism to establish a level of exclusivity to the right. Although inherently just and equitable, it will remain to be seen how different groups (in this case A, B, and C) react to this alternative. It is possible to envision tension arising among more progressive and "modern" groups and more traditional, even isolated, communities.

If constitutive registers are to operate effectively, national, regional or international procedures and criteria may need to be agreed upon in order to process register applications, describe TK involved and, in general, ensure standardisation of the system and enforceability of rights.

#### 4.4 Standardised Registration, Protection, or Erosion of Rights

As noted above, development of standardised forms for the registration of TK may have an important part to play in the establishment of any system for defensive and/or positive protection of TK. This has been the position taken by the Traditional Knowledge Digital Library (TKDL), discussed in the case studies previously, which has developed the TKRC classification system based upon the International Patent Classification (IPC) system of WIPO. TKDL has actively sought to have the TKRC linked to the IPC classification system.

Within the Intergovernmental Committee of WIPO on GRTKF (IGC), the Asian Group has proposed that there is a need to develop an internationally agreed data specification (a set of agreed standards) for databases and registers of TK and biological/genetic resources, including the consideration of related legal questions, such as the relationship of documented TK and recognition of rights associated with TK, and the possibility of creating a legal presumption of ownership on the part of the TK holder with a TK rights system. As part of its proposal, the Asian Group has identified a set of potential criteria for establishing a standardised format for defensive and positive registration purposes, including data for both defensive and positive protection, which has been developed on the basis of criteria drawn from the IPC classification system.<sup>121</sup>

There are practical reasons for seeking to develop a system of classification which would blend with that of the IPC, but such a strategy may also have some drawbacks. On the one hand, it would facilitate the work of patent officers carrying out prior art searches. On the other hand, development of a system of defensive protection based upon criteria laid down by IPR regimes would tend to make TK registers respond to the requirements of the existing IP regime, rather than making IP regimes respond to the nature of TK and the cultural, social and technical realities relating to documentation processes for protection of such knowledge.

As has been seen above, many registers have a very limited value for the purposes of searches of prior art, due to restrictions of confidentiality or the remoteness of registers, as well as for technical reasons such as maintenance of non-electronic or oral databases. Information held in such confidential and marginalised databases may be amongst the most valuable for indigenous interests. However, issues of confidence, trust, as well as technical barriers may effectively exclude such databases from acting as sources of evidence of prior art. In order to develop meaningful systems capable of incorporating a broad range of potential sources of evidence of prior art, including confidential databases and registers, local community registers and oral registers, there is a need for an innovative approach to the issue of defensive protection and consideration of the opportunities to make this process more sensitive to indigenous peoples realities.

With regard to defining specification data for positive protection, the situation is very similar. Once again, the question arises as to whether the adoption and application of criteria for registration based upon the notion of individual property rights established by IP regimes is appropriate when there is as yet no international consensus on the ambit or scope of sui generis legislation for protection of traditional knowledge. Promoting the development of a standardised system for registration of TK in order to secure positive protection may pre-empt necessary debate regarding the nature of sui generis regimes. It is also crucial to consider the potential difficulties which may arise in trying to develop a standardised system for registration based upon experiences in databases which may differ greatly from one part of the world to another. In a world of cultural, intellectual and environmental diversity, flexibility, adaptability and appropriateness are factors which must be balanced against any tendencies towards promotion of a one size fits all solution.

As the role of any register and its content is likely to vary depending upon whether it is declaratory or constitutive in nature, there is a need for further investigation into existing databases and registers and the modalities for establishing some harmonised criteria for registration. It may be considered advisable to carry out such research and review it within the framework of the work of the ICG before suggesting that it be forwarded to any other commission for consideration and possible adoption of international guidelines.

It would appear from the case studies that development of a *sui generis* regime for recognition and protection of TK is a prerequisite for the effective development of any system of registers or databases designed to protect traditional knowledge, in accordance with the desires and interests of indigenous peoples, rather than as merely a source of information for scientific and private sector actors and as a tool for patent authorities.

The Asian Group has proposed a work programme to further development of data specifications for databases and registers of TK and genetic resources. The Asian Group's proposal makes it clear that indigenous peoples and local communities must be both the designers and the beneficiaries of any system of registers of traditional knowledge.<sup>122</sup> To ensure that this occurs it will be necessary to empower indigenous peoples to play a meaningful role in the development of any regime. Furthermore, it will be necessary to consider the interface between customary law and practice and national and international law relating to TK. It is clear, therefore, that more in-depth research needs to be carried out in conjunction with indigenous peoples in order to determine the way forward.

Although, it may be too soon to promote standardised international specifications for data, there is good reason to support the proposal by the Asian Group for further study of existing experiences with databases and registers, and their experiences in methods for recording data inputs relating to traditional knowledge. Any such study should consider the possible need to distinguish different types of traditional knowledge and perhaps for the development of a two track process for development of specification criteria for registration of TK.

For existing codified systems of traditional knowledge, which are widely published and freely available, such as that of Ayuderva in India, the establishment of a system of TK classification to assist in prior art searches based upon the TKRC model being developed by TKDL, with appropriate restrictions on access, is worthy of further consideration, with a view to its possible adoption in the short term. However, any moves to increase the availability of knowledge, whether codified or not, should not occur without due recognition of the rights of indigenous peoples and their inclusion in the process for determining the nature of controls over access.

With regard to the classification of TK from non–codified systems of knowledge, there is a clear need for further work to determine the potential and limitations of databases and registers for protecting traditional knowledge, and the most appropriate manner for classifying knowledge in local national and international registers in order to ensure not only its conformance with the needs of patent authorities but, even more importantly, its accessibility for local communities in terms of proximity, relevance, and utility.

In evaluating the potential utility of establishing international specification criteria for registration of traditional knowledge, there is a need to consider the potential implications for the protection of knowledge which is not registered. Establishment of international specification criteria may have the effect of creating a virtual requirement to register traditional knowledge in order to obtain recognition and protection of rights. Patent authorities may, for instance, be tempted to adopt the position that prior art, for the purposes of reviewing patent applications, will only include traditional knowledge which has been registered in accordance with such international standard, thereby excluding uncodified and unregistered knowledge. Were this to occur, indigenous peoples may end up even worse off than they are now, as a failure to register might be considered to amount to a waiver of rights or an exhaustion of rights, thereby precluding opportunities to claim misappropriation of knowledge which had not been registered. The result would be a creeping expansion of requirements to register traditional knowledge under a system based upon criteria designed for registration of intellectual property, thereby effectively incorporating TK into the existing IPR-based structure and potentially undermining efforts to develop sui generis alternatives.

