

Traditional Knowledge and Intellectual Property

Issues and options surrounding the protection
of traditional knowledge

A Discussion Paper

by *Carlos M Correa*



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Preface

Debate about the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) has broadened since publication of our earlier discussion paper on Trade, Intellectual Property, Food and Biodiversity* in February 1999. One area of concern is its impact on traditional and indigenous knowledge (TK). This paper discusses a number of policy issues surrounding the protection of TK that may be relevant to future negotiations or a deeper treatment of this issue in various international fora. The paper aims to:

- highlight, clearly and concisely, various perspectives on the policy issues raised for developing countries and traditional and indigenous communities within them by the expansion of intellectual property rights (IPRs),
- outline some definitional problems and the rationale and objectives for protection, different strategies for the use of IPRs for such protection, and various modalities of a *sui generis* regime as well as alternatives to these,
- examine the possible functions of a regime on TK, its impact on the intended beneficiaries and key ethical, economic, environmental and social concerns,
- consider the possible contribution of overseas development assistance (ODA) in developing and implementing policies on the protection of TK.

The paper is written for policy makers dealing with these issues across a range of government ministries as well as those groups and agencies with a special interest here. Our aim is to contribute to informed public debate about, and policy making concerning, TK, IPRs and sustainable human development.

The core work of the Quaker United Nations Office (QUNO) in Geneva on trade, development and intellectual property rights has been supported by the Environmental Intermediaries Programme of Quaker Peace and Social Witness of Britain Yearly Meeting. This programme links traditional Quaker concerns for peace and justice with a concern for the environment. Since February 1999, QUNO has hosted a series of meetings aimed at helping strengthen the capacity of developing countries to safeguard the interests of their people and to bring these countries into dialogue with industrialised countries around issues raised by the review of Article 27.3(b) of the TRIPS Agreement. QUNO has received additional support from other donors in 2001 to expand its work in this area, and gratefully acknowledges support from the Rockefeller Foundation in funding production of this discussion paper. Any views expressed are the views of the author and do not necessarily reflect the views of QUNO or the Rockefeller Foundation.

* *Trade, Intellectual Property, Food and Biodiversity: Key issues and options for the 1999 review of Article 27.3(b) of the TRIPS Agreement*, Quaker Peace & Service, London, 1999. Available in English, French, German, Spanish and Swedish at <http://www.quno.org> - click on Geneva pages

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Contact: Brewster Grace, QUNO, Quaker House, Avenue du Mervelet 13, 1209 Geneva, Switzerland.

Tel: +41 22 748 4800, Fax: +41 22 748 4819

E-mail: bgrace@quno.ch

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About the author

Carlos Correa is professor of intellectual property law and director of the University of Buenos Aires' Masters Programme on Science and Technology Policy and Management. He trained as both a lawyer and economist, has served in government in the 1980s as Vice-Secretary for Science and Technology and was a delegate to GATT and WIPO negotiations. He has been a consultant to many regional and international agencies.

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Contents

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| | |
|--|---------------------------|
| Preface | inside front cover |
| Executive summary | 2 |
| 1. The importance and scope of traditional knowledge | 3 |
| 1.1 The scope of TK | 4 |
| 2. Protecting TK | 5 |
| 2.1 Reasons for protection | 5 |
| 2.1.1 Equity | 5 |
| 2.1.2 Conservation | 6 |
| 2.1.3 Preservation of traditional lifestyles | 6 |
| 2.1.4 Avoiding “bio-piracy” | 7 |
| 2.1.5 Promoting use and development | 8 |
| 2.1.6 Other objectives | 8 |
| 2.2. Methods of protecting and conserving TK | 9 |
| 3. Strategies | 11 |
| 3.1 Application of existing IPRs | 11 |
| 3.2 Designing an IPRs <i>sui generis</i> regime | 14 |
| 3.2.1 Single or multiple regimes | 14 |
| 3.2.2 Rights conferred | 14 |
| 3.3 Enforcing customary laws | 15 |
| 3.4 Impact on intended beneficiaries | 16 |
| 3.5 National or international? | 17 |
| 4. The misappropriation option | 18 |
| 4.1 Documentation of TK | 18 |
| 4.2 Proof of origin of materials | 19 |
| 4.3 Consent | 19 |
| 5. TK and IPRs in international fora | 20 |
| 5.1 UNEP/CBD | 20 |
| 5.2 WIPO | 21 |
| 5.3 FAO | 22 |
| 5.4 UNCTAD | 22 |
| 5.5 UNHCHR | 23 |
| 5.6 WTO | 23 |
| 6. Conclusions | 27 |
| Bibliography | 28 |
| Acronyms | inside back cover |
| Table 1 | |
| Proposals for the review of Article 27.3(b) of the TRIPS Agreement | 24/25 |

Boxes

| | | | |
|---|----|---|----|
| 1. Defining traditional knowledge | 4 | 9. Failure to recognise customary laws in Australia | 15 |
| 2. Community rights in the OAU Model Law | 5 | 10. Protection of TK in Peru | 16 |
| 3. The Plant Genetic Resources System | 6 | 11. The case of ayahuasca | 18 |
| 4. Biopiracy – the misappropriation of TK | 7 | 12. WIPO Programme on emerging IP issues | 20 |
| 5. Conflicting views | 9 | 13. US position on TK at the WIPO Committee | 21 |
| 6. Protection of TK under existing modes of IPRs | 11 | 14. The International Treaty on Plant Genetic Resources for Food and Agriculture: Article 9 – Farmers’ Rights | 22 |
| 7. Communities’ Rights in National Constitutions and Laws | 12 | 15. Issues for Overseas Development Assistance | 27 |
| 8. A <i>sui generis</i> regime on traditional medicine | 13 | | |

Executive summary

The protection under intellectual property rights (IPRs) of traditional and indigenous knowledge (TK) has received growing attention since the adoption of the Convention on Biological Diversity (CBD) in 1992. Numerous contributions by academics, NGOs and governments have considered the need to provide some form of protection to TK. However, significant divergences exist as to whether IPRs should be applied and, if that were the case, which would be the rationale and modalities of protection.

First, it is necessary to understand the importance and scope of TK – which includes its widespread use in traditional medicine and farming – and this is described in Section 1, along with the question of its definition. The starting point for any discussion about possible forms of protection should then be to clarify why there is a need to protect it, and what can be achieved.

In Section 2, the main arguments for protection are considered under the headings of equity, conservation, preservation of traditional lifestyles, prevention of biopiracy, and promoting the use of TK and its importance in development. IPRs, as a legal tool, may be appropriate and efficient under certain circumstances, but inadequate or ineffective in others. For example, the recognition or establishment of new types of IPRs on TK may reduce rather than promote the use of such knowledge (eg in medicines or in the exchange of farmers' materials) and policy-makers need to balance the expected benefits against the cost of such limitations. Another problem for some opponents is the essential incompatibility between the concepts of western IPRs and the practices and cultures of local and indigenous communities. Thus, since different objectives (such as equity, conservation, preventing misappropriation, etc) may be sought when the "protection" of TK is pursued, a basic point is the extent to which particular forms of IPRs may be suited or not to reach the objectives.

Different strategies may be followed to protect TK under IPRs, including the application of existing modes of protection, the development of a *sui generis* regime, or a combination of both. These are described in Section 3, as is another option - the enforcement of customary laws which, in some cases, recognise certain forms of ownership over TK. Also mentioned here are concerns about the feasibility, effectiveness, costs and acceptability of possible legal systems for traditional and indigenous communities.

Alternatively, protection may be seen as a mechanism to prevent third parties from unduly appropriating TK - the misappropriation option described in Section 4. The development of a misappropriation regime requires the documentation of TK, the ability to prove the origin of resources used in IPRs claims, and a requirement for consent from its traditional owners. In any case, the difficulties of effectively enforcing rights may be significant and dilute the value of any legal approach.

The issue of TK protection has been dealt with in some national laws and constitutions. A clear legislative pattern, however, does not arise so far. Debates have also taken place in different international fora, where numerous studies and proposals have been made, which are discussed in Section 5. Despite all these efforts, many questions about objectives, tools and feasibility of TK protection remain unanswered. While work on the subject needs to be pursued – with the participation of the intended beneficiaries – attention to legal protection should not overshadow the fact that the access to land and the preservation of the communities' own lifestyles, are indispensable conditions for the preservation and further development of TK.

Section 6 summarises this paper's conclusions. It also recommends that it seems premature to promote international IPRs-type standards for TK protection at present and suggests global rules to prevent misappropriation of TK. It also suggests various ways in which Overseas Development Assistance can be used to clarify and improve the present situation.

1. The importance and scope of traditional knowledge

Public domain in the IPRs field generally includes any information not subject to IPRs or for which IPRs have expired. Thus, to the extent that TK is not covered under any of the IPRs modalities, it would belong to the public domain and be freely exploited. However, this technically correct view ignores the fact that TK may be deemed subject to customary laws that recognise other forms of ownership or possession rights¹.

Traditional and indigenous knowledge (TK) has been used for centuries by indigenous and local communities under local laws, customs and traditions. It has been transmitted and evolved from generation to generation. TK has played, and still plays, an important role in vital areas such as food security, the development of agriculture and medical treatment. However, Western societies have not, in general, recognised any significant value in TK nor any obligations associated to its use, and have passively consented to or accelerated its loss through the destruction of the communities' living environment and cultural values.

Recently, Western science has become more interested in TK and realised that TK may help to find useful solutions to current problems, sometimes in combination with "modern" scientific and technological knowledge. Despite the growing recognition of TK as a valuable source of knowledge, it has generally been regarded under Western intellectual property laws as information in the "public domain", freely available for use by anybody. Moreover, in some cases, diverse forms of TK have been appropriated under intellectual property rights by researchers and commercial enterprises, without any compensation to the knowledge's creators or possessors².

TK is a central component for the daily life of millions of people in developing countries. Traditional Medicine (TM) serves the health needs of a vast majority of people in developing countries, where access to "modern" health care services and medicine is limited by economic and cultural reasons. For instance, the per capita consumption of TM products is, in Malaysia, more than double that of modern pharmaceuticals. TM is also significant in more advanced developing countries such as South Korea, where the per capita consumption of TM products is about 36% more than modern drugs³. It is often the only affordable treatment available to poor people and in remote communities.

Similarly, the use and continuous improvement of farmers' varieties (landraces) is essential in many agricultural systems. In many countries, seed supply fundamentally relies on the "informal" system of seed production which operates on the basis of the diffusion of the best seed available within a community, and on its movement, even over large distances during migration or after disaster⁴. Furthermore, TK is the origin of a great variety of artistic expressions, including musical works and handicrafts.

TM also plays a significant role in developed countries, where the demand for herbal medicines has grown in recent years. The world market for herbal medicines has reached, according to one estimate, US\$43 billion, with annual growth rates of between 5 and 15%. For China, the leading country in this field, WHO estimates that TM generated income of about \$5 billion in 1999 from the international and \$ 1 billion from the domestic market. The European market in 1999 was calculated to be \$ 11.9 billion (where Germany had 38%, France 21% and United Kingdom 12%)⁵. Moreover, many pharmaceutical products are based on, or consist of, biological materials⁶. Plants, in particular, are an important source of medicines⁷. The knowledge of traditional and indigenous farmers relating to cultivated plants has also been a central element for the development of new plant varieties and, most importantly, for food security on a global scale.

The importance of TK for its creators and for the world community at large, and the need to foster, preserve and protect such knowledge, has gained growing recognition in international fora. Thus, in 1981 a WIPO-UNESCO Model Law on Folklore was adopted; in 1989 the concept of "Farmers Rights" was introduced in the FAO International Undertaking on Plant Genetic Resources⁸; in 1992 the Convention on Biological Diversity (CBD) specifically addressed the issue (article 8(j))⁹. In 2000, an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established by the World Intellectual Property Organisation (WIPO) and it first met in April 2001¹⁰.

¹See Dutfield, 2000b, p 285; Fishman, 2001, p 1-3

²Girsberger, 2000, p 3

³Balasubramanian, 1997, p iii

⁴Louwaars, 1996, p I-1

⁵WHOa, 2000, p vi and Pranoto, 2001, p 2

⁶ten Kate and Laird, 1999

⁷See, eg, Lambert, Srivastava and Vietmeyer, 1997, p 1

⁸FAO Resolution 4/89

⁹See also the Report of the UN Secretary General on the Intellectual Property of Indigenous Peoples, EICN.41 Sub.2/1992/30

¹⁰Subsequently referred to as 'the WIPO Committee'

1.1 The scope of TK

TK encompasses very different types of knowledge. These may be distinguished by the elements involved, the knowledge's potential or actual applications, the level of codification, the individual or collective form of possession, and its legal status. The desire to protect TK has generated a significant body of literature and many proposals of regulation and for action in different international fora. Precisely how TK is defined has important implications for the kind and scope of a possible protection regime.

TK includes, for example, information on the use of biological and other materials for medical treatment and agriculture, production processes, designs, literature, music, rituals, and other techniques and arts¹¹. This broad set includes information of a functional and of an aesthetic character, that is, processes and products that can be used in agriculture or industry, as well as intangibles of cultural value.

Mostly, TK comprises of knowledge which has been developed in the past, but which still continues to be developed. Most TK is, in effect, of non-contemporary nature; it has been used for generations and in many cases collected and published by anthropologists, historians, botanists or other researchers and observers¹². However, TK is not static; it evolves and generates new information as a result of improvements or adaptation to changing circumstances.

The context of TK varies significantly and its forms of expression. Some TK is codified, that is, formalised in some way (eg textile designs, ayurveda traditional medicine). A great part of TK¹³, however, is non-codified or tacit, such as, "folk", "tribal" or "indigenous" medicine, which is based on traditional beliefs, norms and practices accumulated during centuries old experiences of trial and error, successes and failures at the household level, and passed to successive generations through oral tradition.

