

ICTSD Programme on IPRs and Sustainable Development



Protecting Traditional Knowledge: Pathways to the Future.



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International Centre for Trade
and Sustainable Development

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ABBREVIATIONS AND ACRONYMS

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties to the Convention on Biological Diversity
FTA	Free Trade Agreement
ICTSD	International Centre for Trade and Sustainable Development
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IP	Intellectual Property
IPR	Intellectual Property Right
TCEs	Traditional Cultural Expression
TK	Traditional Knowledge
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference for Trade and Development
UPOV	Union Internationale pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants)
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

FOREWORD

The present study examines recent trends and proposals for the protection of traditional knowledge. It is the latest contribution of the ICTSD Programme on Intellectual Property Rights and Sustainable Development to a better understanding of the proper role of intellectual property in a knowledge-based economy.

In modern societies, identifying, registering and protecting intellectual property rights (IPRs) has become one of the key drivers of business competitiveness in international trade. While intellectual property is today's competitive instrument in global markets, exploiting and effectively protecting it is complex and difficult. Furthermore, not all knowledge, innovation and creation lends itself to the existing models of industrial and post industrial societies and more specifically the IP system. In this context, the value and usefulness of traditional knowledge (TK) including domesticated seeds, traditional food products, alternative medicine, cosmetics, textiles and crafts has been widely recognized. However, there is much debate on how best to protect such a knowledge system considering its multifaceted nature as well as its implications for various policy issues and sustainable development in general.

As developing countries continue implementing intellectual property-related treaties at the multilateral, regional and bilateral level, appropriate capacity building will be crucial if these countries are to effectively use intellectual property and other tools in pursuit of their sustainable development goals. Exploring ways and means to protect and promote traditional innovations and creations at the local, national and international level and ensure the effective participation of holders of traditional knowledge will be an important part of that challenge.

This second ICTSD study on "Protecting Traditional Knowledge: Pathways to the Future", provides an overview of main arguments and proposals made in the CBD COP, WIPO's IGC and in the WTO with respect to protection of TK. The study seeks to review progress in diplomacy and policy formulation and identify suitable solutions that have been put forward in the international fora for TK protection. The study also proposes that to engage in "forum management" in relation to genetic resources issues and TK protection might be more effective than indulging in forum shopping and run the risk of contradictory outcomes.

The premise of ICTSD's work in this field, like that of its joint project with UNCTAD, is that IPRs have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks, industrial designs, integrated circuits and geographical indications are frequently mentioned in discussions and debates on such diverse topics as public health, food security, education, trade, industrial policy, TK, biodiversity, biotechnology, the Internet, the entertainment and media industries. In a knowledge-based economy, there is no doubt that a better understanding of IPRs is indispensable to informed policy making in virtually all areas of human development.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth in general remains limited and inconclusive. Conflicting views also persist on the impacts of IPRs on a country's development prospects. Some argue that in a modern economy, the minimum standards laid down in TRIPS will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, technology transfer and private investment flows. Others counter that intellectual property, especially some of its elements such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by lifting the prices of essential drugs out of the reach of the poor; limiting the availability of

educational materials for students in developing countries; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers.

It is urgent, therefore, to ask several questions: how can developing countries use intellectual property tools to advance their development strategy? What are the key concerns surrounding IPR issues for developing countries? What are the specific difficulties they face in intellectual property negotiations? Is intellectual property directly relevant to sustainable development and to the achievement of agreed international development goals? Do developing countries, especially least-developed ones, have the capacity to formulate their negotiating positions and become well-informed negotiating partners? It is to address some of these questions that the ICTSD Programme on Intellectual Property and Sustainable Development was launched in July 2000. One central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries - including decision makers, negotiators but also representatives from the private sector and civil society - who will be able to define their own sustainable human development objectives in the field of IPRs and effectively advance them at the national and international levels.

We hope you will find this study a useful contribution to the debate on IPRs and sustainable development, and particularly with regard to current discussions and negotiations of the protection and promotion of traditional knowledge at varying levels.



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EXECUTIVE SUMMARY

Traditional knowledge provides the underpinning for successful ways of subsisting in what are often hostile natural environments. Indeed, there is growing recognition that traditional knowledge, technologies and cultural expressions are not just old, obsolete and maladaptive. They can be highly evolutionary, adaptive, creative and even novel. Moreover, as a body of knowledge, customs, beliefs and cultural works and expressions handed down from generation to generation, tradition forms the “glue” that strengthens social cohesiveness and cultural identity.

Few if any human societies are totally isolated or self-sufficient in all respects. People in traditional societies not only consume knowledge-based and other goods that are produced locally, whether by themselves or their neighbours; they give them, receive them, share them, own them and *exchange* them with others including from different societies.