Where any system of classification criteria involved registration and multiple translation of data, as has been done by the TKDL register, this would lead to significant costs for registration of knowledge, including costs of translation etc. which may be of little, if any, direct benefit for the local communities but may greatly benefit other potential users; in particular, the scientific and commercial sector. There is a need to consider whether this would amount to a cost effective manner for the protection of traditional knowledge, involving as it would the translation of traditional knowledge into multiple languages merely to prevent the potential and probably remote possibility that it may, in fact, be utilised by some third party at some remote date in the future. The practicality of this approach in particular for non-codified knowledge systems is certainly questionable.

#### 4.5 Protection of the Contents of Databases and the Public Domain

As noted above, one of the principal contradictions in the notion of defensive protection is that in order to prevent others from misappropriating TK, indigenous peoples may be required to place their TK in the public domain, where it can be more freely used by all. At the same time, indigenous peoples may be impeded from controlling the use of their TK which has entered into the public domain, even where there was no prior informed consent based upon application of the principle that information in the public domain cannot be the subject of private rights. In fact widespread belief in the immutability of this principle is a misconception and rights over information in the public domain have on occasion been recognised in the USA, Japan and Europe.<sup>123</sup> The search for means to overcome the inequity arising through rigorously applying the principle of the public domain has led to calls to redefine the application of the principle to traditional knowledge.<sup>124</sup> In Peru this has led to recognition of the rights of indigenous peoples to share in the benefits derived from the utilisation of their TK in the public domain. Similarly in a proposed model law for Protection of Traditional Ecological Knowledge in the South Pacific, the application of the principle of the public domain to traditional knowledge is limited under certain conditions as, for example, where such knowledge has been obtained without prior informed consent.<sup>125</sup> This tends to demonstrate a tendency in developing countries to revisit the concept of the public domain in the search for equitable solutions, an issue which will be of much importance in determining the eventual ambit of sui generis protection for TK.

Within the European Union, there is a form of sui generis protection for databases in Europe and other Countries offering reciprocal protection, which offers database producers rights over database contents not open to protection under copyright.<sup>126</sup> Under the European regime a lawful database user is allowed to "extract/or reutilise" only the parts of a database authorised by the database owner,<sup>127</sup> thereby, in effect, granting a right over the contents of the database. The possibility of obtaining reciprocal protection for databases might provide an interesting mechanism for extending protection over TK by countries seeking to develop sui generis regimes for protection of traditional knowledge, where such regimes involve the establishment and recognition of rights over TK held in databases. A proposal has been made for protection of TK through the use of a special database right based on Article 39.3 of TRIPS, which requires governments to protect data provided for the purposes of product approval processes relating to the pharmaceutical and agrochemical sector, against unfair commercial use.<sup>128</sup> Under this proposal protection could be extended to TK through a system retaining three features of article 39.3 of TRIPS: the establishment of rights in data; the enforceability of rights in the data against their use by unauthorised

third parties; and the non-fixation of a predetermined term of protection.<sup>129</sup> The proposal suggests that enforcement rights should be confined to knowledge that complies with a certain definition of novelty, while specifying that knowledge disclosed in the past could be treated as "novel" if the innovation based upon it has not yet reached the market.<sup>130</sup>

One limitation of such a system is that it only provides protection for information within the database and would not as such amount to the granting of a right over the knowledge to the benefit of local communities or indigenous peoples. Furthermore, ownership of the database may be held by a party other than the relevant indigenous knowledge holders.

Despite the potential of such systems to provide an innovative and interesting possibility for protection of TK, there are concerns that *sui generis* database protection will in the long run prove of greater cost than benefit for developing countries. Reichmann argues that "...embracing the European Union's *sui generis* database right...would turn out to be a worse deal for developing countries than the TRIPS Agreement itself, and it would raise the costs, and slow the pace of science and innovation everywhere."<sup>131</sup> His argument is premised on the fact that such database protection will lead to increasing shrinkage of the information commons to the detriment of both the developed and developing world.

The arguments put forward by Reichmann are persuasive, and should be considered by developing countries within the context of international negotiations on IPR. On the other hand, there may be a case for developing a special sui generis form of protection for TK held in databases. One distinction which needs to be considered here relates to the purpose or objective of protection and the manner by which information comes to be in the public domain. Those who promote law and policy designed to maintain the scope of the commons as widely as possible, need to consider the potential injustice of rigorously applying the principle of the commons to TK which has been placed in the public domain without the informed consent of indigenous peoples. It is also important to note that while proposals of IPR experts are frequently designed with a view to maximising commercial benefits, many of those promoting protection of traditional knowledge are more concerned with protection of cultural and spiritual integrity and prevention of misappropriation of knowledge rather than the capture of economic rents.

It is particularly interesting to note that the existence of TK in the public domain is not *per se* a bar to its protection even under existing IP laws. This implies a possibility for redrawing the boundaries of application of the existing system of public domain, so that the right to make use of TK may depend not so much upon where information is found as how it got there and what cultural impacts may arise from its use.

There is already a large body of TK in the public domain which is freely utilised and widely distributed. Much of that knowledge has made its way into the public domain without the prior informed consent of indigenous peoples. There exists a clear need to devise some form of equitable arrangement for ensuring that the benefits drawn from the use of such knowledge should flow back to indigenous peoples and local communities. However, there is at present no international system capable of ensuring such sharing of benefits. In order for any such system to work it would need to ensure that the transaction costs related to transferring benefits did not outweigh the benefits themselves. Furthermore, in many cases, it may prove impossible to identify or locate the rightful heirs of the providers of such knowledge. These issues are analogous to the problems associated with securing the fair and equitable sharing of farmers in the benefits arising from the use of land races (farmers' varieties). Developing a regime for benefit-sharing might include consideration of the possibility of recognising collective innovators' rights similar to the concept of farmers' rights, and establishing some form of trust fund for the sharing of benefits.

Analogies might be made with the concept of trust which guides international gene banks in the CGIAR system. The CGIAR centres hold genetic resources in trust for the global community and require users to seek the prior informed consent of providing countries when seeking IPR over resources.<sup>132</sup> Drawing upon that experience, questions may arise regarding the extent to which development of a concept of trusts for databases of TK might serve to ensure that access to knowledge need not be unnecessarily restrained, while recognising and protecting indigenous and local community rights, and establishing a means for securing equitable sharing of benefits derived from its use.

#### 4.6 Traditional Knowledge Database Trusts

Analysis of the case studies has shown a diversity of applications of databases and registries and demonstrated the complexities of finding a mechanism for managing such databases in accordance with the rights of indigenous peoples. One concept which appears to be emerging as a possible means for securing indigenous rights over TK in a culturally sensitive fashion through use of databases and registers is the notion of a database trust.