TK may be possessed by individuals (eg healing practices and rituals), by some members of a group, or be available to all the members of a group ("common knowledge"), for example with knowledge on herbal-home remedies which is held by millions of women and elders. When its application, and in particular the delivery of TK-based products, can be made through commercial channels TK may be of commercial value. While some TK can be used and understood outside its local/traditional/communal context, this is not always the case. There are often spiritual components in the TK peculiar to each community. Knowledge that cannot be utilised beyond its communal context has little or no commercial value, despite the value that such knowledge may have for the life of the originating community¹⁴.

To summarise, TK includes information of different kinds and functions, developed in ancestral times but subject to contemporary improvement and adaptation. It is expressed in various documented and non documented forms, and may possess commercial value depending on its potential or actual use. The difficulties of defining TK should not, however, impede further work on it at the national or international level (Box 1).

¹¹See, eg, WIPO, 2001, p 25; also Mugabe, 1998

¹²Koon, 1999, p 270

¹³In some countries (such as the Sub-Saharan countries) where there is no long history in writing, TK is predominantly non-codified

¹⁴Koning, 1998, p 265

1. Defining traditional knowledge

Is a precise definition of TK a precondition for any international negotiation on its possible protection or promotion? The different nature and forms of expression of the information embraced by TK, can make it difficult to agree on a legally and scientifically acceptable definition. Indeed, TK is one of several terms used to describe broadly the same subject matter. WIPO currently uses the term to refer to 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 industri-

al, scientific, literary or artistic fields^a.

The difficulty in defining TK should not be an obstacle to elaborating the conditions for the protection of such knowledge^b. Patent law only defines the requirements for protection (novelty, inventive step, industrial applicability), while patents may refer to inventions in mechanical, chemical, electronics, biological and many other fields. Similarly, trade secrets involve any secret and commercially valuable information, and no further definition about their content is required for their legal protection. In TK, an operational concept may be based on the source of the knowledge (traditional and indigenous communities) and on its cultural speci-

ficity, rather than on the specific content of its components. For instance, "mola" is a traditional handmade textile work manufactured by cutting and stitching several layers of cloth to form a multicolored product. The "molas" have been traditionally produced by the native Kuna communities in Panama. Although imitations have been produced in Taiwan, "mola" clearly is a product of Kuna's traditional knowledge which was developed as an expression of their own culture^c.

^aWIPO, 2001, p 25; ^bSee the submission by Pakistan to the First Session of the WIPO Committee, WIPO/GTRKF/1/13 Prov., para 48; ^cWIPO, 2001, p 13

2. Protecting TK

"...it is only logical and in consonance with natural justice that they are given a greater say as a matter of right in all matters regarding the study, extraction and commercialization of the biodiversity."

Mashelkar, 2000, p 2-3

"It is an irony that the communities who have preserved the germplasm used in developing new strains, for thousands of years, are deprived of any direct or indirect benefits. It is natural justice that the rights of the indigenous communities in this matter be legally protected."

Pushpangadhan, 1996, p 168-169

Several proposals have been made, within and outside the IPRs system, to "protect" TK. Such proposals often fail to set out clearly the rationale for its protection. Any system of protection, however, is an instrument for achieving certain objectives. Therefore, a fundamental question, before considering how TK may be protected, is to define why it should be.

2.1 Reasons for protection

One reason for a lack of clarity about the rationale for protection stems from the different meanings given to the concept of protection. Some understand this concept in the context of IPRs, where protection essentially means to exclude the unauthorised use by third parties¹⁵. Others regard protection as a tool to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it¹⁶. Protection here has a more positive role in supporting TK-based communities livelihoods and cultures, as proposed by the Organisation of African Unity's (OAU's) Model Law and its definition of community rights (Box 2).

Overall, however, the main arguments for granting protection to TK include:

- equity considerations,
- conservation concerns,
- the preservation of traditional practices and culture,
- the prevention of appropriation by unauthorised parties of components of TK, and
- promotion of its use and its importance in development.

2.1.1 Equity

The underlying concept in many proposals for the protection of TK is based on equity considerations. TK generates value that, due to the system of appropriation and reward currently in place, is not adequately recognised and compensated. The protection of TK would, therefore, be necessary to bring equity to essentially unjust and unequal relations.

An example of this rationale is found in plant genetic resources. Traditional farmers both conserve and use plant genetic resources. The value of plant genetic resources is preserved and enhanced by their utilisation for planting, seed production and continuous selection of the best adapted farmers' varieties (landraces). Such farmers generally interact among themselves on the basis of barter or exchange across the fence, thus fostering the diffusion of their varieties and their further development.

However, the varieties conserved and developed by farmers are later collected, subject to research and breeding, and enter the commercial channels through seed companies. While the latter can protect the improved varieties under plant breeders'

¹⁵eg Downes, 1997

¹⁶eg Simpson, 1997

2. Community rights in the OAU Model Law

The Organisation of African Unity's *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources* covers community rights:

"Community rights recognise that the customary practices of local communities derive from a priori duties and responsibilities to past and future generations of both human and other species. This reflects a fundamental relationship with all life, and is imbued with an innate demand for respect. Despite the fact that this worldview is

not commonly understood by the dominant western world, the purpose of these rights is to recognise and protect the multi-cultural nature of the human species.

Community rights and responsibilities that govern the use, management and development of biodiversity, as well as the traditional knowledge, innovations and practices relating to them, existed long before private rights over biodiversity emerged, and concepts of individual ownership and property arose. Community rights are thus regarded as natural, inalienable, pre-existing or primary rights. The OAU's Model Law

recognises this a priori character of rights in its Preamble.

The rights of local communities over their biodiversity leads to the formalisation of their existing communal control over biodiversity. This system of rights, which enhances the conservation and sustainable use of biological diversity and promotes the use and further development of knowledge and technologies, is absolutely essential for the identity of local communities and for the continuation of their irreplaceable role in the conservation and sustainable use of this biodiversity".

Source: Ekpere, 2000, p 20

3. The Plant Genetic Resources System

"Both farmers and scientists have relied on the store of genetic diversity present in crop plants that has been accumulated by hundreds of generations who have observed, selected, multiplied, traded, and kept variants of crop plants. The result is a legacy of genetic resources that, today, feeds billions of humans" Brush, 2000, p 3

Conservation (*in-situ*, including on farm, and *ex-situ*), research and development, and the use of plant genetic resources, are components of a complex system in dynamic interaction. Such an interaction is based on market and non-market relationships among different types of agents with specific functions within a system that may be called the "Plant Genetic Resources System". Agents in the plant genetic resources system include traditional farmers and indigenous communities, collectors and curators (conservation

subsystem), research institutions (research and development subsystem) breeders and seed companies (commercial breeding/production subsystem), and farmers (agricultural use subsystem). Each of these groups perform different functions within a particular framework of customary and formal legal rules. The dividing lines between these activities are not, however, always clearly cut. For example, traditional farmers undertake empirical research at the farm level not just on varieties but on cultivation techniques as well. The farmers provide improved varieties, but are not compensated for them. Research institutions (including for-profit, non-profit, governmental, intergovernmental, and academic institutions) use plant genetic resources to undertake basic and applied research, including agro-biotechnology, and to

enhance existing varieties and the availability of gene pools. Breeders use plant genetic resources in breeding programmes. They obtain materials and scientific information from the previous groups, generally on a non-market basis, and produce new or improved varieties for sale in the market. Intellectual property rights, wherever available, strengthen their market position and their ability to recover development expenditures. Seed companies use breeding results to propagate and sell seeds. They operate entirely within the market. In sum, while commercial breeders and farmers benefit downstream from the value created in the system, there is no compensation for those who contributed upstream to the available pool germplasm.

Source: Correa, 2000a

"The knowledge, innovations and practices of indigenous peoples and local communities are manifestations of their cultures. Protecting a peoples' culture means maintaining those conditions that allow a culture to thrive and develop further... Therefore, protecting a peoples' cultural heritage involves inter alia maintaining the link between a people and natural features of the landscape and naturally-occurring species of plants and animals"

Dutfield, 1999, p 514

rights (PBRs) and benefit from them, the farmers are not compensated for the germplasm they have contributed and the value they have created (Box 3). An essential characteristic of farmers' varieties is their variation over time. For this reason, such varieties cannot normally meet the stability and uniformity requirements imposed under PBRs.

The basic point in this criticism is that traditional/indigenous farmers are not paid for the value they deliver, since breeders and seed companies are not charged a price for the samples they obtain, and neither is there any later compensation or sharing of benefits with the farmers. A similar argument applies to other intangible components of TK. For regulatory purposes a distinction may be made between access to and use of genetic resources vis-à-vis access to and use of TK. For instance, national access legislation (as enacted, eg, in The Philippines, Andean Group countries, Brazil and Costa Rica) in some cases applies to genetic resources only, while in others it also covers TK as an intangible component¹⁷.

2.1.2 Conservation

A second factor underlying the claim for protection of TK is based on the importance of such knowledge for conservation purposes. Thus, maintenance of biological diversity in farming systems generates value for the global community¹⁸.

IPRs might be used to generate income to sustain activities that would otherwise be abandoned. If traditional farmers for example, abandoned the use and breeding of farmers' varieties attracted by the higher income obtainable through planting higher yielding modern varieties then a serious loss of biodiversity could occur¹⁹. However, on the conceptual level, it is doubtful whether the protection of farmers' varieties under an IPRs system would have any positive impact on their conservation or stimulate breeding activity, and whether protection would serve the purpose of strengthening the rights of communities and traditional farmers over their resources²⁰.

Under this approach, the protection of TK helps meet society's broader objectives for the conservation of the environment, sustainable agriculture and food security.

2.1.3 Preservation of traditional lifestyles

Others see the protection of TK as providing a framework to encourage the maintenance of practices and knowledge embodying traditional life styles. In this sense, the notion of "protection" is quite different from the notion applied under IPRs. The preservation of TK is not only a key component of the right to self-identification and a condition for the continuous existence of indigenous and traditional peoples; it is also a central element of the cultural heritage of humanity²¹. The crisis affecting the world's diverse cultures and languages is, according to some estimates, far greater than the

¹⁷ten Kate and Laird, 1999, p 20

¹⁸Swanson, Pearce and Cervigni, 1994, p 26

¹⁹Swanson, Pearce and Cervigni, 1994

²⁰IPGRI, 1999, p 16

²¹See various contributions in UNEP, 1999

Prior art - all public knowledge before the priority date which could be relevant to the novelty or unobviousness of an invention

biodiversity crisis. Around 90% of the 6000+ currently spoken languages (and the cultures expressed by them) may have become extinct or face extinction in the next 100 years²².

The Crucible group suggests that by vesting legally recognised ownership of knowledge in communities through IPRs it will raise the profile of that knowledge and encourage respect for it both inside and outside the knowledge holding communities:

“This will make the learning and development of such knowledge a more attractive prospect for the younger members of such communities, thus perpetuating its existence. The possibility of economic returns for the use of that knowledge by third parties acts as a further incentive for community members to respect their knowledge and continue to engage in practices in which that knowledge is used and generated”

However, merely using a law to make something into property that was previously part of the public domain “does not suddenly save it, conserve it, make people respect it or want to use it...Fencing off their knowledge does nothing to protect it from being even more eroded, undermined, or ignored or at risk of being lost”²³.

2.1.4 Avoiding “bio-piracy”

In some cases, the protection of TK aims to prevent the unauthorised appropriation (“bio-piracy”) of traditional knowledge (Box 4) and to ensure benefit sharing - as provided for under articles 8 (j), 15, 16 and 19 of the CBD - rather than the establishment of a system of positive appropriation. The government of India, for instance, has proposed, as a way to harmonise the TRIPS Agreement with the CBD, to incorporate in the Agreement a provision establishing that patents inconsistent with Article 15 of the CBD must not be granted²⁴. This article requires prior informed consent for access to genetic resources, and the sharing of benefits arising from commercial use with the country of origin of the material.

The granting of patents unduly covering TK may be prevented by improving the information available to patent offices for examination of novelty and inventive step

²²Oviedo, Gonzalez and Maffi, 2000, p 6

²³The Crucible Group, 2001, p 10

²⁴WT/GC/W/225

4. Biopiracy – the misappropriation of TK

“Bio-piracy through IPRs has arisen as a result of the devaluation and invisibility of indigenous knowledge systems and the lack of existing protection of these systems. The protection of indigenous knowledge systems as systems of innovation and the prevention of piracy of biodiversity requires a widening of legal regimes beyond the existing IPR regimes such as patents” Shiva, Jafri, Bedi and Holla-Bhar, 1997, p 30

“Bio-piracy” has been defined as the process through which the rights of indigenous cultures to genetic resources and knowledge are “erased and replaced for those who have exploited indigenous knowledge and biodiversity”^a. In fact, a large number of patents have been granted on genetic resources and knowledge obtained from developing countries, without the consent of the possessors of the resources and knowledge. There has been extensive documentation of IPR being sought over resources “as they are”, without further improvement (eg, US patent No. 5,304,718 on quinoa granted to researchers of the Colorado State University; US Plant patent No. 5,751 on ayahuasca, a sacred and medicinal plant of the Amazonia) and on products based on plant materials and knowledge developed and used by local/indigenous communities, such as

the cases of the neem tree, kava, basco, endod and turmeric, among others^b.