Benefiting from trade depends not only on the availability of legal rights that are enforceable beyond the locality, but also on the ability of traditional communities to take advantage of national and international law including property and access rights relating to land, natural resources and intellectual property. It also depends on specific capacity-building measures to address problems of lack of information and production and marketing weaknesses. Indeed, capacity building is absolutely vital.

Traditional proprietary systems relating to scarce tangibles such as land, resources and goods, and to valuable intangibles like certain knowledge and cultural expressions, are often highly complex and varied. As a general rule, knowledge and resources are communally held and, although some specialised knowledge may be held exclusively by males, females, certain lineage groups, or ritual or society specialists (such as shamans), this does not necessarily give that group the right to privatise the communal heritage.

What can be done when local knowledge, resources, cultural products or locally produced manufactured goods spread beyond the control of the local administrative or juridical institutions, either through trade or misappropriation, and are commercialised without the consent of the providing communities or any benefits flowing back to them? Probably very little, at least in the present situation. This problem is what an international TK regime should be able to respond to.

Why legally protect traditional knowledge? It is far from self-evident that just because some TK has commercial value in the local and wider economy, it should therefore be protected. This paper reviews various justifications for protecting TK and finds that there are several plausible reasons to do so. Those countries which seek legal solutions to the lack of TK protection should ideally seek a consensus on what the objective or objectives should be. The same applies to national legal protection. Without clear objectives, laws and policies to protect TK are unlikely to be effective.

“Biopiracy” has emerged as a term to describe the ways that individuals and corporations from the developed world free ride on the genetic resources and traditional knowledge and technologies of the developing countries. It is by no means clear how much biopiracy actually goes on. Apart from lack of information, the answer depends on how one differentiates between legitimate and unfair exploitation. The problem with the “biopiracy” rhetoric is that if you cannot agree on what it is, you cannot measure it. Neither can you agree on what should be done about it. In short, how you define biopiracy goes a long way towards determining what you should do about it.

Objections to traditional knowledge are not necessarily motivated by bad faith and deserve a considered response. To some critics, the creation of a TK regime would represent the removal

from the public domain of a very large body of practical knowledge about the biosphere including solutions to health, agricultural and environmental problems affecting many people. Since the existence of a large public domain is good for everybody such removal, it is argued, would be a bad thing.

Some people have argued that fears over biopiracy are exaggerated. Whether they are right to do so or not, it should be beyond debate that more reliable and accurate information is necessary, and terminology should be better defined if we really want to achieve practical and effective solutions.

Industry commonly expresses the view that ethno-bioprospecting, and natural product research more generally, are scientifically and commercially unproven drug discovery strategies in the present era however effective they may be in the past. While nature used, before the emergence of synthetic chemistry, to provide all of the drugs on the market and traditional knowledge much of the inspiration, most pharmaceutical companies purport to have little if any interest in the “jungle pharmacy”. If they have to comply with complex TK protection regimes and benefit sharing, their scepticism about TK and bioprospecting could well increase further and alternative drug discovery strategies may look even more promising. However, evidence for such admittedly plausible assertions is lacking.

Solutions to the protection of traditional knowledge in IPR law are being sought in the forms of “positive protection” and “defensive protection”. Positive protection refers to the acquisition by the TK holders themselves of an IPR such as a patent or an alternative right provided in a sui generis system. Defensive protection refers to provisions adopted in the law or by the regulatory authorities to prevent IPR claims to knowledge, a cultural expression or a product being granted to unauthorised persons or organisations.

As such, TK is being debated at international level in various intergovernmental forums and processes. These include the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Sometimes, the negotiations focus specifically on TK protection, whether positive or negative, or else TK is discussed in the context of a wider negotiation, such as the WTO’s review of implementation of Article 27.3(b) of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), or the COP and its subsidiary working groups’ elaboration of an International Regime on Access and Benefit Sharing. The most substantial negotiations seem now to be those taking place at WIPO. These have reached the point of producing (but not agreeing upon) a set of draft provisions on the protection of traditional knowledge and of traditional cultural expressions.

Among the most promising approaches are the possibility of designing regimes based on customary law, a misappropriation regime, and disclosure of origin.

In traditional societies customs are often of major importance in regulating social and economic behaviour. Customs are established modes of behaviour within a cultural community that may have the force of law. Customary norms and rules exist in all cultures, although not all cultural communities have dedicated judicial institutions to enforce them and to resolve disputes.