One of the clearest examples of the possible utility of concept of a trust in the case of an existing database relates to the BioZulua experience, where it is proposed that the register vests in the state, but the rights vest in the communities. Likewise with the Peruvian confidential register the state is to use the information in this register in order to protect indigenous rights by actively challenging patents, etc; once again showing the beneficiaries to be primarily indigenous peoples. The state is also obliged to establish a trust fund to be managed by indigenous peoples for the distribution of benefits. Similarly, experiences in AIATSIS in Australia and the Vanuatu Cultural Centre demonstrate the existence of a growing practice of databases assuming a quasi trust role for protection of indigenous peoples' knowledge. AIATSIS, which holds the worlds' largest collection of material on aboriginal peoples of Australia and the Torres Straits Islands, includes a sensitivity notice on its web page which also advises researchers that indigenous peoples may place restrictions on the use of information.<sup>133</sup> The Vanuatu Cultural Centre has a programme of volunteers collecting traditional knowledge in a number of media including tape recordings. These are held at the centre in trust for local communities.

Building upon their experience with the Honey Bee Network, proposals are coming from India for establishment of a Global Innovation Foundation to manage and protect community innovators' information and interests in a manner similar to the performing arts society which provides protection for performers' interests.<sup>134</sup> The objective would be to obtain benefits from innovations and ensure that the benefits from the exploitation of TK would flow back to indigenous and local community innovators. This proposal also incorporates elements of the concept of trusts.

The notion of securing indigenous rights to benefit-sharing through the use of trusts is not a new one, and various examples exist of trust funds established to compensate for access to and use of TK, such as the Forest People's Fund, Suriname, and the Healing Nature Conservancy.<sup>135</sup> Trust funds take on many different guises and can be established at the community, national or international level.<sup>136</sup> Possible objectives of such a trust might include promoting greater understanding and awareness of the diversity and importance of cultural diversity and traditional knowledge, strengthening traditional knowledge and innovation systems, promoting the fair and equitable sharing of benefits arising from use of TK, and defensive and positive protection of TK. Establishing meaningful objectives for any database trust or register will provide incentives for registration of TK.

Most conservation or biodiversity prospecting trusts receive initial funding from multilateral donors such as the World Bank/Global Environment Facility, UNDP, bilateral donors through ODA funding, private foundations, NGO's, and/or host governments.<sup>137</sup> Establishing a TK database trust as a means to protect traditional knowledge offers the possibility of a more sensitive form of defensive protection but also allows for progressive development of the trust as a source of TK for research and development as well as for educational purposes and promotion of local use of traditional knowledge. Incorporating indigenous representation onto the board of any trust will help ensure its legitimacy and effective implementation. The majority of the board of AIATSIS are, for instance, Aboriginal and Torres Straits Islanders.

Properly conceived and managed database trusts may create opportunities to not only protect resources against unapproved external use but to also strengthen traditional knowledge and innovation systems, and help to ensure that pressures on TK, including those arising from national education, health, and agriculture programmes may be alleviated and build a greater sense of awareness of indigenous peoples' roles, not merely as the source of TK but as the managers of their own body of traditional science.

The difference between a TK database trust and more common conservation trusts is the double role which a database trust would play: first, as a trust for the protection and management of TK, and second, as a trust for the management and distribution of benefits derived from access to and use of TK.

At present this notion of trust is still only poorly recognised in existing database management. However, one area where it might be of most interest in the short-term relates to instances of sui generis protection of the contents of TK databases. As noted previously, many existing databases are owned and operated by non-indigenous peoples, thereby placing indigenous interests in third party hands. Developing codes of preferred practices and establishing a concept of trusts to be applied to the management of TK held in databases such as NAPALERT, BioZulua, TKDL, TEK\*PAD, and MEDLINE, as well as those held by academic institutions such as Duke University and the Smithsonian Institute, gene bank collections and botanical gardens, such as those of IPGRI and the Kew Gardens could help secure indigenous peoples' control over TK which has come into the public domain without their prior informed consent. Placing TK in such databases under a trust in favour of indigenous peoples may help diminish the problems inherent in granting rights over databases to parties other than the custodians of such knowledge.

However, trusts can also have the effect of concentrating power over knowledge in the trust and the trustees. Even where the trustees are indigenous this does not mean that all indigenous peoples or communities will necessarily have their interest directly represented. Trusts should not therefore be employed without due consideration of their potential cultural impact, and if established to secure indigenous peoples' management of TK, they should be set up at the level of communities or of individual indigenous peoples.<sup>138</sup>

A logical extension of the discussion on trusts and databases concerns repatriation of TK held in international or overseas databases and registers.<sup>139</sup> Any discussion of fair and equitable sharing of benefits relating to TK held in databases and registers should pay attention to the potential role of repatriation as a form of benefit-sharing. One recent example of the principle of responsibility for repatriation of TK involved Andean communities in Peru who, with the assistance of Association Andes, a Cusco-based NGO, secured the transfer to local communities of potato varieties from the International Potato Center, many of which had been lost to local use but had been held at the Center's facilities. Repatriation of TK, which might be of use to indigenous peoples—but could have been lost over the years—could serve a wider process of sharing benefits and supporting indigenous peoples livelihoods.

Amongst the millions of pages of TK available through open access databases, very little is available in the languages of the original custodians of such knowledge, making such knowledge inaccessible to the communities and indigenous people from whose ancestors it was obtained. Repatriation in original languages therefore offers a great opportunity for sharing of benefits.

### **5** Conclusions and Recommendations

Databases and registers are not an end in themselves but are rather a tool or mechanism through which economic, scientific, social, cultural, and environmental goals can be met.

Depending on the specific objective of any regime to protect TK, registers and databases may play a substantial role. They can serve to: promote documentation; preserve and maintain TK; provide a means to assist patent search procedures and identify prior art; identify communities which might be entitled to benefit—sharing and assign exclusive rights; provide the means for recording the existence of TK over which positive rights have been recognised under national or customary law; and serve as the mechanism for obtaining protection of TK through *sui generis* database protection.

However, databases and registers alone do not provide a means for the effective protection of TK. Rather, they must be seen as one element or mechanism in a wider system of TK governance including customary law and practice, national access and benefit—sharing legislation, and *sui generis* TK law and policy.

Databases can play an important role in defensive protection of TK. However, existing law and policy regarding sources of prior art is insensitive to the nature of TK, its confidentiality, and the rights and interests of indigenous peoples over its future uses. Requiring that TK be placed in the public domain as a condition for recognising it as prior art is a double–edged sword. In effect, this requires the renunciation of rights over TK in order to prevent weakness in IPR regimes being utilised as a means for its misappropriation.

Positive protection of TK, whether or not utilising registers, poses an even greater challenge, particularly with regard to TK shared among many local communities or indigenous peoples. Systems that assign exclusive rights over TK to a specific community or people—however just and equitable they may be conceived to be—may lead to the effective denial and/or exhaustion of the legitimate rights of other local communities or indigenous peoples. Recognition of these and other tensions in the development of mechanisms for protection of TK, will be crucial in the process of designing and proposing *sui generis* regimes and registers, themselves.