Many of these patents have been revoked by the competent national authorities. Thus, the Council of Scientific and Industrial Research (CSIR) from India asked for a re-examination of the US patent No. 5,401,5041 granted for the wound healing properties of turmeric. The US Patent and Trademark Office (USPTO) revoked this patent after ascertaining that there was no novelty; the innovation having been used in India for centuries. In early 2000 the patent granted to WR Grace Company and US Department of Agriculture on neem (EPO patent No. 436257) was also revoked by the European Patent Office on the grounds of its use having been known in India. A reexamination request for the patent on Basmati rice lines and grains (US Patent No. 5,663,484) granted by the USPTO was also made by the CSIR^c.

The US government has justified the problems posed by these patents as follows:

“Informal systems of knowledge often depend upon face-to-face communication, thereby limiting access to the information to persons in direct contact with one another. The public at large

does not benefit from the knowledge nor can the knowledge be built upon. In addition, if information is not written down, that information is completely inaccessible to patent examiners everywhere as prior art when they are examining patent applications. It is possible, therefore, for a patent to be issued claiming as an invention technology that is known to a particular indigenous community. The fault lies not with the patent system, however, but with the inaccessibility of the knowledge involved beyond the indigenous community. The US patent granted for a method of using turmeric to heal wounds, referred to during India’s intervention in June 1999 and again in October 1999, is an example of a patent issued because prior art references were not available to the examiners. In that instance, however; the patent system worked as it should. The patent claim was cancelled based on prior art presents by a party that requested re-examination”^d.

^a Shiva, Jafri, Bedi and Holla-Bhar, 1997, p 31

^b Mooney, 1998, p 152-154; Mashelkar, 2000.

Some cases of misappropriation under PBRs of varieties obtained from CGIAR Centers were also reported in Australia; ^cUS General Declaration to the First Meeting of the WIPO Committee, May 1, 2001

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

Article 8 (j) of the CBD

(see Section 4.1). This would not be sufficient in the USA, however. According to section 102 of the US patent law, information that has been published in a written form in the USA or in any other country is not patentable. But if the information was publicly used but not documented in a foreign country, novelty is not lost. Unless this relative standard of novelty is modified, the problems of appropriation of TK under US patents will remain unsettled.

2.1.5 Promoting use and development

The promotion of the use of TK is an important objective in itself. Article 8 (j) of the CBD, often quoted in relation to the protection of TK, requires the promotion of the “wider application” of TK. It may be argued that protecting TK against loss and misappropriation, or ensuring compensation to TK holders, are necessary elements to stimulate the broader use of such knowledge.

Protection may be, in this context, a tool for facilitating access to TK²⁵. Some form of protection may create the basis of trust required for the local/indigenous communities to part with their knowledge, and improve their position to obtain value from it²⁶. If some rights were recognised, knowledge holders may be more prepared to provide access to their knowledge and, if fairly compensated, they will have more incentives to conserve it and ensure future access.

However, the recognition or establishment of new types of IPRs on TK may reduce, rather than promote, the use of such knowledge. In dealing with TK, policy makers need to balance very carefully the expected benefits from a possible IPRs-like protection of TK, with the costs that are likely to arise from the limitations on its use. This may be particularly important in the case of TM, since an IPRs-like protection may reduce the access to products and treatment that are essential for a large part of the developing countries’ population, particularly the poor. In the case of farmers’ varieties, IPRs protection may also reduce the exchange of materials and the biodiversity created on-farm²⁷. The impact on genetic diversity of modern breeding promoted by IPRs in the Netherlands has been a “narrowing circle of genetic diversity”, characterised by the replacement of landraces by breeder’s varieties developed for high input/high production agriculture, and by the narrowing down of the gene pool used to breed new varieties²⁸.

Thus, rather than “protecting” TK in a way that limits access to it, governments may aim to promote the use of TK, complimenting this with measures to prevent misappropriation. An example of this approach is provided by Act No. 8423 (1997) of the Philippines, which aims “to accelerate the development of traditional and alternative health care” by improving the manufacture, quality control and marketing of traditional health care materials²⁹.

Promoting development may also be a fundamental motivation behind protecting TK from destruction and loss. TK is an underutilised resource in the development process³⁰. Legal protection may help to exploit the opportunities of TK-based products and services³¹. TK may also be a critical resource for strengthening local innovation, and innovation is important for reinforcing (even rebuilding) local cultures³².

2.1.6 Other objectives

In addition to the above objectives, there may be other goals for the protection of TK. However, the protection of TK is not an end by itself; it may provide a means to achieve different objectives, the definition of which is essential to determine the need for, the scope and the extent of protection. There seems to be no doubt about the need to bring equity to today’s essentially asymmetric relations, and to preserve TK as a component of a strategy for sustainable human development. However, it is necessary to clarify what the society would intend to reach through protection, and how its goals can be effectively realised, bearing in mind that there is also a human rights dimension to the protection of TK. The establishment of property or other rights is only a means and the protection of TK does not necessarily require the recognition of property rights (Section 2.2).

Protection may also have non-economic purposes, such as a moral recognition of the authorship. Authors are entitled to both economic and moral rights under authors’ rights systems that follow the Continental European approach. The TRIPS Agreement, however, allows Members not to comply with article 6 *bis* of the Berne Convention which provides for the protection of moral rights. Moral rights have been enforced in some common-law countries as well. In the UK, for instance, moral rights were introduced in the 1988 Copyright Act³³. In the USA, copyright is classified as “personal” property and the authors enjoy personality protection, such as the rights of first

²⁵R. Lettington, Personal communication, Oct 2001

²⁶See, eg Drahos, 1997

²⁷Louwaars and Engels, 2000, p 281

²⁸Jongerden and Ruivenkamp, 2000, p 265-269

²⁹Section 3.d

³⁰See

<http://www.worldbank.org/afr.ik>

³¹UNCTAD, 2000, p 17

³²Renée Vellée, personal communication, Aug 2001

³³Groves, 1997, p 445

publication. The Visual Artists Rights of 1990 provided protection for the paternity and integrity rights of certain graphic artists, sculptors and photographers³⁴. Such rights, which are recognised by the Universal Declaration of Human Rights (article 27)³⁵, generally relate to the paternity and integrity of a work. They are inalienable, although subject to waiver in particular circumstances³⁶. This kind of protection would provide traditional and indigenous communities with legal means to prevent any acts that distort the paternity or affect the integrity of TK. Moral rights, however, apply in the area of copyright (which protects the original expression of ideas) but not to other components of IPRs, such as patents.

Certain acts that unduly take advantage of a competitors' reputation may be dealt with under the discipline of unfair competition (which condemns dishonest commercial practices) or, in common-law countries, under the doctrine of "passing-off" (the wrong of misrepresenting one's business goods or services as another's, to the latter's injury, generally by using a confusing trademark or trade name). Applying these disciplines assumes, however, the existence of a competitive relationship, which may not exist when pieces of communities knowledge are imitated.

2.2. Methods of protecting and conserving TK

IPRs are seen as one possible means to "protect" TK. There are both ardent proponents and critics of extending IPRs to the knowledge of indigenous and traditional communities, including landraces (Box 5). Those who advocate the application of IPRs to TK find that there are many examples of TK that are or could be protected by the existing IP system, or by modifying certain aspects of the current forms of IPRs protection³⁷.

Those who are reluctant or opposed to the idea of applying existing IPRs or creating a new form of IPRs to protect TK base their arguments on both practical reasons and principles, namely the essential incompatibility between the concepts of Western IPRs and the practices and cultures of local and indigenous communities³⁸. For some opponents, bringing communities and their resources into the fold of the market economy could overwhelm and ultimately destroy those societies³⁹. Others argue that, given the difficulties inherent in establishing IPRs protection for TK, national IPRs legislation and international conventions should just ensure that such knowledge is not unduly appropriated and preserved outside the IPRs system (Section 4).

³⁴D'Amato and Long (eds) 1996, p 113-118

³⁵This article also recognises the "material interests resulting from any scientific, literary or artistic production"

³⁶Under the French law moral rights are declared "perpetual, inalienable and imprescriptible" (Law of 11 March 1957, article 6).

³⁷See, eg, WIPO, 2001

³⁸For various arguments, see The Crucible Group, 2001

³⁹Nijar 1996, p 24

5. Conflicting views

"There are many examples of TK that are or could be protected by the existing IP system. In addition, while many informants believe that the present IP system does not adequately recognize TK holders' rights, they are interested in undertaking further work on how the IP laws and system can be modified to curb those aspects of IP laws and systems "which allow piracy or are seen to condone it". Several informants also suggested certain modifications to IP law to improve its functionality in TK protection, and, others, new IP tools"

WIPO, 2001, p 223

"Patent and copyright not only presume that the act of innovation is largely individual rather than social, but that innovators are motivated by financial gain, and that it is the role of the state, rather than innovators, to ensure that new knowledge is used responsibly. In my experience, custodians of local knowledge believe that knowledge is socially created, through interaction amongst humans and non-humans; that individuals are obliged to put their

knowledge to use unselfishly; and that teachers of knowledge possess an inalienable responsibility to ensure its proper use"

Barsh, 2001

"In order to protect and encourage [TK], the necessary conditions may be in place, namely, security of tenure over traditional terrestrial and marine estates; control over and use of traditional natural resources; and respect for the heritage, languages and cultures of indigenous and local communities, best evidenced by appropriate legislative protection (which includes protection of intellectual property, sacred places, and so on)"

Executive Secretary of the Biodiversity Convention, in Traditional Knowledge and Biological Diversity, UNEP/CBD/TKBD/1/2, October 18, 1997, para 9

"Many participants, particularly representatives from indigenous organizations, felt that most existing legal framework didn't reflect adequately their concerns. They argued that the premise of Intellectual Property is based on terms and conceptual founda-

tions that remain outside their worldview. As an alternative, some advocated an integrated approach to the protection of traditional knowledge as illustrated by the ANDES initiative called "el parque de la papa" which aims to create a protected area of agro-biodiversity, genetic resources and traditional knowledge. Often discussions over specific mechanisms to increase the equality of resource transactions overlook the fundamental inequalities that exist between actors. Therefore, the expanded participation of indigenous groups and local communities at the design, development and implementation stage are essential to processes of building socially responsible regimes for the regulation of resources. Furthermore, issues such as equitable benefit sharing may be secondary to the more basic issue of defining ownership rights".

Report of the Multistakeholder Dialogue on Trade, Intellectual Property and Biological and Genetic Resources in Latin America, Cusco, Peru, 22-24, February 2001 (<http://www.ictsd.org/dialogueweb/texts/report2.htm>).

Farmers' Rights - "[R]ights arising from the past, present and future contribution of farmers in conserving, improving and making available Plant Genetic Resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits of farmers and supporting the continuation of their contributions...". FAO Resolution 5/89

The appropriateness of applying IPRs to TK depends upon the nature of the objectives pursued and the extent to which they can be fulfilled by different IPRs. Thus, IPRs may be an instrument to reach equity in the relations between TK holders and acquirers of their knowledge, to the extent that the former may enjoy and effectively exercise rights to prevent the unauthorised use or charge a price for the use of their knowledge. However, such objectives may be attained without the recognition of IPRs - which generally entail the granting of exclusionary rights - by other means, such as by implementing, through national legislation, the benefit sharing required by the CBD⁴⁰. The Executive Order No. 247 Order of The Philippines, for instance, provides that the rights of indigenous and local communities must be taken into account with regard to informed consent procedures. The Order distinguishes the rights in accordance to the type of community. In the case of local communities, prospecting of biological and genetic resources shall be allowed only with their prior informed consent. When indigenous communities are involved, prospecting shall be allowed within their ancestral lands and domains only with their prior informed consent, which shall be obtained in accordance with the customary laws of the concerned community.

Different alternatives to IPRs for dealing with TK or some components thereof have been proposed⁴¹. This is the case, for instance, of proposals relating to "tribal" or "communal" rights⁴², "community intellectual rights"⁴³, "traditional resource rights"⁴⁴ and, most notably, to "Farmers' Rights" as a means of compensating traditional farmers for their contribution to the *in situ* conservation of plant genetic resources⁴⁵.

All these legal tools may, however, be insufficient to prevent TK loss if communities are not able to keep their land and their traditional cultures and lifestyles. The destruction of the traditional living space of indigenous and local communities prevents the holders of TK from living as they previously have or causes them to vanish altogether⁴⁶. In fact, too much emphasis on IPRs for TK may distract attention from the real factors that put the preservation of TK at risk which include such things as security of tenure, control of resources, respect for traditional culture and ownership rights.

As well as the recognition of rights to their land and lifestyles, a multiplicity of mechanisms may be used in order to ensure that the conditions for the preservation of TK are maintained. Thus, the preservation of farmers' varieties may be undertaken under *in situ* conservation programmes sponsored by national governments, international and private organisations⁴⁷. There are examples of innovative forms of management of the biodiversity and indigenous agroecology, where mainstream conservationist practices are reconstructed within the indigenous and ecological context⁴⁸. According to the US delegation to WIPO:

"where preservation, conservation and protection are the goals rather than exploitation, however, a different strategy must be developed. In the United States, for example, preservation of Native American work is achieved through several legislative avenues, including the registration of official insignia of Native American Tribes, and the Indian Arts and Crafts Act. For more than seven decades the U.S. has also been involved in the preservation of folklore. In 1976, Congress created the American Folklife Center. The Center incorporates the Archive of Folk Culture, which was established at the Library in 1928 as a repository for American Folk Music. The Center and its collections have grown to encompass all aspects of folklore and folklife from this country and around the world, including over one million photographs, manuscripts, audio recordings, and moving images. It is the United States' first national archive of traditional life, and one of the oldest and largest of such repositories in the world"⁴⁹.

In sum, a clear distinction should be made between the legal concept of protection (conferring rights over TK), with the more practical ideas of protecting TK from destruction/loss or promoting its use through non-IPRs mechanisms. The tools to be used will radically differ depending on the objectives pursued and on which of the two approaches to deal with the issue is adopted. The following sections discuss the possible scope and implications of IPRs-related tools⁵⁰.