Securing the protection of traditional knowledge, technologies and resources according to the local customary regulations requires the existence of effective local governance structures and customary law, including property regimes, and respect for these structures and regimes from outsiders. This is easiest to achieve in countries where customary law systems can operate with relative freedom and where rights are enforceable. In such cases, the possibility arises for traditional rules and norms to

be asserted with as much (or as little) legal effect within that country as, say, patent rights, trade marks and copyrights. But whether customary laws regulating cultural, intellectual and physical property are fully incorporated into national legal systems, are enforceable in local courts alone, or are just given some minimal recognition at the state level, the common assumption that traditional knowledge and resources are by definition part of the public domain becomes much more open to challenge than if customary law has no recognition at all. This is extremely important since so much of what TK holders apparently want to protect *is* considered to be in the public domain.

Arguably, a TK misappropriation regime should incorporate: (1) the concept of unfair competition; (2) moral rights; and (3) cultural rights. Unfair competition would deal with situations in which TK holders engaged in commercial activities pertaining, for example, to know-how, medicinal plants, artworks or handicrafts, had their trade affected by certain unfair commercial practices committed by others. Moral rights are provided in Article 6*bis* of the Berne Convention for the Protection of Literary and Artistic Works. Moral rights usually consist of the right of authors to be identified as such (sometimes referred to as the right of paternity), and to object to having their works altered in ways that would prejudice their honour or reputation (the right of integrity). It could be argued that free-riding on the knowledge, cultural works, and expressions of traditional communities who are not themselves interested in commercialising them does no direct harm. Consequently, the doctrine of misappropriation does not apply to such acts. But is it really the case that there are no victims? One could reply that such behaviour infringes on certain cultural rights that these communities are entitled to enjoy. Of these, the following may be relevant: the right to protection of artistic, literary and scientific works; the right to develop a culture; the right to respect of cultural identity; the right of minority peoples to respect for identity, traditions, language, and cultural heritage; the right of a people to its own artistic, historical, and cultural wealth ; and the right of a people not to have an alien culture imposed on it.

To the extent that unauthorised or improper use of a cultural group's artefacts and expressions imbued with cultural, spiritual or aesthetic value erodes the integrity of the culture of origin, it is reasonable to treat such uses as manifestations of a form of misappropriation that the law should arguably provide remedies for.

"Disclosure of origin" has become a collective term for certain requirements to be incorporated into patent law. These requirements vary widely in terms of the weight and nature of the legal, administrative or informational burdens placed on patent applicants and owners. We argue that the most promising version is what we call "proof of legal acquisition". One way to implement this is to require patent applicants to submit with their application official documentation from provider countries proving that genetic resources and - where appropriate - associated TK were acquired in accordance with the ABS regulations including conformity with such obligations as prior informed consent, with the terms mutually agreed between providers and the recipients, and with the need to comply with CBD Article 8(j) on the knowledge, innovations and practices of indigenous and local communities.

Proof of legal acquisition seems to have more promise as an effective measure in terms of encouraging equitable processes and outcomes to the economic benefit of both providers and users. Admittedly, the fact that so many resources and so much traditional knowledge related to patents are acquired or is learned about without having to go to any of the countries of origin or source would also limit its application. But linking the patent right to the legality of the acquisition of the relevant resources or knowledge appears to have some practical advantages.

In concluding this paper, two important questions arise in international negotiations that need to be considered carefully. First, should efforts be devoted to developing a national *sui generis* system

first in order to gain experience that makes it easier to determine what a workable international solution should look like, or is a multilateral settlement a pre-condition for the effective protection of the rights of TK holders in any country? Second, how might concerned countries overcome the limitation with national *sui generis* systems to protect TK, which is that they will have no extra-territorial effect?

Should efforts be devoted to developing a national *sui generis* system first in order to gain experience that makes it easier to determine what a workable international solution should look like? Or is a multilateral settlement a pre-condition for the effective protection of the rights of TK holders in any country? And what kind of a multilateral settlement is feasible anyway?

While each country will no doubt come up with good reasons to answer these questions differently, there seems to be a consensus among countries supporting *sui generis* systems of positive protection and groups representing TK holding people and communities that the problem with having a national system in a world where few such systems exist is that no matter how effective it may be at the domestic level, it would have no extra-territorial effect. Consequently, TK right holders would not be able to secure similar protection abroad, and exploitative behaviour in other countries would go on as before.

There may be a way out of this problem. If a group of concerned countries decided to act strategically as a group, some interesting possibilities could emerge. Members of such a group could agree upon harmonised standards and then apply the reciprocity principle so that protection of TK would only be extended to nationals of other members. Of course, the group should not be an exclusive club. Other interested countries should also be able to join subject to their enactment of similar legislation.

It is inappropriate for countries to come up with a one-size-fits-all *sui generis* system. Any new international norms will have to be flexible enough to accommodate the world's cultural and jurisprudential diversity. If not, they will fail. Close collaboration with TK holders and their communities is essential in the design of the *sui generis* system. This point cannot be emphasised strongly enough.