Development of international standardised specification data for databases and registers would assist defensive and positive protection within the framework of existing intellectual property rights law and policy. Adoption of such standardised specification data at this stage would, however, indicate a preference for protection of TK as a form of intellectual property in a manner similar to existing IPR. Furthermore, adoption of such standards at this time could have the effect of pre–empting the ongoing debate on development of international *sui generis* regimes for protection of TK.

Traditional knowledge has been recognised by a number of countries as being the cultural patrimony of indigenous peoples. This would seem to imply that the role of governments and international organisations in the development of regimes for the protection of TK must be that of facilitators in the development of TK regimes rather than that of arbiters over TK. The development of legislative, administrative and policy measures to secure the rights of indigenous peoples and local communities should be carried out with view to the adoption of systems of protection which accord due respect for the nature of cultural patrimony. This would suggest that the development of any TK regime must be guided by the customary law and policy of indigenous peoples and local communities, recognising the probability that TK as cultural patrimony may be inalienable.

Considering the number and diversity of indigenous peoples and local communities and, consequently, the diversity of customary laws and practices, any international system for the protection of TK must be based upon flexibility, sensitivity to local realities, and adaptability to changes in customary law and practice. To this end, there is a need for full participation of indigenous peoples in the development not only of registers per se but also in the process for development of any regime, sui generis or otherwise, for protection of TK. Only in this way can full consideration be given to indigenous peoples cultural, religious, moral and social concerns, which, in many cases outweigh purely economic considerations, as well as to their customary laws and practices.

Intangible TK is flowing rapidly and without restriction under the pressures of modern scientific and commercial research and development needs, aided by the existence of modern communications and database technology. If a sui generis system to protect TK, including registers or other mechanisms, is to be set up to safeguard indigenous interests over TK, it must be done promptly. This poses a potential conflict between the need to promote full and informed consultation and participation of indigenous peoples and the need to take action to prevent further loss of control over TK. In response to such conflicting pressures, governments and the international community should consider the development and adoption of interim measures, which enhance protection of TK without pre-empting necessary participatory debate regarding the most appropriate means for securing its long-term protection.

Measures to secure indigenous rights over information in the public domain such as through sui generis databases provide a potential mechanism for interim protection of TK, while international negotiation, development and adoption of appropriate law and policy advances. However, the granting of rights to database proprietors over the content of databases does not in itself provide indigenous peoples with a measure of control over access to and use of such their knowledge. There appears to be an underlying concept of trust which has been intentionally or unintentionally incorporated into the development and management of many databases and registers. Further developing the concept of trusts through practical initiatives with a view to providing indigenous peoples and local communities with increased opportunities to exercise control over their TK held in databases may warrant further consideration. Collaborative efforts with research institutions, national authorities, NGO's, etc., as well the establishment of database trusts by local communities, and indigenous peoples, may offer innovative means for both promoting and protecting TK.

#### Recommendations

- As a basic guiding principle, there is a need to ensure that, all reasonable efforts are made to obtain prior informed consent from the relevant indigenous peoples as a condition for placing information in a database, whether that TK is in the public domain or not. Explicit institutional policies need to be developed by museums, botanical gardens, universities, companies and all entities working with biological materials and related TK.
- 2. Databases, registers, publications, scientific papers, or other means through which TK is made available to the public should incorporate initial advisory notes which explicitly state, as a minimum, that:
  - the authors fully recognise the rights of indigenous people over their TK, including any intellectual property or *sui generis* property rights
  - PIC was obtained for the use of the TK
  - the use of TK for commercial or other ends must be appropriately recognised
  - the need for the sharing of benefits derived from the use of TK with indigenous peoples

This practice should be promoted at all levels and target, for example, publishing houses, editorials, research institutions and individual researchers. Although the effectiveness, practicality, and enforceability of these advisory notes may be questioned, they are an important starting point to raise awareness, guide and orient users' conduct, and promote respect and sound ethical and professional practices. The establishment of such standard advisory notes will demonstrate an immediate level of awareness of the sensitivity of indigenous peoples' regarding protection of their TK and help build confidence and the basis for better partnerships between research institutions the private sector and indigenous peoples.

- 3. Access to databases and registers should require acceptance of the rights of indigenous peoples over their TK as a precondition for access as a means to ensuring appropriate use of TK. To this end, the proprietors and managers of databases and registers should establish protocols governing access to and use of TK. Access to database files either electronically or otherwise should involve a step including acceptance of the conditions of the protocol.
- National governments and international 4. organisations should review existing law and policy with a view to the development of more sensitive and directed search procedures designed to enable patent authorities to access a wider range of sources of prior art, including local community and indigenous peoples databases and registers, confidential registers and oral registers. Consideration should be given to the potential merits of requiring disclosure of origin and source of TK in patent applications as a mechanism for assisting patent authorities to carry out more directed searches of prior art. The sources of prior art should be expanded to include oral, visual and other manifestations of prior art.
- 5. National governments and responsible international organisations should consider the possibilities of adopting interim measures which reduce pressure on indigenous peoples and their knowledge systems by creating obligations for users to demonstrate prior informed consent as a condition for scientific and commercial use of TK. Particular attention should be given to the ongoing discussions on user measures within the framework of the CBD, and to proposals for the inclusion of requirements for disclosure of origin and/or legal provenance of TK in IPR applications procedures.
- 6. In development of national *sui generis* TK regimes, consideration may be given to establishing a system which recognises and incorporates local community and indigenous peoples' databases and registers whether

documented or orally maintained within a national network of registers of TK. This practice may serve to extend the remit of national registration and evidence of prior art, as well as generating wider respect for the national system of registration and for the value of TK.

- To secure increased participation of indigenous 7. peoples in international processes for the development of law and policy relating to the protection of TK, national governments should include indigenous representation on national delegations. International bodies such as WIPO and the WTO need to develop mechanisms to ensure increased indigenous participation in decision making processes through the development of participatory processes, for diffusion of information to local and indigenous communities, consideration of options for protection of TK and the transmission of the results of such consultative processes through independent indigenous representation at relevant meetings.
- 8. International organisations, governments and other bodies should carry out further investigation into the potential, complexities and limitations of developing international standardised specification data for the registration of TK for defensive and protective purposes. Consideration should be given to the possibilities of adopting a two-track approach to the development of classification systems for TK, making a clear distinction between systems of codified systems of knowledge, which have been widely published and which are freely available in the public domain, and other TK systems.
- 9. International organisations, multilateral, bilateral and other funding agencies should consider the provision of support for initiatives to develop database trusts, whether through modification of the operation and management processes including, as appropriate, the governance structures of existing databases and registers, as well as through the funding of local community and indigenous peoples initiatives in this area.
- 10. Protection of rights over traditional knowledge should not be made conditional upon registration of TK. Such a precondition for the granting of protection would run counter to current practice in intellectual property regimes, and would impose an extra burden on indigenous and local communities.