⁴⁰Each Contracting Party is bound to take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms (article 15. 7)

⁴¹For a review on the literature on the subject, see Dutfield, 2000a

⁴²Greaves, 1994

⁴³Berhan and Egziabher, 1996, p 38

⁴⁴Posey and Dutfield, 1996

⁴⁵Correa, 2000b

⁴⁶Girsberger, 2000, p 4

⁴⁷Brush, 2000, p 4

⁴⁸Gari, 2001

⁴⁹General Declaration of the USA to the First Session of the WIPO Committee, May 1, 2001. A Center for Arab and Mediterranean Music was established by Tunisia in 1992 (see the Report of the WIPO Committee, para 35)

⁵⁰For non-IPRs-related approaches see, eg, UNEP, 1999; UNCTAD, 2000

3. Strategies

3.1 Application of existing IPRs

The possibility of applying the existing modes of IPRs protection to different components of TK has been extensively explored; a useful summary of some of these developed by Latin American countries is shown in Box 6.

Some elements of traditional medicine may be protected under patents. Patents have been granted on natural components, as well as on combinations of plants for therapeutic use⁵¹. However, since most of the TK is not contemporary and has been used for long periods, the novelty and/or inventive step requirements of patent protection may be difficult to meet. It would be easier to comply with a more flexible novelty requirement such as that for plant varieties in UPOV for plant varieties that

⁵¹Eg EP 0519777 on formulations made from a variety of fresh plants; and WO 93/11780 on a skin therapeutic mixture with cold-processed aloe vera extract (with yellow sap and aloin removed). Correa, 2000c

6. Protection of TK under existing modes of IPRs

Copyright

Copyright can be used to protect the artistic manifestations of TK holders, especially artists who belong to indigenous and native communities, against unauthorised reproduction and exploitation. It could include works such as: literary works, eg tales, legends and myths, traditions, poems; theatrical works; pictorial works; textile works, eg, fabrics, garments, textile compositions, tapestries, carpets; musical works; and, three-dimensional works, eg, pottery and ceramics, sculptures, wood and stone carvings, artifacts of various kinds.

Related rights to copyright, such as performing rights, could be used for the protection of the performances of singers and dancers and presentations of stage plays, puppet shows and other comparable performances.

Inventions

The patent system could be used for the protection of technical solutions that are industrially applicable and universally novel and involve an inventive step. For genetic resources and TK, patents may be taken out for instance for products isolated, synthesised or developed from genetic structures, micro-organisms and plants or animals or organisms existing in nature. Patent protection may also be obtained for processes associated with the use and exploitation of those resources, and also processes known to the native communities that meet the same conditions. All the results of biotechnology applied to genetic and biological resources, and also undisclosed techniques for obtaining practical results, could in principle be protected with patents.

Plant varieties

New plant products, cultivars and varieties of all species of plants may be pro-

tected under plant breeders' rights (PBRs). To be protected, a variety has to be different from known varieties and uniform and stable in its essential characteristics, even after a number of reproduction cycles. Varieties developed by the possessors of TK could also be legally protected in this way. Improvements to varieties representing the natural state of plant diversity could also constitute new varieties eligible for protection.

Industrial designs

The design and shape of utilitarian craft products such as furniture, receptacles, garments and articles of ceramics, leather, wood and other materials may qualify for protection as industrial designs.

Trademarks

All goods manufactured and services offered by manufacturers, craftsmen, professionals and traders in native and indigenous communities, or by the bodies that represent them or in which they are grouped (cooperatives, guilds, etc), may be differentiated from each other with trademarks and service marks. The trademark is an essential element in the commercial promotion of goods and services both nationally and abroad.

Trade names

Any manufacturer, craftsman, professional person or trader in a native or indigenous community, including the bodies that represent such persons or in which they are grouped (cooperatives, guilds, etc), may identify themselves with trade names. The trade name is also used to promote the activities of the person or entity that it identifies, both within and beyond the borders of the country of origin.

Geographical indications and appellations of origin

Geographical indications, especially appellations of origin, may be used to

enhance the commercial value of natural, traditional and craft products of all kinds if their particular characteristics may be attributed to their geographical origin. A number of products that come from various regions are the result of traditional processes and knowledge implemented by one or more communities in a given region. The special characteristics of those products are appreciated by the public, and may be symbolised by the indication of source used to identify the products. Better exploitation and promotion of traditional geographical indications would make it possible to afford better protection to the economic interests of the communities and regions of origin of the products.

Repression of unfair competition

The protection of undisclosed information is achieved by the repression of unfair competition. The provisions against unfair competition may also be used to protect undisclosed TK, for instance traditional secrets kept by native and indigenous communities that may be of technological and economic value. Acknowledging that secret TK may be protected by means of unfair competition law will make it possible for access to that knowledge, its exploitation and its communication to third parties to be monitored. Control over the knowledge, and regulation of the manner in which it may be acquired, used and passed on, will in turn make possible to arrange contracts for the licensing of secret TK and derive profits from its commercial exploitation. It is necessary to publicise more, within the sectors and communities concerned, the opportunities that the secrecy regime offers for controlling the dissemination and exploitation of TK.

Source: GRULAC, 2000

"...it is an anomaly that the higher level of protection is available only for - wines and spirits. It is proposed that such higher level of protection should be available for goods other than wines and spirits also. This would be helpful for products of export interest like basmati rice, Darjeeling tea, alphonso mangoes, Kohlapuri slippers in the case of India."

Indian delegation to WTO, WT/GC/W/147

⁵²See also Section 7 of the TRIPS Agreement

⁵³See article 39.2 (a) of the TRIPS Agreement

had been previously commercialised or disposed of for purposes of exploitation. According to article 6 of UPOV:

"The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date, and (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date".

Some valuable TK may be kept secret, such as in cases of applications of plants for therapeutic purposes. Holders of this knowledge may be protected against disclosure under unfair competition rules, which do not require previous registration or other formalities. Most laws require, as a condition for protection,⁵² that the person in control of the information adopt the steps necessary, under the relevant circumstances, to keep the information confidential. In other words, there should be deliberate acts aimed at protecting, as secret, the relevant information. This may happen in certain cases of possession of TK (eg by tribal healers) but in others (eg plant varieties) the communities' practice is generally to permit and even promote the exchange and use of the knowledge by other farmers. Such exchange would not necessarily lead, however, to a loss of secrecy if the knowledge does not become generally known to persons within the circles that normally deal with the kind of information in question⁵³.

Geographical indications (GIs) may, in some cases, be a suitable mechanism to enhance the value of agricultural products, handicrafts and other TK-derived products. Several developing countries have indicated within WTO their interest in an enhanced protection in GIs. Egypt proposed that the additional protection conferred

7. Communities' Rights in National Constitutions and Laws

The Constitution of the Philippines of 1987 says: "The State shall recognize, respect and protect the rights of the indigenous cultural communities to preserve and develop their cultures, traditions and institutions" (Section 17, Article XIV).

Thailand's Constitution of 1997 states: "Persons so assembling as to be a traditional community shall have the right to conserve or restore their customs, local knowledge, arts or good culture of their community and of the nation and participate in the management, maintenance, preservation and exploitation of natural resources and the environment in a balanced fashion and persistently as provided by law." (Section 46).

The Constitution of Ecuador (1998) recognises "collective intellectual property rights" on communities' ancestral knowledge (Article 84). The Intellectual Property Law (No. 83, 1989) establishes a *sui generis* system of collective intellectual rights of indigenous and local communities (Article 377).

According to the Constitution of the Federative Republic of Brazil of 1998: "The Indians shall be accorded recognition of their social organization, cus-

toms, languages and traditions and the original rights in the lands that they occupy by tradition, it being the responsibility of the Union to demarcate them, protect them and ensure respect for all their property" (Article 231).

The Constitution of the Republic of Venezuela of 1999 says: "The collective intellectual property of indigenous knowledge, technology and innovations is guaranteed and protected. Any work on genetic resources and the knowledge associated therewith shall be for the collective good. The registration of patents in those resources and ancestral knowledge is prohibited" (Article 124).

The Costa Rican Biodiversity Law establishes that: "The State expressly recognises and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognised by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior

declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status. This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices" (Article 82).

In Brazil, the Provisional Measure 2.052-6 (21.12.2000) provides that the State recognises the indigenous and local communities' rights to decide on the use of traditional knowledge associated to genetic resources. This knowledge is protected against "illicit exploitation" and other unauthorised uses (Article 8 (1) and (2)). This Measure has been subsequently renewed (and partially amended) by acts of the Brazilian Executive Power. (Provisional Measure No. 2.126-11, 26 April 2001)

Decision 391 of the Andean Group (1996) recognises the rights of indigenous, Afro-American and local communities to decide on their knowledge, innovations and traditional practices associated to genetic resources and derived products (Article 7).

for geographical indications for wines and spirits (Article 23.1 of the TRIPS Agreement) be extended to other products, particularly those of interest to developing countries⁵⁴ and also India has argued for this. Proposals relating to the expansion of the products covered by an additional protection have been supported by countries such as Cuba, Dominican Republic, Honduras, Indonesia, Nicaragua and Pakistan⁵⁵, the African Group⁵⁶ and Venezuela⁵⁷. GIs, however, do not protect a specific technology or knowledge as such, but only prevent the false use of the geographical indication. Trademarks may also be used to protect signs or symbols of commercial interest to local and indigenous communities.

Copyrights and/or industrial designs can be applied to artistic works, provided that the problems arising from collective authorship are solved. The protection of folklore is a possible way to address such problems. The UNESCO/WIPO Model Provisions for National Laws for the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions⁵⁸, provide a possible framework for the protection of this component of TK. The Model Provisions attribute rights not only to individuals, but also to communities, and allow the protection of ongoing or evolutionary creations. Some countries, such as Bolivia and Morocco, have implemented rules based on the framework of the Model Provisions. In China, copyright protection also includes expressions of folklore. Some national laws and constitutions have also recognised, more broadly, intellectual rights to communities (Box 7).

Under copyright protection, as a result of the “idea/expression” dichotomy, only the expression of an idea in a work and not the underlying ideas are protectable⁵⁹. This excludes the use of copyright as a means of protecting and compensating methods or knowledge of a functional character.

Whatever the IPRs form of protection for a certain component of TK may be, a serious obstacle that title-holders (either communities or individuals) are likely to face is the cost of acquisition of rights (when registration is required such as in the case of patents, industrial designs and trademarks) and, more generally, of enforcement of the relevant rights. Administrative and judicial procedures are often long and costly. The availability of IPRs protection for TK may be, therefore, of little or no real value to those who may claim rights in TK (see Section 3.4).

⁵⁴WT/GC/W/136

⁵⁵WT/GC/W/208

⁵⁶WT/GC/W/302

⁵⁷WT/GC/W/282

⁵⁸See WIPO, 2000

⁵⁹See article 9. 2 of the TRIPS Agreement

8. A *sui generis* regime on traditional medicine

Thailand has developed a comprehensive *sui generis* regime for TM. The “Thai Traditional Thai Medicinal Intelligence Act” distinguishes three different categories of “Traditional Formulations”:

National Formulae are formulations given to the Nation which are crucial for human health.

The Act stipulates that the ministry of Public Health has authority to announce a certain formula of traditional Thai medicine as a national formula. In this case, the traditional formula must be of significant benefit or have special medical value. After the announcement, the rights of such a formula belong to the State. The commercial use of a national formula for the production of drugs or for research and development, is subject to permission from the government (criminal sanctions are provided for under the Act for infringement).

Private Formulae can be freely used by the owner. Third parties must obtain permission from the owner to use the formula. The request for the registration

of a private formula can be submitted by an inventor or developer of the formula; or an inheritor of the inventor or developer of such a formula. The Act grants exclusive rights by allowing the owner of the registered personal formula to use the formula for research and to sell and distribute any product developed or manufactured by using the formula. However, there are certain limitations to the exclusive rights. The rights over a registered personal formula subsist throughout the life of the owner and for a further 50 years from the date the applicant dies. One of the main objectives of the *sui generis* protection is that the exclusive monopoly granted by the State should enable the owners of traditional knowledge to be adequately compensated for their contribution^a.

General formulae, finally, are well known traditional formulae that remain free to use by anybody.

One important feature of this law is that all three types of formula can continue to be used free domestically by tradi-

tional healers or Thai communities in a limited quantity. The law also provides for measures aimed at the conservation and sustainable use of the medicinal plants, specially those at high risk of extinction. In addition, the Institute of Thai Traditional Medicine was formally established (after having been in operation for seven years). The Institute is governed by a committee composed of equal numbers of NGOs and governmental officials. Registration and other activities are distributed among 75 provincial offices throughout Thailand. A “Thai Traditional Knowledge Developing Fund” was also created. The Thai regulations have permitted the registration of over 700 licensed local manufactures producing traditional medicine. In 1998, there were already 4,300 formulations registered with Thai FDA and still increasing. The total value of production in 1999-2000 was around 320 million bahts, without including traditional medicines individually produced by healers^b.