But even this may not be enough. Groups and individuals that have control over their own destinies are far better placed to benefit from legal protection of their knowledge. For example, indigenous groups empowered with rights to control access to their lands and communities have a better chance of preventing misappropriation of their knowledge and negotiating favourable bioprospecting arrangements. But in all too many cases, indigenous groups and TK holders suffer from extreme poverty, ill health, unemployment, lack of access to land and essential resources, and human rights violations. With so many immediate problems awaiting a solution, there are serious limits to what can be achieved in Geneva.

The fact that TK and (albeit to a lesser extent) TCEs are now being discussed in so many different international forums means there are both opportunities and challenges. Opportunities arise from the fact that these topics are now the subject of substantive proposals in various forums which have the broad support of many countries. On the other hand, handling the TK issue is complicated by the number of forums in which it is being discussed and by the need to be consistent, far-sighted and aware of the stakes involved. Consistency is important because government representatives can sometime express contradictory positions on the same subject in different forums. Some of these positions may be ill-informed and inimical to the national interest. The more forums there are, the greater is the danger of this happening. Adopting a long-term vision is essential. When it comes to TK, clear and realistic goals must be formulated based on an informed calculation of what is necessary and feasible.

PART 1: TRADITIONAL KNOWLEDGE: WHY IT SHOULD (OR SHOULD NOT) BE PROTECTED

1 THE ROLE OF KNOWLEDGE IN TRADITIONAL SOCIETIES

1.1 Trading in traditional knowledge and resources

It is common to say that while the modern economy is knowledge-based, earlier and present-day traditional societies are purely resource-based. But this is not the case. Knowledge, technology and resources are the basis of all economies including those of traditional societies. Traditional knowledge provides the underpinning for successful ways of subsisting in what are often hostile natural environments. Indeed, there is growing recognition that traditional knowledge, technologies and cultural expressions are not just old, obsolete and maladaptive; they can be highly evolutionary, adaptive, creative and even novel. Moreover, as a body of knowledge, customs, beliefs and cultural works and expressions handed down from generation to generation, tradition forms the “glue” that strengthens social cohesiveness and cultural identity.

Few if any human societies are totally isolated or self-sufficient in all respects. People in traditional societies not only consume knowledge-based and other goods that are produced locally, whether by themselves or their neighbours; they give them, receive them, share them, own them and *exchange* them with others including from different societies.

Traditional communities are finding it ever more necessary to secure a reliable flow of income so that they can achieve greater self-sufficiency. They may try to earn money by working outside the community, although doing so is seldom lucrative. Another way, and often a more appealing option, is to establish market links. Community members may take the initiative and sell local resources, manufactured goods and artworks in local and regional markets, as many communities have done for centuries.

Or they may establish an agreement with a company, perhaps from another country, that is interested in commercialising the community’s knowledge, resources, or arts and crafts.

Trade can be a two-edged sword for these communities. Undoubtedly, commerce in such products as medicinal plants, traditional crop varieties and handicrafts can and does benefit local people. However, trade can also increase dependence on outsiders and vulnerability to exploitation. On the one hand, traditional communities are already locked into the world economic system and cannot simply opt out. On the other, prices of such produce tends to be low and, even when products have a high economic value, traditional communities seldom receive a fair percentage of the value added to products that are processed and transported long distances. Moreover, it may be argued that traditional communities are bound to become victims of the vagaries of market forces if they get involved in selling low value products. Trade in exported products whose popularity may be short-lived will increase dependence on the trade and on the companies that groups work with, making trade-based relations essentially paternalistic.

Benefiting from trade depends not only on the availability of legal rights that are enforceable beyond the locality, but also on the ability of traditional communities to take advantage of national and international law including property and access rights relating to land, natural resources and intellectual property. It also depends on specific capacity-building measures to address problems of lack of information and production and marketing weaknesses. Indeed, capacity building is absolutely vital.

1.2 Knowledge and resource regulation in traditional societies

Traditional proprietary systems relating to scarce tangibles such as land, resources and goods, and to valuable intangibles like certain knowledge and cultural expressions, are often highly complex and varied. Generalisations should be made with extreme caution. However, it appears frequently to be the case that knowledge and resources are communally held. While individuals and families may hold lands, resources or knowledge for their own use, ownership is often subject to customary law and practice and based on the collective consent of the community.

Nonetheless, the idea that traditional property rights are always collective or communal in nature while Western notions of property are inherently individualist is an inaccurate cliché. While this may appear to contradict what we have just stated, specialised knowledge may be held exclusively by males, females, certain

lineage groups, or ritual or society specialists (such as shamans) to which they have rights of varying levels of exclusivity. But in many cases, this does not necessarily give that group the right to privatise what may be more widely considered to be the communal heritage.