### Endnotes

1 The co–author wishes to acknowledge the support of the Japan Society for the Promotion of Science.

2 Pers. Comm., N S Gopalakrishnan, 20 October 2003. 3 See Peruvian Law 27811, 2002, Article 11. Collective knowledge and cultural heritage: Collective knowledge forms part of the cultural heritage of indigenous peoples. Article 12. Inalienability and indefeasibility of rights: Because they form part of the cultural heritage, the rights of indigenous peoples in their collective knowledge shall be inalienable and indefeasible. 4 See Peruvian Law 27811, 2002, Article 9. Role of present generations: The present generations of the indigenous peoples shall preserve, develop and administer their collective knowledge for the benefit of future generations as well as for their own benefit. Article 10. Collective nature of the knowledge: The protective knowledge protected under this regime shall be that which belongs to an indigenous people and not to particular individuals forming part of that people. It may belong to two or more indigenous peoples. The rights shall be independent of those that may come into being within the indigenous peoples, which may have recourse to their traditional systems for the purposes of the distribution of benefits.

**5** See L Glowka, F Burhenne–Guilmin, H Synge, "A Guide to the Convention on Biological Diversity", *Environmental Law and Policy Paper* No. 30. IUCN Environmental Law Centre, IUCN Biodiversity Programme. Gland, Cambridge, 1994.

6 See WIPO/GRTKF/IC/2/16, WIPO/GRTKF/IC/3/17, WIPO/GRTKF/IC/4/14.

**7** The Asian Group expressed that it was crucial that documentation would ensure the protection of TK to avoid its loss when older generations passed away (see WIPO/GRTKF/IC/ 2/16 (in English) paragraph 118).

**8** Panama stated that the register and the database established by Law 20, 2000, did not only provide information but also recorded traditional knowledge rights (see WIPO/ GRTKF/IC/2/16 (in English) paragraph 133).

**9** See India's statement on behalf of the Asian Group during the WIPO IGC Second Session (WIPO/GRTKF/IC/2/16 (in English) paragraph 118). The group stated that it is appropriate to establish TK registers for purposes including prior art searches and prevention from erosion.

10 See WIPO/GRTKF/IC/3/17 paragraph 126.

11 See document WIPO/GRTKF/IC/4/14.

12 Countries including Algeria, Venezuela, Peru, Mexico, United States of America, Korea, Australia and groups including African Regional Industrial Property Organization (ARIPO) and the Saami Council during the Fourth Session of the WIPO IGC gave their support for the establishment of a toolkit for TK documentation (see WIPO/GRTKF/IC/4/5).

**13** During the Third Session of the WIPO IGC, countries like Panama stressed the need for capacity building and expected to receive assistance from WIPO to develop a TK database (see WIPO/GRTKF/IC/3/17 paragraph 146).

14 See WIPO, "Intellectual Property Needs and Expectations of TK Holders", WIPO Report on Facts Finding Missions on Intellectual Property and TK (1998–1999) Geneva, April 2001. See also, WIPO/GRTKF/IC/3/9 paragraph 25.

15 Pers. Comm., Shakeel Bhatti, October 2003.

**16** The West Kitkimeot Slave Study defined TK as follows: Traditional knowledge is knowledge that elders hold from experience and is passed down to them through the generations. It is continuous and grows. Interpretation of knowledge is important. Traditional knowledge is not just the past, but the future combined with the past.

**17** Nunavut Tunnagavik Inc., Social and Cultural Development Department, "Intellectual Property Rights: Issues in Nunavut", 19 May 2003. Bell, Mike, Nunavut Literacy Development in the Context of Inuit Qaujimajatuqanginnut, 2002.

18 See <a href="http://www.coica.org/interna.asp?s=5&r=1">http://www.coica.org/interna.asp?s=5&r=1></a>.
19 See J L Simet, "Copyrighting Traditional Tolai Knowledge?" in K Whimp & B Mark, *Protection of Intellectual, Biological & Cultural Property in Papua New Guinea*, Asia Pacific Press, 2000. pp. 62–80.

20 See G Dutfield, 2001. "TRIPS–Related Aspects of Traditional Knowledge", Case Western Reserve Journal of International Law

33, No. 2, Spring 2001, ABI/INFORM Global pp. 245–248. 21 O J Lynch, "Promoting Legal Recognition of Community– Based Property Rights, Including the Commons: Some Theoretical Considerations", see <a href="http://www.ciel.org/">http://www.ciel.org/</a> Publications/promotinglegalrecog.pdf>.

22 See Mugabe, Intellectual Property Protection and Traditional Knowledge: An Exploration in International Policy Discourse, Nairobi, Kenya, ACTS Press, 1999, p. 3. Also, see WIPO, "Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact–Finding Missions on Intellectual Property and Traditional Knowledge (1998–1999)", Geneva, WIPO Publication, 2001, p. 23.

**23** S Laird, *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice.* WWF, UNESCO, Royal Botanic Gardens Kew. Earthscan Publications Ltd. London, Sterling, VA, 2002. **24** Numerous publications and reports have documented this debate. For a comprehensive review and synthesis of these discussions, see G Dutfield, *Intellectual Property Rights, Trade and Biodiversity.* IUCN. Earthscan Publications Ltd. London, 2000. Chapters, 1–5. Another landmark document is the Crucible Group, "People, Plants and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity and Rural Society". International Development Research Center, Ottawa, 1994.

**25** B Tobin and K Swiderska, "Speaking in Tongues: Indigenous Participation in the Development of a *Sui Generis* Regime to Protect Traditional Knowledge in Peru", IIED, London 2001, available at <a href="http://www.iied.org/">http://www.iied.org/</a>.

26 Some interesting conceptual examples include: COICA, OMAERE, OPIP, Biodiversity, Collective Rights and a Sui generis Regime on Intellectual Property. Quito, Ecuador, 1999; K P Achar, People's Biodiversity Register: Documentation of People's Knowledge and Perceptions about Biodiversity and Conservation. BCPP, KSCST, WWF India. Karnataka, 1997; J Vogel, The Biodiversity Cartel. Transforming TK into Trade Secrets. SAN REM, Ecociencia, Usaid, CARE. Quito, 2000. B Tobin, "Redefining Perspectives in the Search for Protection of Traditional Knowledge", RECIEL 10, No. 1, 2002. Legislation includes : Panama Law No. 20 on a special regime on intellectual property over collective rights for indigenous peoples (2000) or Peru's Law 27811 for the protection of indigenous peoples' collective rights over biodiversity (2002). Draft models include the Organization of African Unity Model Legislation on Community Rights and Access to Biological Resources (1999) or the Model Regional Framework for the Protection of TK and Expressions of Culture for the Pacific island countries (2002). In terms of policy declarations there is an extremely varied range of declarations, particularly from indigenous people's , calling for the need to establish a system for the protection of TK (Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (1993); Second International Indigenous Forum on Biodiversity: Submission to the Workshop on TK (1997), etc). 27 D Downes and S Laird et al, "Community Registers of Biodiversity Related Knowledge: Role of Intellectual Property in Managing Access and Benefit-Sharing", 1999, UNCTAD Biotrade Initiative.