^a Kuanpoth, 2001, p 6-7; ^b Subcharoen et al, 2000

3.2 Designing an IPRs *sui generis* regime

Another approach, that has been strongly advocated by some academics and many NGOs, would be the development of a *sui generis* regime of IPRs, that is, a legal regime “of its own kind” which is specifically adapted to the nature and characteristics of TK. A model of *sui generis* national legislation that would give communities property-like rights over their collective knowledge was developed by the Third World Network (Community Intellectual Rights Act) in 1994. Box 2 discusses the OAU Model Law and there are also proposals made by some Latin American countries for the adoption of a *sui generis* regime for TK in the context of the Free Trade Agreement for the Americas⁶⁰. Although this approach has received considerable attention in the literature, little progress has been made in terms of actually implementing this kind of protection. The establishment of a *sui generis* regime poses, in fact, many complex conceptual and practical issues. Briefly these are⁶¹:

- definition of the subject matter of protection
- requirements for protection
- extent of rights to be conferred (rights to exclude, to obtain a remuneration, to avoid misappropriation)
- title-holders (individuals/communities)
- modes of acquisition, including registration
- duration
- enforcement measures

3.2.1 Single or multiple regimes

If the *sui generis* route is adopted, a critical policy issue is whether the search for a regime of protection of TK should aim at a single, comprehensive, regime covering all manifestations of TK, or for a set of different, specific regimes adapted to the nature of the subject matter to be protected.

Development of a single regime requires dealing with quite diverse subject matters (eg artistic works, farmers’ varieties, traditional medical methods) for which it might be hard to define common rules. An alternative approach is to consider the adoption of specific regimes for well-defined components of TK, such as for:

- artistic creations, including expressions of folklore;
- plant genetic resources for food and agriculture and associated knowledge;
- traditional medicine (TM).

UNESCO/WIPO have already done important work on folklore that could be revitalised under their auspices and aim to promote the adoption of national laws and possibly an international convention on the matter⁶².

A *sui generis* protection for plant varieties may distinguish different levels of protection according to the degree to which uniformity, stability or other standards are met. Thus, the rights conferred may vary depending on whether the varieties meet the uniformity and stability standards, present a constant desired trait but an otherwise high level of variability, or are essentially characterised by their heterogeneity and variability. The latter precisely are the features that confer farmers’ varieties great value as a source of germplasm for agricultural use. Work on this issue should probably involve FAO (in cooperation with IPGRI) and WIPO but the technical problems to be faced in developing such regimes should not be underestimated⁶³.

There is also room for designing a legal regime specifically addressed to TM (Box 8), including knowledge on the properties of certain biological materials used in isolation, in their wild form, or as part of a preparation or mixture, as well as diagnostic methods and treatment, including physical, mental and spiritual therapies. The importance of TM as a source of primary health care was first officially recognised by the World Health Organisation (WHO) in the Primary Health Care Declaration of Alma Ata (1978). WHO has addressed (through its Traditional Medicine Programme) different facets of TK, and might provide the forum for developing model laws and international rules on the matter⁶⁴.

3.2.2 Rights conferred

Any *sui generis* regime must define the nature of the rights conferred. In most cases, IPRs grant *exclusive* rights, ie the faculty to prevent third parties from exploiting the

⁶⁰FTAA.TNC/w/133/Rev 1; see also COICA, 1999

⁶¹Correa, 2000a

⁶²The WIPO “Performances and Phonograms Treaty” refers to “folklore” among the protected performances (article 2.a). The European Commission has produced, in October 2000, a “Report on the International Protection of Expressions of Folklore under Intellectual Property Law”

⁶³See, for some possible options, IPGRI, 1999

⁶⁴See WHO 2000b

"Some indigenous peoples understand themselves to be a nation within a nation or a nation whose peoples cross the borders of two or more nations. Some governments consider themselves to be the sole and entirely sufficient voice of all the peoples within their sovereign territory"

The Crucible II Group, 2000, p 77

protected subject matter. Some types of IPRs, however, do not entail exclusivity. For instance, the TRIPS Agreement does not require the granting of exclusive rights over undisclosed information.

The granting of exclusive rights may, as mentioned previously, limit rather than promote the use of TK. It may also be in contradiction to the practices and values of traditional and indigenous communities. An alternative would be to provide for a right to remuneration, not associated to the exercise of an exclusive right. However, this alternative may also contradict, in many cases, the practices and values of traditional and indigenous communities. Several situations in the intellectual property field use remuneration-based systems. The public lending right, for instance, provides the right to a remuneration (that in certain countries is directly made by the State) for the lending of books from public libraries. The respective amount is distributed among authors in accordance with certain criteria, such as the number of books in the libraries' stocks. Another example is the blank tape royalty established in many European countries, which applies on tapes suited for private use. This royalty aims to compensate for copying of audio and video tapes without the author's consent, and it is premised on the impossibility of actually controlling private copying.

A possible way of protecting TK is through a regime that aims at preventing the misappropriation of such knowledge. This type of regime would not require the establishment of any form of monopolisation that could contradict communities' practices and values. Instead, it would create a legal framework to prevent the use of knowledge or products acquired in violation to rules on the access to genetic resources and associated knowledge, or to customary law (Section 4). Legislation establishing conditions on access to genetic resources has been enacted in some countries, in line with the CBD. Such legislation generally includes the following type of obligations on the party having access: full information about new products and/or knowledge developed from accessed materials; priority access by the providing country to such new products and/or knowledge; a share in financial and other benefits derived from the commercial exploitation of accessed materials; obligatory deposit of a specimen of each accession; transfer to third parties only after authorisation; involvement of local scientists in collection/research⁶⁵.

3.3 Enforcing customary laws

Finally, protection may be achieved by ensuring the enforcement of existing customary rules, which - in accordance with evidence collected by WIPO - in some cases include elements comparable to IPRs⁶⁶. For instance, the draft "Biodiversity and Community Knowledge Protection Act" of Bangladesh prohibits the violation of "Common Property Regimes" that include various rights, relations, arrangements and cultural practices, whether or not they have legal expressions or recognition, by which communities own, use and have access to biological and genetic resources⁶⁷.

This option may, however, entail political consequences within the nation-states

⁶⁵See Caillaux Zazzali and Ruiz Müller, 1998; ten Kate and Laird, 1999; Barber, Glowka, and La Viña, (forthcoming 2001)

⁶⁶See also Valencia, 1998

⁶⁷Ahmed, 2000

9. Failure to recognise customary laws in Australia

"The claim of communal proprietorship in sacred images was rejected by the Federal Court in *Yumbulul v. Reserve Bank of Australia*. That case concerned an attempt by representatives of the Galpu Clan to prevent the reproduction by the Reserve Bank, of the design of a Morning Star Pole on a commemorative banknote. The pole had been created by a member of the clan who had obtained his authority and knowledge to create the pole through initiation and revelatory ceremonies. The Galpu asserted that the communal obligation of the artist was such that he owed an obligation to the clan to prevent the design of the pole from being used in any way which was culturally offensive.

Although sympathetic to this argument, the trial Judge considered that the artist who had created the pole had successfully disposed of his intellectual property rights through a legally binding agreement. He lamented that "Australia's copyright law does not provide adequate recognition of Aboriginal community claims to regulate the reproduction and use of works which are essentially communal in origin" and concluded by recommending that "the question of statutory recognition of Aboriginal communal interests in the reproduction of sacred objects is a matter for consideration by law reformers and legislators". In *Milphurruru v. Indofurn Pty Ltd*

(1995) the court awarded damages for breach of copyright to a number of Aboriginal artists whose designs were wrongfully reproduced on carpets. The court agreed that this was a particularly egregious breach of copyright, involving a culturally demeaning use of the infringed works. However, the court considered itself unable to compensate the communities whose images were used in culturally inappropriate ways, as "the statutory remedies do not recognise the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories".

Source: Blakeney, 2000

that are well beyond the issue of protection of TK. The relationship between indigenous peoples and national governments is problematic in many countries. Some States recognise customary law, while they are extremely jealous about sovereignty. In other cases, the laws of the State ignore and do not provide means for effectively enforcing customary law (see Box 9).

3.4 Impact on intended beneficiaries

Given the great number and cultural diversity of traditional and indigenous communities, and the different components of TK, it is extremely difficult to identify the concerns of the intended beneficiaries of new systems of protection. For many such communities, the application of IPRs-like concepts, particularly, monopolistic rights, is essentially in contradiction to their beliefs and practices, based on openness and sharing of knowledge⁶⁸. However, there might be cases (for instance, in the area of TM) where the control of knowledge (often on the basis of rituals) through IPRs⁶⁹ would be acceptable and desirable for the possessors of TK. Reviews of anthropological literature reveal that concepts close or equivalent to individual forms of IPRs are quite common in indigenous and traditional proprietary systems⁷⁰.

While representatives of traditional and indigenous communities have participated in different national, regional and international workshops, working groups, encounters and dialogues, devoted to the debate and definition of modes of protection of TK, there is still not a clear picture about where their interests lie and the extent to which different legal systems for the protection of their knowledge may be acceptable to them (Box 10). Clarifying these issues seems to be a prerequisite to the development of any possible legal regime on the matter.

There are also questions about the feasibility and effectiveness of the possible legal systems to be established. The collective nature of most TK poses complicated problems about the attribution and exercise of rights. With plant varieties, for instance, the registration of the varieties as a condition for protection, though advisable in order to attain some degree of legal certainty, may pose a very heavy burden on farmers, especially the poorest. It would also require the establishment of new public functions, with their associated costs in terms of administration and bureaucracy.

Finally, the availability of rights is useless if the legal system can not be actually

⁶⁸Nijar, 1996, p 24

⁶⁹The availability of protection, however, would be conditional upon the possibility of meeting the respective requirements for protection, for instance, novelty for patents and secrecy in the case of confidential information.

⁷⁰See, eg Dutfield, 2000b, p 281

10. Protection of TK in Peru

The government of Peru elaborated a first draft of a proposal for the Protection Regime for the Collective Knowledge of Indigenous Peoples in May 1998^a. Broad consultations were then held with the private sector, NGOs and sectors representing indigenous communities. Based on these deliberations, a new text of the draft was published in the Official Journal El Peruano of 21 October 1999. A new round of consultations then took place and led to a revised version, which was published on 31 August 2000.

The Protection Regime for the Collective Knowledge of Indigenous Peoples recognises that the traditional knowledge of the indigenous peoples helps to conserve and make sustainable use of the components of biodiversity. It establishes a *sui generis* system to give adequate protection to those possessing traditional knowledge. The proposed Regime recognises the indigenous people's ownership and associated rights over their traditional knowledge, as well as their right

to decide on how it should be used. A voluntary register is to be set up within the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI). The text also states that indigenous peoples may enter into "knowledge licensing contracts" which specify the terms for the use of their knowledge. One requirement for access to knowledge that is not within the public domain is prior informed consent by the people possessing the knowledge. An innovative and extremely important feature of the Regime is the creation of a Fund for the Development of Indigenous Peoples, which will receive 0.5% of the sales resulting from the marketing of products developed on the basis of traditional knowledge.

Article 7 states that: "pursuant to this Decision and supplementary domestic legislation, the member countries recognise and uphold the rights and decision-making authority of indigenous, Afro-American and local communities, over their knowledge, innova-

tions and traditional practices associated with generic resources and their derivatives."

Despite the efforts made by the government to elaborate and adopt the proposed regime, traditional and indigenous communities have showed little enthusiasm and support for the initiative. However, after receiving limited feedback in initial stages, the proposed draft was rejected by indigenous groups which found its format and basic concepts incompatible with their own understanding of resource rights. With no funds to continue consultations, INDECOPI is pausing with the project to consider how to develop a more extensive process of participation, and to ensure the development of a new draft that is acceptable to local and indigenous communities^b.

^a See WT/CTE/W/176; ^b See the Report of the Multistakeholder Dialogue on Trade, Intellectual Property and Biological and Genetic Resources in Latin America, Cusco, Peru, 22-24 Feb 2001 (<http://www.ictsd.org/dialogueweb/texts/report2.htm>)

enforced. This depends on how easy it is or not to copy, on the existence of preventive measures and remedies and, above all, on the capacity to identify infringements and bear the costs of administrative and judicial procedures. Enforcement problems may be very substantial and often insurmountable, for most traditional and indigenous communities. Hence, decision makers should carefully balance the possible benefits and costs of establishing legal systems for the protection of TK, and evaluate what other policies (notably in terms of land tenure, recognition of customary practices, preservation and promotion of the use of TK) would be needed in order to effectively protect TK from erosion and ensure its continuous development and wider use.

3.5 National or international?

Nothing prevents States, including WTO members, from developing *sui generis* systems (whether based on IPRs or not) at the national level for the protection of TK in different areas. So far some national constitutions and a few national laws enacted (eg Costa Rica⁷¹, Brazil⁷², Panama⁷³, Thailand⁷⁴, Philippines⁷⁵) or under consideration deal with communities rights over their knowledge (See Box 2 on the OAU's model law⁷⁶). In India, section 36 (iv) of the Biodiversity Bill provides for the protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a *sui generis* system. For ensuring equitable sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 stipulate prior approval of the National Biodiversity Authority (NBA) before their access. While granting approval, NBA will impose terms and conditions, which secure equitable sharing of benefits.

A regime of IPRs protection implemented at the national level, however, only creates territorial rights, that is, they cannot be claimed and enforced in third countries. Since in many cases the appropriation of TK is made by foreign companies, which eventually obtain IPRs protection abroad, the existence of a national system of protection leaves many of the problems (especially "biopiracy") unresolved. There may be implications for the global enforcement of private judgments and injunctive relief in commercial litigation and on national sovereignty arising out of the proposed "Hague Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters", which is being negotiated under the Hague Conference on Private International Law⁷⁷. Under the draft treaty, member countries agree to enforce judgments made according to the national law of the country with original jurisdiction. Hence, decisions regarding TK protection under a particular national law would become enforceable in other jurisdictions.

An important question is, therefore, whether the road towards the establishment of TK protection systems should start at the national level and gradually evolve towards international rules or whether, conversely, the latter should provide the framework to develop national rules. In general, in IPRs, international rules have been built up on national laws with the aim of harmonising existing regulations or to internationalise certain legislative models. Nothing, however, prevents the search for an international framework at an early stage. The latter approach was taken with the Washington Treaty on Integrated Circuits, which was inspired by legislation adopted by USA, European Community and Japan.