In short, customary laws regulating access and use of local knowledge, resources, cultural products and locally produced manufactured goods do exist. But what can be done when these spread beyond the control of the local administrative or juridical institutions, either through trade or misappropriation, and are commercialised without the consent of the providing communities or any benefits flowing back to them? Probably very little, at least in the present situation. This problem is what an international TK regime should be able to respond to.

2 JUSTIFYING TK PROTECTION AND THE NEED FOR CONSENSUS AND CLEAR OBJECTIVES

Why legally protect traditional knowledge? Many advocates of TK protection will consider this to be hardly worth asking. But it is far from self-evident that just because some TK has commercial value in the local and wider economy, it should therefore be protected. A popular view is that TK should be protected because pharmaceutical corporations and bioprospectors are misappropriating it and making huge profits. It follows that if corporate “biopiracy” were not taking place on a sufficient scale to require a legal response, there would be no reason to protect traditional knowledge at all. But if it turns out that corporate copying of TK is less common than commonly believed, should we simply abandon efforts to give legal expression to the demands and concerns of TK holders and their communities relating to extra-community use of their knowledge?

I argue that whether or not, in the words of Justice Peterson in a famous British copyright infringement case in 1916, “what is worth copying is prima facie worth protecting”,¹ there are various other reasons to protect TK than that corporations find it worthwhile to copy it and yet rarely have to compensate the knowledge holders. This chapter reviews various justifications for protecting TK and finds that there are several plausible reasons to do so. Those countries which seek legal solutions to the lack of TK protection should ideally seek a consensus on what the objective or objectives should be. The same applies to national legal protection. Without clear objectives, laws and policies to protect TK are unlikely to be effective. There are various plausible reasons to protect TK. The text that follows covers some of the most contentious of these.

2.1 To improve the lives of TK holders and communities

Great as its wider economic potential may be, traditional knowledge is valuable first and foremost to indigenous and local communities that depend on TK for their health, livelihoods and general well-being. Thus, a TK regime that encouraged the conservation and continued use of TK relating to health and food production could potentially improve the lives of millions of people.

According to the World Health Organization, up to 80 per cent of the world’s population depends on traditional medicine for its primary health needs.² While the high cost of pharmaceuticals is a factor in this, for many ailments traditional medicine is preferred, even by many urban populations.

Traditional low-input agricultural systems, based on extensive and applied knowledge about natural processes and local ecosystems have successfully enabled millions of people to subsist for thousands of years in some of the most hostile environments. However, many TK-based agricultural systems have fallen into

decline. This situation does not necessarily mean that people are abandoning them because they are obsolete. Factors in this decline include the spread of market economies, commercialisation of agriculture with the introduction of export crops and Green Revolution technologies, all-too-prevalent assumptions that Western techniques and methods such as high-input monocultural agriculture are superior to local ones like intercropping, and the imposition of inappropriate laws and regulations by governments. The results are likely to be increasing impoverishment rather than the opposite.

Despite this, the original agricultural systems are intact in many parts of the world and continue to be the basis of much innovation. For example, in some parts of the world farming communities continue effectively to manage agricultural genetic diversity, experiment on-farm with traditional *and modern* crop varieties and to produce their own varieties whose performance may be better than those provided by extension services.³

2.2 To benefit national economies

Some traditional medicines are used as inputs in biomedical research, suggesting that they may constitute a source of income not just as drugs in themselves but as the sources of chemical substances forming the basis of new pharmaceuticals. Indeed, traditional communities have already been responsible for the discovery, development, and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, agricultural and forest products, and handicrafts that are traded internationally and generate considerable economic value - but not for those communities. However, policies that enable traditional communities and provider countries to capture more of the value while at the same time encouraging commercially-oriented natural product research are generally lacking.

TK is also used as an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides. In most cases, firms based in developed countries that can harness advanced scientific, technological and marketing capabilities capture virtually all the value added. This situation needs to be addressed so that TK holders, their communities and developing countries can capture much more value. However, one should not overestimate the industrial demand for *in situ* genetic resources and associated TK. While enhanced abilities to screen huge quantities of natural products and analyse and manipulate their DNA structures might suggest that bioprospecting will become more popular, it seems more likely that advances in biotechnology and new drug discovery approaches will, in the long term, reduce industrial interest in natural product research for food, agriculture and health, as well as associated TK.⁴

If we just consider pharmaceuticals, while many companies invest in natural product research, such an approach competes with others such as combinatorial chemistry, rational drug design, genomics,⁵ proteomics⁶ and RNA interference⁷ that many in the industry consider to be more promising.⁸ Moreover, many of these firms

maintain large 'compound libraries' and often see no reason to prospect for more compounds. Nevertheless, as long as it remains extremely difficult for therapeutic molecules to be designed and manufactured from scratch without using existing chemical structures as initial leads, many firms will continue to screen natural compounds. Even the new combinatorial chemistry techniques need to work on existing lead structures, which will originate from natural or mineral sources, to generate the large compound libraries firms use in their screening programmes.⁹ So, combinatorial chemistry does not necessarily conflict with natural product research. Even so, interest in genetic resources does not necessarily indicate interest in TK. Many firms claim to have no interest at all in TK.