**28** The terms 'register' and 'registry' are often used interchangeably however for the purpose of this report we will confine ourselves to the use of the term 'register' when referring to registration for the purpose of obtaining legal rights.

**29** D Downes and S Laird et al, "Community Registers of Biodiversity Related Knowledge: Role of Intellectual Property in Managing Access and Benefit–Sharing", 1999, UNCTAD Biotrade Initiative.

30 The BioZulua database in Venezuela (see case study in Part II of this report) is protected by copyright.
31 Within WIPO, the Standing Committee on Information Technology, the Committee of Experts of the Special Union for International Patent Classification Union, the Standing Committee on the Law of Patents, and the Intergovernmental Committee on Intellectual Property and Genetic Resources, TK and Folklore have all discussed and made conceptual progress in regards to the role of TK digital databases,

improving patent search procedures when TK might be included, developing a centralised TK clearing house, among others. For further analysis, see M Ruiz, The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries, Trade Related Agenda, Development and Equity. Occasional Papers 9. South Centre, October 2002.

32 The IPRA basically calls for the development of a web encyclopedia of TK. See D Pitt, Roles for the Internet in TK: The Idea of a Web Encyclopedia. Summary submitted for the UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, Geneva, 30 October- 1 November 2000. 33 The launch of the Traditional Ecological Knowledge Prior Arts Database (TEK\*PAD), developed by the American Association for the Advancement of Science - Science and Human Rights Program <http://ip.aaasorg/tekindex.nsf>, and financially supported by the Center for the Public Domain<http://www.centerpd.org>, has brought about considerable controversy. It basically provides a large database of TK which, apparently, has been set up with no direct participation of indigenous peoples and "basically relies on a Western definition of what constitutes disclosed TK in the public domain".

34 WIPO, "Intellectual Property Needs and Expectations of Traditional Knowledge Holders WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999)", Geneva, WIPO Publication, 2001. <a href="http://">http://</a> www.wipo.int/tk/en/tk/ffm/report/final/index.html>.

35 On TKDL, see <http://www.southcentre.org/info/ southbulletin/bulletin 39/bulletin39-04.htm>' on TEK\*PAD, see Communication, P Hardison to Canadian Indigenous Information Network, 4 August 2003.

36 Preston Hardison states that TEK\*PAD "claims to 'protect' indigenous knowledge by making available, without consultation or consent, detailed knowledge of the 571 federally recognised tribes in the United States, and many First Nations in Canada that has been compiled into databases not controlled by these tribes and owned (i.e. with intellectual property protection) by non-natives. This only 'protects' the knowledge from monopolistic commercial exploitation. The public domain model for defensive protection of indigenous knowledge appears to have a very narrow concept of 'misappropriation'. While the monopolisation of IK through the patent system counts as misappropriation, the document or the project does not protect it from nonmonopolistic commercial exploitation, or non-commercial misappropriation." Communication, P Hardison to Canadian Indigenous Information Network, 4 August 2003. 37 S Laird, M Alexiades, K Bannister, and D Posey, "Publication

of Biodiversity Research Results and the Flow of Knowledge' in S Laird (ed) Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice. WWF, UNESCO, Royal Botanic Gardens Kew. Earthscan Publications Ltd. London, Sterling, VA, 2002. **38** The precautionary principle may be loosely defined as saying that, in the face of uncertainty, the best course of action is to assume that a potential problem is real and should be addressed.

39 K Bannister and K Barret (in press), "Weighing the proverbial 'ounce of prevention' versus the 'pound of cure' in a biocultural context: a role for the precautionary principle in ethnobiological research in L Maffi, T Carlson and E Lopes Zent (eds) Ethnobotany and Conservation of Biocultural Diversity. Advances in Economic Botany Series, New York Botanical Garden, New York. Cited in S Laird, M Alexiades, K Bannister, D Posey, "Publication of Biodiversity Research Results and the Flow of Knowledge", in S Laird (ed) *Biodiversity and Traditional* Knowledge: Equitable Partnerships in Practice. WWF, UNESCO, Royal Botanic Gardens Kew. Earthscan Publications Ltd. London, Sterling, VA, 2002.

40 Ibid.

41 See WIPO/GRTKF/IC/2/10.

42 See <http://www.aiatsis.gov.au/>.

43 See WIPO/GRTKF/IC/5/12.

44 D Downes and S Laird et al, "Community Registers of Biodiversity Related Knowledge: Role of Intellectual Property in Managing Access and Benefit–Sharing", 1999, UNCTAD Biotrade Initiative.

45 Pers. Comm., Mick Dodson of AIATSIS, 2001.

46 S M May and L Brooke, "Inuit Science: Nunavik's Experience in Canada" in IUCN Inter-Commission Task Force on Indigenous Peoples, Indigenous Peoples and Sustainability: Cases and Actions, 1997 at 355. 47 Statistics Canada 2001 Aboriginal Peoples Survey, Ottawa, ON 2003.

48 A copy of the James Bay and Northern Quebec Land Claims Agreement (JBNQA) can be found at www.ainc-inac.gc.ca/pr/ agr/que/jbnq\_e.html. An information sheet on the JBNQA can also be found at <http://www.ainc-inac.gc.ca/pr/info/ info14 e.html>.

49 S M May and L Brooke, "Inuit Science: Nunavik's Experience in Canada" in IUCN Inter-Commission Task Force on Indigenous Peoples, Indigenous Peoples and Sustainability: Cases and Actions, 1997 at 355. 50 Ibid.

51 Ibid at 357-8.

52 Other Inuit databases include the Nunavut and Inuvialuit Land Use and Occupancy Database, Nunavut Atlas, Labrador Inuit Land Use and Ecological Knowledge Database, Hudson Bay Programme Traditional Ecological Knowledge Study, North Slope Borough Geographical Information Systems, ICC Alaska Northwest Alaska Beluga Whale Mapping Project.

53 Backgrounder on Inuit Nunavik Land Use and

Ecological Knowledge Database at

<http://www.inuitcircumpolar.com/nilu.htm>.

54 Ibid.

55 Ibid.

56 Pers comm., Shakeel Bhatti, 27 October 2003.

57 Recommendation, see <a href="http://www.ainc-inac.gc.ca/pr/agr/">http://www.ainc-inac.gc.ca/pr/agr/</a> nunavik/lus e.html>.

58 Pers comm., Shakeel Bhatti, 27 October 2003.

59 R. v. Côté, [1996] 3 S.C.R. 139. A copy of this case can be found at <http://www.lexum.umontreal.ca/csc-scc/en/pub/1996/ vol3/html/1996scr3\_0139.html>.