Efforts to develop an international framework, however, may deviate attention from the resolution of important domestic problems, such as those related to self-determination and land rights. In addition, if the legal approaches to be followed are negotiated with large countries which emphasise trade aspects, the room for manoeuvre to act at the national level may be limited. So far there are no binding international rules restricting States' capacity to address the issue of communities rights over TK. Finally, for TK holders it will be far more difficult to make their views heard in international fora than at the national level.

⁷¹Ley de Biodiversidad, 1998

⁷²See Provisional Measure No 2.126-11, 26 April 2001

⁷³See Ley del régimen especial de propiedad intelectual sobre los derechos colectivos de los pueblos indígenas, para la protección y defensa de su identidad cultural y de sus conocimientos tradicionales (Law of the special intellectual property regime on collective rights of indigenous peoples, for the protection of their cultural identity and knowledge), Law No 20/00 (2000)

⁷⁴The Traditional Medicines Bill would, if enacted, protect TK-related to medical uses of plants

⁷⁵See Indigenous Peoples Rights Act 1997 of the Philippines. The Executive Order 247 of the Philippines provides for the participation of interested communities in the process of granting "prior informed consent"

⁷⁶See also the work of "The Crucible Group" on *sui generis* laws

⁷⁷See Love, 2001

4. The misappropriation option

"In order to ensure the protection and recognition of TK mechanisms which 'will prevent appropriation of our resources and knowledge' should be established. These would include 'appropriate mechanisms for maintaining and ensuring rights of indigenous peoples to deny indiscriminate access to the resources of our communities or peoples and making it possible to contest patents or other exclusive rights to what is essentially indigenous' (Article 14)"

Statement from the International Consultation on Intellectual Property Rights and Biodiversity organised by the Coordinating Body of the Indigenous Peoples of the Amazon Basin (COICA), Sep 1994

"One of the concerns of the developing world is that the process of globalization is threatening the appropriation of elements of this collective knowledge of societies into proprietary knowledge for the commercial profit of a few."

Mashelkar, 2000, p 6

Some indigenous communities have felt outraged by the appropriation under IPRs, by Western companies, of part of their cultural heritage, including plant materials for agricultural and pharmaceutical purposes. The cases of the neem tree, ayahuasca (Box 11), and quinoa, among others, illustrate this situation, and have given rise to communities' demands for "protection" against misappropriation of their knowledge. Many proposals made by academics and NGOs respond to such demands, while some go further in seeking the development of more comprehensive systems of protection.

One approach is to develop a regime preventing the misappropriation of TK. National laws would be free to determine the means to prevent it, including criminal and civil remedies (such as an obligation to stop using the relevant knowledge or to pay compensation for such use), as well as how to empower communities for the exercise and enforcement of their rights. Protection would not be subject under this scheme - as with trade secrets - to any kind of registration and would last as long as the conditions that give rise to it continue to exist. There is support for this from the COP decision V/16 which requested Parties to the CBD to support the development of registers of TK, "taking into account strengthening legislation, customary practices and traditional systems of resource management, *such as the protection of traditional knowledge against unauthorized use*" (para 17) (emphasis added).

A large number of conceptual issues still need to be clarified for the protection of TK. There is also a lack of a validated model of regulation and little national experience so far. Thus it seems prudent that possible international negotiations on the subject should proceed step by step with very focused objectives. As a first stage, the requirements for the development of a misappropriation regime include documentation of TK, proof of origin and consent.

4.1 Documentation of TK

Several developed and developing countries have agreed on the importance of documenting TK⁷⁸. Once published in this documentation, novelty on the disclosed information could not be claimed. Following patents on brinjal, etc, in India, work has begun to prepare an easily navigable computerised database of documented TK relating to the use of medicinal and others plants (which is already under public domain) known as TK Digital Library (TKDL). Such digital databases would enable Patent Offices all over the world to search and examine any prevalent use/prior art. And thereby prevent grant of such patents and biopiracy. The TKDL initiative was spearheaded by the Department of Indian Systems of Medicine & Homeopathy (ISMH) which set up an inter-disciplinary task force to develop the proposal⁷⁹. It also proposed a Traditional Knowledge Resource Classification (TKRC) to enable the retrieval of information on traditional knowledge in a scientific and rational manner for patent examination. The International Patent Classification (IPC) Union agreed in February 2001 to set up a task force on the TKRC. For the Indian government, the documentation of TK not only permits the prevention of biopiracy, but it may also provide a basis for sharing of benefits arising out of the use of such knowledge. Documentation, however, will not ensure benefit sharing with the holders of such knowledge. It may even foreclose that possibility, to the extent that the documented knowledge is deemed part of the prior art.

11. The case of ayahuasca

Ayahuasca (*Banisteriopsis caapi*) is a plant used for many medicinal and ritual purposes. Ayahuasca is the vernacular name among the Amazon Quichua people, in whose language ayahuasca means "vine of the spirits". It is a sacred plant for many indigenous peoples of Amazonia. In 1986, after research in Ecuadorian Amazonia, a US scientist (and president of the

International Plant Medicine Corporation) was granted a patent on ayahuasca (US Plant patent No 5,751).

The US Patent and Trademark Office (USPTO) revoked it in November 1999. The USPTO based its decision on the fact that publications describing *Banisteriopsis caapi* were "known and available" prior to the filing of the

patent application. The USPTO's decision came in response to a request for reexamination of the patent by the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA), the Coalition for Amazonian Peoples and Their Environment, and lawyers at the Center for International Environmental Law (CIEL).

Source: Gari, 2000, p 8-9

Among the projects initiated in India to impede the consideration of such knowledge as “new” and, therefore, patentable in some jurisdictions, the NGO “Gene Campaign” has worked on documentation of biodiversity and knowledge about it in possession of tribal populations. These include the Mundas and Oraons of the Chotanagpur region of South Bihar (now part of the new state of Jharkhand); the Bhils and Bhilalas of Madhya Pradesh; the Tharus of the Terai region in the lower foothills of Uttar Pradesh; the Mishings, Ahom, Assamese and Tiwa of Assam in North East India. Educated tribal youth were recruited to help document medicinal plants and related knowledge. Elders in the village, medical practitioners and traditional healers were consulted in the collection and understanding of the information.

4.2 Proof of origin of materials

Another component of a misappropriation regime may be the obligation to identify, where necessary, the origin of resources covered by IPRs claims. This would allow protection of any rights of the countries supplying the materials and the application, if appropriate, of the benefit-sharing principle contained in the CBD. The establishment of such an obligation is highly controversial, as was shown by Colombia’s experience in trying to have it discussed in the Patent Law Treaty conference in 2000. The Colombians were dissuaded by other WIPO members from tabling this proposal but they accepted as a compromise the setting up of the WIPO Committee mentioned previously. The problem is for some governments and experts that it would impose an additional requirement - inconsistently with article 27.1 of the TRIPS Agreement which lays down the requirements for patentability - on applicants, who may lack the information necessary to comply with such obligation.

The Andean Pact Decision 391 established that any IPRs or other claims to resources shall not be considered valid, if they were obtained or used in violation of the terms of a permit for access to biological resources residing in any of the Andean countries, as regulated under that Decision.

In the Indian Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of the biological resource or knowledge in the patent application, and prior disclosure of knowledge, oral or otherwise. Patent applicants must disclose in their patent applications the source of origin of the biological material used in the invention. According to section 6 of the Indian Biodiversity Bill, in addition, anybody seeking any kind of IPRs on research based upon a biological resource or knowledge obtained from India, needs to obtain prior approval of the NBA. The NBA will impose benefit-sharing conditions. Section 18 (iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such a biological resource.

The European Directive on Biotechnological Inventions refers to the disclosure of information on the origin of biological materials in a preambular provision⁸⁰.

4.3 Consent

A misappropriation regime aiming at avoiding the monopolisation of TK and related materials, may be based on the recognition of a right to prevent and/or require compensation for the use of TK when it was acquired without the consent of its creators/possessors, or in a manner contrary to access legislation or in violation of customary law. For instance, the Special Rapporteur on Indigenous Peoples of the Commission on Human Rights has drafted Principles and Guidelines for the protection of the heritage of indigenous peoples. The draft Principles and Guidelines include articles relevant to IP laws and the operation of the TRIPS Agreement including obligations requiring:

- national laws to deny to any person or corporation the right to obtain patent, copyright or other legal protection for any element of indigenous peoples’ heritage without adequate documentation of the free and informed consent of the traditional owners for the sharing of ownership, control, use and benefits;
- national laws to ensure the labeling and correct attribution of indigenous peoples’ artistic, literary and cultural works whenever they are offered for public display or sale⁸¹.

⁷⁸See the submissions by Switzerland (IP/C/W/2, India (IP/C/W/198) and the USA (IP/C/W/209)

⁷⁹It drew in experts from Central Council of Research of Ayurveda and Siddha, Banaras Hindu University, National Informatics Centre, Council of Scientific & Industrial Research and Controller General of Patents and Trade Marks

⁸⁰No 96/9/EC of 11 March 1996

⁸¹Walker, 2000

5. TK and IPRs in international fora

The issue of TK has been addressed in several international organisations and fora. The adoption of article 8(j) of the CBD triggered the consideration of this issue. That provision is couched in programmatic terms, which are not operative or self-executing. In order to be applicable, national laws should determine how the communities' rights are to be recognised and enforced. However, it was an important step towards a more systematic treatment of the issue at the national and international levels.

Issues relating to TK and intellectual property have been dealt with by UNEP/CBD, WIPO, UNCTAD and WTO. Some of these organisations have cooperated with each other. Thus, WIPO and UNEP undertook joint case studies on the role of IPRs in sharing of benefits from the use of TK and associated biological resources⁸², and FAO and the CBD Secretariat regularly cooperate on issues of common interest in agriculture. Of course, the role of these different organisations and fora significantly varies. While WIPO, WTO, FAO and the CBD may provide the framework for international negotiations, currently no negotiations are conducted under the auspices of UNCTAD, although it has convened a workshop on TK. In addition, while WIPO is a specialised UN Organisation that promotes the protection of intellectual property and WTO deals with international trade (including TRIPS) in general, the CBD and FAO have a thematic focus on issues relating to genetic resources (as applied to agriculture in the case of FAO).

5.1 UNEP/CBD

Since 1996⁸³, the Conference of the Parties (COP) has considered issues related to IPRs, both at its third session in November 1996 and at its fourth session in May 1998. The implementation of article 8 (j) has been extensively examined under the CBD⁸⁴. In particular, the Fourth COP established in April 1998 an ad hoc Open-ended Inter-Sessional Working Group on Article 8(j) to, inter alia, develop a programme of work for the implementation of Article 8(j) and related provisions and to provide advice on the development of legal and other appropriate forms of protection for subject matter covered by Article 8(j)⁸⁵.

In June 1999, the Inter-Sessional Meeting on the Operation of the Convention explored options for access and benefit sharing mechanisms. In this context, the meeting explored the relationship between IPRs, the TRIPS Agreement and the CBD. The meeting recognised the need to ensure mutual supportiveness between the TRIPS Agreement and the CBD and recommended that COP-5 transmit its findings on Article 8 (j) to the WTO and WIPO. It also recommended to COP-5 to invite the WTO to acknowledge relevant provisions of the CBD and to take into account that the objectives of the TRIPS Agreement and the CBD are interrelated.

A panel of experts on access and benefit sharing was set up and held its first meeting in 1999 focusing on mutually agreed terms and contractual approaches to

⁸²WIPO Statement to the CTE and TRIPS Council, WT/CTE/W/182, 6 Feb 2001

⁸³Based on Walker, 2000.

⁸⁴Farmers' Rights and Rights of Similar Groups – The Rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the CBD (UNEP/CBD/IC/2/14), "Knowledge, Innovations and Practices of Indigenous and Local Communities: Implementation of Article 8(j)" (UNEP/CBD/COP/3/19), The Relationship Between IPRs and the Relevant Provisions of the TRIPS Agreement and the CBD (UNEP/CBD/ISOC/5), "Legal and Other Appropriate Forms of Protection for the Knowledge, Innovations and Practices of Indigenous and Local Communities Embodying Traditional Lifestyles Relevant for the Conservation and Sustainable Use of Biological Diversity" (UNEP/CBD/WG8J/1/2)

⁸⁵COP Decision IV/9. See <http://www.biodiv.org>

12. WIPO Programme on emerging IP issues

Since 1998, WIPO has undertaken a programme that explores emerging intellectual property issues. The programme for 2000/2001 covered^a:

1. Protection of traditional knowledge, innovations and creativity - including commissioning a study on customary law and regulatory systems that apply to the protection of informal knowledge; commissioning a feasibility study on the use of IP law or practice to protect informal knowledge; and organising an annual Round Table on the protection of traditional knowledge for the holders of such knowledge.
2. Biotechnology and biodiversity -

including an examination of the social, economic and ethical implications of IPRs in relation to the Human Genome Project and the Human Genome Diversity Project and commissioning a study on the IP aspects of access to and benefit sharing in biological resources.

3. Protection of folklore - including convening several expert meetings to examine alternatives for the development of standards for the protection of folklore at national, regional and international levels; a national pilot project on the documentation, conservation, sustainable use and beneficial commer-

cialisation of folklore; and provision of advice on the development and implementation of national laws and systems relevant to the protection of folklore.

4. Intellectual property and development - including a seminar on the role of IP in economic, social, cultural and technological development and the preparation and dissemination of a study on the role of IP in the transfer of environmentally-sustainable technology to developing countries with reference to obligations under multilateral arrangements including Article 66(2) of the TRIPS Agreement.