Although his research focuses mainly on India, Gupta's list of technological fields in which traditional societies can be highly innovative and contribute substantially to local and national economies, his findings are surely relevant elsewhere. These fields are as follows: (i) crop protection; (ii) crop production; (iii) animal husbandry; (iv) grain storage; (v) pisciculture; (vi) poultry; (vii) leather industry; (viii) soil and water conservation; (ix) forest conservation; (x) farm implements; (xi) organic farming; (xii) local varieties of seeds; (xiii) informal institutions (common property resources); and (xiv) ecological indicators.¹⁰

In 1999 the Indian government established a National Innovation Foundation. The NIF's goals are as follows:¹¹

1. To help India become an inventive and creative society and a global leader in sustainable technologies.
2. To ensure evolution and diffusion of green grassroots innovations in a time bound and mission oriented manner.
3. To support scouting, spawning, sustaining and scaling up of grassroots green innovations and link innovation, enterprises and investments.

4. To strengthen research and development linkages between excellence in formal and informal knowledge systems and create a knowledge network.
5. To promote wider social awareness and possible commercial and non-commercial applications of innovations

No other government has made such a significant official commitment to harnessing traditional technologies for sustainable development. Given that many traditional societies are rich sources of innovation in the above-mentioned technological fields among others, India's initiative merits investigation by policymakers and development agencies elsewhere in the world.

In short, it seems that protecting TK has the potential to improve the performance of many developing-country economies by enabling greater commercial use of their biological wealth and increasing exports of TK-related products. At the same time, it is important not to overestimate TK's economic potential.

So far we have neglected traditional cultural expressions (TCEs) from the discussion. In fact, TCEs may be very promising sources of wealth not just for communities but also for national economies. For example, trade in handicrafts is substantial. According to Fowler, "artisan

handicrafts represent an estimated US\$30 billion world market. In addition, handicraft production and sales represent a substantial percentage of gross domestic product (GDP) for some countries".¹²

However, the continued production and further development of traditional handicrafts and artworks are threatened sometimes by the disappearance of traditional skills. Another serious problem is copying and mass production by outsiders, who thereby deprive artisans of a source of income. Copyright infringement tends to be a major problem. And even where copyright legislation is in place, collection and distribution of royalties amongst the key parties (i.e. composers, performers, publishers and the recording companies) is difficult without an efficient, transparent and *fully* accountable collective management structure that seeks primarily to benefit local musicians rather than international ones.¹³ Indeed, while a weak copyright system may on balance benefit some nations by decreasing the rate of imported intellectual property goods in certain areas such as software and educational products, such a policy may also undermine those industries which a developing nation may wish to nurture. The local music industries in Mali and South Africa have complained that they suffer heavily from losses and damages due to copyright infringement.¹⁴

2.3 To prevent "biopiracy"

The vast majority of countries formally recognize that cross-border exchange of genetic resources and traditional knowledge be carried out in compliance with the principles of the Convention on Biological Diversity. For a number of reasons, intellectual property rights, particularly patents but also plant variety protection, have become central to discussions on this matter. These reasons relate to the following:

1. The conviction - widely held among developing countries and NGOs - that biodiversity and associated traditional knowledge have tremendous economic potential.
2. The fact that patent claims in various countries may incorporate biological and genetic material including life forms within their scope.
3. The belief, also shared by developing countries and NGOs, that this feature of the patent system enables corporations to misappropriate genetic resources and associated traditional knowledge or at least to unfairly free-ride on them.¹⁵
4. The ability of modern intellectual property law to protect the innovations produced by industries based mainly in the developed world and its *inability* to protect adequately those in which the developing

countries are relatively well-endowed.

5. The perception that as a consequence of reasons 2 - 4, the unequal distributions and concentrations of patent ownership and the unequal share of benefits obtained from industrial use of biogenetic resources are closely related.

“Biopiracy” has emerged as a term to describe the ways that corporations from the developed world free ride on the genetic resources and traditional knowledge and technologies of the developing countries. While these and other corporations complain about “intellectual piracy” perpetrated by people in developing countries, the latter group of nations counters that their biological, scientific and cultural assets are being “pirated” by these same businesses. Intellectual piracy is a political term, and as such is inaccurate and deliberately so. The assumption behind it is that the copying and selling of pharmaceuticals, music CDs and films anywhere in the world is intellectual piracy irrespective of whether the works in question had patent or copyright protection under the domestic laws. After all, if drugs cannot be patented in a certain country, copying them by local companies for the domestic market and/or overseas markets where the drugs in question are also not patented is hardly piracy in the legal sense of the word.