**60** C Correa, Protection and Promotion of Traditional Medicine Implications for Public Health in Developing Countries, South Centre 2002, see <a href="http://">http://</a> www.southcentre.org/publications/traditionalmedicine/ toc.htm>.

61 K S Bhat, Medicinal Plants Information Databases. In: Food and Agriculture Organisation Medicinal Plants for Forest Conservation and Health Care, Non Wood Forest Products 11, FAO, Rome, 1997.

62 O Johnson, "A Marriage of Medicines: Sharing the Amazon's Secrets", available at <http://www.paho.org/English/DPI/ Number15\_article5\_4.htm>.

63 Pers. Comm., Shakeel Bhatti, 27 October 2003.

64 Comments of Piaroa elder Andres Guevara, see http://www.tierramerica.net/2002/1208/noticias4.shtml 65 O Johnson, "A Marriage of Medicines: Sharing the Amazon's Secrets", available at <http://www.paho.org/English/DPI/ Number15\_article5\_4.htm>.

66 This case study has been prepared primarily on the basis of information provided by Dr V.K. Guptha.

67 See "Background Paper on the Neem Patent Challenge". available at <http://www.ifoam.org/press/neem\_back.html>. 68 Ibid.

69 See WIPO IPC/CE/31/6, available at <http://www.wipo.org/ classifications/en/ipc/ipc\_ce/31/pdf/6.pdf>.

**70** Drugs and Cosmetics Act, No. 23 of 1940.

71 WIPO Special Union for the International Patent

Classification (IPC Union) Committee of Experts Thirty-Second Session, Geneva, 24-28 February 2003. Development of Classification Tools for Traditional Knowledge. WIPO/IPC/CE/ 32/8, available at <www.wipo.int/classifications/en/ipc/ipc\_ce/ 32/doc/ipc\_ce32\_8.doc>.

72 Pers. Comm., V K Gupta, Director TKDL, Geneva, July 2003.

73 Pers. Comm., V K Gupta, Director TKDL, Geneva, July 2003.

74 Pers. Comm., V K Gupta, Director TKDL, Geneva, July 2003. 75 It may be considered a seed bank, since it holds seed

samples rather than genetic material.

76 Farmers Rights Information System, see 

77 Pers comm., Bala Ravi, October 2003.

78 After 2001, all collection forms can also be called informed consent forms since they incorporate informed consent.

79 Pers. comm., Bala Ravi, October 2003. 80 Ibid.

81 This is assigned at the Foundation.

82 Ibid.

83 Pers. Comm., Bala Ravi, October 2003.

84 Ibid.

85 Ibid. 86 Ibid.

87 Retrieved: 24 April 24 2003, from <http://

knownetgrin.honeybee.org/honeybee\_register.htm>. Some of the external contributors are from countries such as the Philippines, Vietnam, Colombia, Tanzania, Mongolia, Bhutan, Bangladesh, Sri Lanka, Mexico, Alaska and other countries from the African and South American regions. 88 Retrieved: 7 April 2003, from <http://www.nifindia.org/ secondaward/sec11.htm>.

89 Retrieved: 19 June 2003, from <http://www.gian.org/ aboutgian/introduction.htm>.

90 See Prior Informed Consent form at

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91IIMA-SRISTI Collaboration for Scouting, Documentation and Augmentation of Grassroots Green Innovations 1993–99. Available at <http://www.sristi.org/IIM-Sristi.htm>. 92 Retrieved: 7 April 2003, from <http:// www.nifindia.org/ secondaward/sec11.htm>.

93 Pers. Comm., Anil Guptha, June 2003.

94 Ibid.95 "Innovations, Incentives and Institutions: Honey Bee Network", see <http://nifindia.org/secondaward/sec1.htm>. 96 For further discussion on the difficulties of recognising and adding value to grassroots innovation and TK, see A K Gupta et al, "Mobilizing grassroots' technological innovations and traditional knowledge, values and institutions: articulating social and ethical capital", FUTURES 35, 2003, pp. 975-987. 97 See <http://www.sristi.org/index.html> (June 2003), <http://www.sristi.org/honeybee.html> (June 2003), <http://www.nifindia.org/> (June 2003), <http: //www.gian.org/> (June 2003), <http://nifindia.org/ secondaward/sec1.htm> (June 2003), and <http:// www.sristi.org/IIM-Sristi.htm> (June 2003). 98 Ibid.

**99** See Indian Biodiversity Conservation Act 2002 at <a href="http://www.eta.action.eta //www.forests.tn.nic.in/biodiversity\_act.htm>; Panama's law on folklore, see <http://www.grain.org/brl/panamatk-2000-en.cfm/>; Peru's Collective Regime on Traditional knowledge and Portugal's Law on Traditional Knowledge, see <http://www.wipo.int/tk/en/laws/index.html>. An article on Thailand's Register of traditional medicine can be found on the Biotechnology and Development Monitor website at <http:// www.biotech-monitor.nl/3206.htm>; for information about the Andean Community, see <http://www.comunidadandina.org/ endex.htm>; for information on the Organization of African Unity, see <http://www.itcilo.it/english/actrav/telearn/global/ ilo/law/oau.htm>; for information on the South Pacific Forum see <http://www.forumsec.org.fj/Home.htm>. 100 Article 2. Law. No. 20. 26 June 2000.

101 Article 2, Executive Decree No.12, 20 March 2001. 102 Article 15 Law No. 20, 26 June 2000.

103 Although various efforts were made by national authorities to promote indigenous participation over the years, there has been significant and continuing criticism by indigenous peoples of their lack of involvement in the preparation of the legislative proposal. For discussion of the participatory process for development of the Peruvian regime, see B Tobin and K Swiederska, "Speaking in Tongues: Indigenous participation in the development of a sui generis regime to protect traditional knowledge in Peru", IIED, London, 2001, available at <http://www.iied.org>.

104 The national registers and their defensive nature, are closely related to Andean Community Decision 486 on Industrial Property which requires patent applicants to provide evidence of legal access to genetic resources and TK, used in development of inventions. INDECOPI could use these registers to assess patent applications in relation to their novelty and inventiveness. For a review of relevant provisions of Decisión 486, see M Ruiz, "The Andean Community's New Industrial Property Regime: Creating Synergies Between the CBD and

IPRs", Bridges. Between Trade and Sustainable Development. Year 4, No. 9. Nov-Dec 2000.

105 It is still to be seen whether sending public officials to the field will have any real effect with regards to assisting in the development of TK registers. Registering TK will be probably the ultimate phase of a complex consultation procedure within and among indigenous peoples' groups where public officials might have very little involvement.

106 Presentation by Dr Eliane Karp, President of CONAPA, at a Meeting of the Like-Minded Megadiverse Group, Cusco, November 2002.

107 See declarations of Aguaruna Federations in B Tobin and K Swiderska, "En Busca de un lenguaje comun: Participaccion indigena en el desarrollo de un regimen sui generis para la proteccion del conocimiento tradicional en Peru", IIED 2002. . Available at <http://www.iied.org/>.