^a See Walker, 2000

access to genetic resources; benefit-sharing options and mechanisms; access legislation; the concept of prior-informed consent; IPRs; regulatory and incentive measures; and related capacity building. The report of the Panel was adopted by COP-5 in Nairobi, May 2000. Delegations generally supported extending the Panels' mandate and proceeding with the development of international guidelines on access to and the sharing of benefits from genetic resources⁸⁶.

IPRs and the relationship between the TRIPS Agreement and the CBD were discussed under Item 23 of the Provisional Agenda - Access to Genetic Resources - at COP-5 in Nairobi, 15-26 May 2000. The COP adopted a decision on access to genetic resources containing three sections:

1. access and benefit sharing (ABS) arrangements;
2. the relationship between IPRs and the TRIPS Agreement; and,
3. *ex situ* collections acquired prior to the CBD's entry into force and not addressed by the FAO Commission on Genetic Resources for Food and Agriculture.

The COP invited Parties to the CBD and relevant organisations to submit information about the role of IPRs in the implementation of ABS arrangements by 31 December 2000. The decision also invites relevant international organisations to analyse the functioning of IP systems as they relate to access to genetic resources, including the possibility of requiring information on the origin of genetic resources as part of the application procedure for IPRs. The decision also invites the WTO to acknowledge relevant CBD provisions and to take into account the relationship between the CBD and the TRIPS Agreement.

5.2 WIPO

WIPO developed (jointly with UNESCO) Model Provisions for National Laws for the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions⁸⁷. In 1998, WIPO created a Global Intellectual Property Issues Division, which undertook several studies on TK (Box 12) and, in particular, organised fact finding missions in different parts of the world to identify the issues at stake and the concerns of TK holders⁸⁸.

The WIPO Intergovernmental Committee on Intellectual Property and Traditional Knowledge, Genetic Resources, and Folklore, was established in 2000⁸⁹ and met for the first time on 30 April - 2 May 2001. After a shaky start, when proceedings were

⁸⁶A second meeting was held in March 2001.

See the reports at <http://www.biodiv.org>

⁸⁷See the Report of the WIPO-UNESCO Working Group on the Protection of Aboriginal Folklore, 1981

⁸⁸WIPO 2001 and <http://www.wipo.int/tradition> acknowledge. See also

"Protection of Traditional Knowledge: A Global Intellectual Property Issue" (WIPO/RT/LDC/1/4),

"Protection of Traditional Knowledge: A Global Intellectual Property Issue" (WIPO/IP/TK/RT/99/2), and

"Intellectual Property and Genetic Resources – An Overview" (WIPO/IP/GR/00/2)

⁸⁹See document WO/GA/26/6, 25Aug 2000

13. US position on TK at the WIPO Committee

"All these facts lead to one question: is it possible, or even desirable, to establish a comprehensive, uniform set of rules at the international level to govern the use of genetic resources, traditional knowledge and folklore? At the very least, we wonder whether it is advisable to undertake such activity before individual countries have, in conjunction with the communities within their borders, established their own regimes for protection within their own territories and have gained experience in the application of that protection and its effect on the communities involved. We believe that WIPO member States should consider these issues carefully in the framework of this Committee.

...[It] must be noted that the newer generation of intellectual property laws all share a certain characteristic with the older generation of intellectual property laws of copyright, patents, trademarks: namely that of an incentive mechanism for innovation. As forward-looking sys-

tems that seek to encourage the development of new forms of expression and invention, the newer types of intellectual property still are based on this basic principle and share characteristics such as a date of creation, the known identity of one more creators, defined parameters of the relevant product and limited duration of protection.

A regime to protect traditional knowledge, as many of the participants in WIPO's Fact Finding Missions pointed out, cannot by definition adhere to these principles. Thus, developing a new intellectual property-type regime in this area does not appear to [be] the best fit even [for] the holders of such knowledge.

Moreover, there are so many different expectations, goals and native systems, for approaching ownership and the transgression of ownership that a useful, enforceable global system would be virtually impossible to create. Indeed a "one size fits all" approach might be

interpreted as demonstrating a lack of respect for local customs and traditions. Questions have been raised as to the definitions of beneficiaries, economic valuation and other critical terms of reference. We also note with interest the variety of local rules and procedures that have developed within certain indigenous communities. Clearly these local rules must be respected and care must be taken to avoid their preemption.

All in all, as the United States has noted on various occasions, many of the goals of indigenous and local communities in "protecting" their traditional knowledge, medicine, folklore, etc., stems from their concern for self-determination, health, justice, cultural heritage and land issues. These are serious interests that must be examined fully within the appropriate national contexts".

Source: General Declaration of the USA to the First Session of the WIPO Committee, April 30-3 May, 2001

delayed by a dispute over the selection of a chair, many delegations present at the WIPO Committee reported on the steps taken at the national level for the protection of TK. They were generally sympathetic with the idea of addressing the legal protection of TK under IPRs. The USA, however, questioned the desirability of establishing international rules on genetic resources, TK and folklore (see Box 13), while other delegations indicated the need for further analysis on the matter.

5.3 FAO

The protection of TK has also been raised in relation to the definition and implementation of the concept of Farmers' Rights introduced during the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture, which began in 1994. Article 9.2(a) of the final text, which was adopted as a new treaty by the FAO Conference in Rome in November 2001, requires measures for the protection of "traditional knowledge" but, in view of the scope and purpose of the Treaty, it only refers to knowledge "relevant to plant genetic resources for food and agriculture" (Box 14). Article 9.2 is, thus, narrower in scope than Article 8(j) of the CBD, and would not apply, for instance, to knowledge relating to medicinal or industrial uses of plant genetic resources. Under this approach, the issue of protection of TK may be circumscribed to knowledge incorporated in farmers' varieties (landraces) and certain associated knowledge (eg specific cultivation practices). The development of a *sui generis* regime for the protection of farmers' varieties becomes, in this context, one of the possible components of Farmers' Rights.

5.4 UNCTAD

The United Nations Conference on Trade and Development (UNCTAD) held on 30 October-1 November 2000, an "Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices". Over 250 people from 80 countries participated, including representatives of governments, indigenous groups, NGOs, Inter-Governmental Organisations (IGOs), academia, private companies, and international agencies and some 50 papers on country experiences were presented⁹⁰. The meeting's outcome, which reflected the diversity of views of experts, was taken up in February 2001 by UNCTAD's Commission on Trade in Goods and Services, and Commodities, which negotiated agreed recommendations to governments, to the international community, and to UNCTAD. Recommendations to governments included: to raise awareness about protection of TK, to support the innovation potential of local and indigenous communities, to facilitate the documentation of TK and to promote the commercialisation of TK-based products⁹¹.

⁹⁰Most are available on http://www.unctad.org/trade_env/index.htm. See also Systems and National Experiences for Protecting TK, Innovations and Practices, TD/B/COM.1/EM.13/2, 22 Aug 2000

⁹¹See Report of the UNCTAD Commission on Trade in Goods and Services, Feb 2001, at <http://www.unctad.org/en/special/c1dos5.htm>

14. The International Treaty on Plant Genetic Resources for Food and Agriculture: Article 9 – Farmers' Rights

The International Treaty on Plant Genetic Resources for Food and Agriculture was approved by the Conference of the UN Food and Agriculture Organisation (FAO) on 3 November 2001. Article 9 states:

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

ture production throughout the world.

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

(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;

(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and

(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

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

" A material transfer agreement would be necessary where the inventor wishes to use the biological material and a transfer of information agreement would be necessary where the inventor bases himself on indigenous or traditional knowledge. Such an obligation could be incorporated through inclusion of provisions in Article 29 of the TRIPS Agreement requiring a clear mention of the biological source material and the country of origin..."

Indian delegation to WTO,
WT/GC/W/147

5.5 UNHCHR

The UN Working Group on Indigenous Populations has the mandate to develop international standards for the rights of indigenous peoples, including in relation to their knowledge and cultural integrity. Protection of TK has been dealt with, in this framework, as a component of the broader right to practice and revitalise indigenous cultural traditions and customs⁹².

A report by the High Commissioner on Human Rights notes that there are tensions between IP protection and the protection of the knowledge of local and indigenous communities (such as those relating to the use of such knowledge by people outside the community without the knowledge holders' consent and to the equitable compensation) that may "require amendments, adaptations and additions to IP systems"⁹³. The High Commissioner is preparing a further report on the implications of the TRIPS Agreement on the rights of indigenous peoples.

5.6 WTO

The Council of TRIPS is an important forum for the discussion of IPRs, biodiversity and the protection of TK, particularly in the context of the review of article 27.3 (b). However, the CBD Secretariat has not yet been given permanent observer status to the Council of TRIPS. The number of admitted observers is very limited and NGOs are not allowed to participate. Various countries have made submissions about the review of article 27.3 (b), which in some cases include suggestions on TK (Table 1).

The relationship between the TRIPS Agreement and the CBD has been addressed by the Secretariat of the WTO⁹⁴. This relationship, including the protection of TK, was examined by the Committee on Trade and Environment (CTE) at the WTO. The CTE was formally established in 1995 by the WTO General Council to examine the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to Multilateral Environmental Agreements (MEAs). The CTE considered the provisions of the TRIPS Agreement relevant to its work on the environment under Item 8 of its agenda. Some developing countries have argued that the TRIPS Agreement must be reviewed in light of the obligations on States under Article 8(j) of the CBD⁹⁵.

The African Group has been particularly active in relation to the review of article 27.3(b). It wants that provision to be harmonised with the CBD, the objective of which is "to protect the rights of indigenous people and local farming communities and to protect and promote biological diversity". The proposal of the African Group demanded that such harmonisation also be made with the FAO International Undertaking on Plant Genetic Resources, which "seeks to protect and promote Farmers' Rights and to conserve plant genetic resources". The group argues that:

"by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities"⁹⁶.

India has noted that while the TRIPS Agreement obliges Members to provide product patents for micro-organisms and for non-biological and microbiological processes, and to provide for the protection of plant varieties, the CBD:

"categorically reaffirms that nation states have sovereign rights over their own biological resources, recognizes the desirability of sharing equitably the benefits arising from the use of these resources as well as traditional knowledge, innovations and practices relevant to the conservation of biological diversity and its sustainable use, and acknowledges that special provisions are required to meet the needs of developing countries".

In order to reconcile any contradictions, India suggested that the innovators share with holders of TK the benefits arising from its exploitation, through "material transfer agreements/transfer of information agreements".

In the view of the government of India, however:

"the modalities for protecting TK are still emerging and evolving. The nature of entitlements and share in benefits is also a gray area. Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue"⁹⁷.

Brazil has noted the conceptual and operational difficulties in bringing TK under the TRIPS Agreement⁹⁸, while for Venezuela, binding international rules on the

⁹²See, in particular, article 12 of the draft UN Declaration of the Rights of Indigenous Peoples as agreed at the 11th Session (1993) of the Working Group on Indigenous Populations

⁹³UN Economic and Social Council, "Economic, Social and Cultural Rights - The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. Report of the High Commissioner", E/CN.4/Sub.2/2001/13, Jun 2001

⁹⁴See Environment and TRIPS (WT/CTE/W/8 and W/8/Corr.1), The CBD and TRIPS (WT/CTE/W/50), The Relationship Between the CBD and TRIPS with a Focus on Article 27.3(b) (WT/CTE/W/125).

⁹⁵See "Protection of biodiversity and traditional knowledge – the Indian experience", Submission by India to the WTO, WT/CTE/W/156

⁹⁶WT/GC/W/202

⁹⁷See WT/CTE/W/156, IP/C/W/198, 14 Jul 2000

⁹⁸See IP/C/W/228

Table 1. Proposals for the review of Article 27.3(b) of the TRIPS Agreement

Africa

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|---|---|---|
| Kenya ^a | <ul style="list-style-type: none"> - Need five-year extension of transition period - Harmonise TRIPS with CBD | <ul style="list-style-type: none"> - Need five-year extension of transition period - Increase scope of 27.3(b) to include protection of indigenous knowledge and farmers' rights - Harmonise TRIPS with CBD |
| African Group ^b | <ul style="list-style-type: none"> - Review should be extended and there should be an additional five year transition period afterwards - Review should clarify that plants, animals, micro-organisms, their parts and natural processes cannot be patented - TRIPS should contain provisions to promote, not undermine, the conservation and sustainable use of genetic material - TRIPS should contain provisions to prevent bio-piracy | <ul style="list-style-type: none"> - Review should be extended and there should be an additional five year transition period afterwards - <i>Sui generis</i> laws should allow for protection of community rights, the continuation of farmers' practices and the prevention of anti-competitive practices which threaten food sovereignty - The flexibility to protect farmers' rights and traditional knowledge in the context of <i>sui generis</i> systems for plant varieties must be retained and construed in consistency with the CBD, the FAO International Undertaking on Plant Genetic Resources and the OAU Model Law on Farmers', Breeders' and Community Rights. |
| Southern Africa Development Cooperation (SADC) ^c | <ul style="list-style-type: none"> - The transition period for implementation of 27.3(b) should be extended and the 2000 review should be postponed. - Harmonise TRIPS with CBD. - The exclusion for essentially biological processes should extend to micro-biological processes. | <ul style="list-style-type: none"> - The transition period for implementation of 27.3(b) should be extended and the 2000 review should be postponed. - Retain the <i>sui generis</i> option. |

^aWT/GC/W/23, 5 Jul 1999; ^bWT/GC/W/302, 6 Aug 1999 and IP/C/W/206, 20 Sep 2000; ^cWT/L/317, 1 Oct 1999

Asia (developing)

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|--|---|--|
| India ^a | <ul style="list-style-type: none"> - Harmonise TRIPS with CBD either by requiring information on providers of genetic resources and countries of origin of biological material under TRIPS Art. 29, or by incorporating a provision that patents inconsistent with CBD Art. 15 must not be granted. - Exclude patents on all life forms. If this is not possible, then at least exclude patents based on traditional/indigenous knowledge and products and processes essentially derived from such knowledge. - There must be disclosure of the country of origin of the biological resource and associated knowledge, and proof of the provider's consent, to ensure equitable sharing of benefits. - It should be left to national policy to decide what are patentable microorganisms, including in light of Art. 27.2 (morality and ordre public). - Developing countries like India cannot accept any further strengthening of the protection presently provided to life forms. | <ul style="list-style-type: none"> - There are various ways to develop an effective <i>sui generis</i> system and no reason why countries cannot develop their own models. - It would be essential to ensure that the preservation of farmers' rights is not considered a dilution of effectiveness of the system. - What is an effective <i>sui generis</i> system may be best left to each Member to evolve in its legal system and practice. |
| South Asia Association for Regional Cooperation (SAARC) ^b | <ul style="list-style-type: none"> - There is a need to prevent piracy of traditional knowledge built around biodiversity and to seek the harmonisation of TRIPS with CBD to ensure appropriate returns to traditional communities. | |
| Singapore ^c | <ul style="list-style-type: none"> - Should extend to plants and animals (ie no exclusions) - TRIPS should not be used to enforce benefit-sharing arrangements or any common approach to benefit-sharing | <ul style="list-style-type: none"> - UPOV would be a useful reference for the basic level of protection |

^aIP/C/W/195 12 Jul 2000; WT/GC/W/255, 16 Jul 1999; IP/C/W/196 12 Jul 2000; IP/C/W/161, 3 Nov 1999 and WT/GC/W/294 5 Aug 1999.