Similarly, biopiracy is an imprecise term, and there are good reasons to keep it so, at least in the international arena. But such “strategic vagueness” is not a helpful approach for those working on legal solutions in such forms as national laws, regulations or international conventions.

Let us start by elucidating, as far as we can, the actual meaning of the word. To start with the obvious, “biopiracy” is a compound word consisting of “bio”, which is short for “biological”, and “piracy”. According to the Concise Oxford Dictionary, “piracy” means the following: (1) the practice or an act of robbery of ships at sea; (2) a similar practice or act in other forms, especially hijacking; and (3) the infringement of copyright.

Apart from the use of “piracy” for rhetorical effect, the word does not seem to be applicable to the kinds of act referred to as biopiracy. But let us now turn to the verb “to pirate”. The two definitions given are: (1) appropriate or reproduce (the work or ideas etc. of another) without permission for one’s own benefit; and (2) plunder.

These definitions seem to be more appropriate since inherent to the biopiracy rhetoric are misappropriation and theft. In essence, “biopirates” are those individuals and companies accused of one or both of the following acts: (i) the misappropriation of genetic resources and/or traditional knowledge through the patent system; and (ii) the unauthorised collection for commercial ends of genetic resources and/or traditional knowledge. But since biopiracy is not just a matter of law but is also one of morality and of fairness, we need to acknowledge that where the line should be drawn between an act of biopiracy and a legitimate practice may not always be easy to draw. The difficulty in drawing the line is compounded by the vagueness in the way the term is applied.

To illustrate this point, a wide range of acts listed below have been considered as acts of biopiracy of traditional knowledge.

Collection and use:

- The unauthorised use of common TK
- The unauthorised use of TK only found among one indigenous group
- The unauthorised use of TK acquired by deception or failure to fully disclose the commercial motive behind the acquisition
- The unauthorised use of TK acquired on the basis of a transaction deemed to be exploitative
- The unauthorised use of TK acquired on the basis of a conviction that all such transactions are inherently exploitative (“all bioprospecting is biopiracy”)
- The commercial use of TK on the basis of a literature search

Patenting:

- The patent claims TK in the form in which it was acquired
- The patent covers a refinement of the TK
- Patent covers an invention based on TK *and* other modern/traditional knowledge

It is by no means clear how much biopiracy actually goes on. Apart from lack of information, the answer depends on how one differentiates between legitimate and unfair exploitation. The distinction is not always obvious. The answer also depends on whether resources are considered to be wild and unowned or domesticated and owned. A common view among critics of conventional business practice is that most companies do not recognise that they may have a moral obligation to compensate communities providing genetic material for their intellectual contribution, *even when* such material is assumed to be “wild”. Often genetic resources considered “gifts of nature” are in fact the results of many generations of selective crop breeding and landscape management. Essentially the argument is that failing to recognise and compensate for the past and present intellectual contributions of traditional communities is a form of intellectual piracy.

The likely response from industry is that this is not piracy since the present generation may have done little to develop or conserve these resources. The argument might continue that this is, at worst, a policy failure, and that measures - outside the IPR system - could be put into place to ensure that traditional communities are rewarded.

As for the patent-related version of “biopiracy”, there is little doubt that companies are in an advantageous position in the sense that, while a useful characteristic of a plant or animal may be

well-known to a traditional community, without being able to describe the phenomenon in the language of chemistry or molecular biology, the community cannot obtain a patent even if it could afford to do so.¹⁶ While it is unlikely that a company could then obtain a patent simply by describing the mode of action or the active compound,¹⁷ it could claim a synthetic version of the compound or even a purified extract. In the absence of a contract or specific regulation, the company would have no requirement to compensate the communities concerned.

The whole point of this discussion is not to deny the existence of biopiracy (please see 3.3 below), but to show that the lack of clarity is becoming counterproductive. The problem with the “biopiracy” rhetoric and the “strategic vagueness” behind its usage is that if you cannot agree on what it is, you cannot measure it. Neither can you agree on what should be done about it. One extreme view is that all bioprospecting is biopiracy. If so, the answer is to ban access outright. If biopiracy is merely an irritation, then such a ban need not be enforced too rigorously, since legal enforcement of higher-stakes areas of the law would have to take priority. If biopiracy causes demonstrable economic and/or cultural harm, the country should invest in enforcing the ban. On the other hand, if the problem is that provider countries or communities are unable to negotiate beneficial agreements, the answer may be to improve the provision of legal and technical assistance. If the problem is that the patent system legitimises or encourages misappropriation, then we may need to improve the standards of examination, ban patents on life forms and natural, or even modified, compounds, or incorporate a disclosure of origin requirement. In short, how you define biopiracy goes a long way towards determining what you should do about it.