**108** Some authors question whether translating oral traditions of indigenous peoples to written or electronic forms (including registers or databases) actually benefits the cultural process within communities (due to a symbolic translation of ideas) and, ultimately, whether the preservation of TK objective will actually be met. Indeed the question of whom will the TK be preserved for, needs further analysis. Scientists and researchers will certainly have access and a partial understanding of the TK. It is not as clear whether communities themselves will perceive their TK as preserved in any way. For further discussion of this point see D M Schoenhoff, The Barefoot Expert: The Interface of Computerized Knowledge Systems and Indigenous Knowledge Systems, Greenwood Press, Westport, Connecticut, 1993. 109 Depending on the system within which the database or register operates, a previous step of verification and processing of the TK application could be required. This may require an autonomous body or entity and an administrative phase to assess the application.

110 For an extensive review of this issue see WIPO. "Technical Proposals on Databases and Registers of Traditional Knowledge and Biological/Genetic Resources", WIPO/GRTKF/4/14, December 6. 2002. Particularly relevant in this report are the Proposed Data Specification for Technical Aspects of Databases and Registers of Traditional Knowledge and Genetic Resources mentioned in point 3.1. These refer to standard field definitions, technological standards, and security standards.

111 For details of how a specific ethnobotanic database could operate, see M Saenz García, "Management of Information for Ethnobotanical Registers" in J Vogel (ed) The Biodiversity Cartel. Transforming TK into Trade Secrets. SAN REM, Ecociencia, Usaid, CARE. Quito, 2000, ch. 7.

112 Brent Berlin provides numerous examples of how plants are taxonomically grouped from an indigenous peoples' perspective and classification criteria and how to, in turn, associate and relate these to modern, scientifically accepted taxonomic classifications. See G Martin, Ethnobotany. A People and Plants Conservation Manual. WWF International, UNESCO, Royal Botanic Gardens Kew. Chapman & Hall, London, 1995. 113 See CIEL, "Comments on Improving Identification of Prior Art. Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patent and Trademark Office", 2 August 1999.

114 For discussion of disclosure of origin and other user measures, see C S Barber, S Johnston and B Tobin, User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity, UNU-IAS, Tokyo, March 2003.

115 IP/C/W/400. "Council for Trade-Related Aspects of Intellectual Property Rights, Article 27.3(b), the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge: Communication from Switzerland". 116 Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge WIPO/GRTKF/IC/5/10.

117 Pers comm., Shakeel Bhatti, 27 October 2003. 118 For further comments on how these different tools and instruments might serve to protect TK, see M Ruiz, Protección Sui generis de Conocimientos Indígenas en la Amazonía. Parte II. Corporacion Andina de Fomento, Sociedad Peruana de Derecho Ambiental, Parlamento Amazónico. Lima, Perú, 2002.

119 A Maori version, an English translation, and a modern English translation of the "Treaty of Waitangi" can be found at <a href="http://www.govt.nz/en/aboutnz/?id=77737fd3275e394a8ed9">http://www.govt.nz/en/aboutnz/?id=77737fd3275e394a8ed9</a> d416a72591do>.

120 This report will not analyse the costs which a register system might imply. However, from the nature of the activities which need to be undertaken, for example verifying whether TK corresponds to a particular group or whether this particular group is entitled to share benefits, it seems obvious that there could be important administrative costs which need to be taken into account whether it is a declarative or constitutive register which is at stake.

121 WIPO/GRTKF/IC/4/14.

**122** The Asian Group's proposal states that: Communities should lead the compilation, operation and control of databases and registers of TK and associated biological/genetic resources. National and local actors should facilitate this, keeping in mind IP considerations as well as other benefits of documentation, such as conservation of TK and associated biological/genetic resources. WIPO should facilitate capacity building and networking of actors and processes for protection of IP relating to these databases, and that "The custodians of TK and associated biological/genetic resources should retain full control of the use of the documentation data of those resources and knowledge once they are compiled in databases and registries.".

**123** B Tobin, "Certificates of Origin: A role for IPR regimes in securing prior informed consent", in J Mugabe et al, Access to Genetic Resources: Strategies for Sharing Benefits, ACTS Press Nairobi, 1997.

124 B Tobin, "Redefining Perspectives in the Search for Protection of Traditional Knowledge", *RECIEL* 10, No. 1, Blackwell Publishers Ltd 2001.

**125** The law referred to is the model law "Traditional Biological Knowledge, Innovations and Practices Act", which is under review. The Act extends to knowledge, innovations and practices in the so-called "public domain", where, for example, the knowledge, innovation or practice has been obtained without prior informed consent.

**126** D Downes and S Laird, "Community Registries of Biodiversity Related Knowledge: The Role of Intellectual Property in Managing Access and Benefit–Sharing", Prepared for UNCTAD Biotrade Initiative, 1999. See also N P de Carvalho, "From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?", 41 Rev. ABPI [Brazilian Association of Intellectual Property], 1999.

127 Ibid.

128 N P de Carvahlo, "From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?", 41 Rev. ABPI [Brazilian Association of Intellectual Property], 1999.
129 G Dutfied, "Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation", ICTSD–UNCTAD, 2002.
130 [bid.

**131** J H Reichmann, "A Compensatory Liability Regime for Applications of Traditional Knowledge", A draft paper presented to the Cardozo Symposium on the Legal Protection of Traditional Knowledge, New York, 23–24 February 2001.

**132** For further details on the operation of the CGIAR system as it applies to gene banks, see SGRP. Booklet of CGIAR Centre Policy Instruments, "Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights", Volume I. Rome, September, 2001).

133 See <http://www.aiatsis.gov.au/>

134 Pers. Comm., Anil Guptha, June 2003.
135 For discussions of trust funds for sharing financial benefits of biodiversity, see M Guerin–McManus, K Nnadozie and S Laird, "Sharing Financial Benefits: Trust Funds for Biodiversity Prospecting", in S Laird (ed), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, Earthscan, 2002.
136 Trusts can be developed at any level. The Suriname Forest People's Fund, is a community fund established to facilitate benefit–sharing from biodiversity prospecting and foster biodiversity conservation with start–up capital of US\$50,000.
While Nigeria's national Fund for Integrated Rural Development

and Traditional Medicine began with US\$40,000. At the other end of the scale are experiences such as Colombia's ECOFONDO, designed to promote the nation's environmental conservation which received US\$41.6 million in debt for nature swap. 137 Ibid.

138 Pers. comm., Preston Hardison, May 2003.

**139** For details on the issue of repatriation, see M Ruiz and R Pooma, "Going Home: A Manual on the repatriatioon of Information from Ex Situ Conservation and Research Institutions to Countries of Origin". Royal Botanic Gardens Kew. Darwin Initiative. London, 2000.

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