^b WT/L/326 of 22 Oct 1999. ^cJOB(00)/7853.

Developing country groups

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|---|--|---|
| Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe ^a | <ul style="list-style-type: none"> - It should be clarified that the provisions on patenting of micro-organisms only apply to genetically modified micro-organisms. - Should provide that where a country grants patent protection to plant-based inventions, applicants are obliged to (a) declare the origin of materials and demonstrate prior consent of the country of origin and where relevant the indigenous or farming communities; and (b) pay compensation to the country or communities that had the material or the traditional knowledge used. | |
| Group of 77 ^b | <ul style="list-style-type: none"> - Future negotiations must seek mechanisms for a balanced protection of biological resources and disciplines to protect traditional knowledge | |

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|--|---|--|
| Least Developed Countries (LDC) Group ^c | <ul style="list-style-type: none"> - There should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological processes, are not patentable - Incorporate provision that patents must not be granted without prior informed consent of country of origin - Patents inconsistent with CBD Art 15 should not be granted - Need for extended transition period | <ul style="list-style-type: none"> - Must be flexible enough to suit each country's seed supply system - Need for extended transition period |
| Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda ^d | <ul style="list-style-type: none"> - Article 27.3(b) should be amended in light of the provisions of CBD and the IU, in which the conservation and sustainable use of biological diversity, the protection of the rights and knowledge of indigenous and local communities and the promotion of farmers' rights are fully taken into account - The review should also: clarify the artificial distinction between biological and microbiological organisms and processes; ensure the continuation of traditional farming practices including the right to save and exchange seeds and sell their harvests; and prevent anti-competitive practices that will threaten food sovereignty of people in developing countries | |
| Cuba, Egypt and Honduras ^e | - The transition period for developing countries must be extended | |

^a JOB(99)/3169 and Add. 1. ^b WT/MIN(99)/3 of 2 Nov 1999. ^c WT/GC/W/251 of 13 Jul 1999. ^d WT/GC/W/354 and WT/GC/W/355 of 11 Oct 1999. ^e WT/GC/W/209 and Corr. 1 of 17 Jun 1999.

Latin America

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|--|--|---|
| Bolivia, Colombia, Ecuador, Nicaragua, and Peru ^a | The Ministerial Conference should adopt a mandate to: (a) carry out studies in order to make recommendations on the most appropriate means of recognising and protecting traditional knowledge as the subject matter of IPR; (b) initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of TK; (c) complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of the new round of trade negotiations | |
| Brazil ^b | <ul style="list-style-type: none"> - Flexibility for members to exclude plants and animals should be retained. - Art. 27.3(b) should be amended to allow members to require further conditions for patentability, viz (1) identification of source of genetic material; (2) traditional knowledge used to obtain that material; (3) evidence of fair and equitable benefit-sharing; and (4) evidence of prior informed consent for the exploitation of the patent - Art. 27.3(b) should bear an interpretative note clarifying that discoveries or naturally occurring materials are not patentable | <ul style="list-style-type: none"> - Flexibility for members to decide on the most effective means of a <i>sui generis</i> system should be retained. UPOV is not the only reference to fulfill the criterion of effectiveness |
| Venezuela ^c | Introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognise collective rights | |

^aWT/GC/W/362 of 12 Oct 1999. ^b IP/C/W/228 of 24 Nov 2000. ^c WT/GC/W/282 of 6 Aug 1999

Industrialised countries

| WTO member(s) | Proposals on the life patenting provisions | Proposals on the <i>sui generis</i> provision |
|-----------------------------|---|--|
| European Union ^a | <ul style="list-style-type: none"> - No lowering of standards of protection - No extension of transition periods - The EU does not favor incorporating overly complex requirements which oblige patent applicants to provide an official certificate of the source and origin of the genetic material and the related traditional knowledge used, evidence of fair and equitable benefit sharing and evidence of prior informed consent from government or local communities for the exploitation of the subject matter of the patent. The EU is open to other solutions on sharing information about origins of patented biological material. | |
| Japan ^b | - No lowering of standards of protection | <ul style="list-style-type: none"> - A system under the UPOV Convention is an effective <i>sui generis</i> system - The proper balance between breeders' rights and farmers' rights will be solved by adopting a UPOV system |
| Norway ^c | - It should be considered whether a provision on the disclosure of the origin of genetic resources should be inserted in the TRIPS Agreement to ensure a more effective implementation of the CBD. | - There should be flexibility with regard to the implementation of the <i>sui generis</i> option to allow for effective benefit sharing with indigenous and local farming communities. |
| Switzerland ^d | <ul style="list-style-type: none"> - No lowering of standards of protection - The exclusion for plants and animals is a balanced provision that takes into accounts members' needs and interests. | - Agrees with Singapore that the UPOV system is a useful reference for the basic level of protection of any <i>sui generis</i> system for the protection of plant varieties. Nonetheless, also agrees that there may be other <i>sui generis</i> systems that meet the requirements of Article 27.3(b) besides UPOV and considers the elements listed by the USA to be helpful in drawing up such systems. |
| United States ^e | - Eliminate the exclusion for plants and animals so that they must be patentable in all countries | <ul style="list-style-type: none"> - Incorporate UPOV 91 into TRIPS - The US believes that an effective <i>sui generis</i> system would: apply to all varieties in the plant kingdom; apply to varieties that are new, distinct, uniform and stable; grant rights only to breeders; grant rights of at least 20 year duration; prevent others from commercialising protected varieties without authorisation; etc. |

^aWT/GC/W/193, 2 Jun 1999 and IP/C/W/254 13 Jun 2001. ^bWT/GC/W/242, 6 Jul 1999. ^c IP/C/W/293, 29 Jun 2001. ^d IP/C/W/284, 15 Jun 2001.

^e WT/GC/W/115, 19 Nov 1998 and IP/C/W/209, 20 Sep 2000.

protection of TK should be developed in the framework of the Agreement. It has suggested:

“to establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders”⁹⁹.

Developed countries have not contested the possibility of and the right of countries to protect TK. Thus, the USA has argued that there is no inconsistency between the CBD and the TRIPS Agreement, encouraged the development of data bases on TK¹⁰⁰, and pointed out that “national or local legislation or regulation” could be adopted to establish the basis for “contractual arrangements” between suppliers and recipients of TK¹⁰¹. The USA, however, does not favour any treatment of the protection of TK, at least in the framework of the TRIPS Agreement.

The EU and its Member States, instead, “support the development of an international model for the legal protection of traditional knowledge”. The EU expressed its hope that the issue be taken by the WIPO Committee in cooperation with the CBD, and that: “once a model is in place, attention can then be focused on how and to what extent the protection of traditional knowledge can be included in the TRIPS Agreement”¹⁰².

To summarise, developing countries’ positions aim at some recognition and protection of TK, but considerable hesitation seems to exist about how to deal with the subject, the nature and scope of protection, and the extent to which the issue should be brought under the TRIPS Agreement. Some countries seem to be more concerned with avoiding the misappropriation of TK and with the implementation of the sharing of benefits principle (through the use of MTAs), than with the development of an IPRs regime for TK. Others seem to aim at preserving the room existing at the national level to legislate on the matter, while at least one country has so far proposed to develop mandatory provisions in the context of the TRIPS Agreement. Significant preparatory work will be necessary to envisage international negotiations on the matter¹⁰³. Since according to the WTO rules only Member States and accredited observers are allowed to participate in the WTO deliberations, local and indigenous communities may only influence them through their respective governments. They have no voice to express their views directly in that forum.

⁹⁹WT/GC/W/282

¹⁰⁰Switzerland has also agreed on the usefulness of documentation of TK (IP/C/W/209).

¹⁰¹See IP/C/W/257, 3.4.0

¹⁰²See IP/C/W/254, 3.4.01

¹⁰³The WIPO Committee may provide a forum for such preparations

6. Conclusions

The protection of TK raises a number of policy issues, notably the objectives and modalities of such protection, and its impact and implications for its intended beneficiaries. Such issues are extremely complex, since there are broad differences about the definition of the subject matter, the rationale for protection, and the means for achieving its purposes. The issues relating to TK should be addressed in an holistic manner, including ethical, environmental and socio-economic concerns. There are, in addition, many still unresolved technical issues such as the problem of collective ownership and the modes of enforcement of rights.

The development of any regime for the protection of TK should be grounded on a sound definition of the objectives sought, and on the appropriateness of the instrument selected to achieve them. IPRs may be one of the tools to be used, but their limits and implications should be clearly understood. In particular, a balance should be obtained between the protection and the promotion of the use of such knowledge.

It is unclear the extent to which the various proposals made for the protection of TK reflect the aims and cultural values of the traditional and indigenous communities they intend to serve. There is a risk of transferring to such communities concepts and paradigms which are not suited to their realities, or which may prove ineffective to solve the problems they are supposed to address. The consideration of TK protection should not overshadow the fact that the preservation and use of TK requires above all ensuring the survival and improvement of living conditions, in their environment and cultural milieu, of such communities.

Given the lack of clarity about the objectives, nature, scope and implications of possible IPRs-based regimes for TK protection, it seems premature to promote the development of international standards in the framework of WTO and other fora. A possible intermediate approach, until the outstanding issues are clarified, may be to develop global rules to prevent the misappropriation of TK and to undertake the other activities described for ODA (Box 15).

Future action in this field may thus include:

- promoting the development, at the national level, of an holistic approach towards the protection of TK, including the resolution of underlying issues such as land rights and the need to respect and maintain the lifestyles of local and indigenous communities;
- considering the differing needs for the protection and promotion of TK in different areas, such as TM and plant genetic resources;
- implementing Farmers Rights at the national level;
- moving towards, in the short term, the establishment of a misappropriation regime;
- continuing work in WIPO, UNCTAD, WTO and in other fora in order to clarify the possible role, scope and content of systems of protection for TK;
- ensuring a broad and effective participation of representatives from local and indigenous communities in the definition and implementation of any system for the protection of TK.

15. Issues for Overseas Development Assistance

Overseas Development Assistance may aim at helping to

- develop workable models for the preservation and promotion of the use of TK including, as appropriate, legal mechanisms on the protection of such knowledge against misappropriation;
- support the collection and analysis of information on customary laws and

practices relating to TK;

- improve the coordination of the activities and initiatives in different international organisations and fora;
- speed up the development of guidelines for the implementation of article 8 (j) of the CBD at the national level;
- consider the protection of TK in the

context of the recognition and implementation of human rights;

- ensure the broadest possible participation of local and indigenous communities in the deliberations and decision making relating to TK; and
- improve awareness of the role of TK in fostering local innovation and development.

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Acronyms

| | | | |
|--------|---|--------|---|
| CBD | Convention on Biological Diversity | ODA | Official Development Assistance |
| COICA | Coordinating Body of the Indigenous Peoples of the Amazon Basin | OAU | Organisation of African Unity |
| COP | Conference of the Parties (CBD) | PBRs | Plant Breeders' Rights (UPOV) |
| CTE | Committee on Trade and Environment (WTO) | TK | Traditional and indigenous knowledge |
| FAO | Food and Agriculture Organisation of the United Nations | TM | Traditional medicine |
| GATT | General Agreement on Tariffs and Trade | TRIPS | Trade-Related Aspects of Intellectual Property Rights (WTO) |
| GIs | Geographical indications | UNCTAD | United Nations Conference on Trade and Development |
| GRULAC | Group of Latin American Countries in the Caribbean | UNEP | United Nations Environment Programme |
| IGO | Inter-Governmental Organisation | UNESCO | United Nations Educational, Social and Cultural Organisation |
| IP | Intellectual Property | UNHCHR | United Nations High Commission for Human Rights |
| IPRs | Intellectual Property Rights | UPOV | Union Internationale pour la Protection des Obtentions Végétale [International Union for the Protection of New Varieties of Plants] |
| IU | International Undertaking on Plant Genetic Resources [for food and agriculture] | WIPO | World Intellectual Property Organisation |
| NBA | National Biodiversity Authority (India) | WTO | World Trade Organisation |
| NGO | Non-Governmental Organisation | | |

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