3 OBJECTIONS TO PROTECTING TK

Objections to traditional knowledge are not necessarily motivated by bad faith and deserve a considered response.¹⁸ Three commonly expressed objections are as follows. First, that at a time when the public domain is threatened by every more comprehensive intellectual property protection we should not be creating new rights or extending existing ones that will accelerate the enclosure of the public

domain. The second is that biopiracy claims are exaggerated or even mythical. Since biopiracy is therefore not a genuine threat to TK holders and their communities, there is no need for a TK protection regime. Third, if commercial users have to pay to access or use knowledge that has hitherto been freely available they will simply not use it and no benefits will be generated to be shared with the TK holders and their communities.

3.1 Traditional knowledge and the public domain

To some critics, the creation of a TK regime would represent the removal from the public domain of a very large body of practical knowledge about the biosphere including solutions to health, agricultural and environmental problems affecting many people. Since the existence of a large public domain is good for everybody such removal, it is argued, would be a bad thing. Undoubtedly, some of the more extreme claims for TK protection to some extent justify this concern. But one may counter such a view on the following three grounds.

(i) Traditional knowledge holders and communities have their own regimes to regulate access and use of knowledge

Many traditional societies have their own custom-based “intellectual property” systems, which are sometimes quite complex. Customary rules governing access to and use of knowledge do not necessarily differ all that widely from western intellectual property formulations, but in the vast majority of cases they almost certainly do. Nonetheless, there is a tendency to treat such rules with disrespect or to ignore them as if they do not exist. However, knowledge thought to be part of the public domain may in some cases turn out under customary law to remain subject to the legal claims of individuals and communities. Even if one disregards customary law, the unauthorised dissemination or use of certain publicly available traditional knowledge could sometimes be challenged on

the basis of concepts existing in the western legal system, such as copyright, breach of confidence and misappropriation. Accordingly and in consequence, nothing is being taken from the public domain that should be there, but only what should not be.

(ii) Recognising existing rights, not creating new ones

Demands for TK protection are not necessarily seeking the creation of new rights but the wider recognition and enforceability of those which already exist, basically those custom-based knowledge regulatory regimes referred to above. Accordingly, a TK protection regime would merely translate and codify existing rights, thereby making them enforceable in national courts and possibly across international borders as well. In this sense, TK protection would neither add to nor subtract from the public domain, but would merely help to clarify what is and what is not in it.

(iii) Not everything in the public domain should be in the public domain

The public domain is being promoted in opposition to privatisation as part of a debate about intellectual property rights, a discussion that does not easily accommodate the specific interests and claims of non-Western societies. Why is this the case? Disclosed TK has from the distant past to the present been treated as belonging to nobody. Consequently, many indigenous peoples’ representatives are

concerned that pro-public domain rhetoric, sympathetic as many of them are about the sentiments behind it, may inadvertently threaten their rights. Indeed, the public domain concept is problematic from the perspective of many traditional societies in which TK holders or others, such as tribal elders, have permanent responsibilities concerning the use of such knowledge, irrespective of whether it is secret,

is known to just a few people, or is known to thousands of people throughout the world.¹⁹ Custodianship responsibilities do not necessarily cease to exist just because the knowledge has been placed in the so-called public domain. There is no doubt that a tremendous amount of TK has been disclosed and disseminated over the years without the authorisation of the holders.

3.2 “There’s no such thing as biopiracy ...”

Despite the emotional tone of the debate, as shown above, “biopiracy” is used in various ways. To some extent this invites cynicism. If we cannot agree on what biopiracy is, and if so much of the evidence put forward to justify concern is anecdotal in nature, it is hardly surprising that some people have countered that fears over biopiracy are exaggerated. Whether they are right to do so or not, it should be beyond debate that more reliable and accurate information is necessary, and terminology should be better defined if we really want to achieve practical and effective solutions. Fortunately, several countries have taken the initiative of documenting cases of biopiracy and presenting them for debate in international forums. Perhaps the most notable initiative is that of Peru, which has established a National

Anti-Biopiracy Commission and whose work has been reported on at the WIPO IGC.²⁰

Nonetheless, one should make clear that if there is such thing as intellectual property piracy then there is certainly such a thing as biopiracy. If unauthorised access, use, ownership claiming and commercialisation of TK conflicts with the customary laws of the source communities, then biopiracy is occurring as far as those communities are concerned whether or not “biopiracy” is the word the communities themselves would use to describe such acts. And if genetic resources are being accessed, used, “owned” and commercialised in ways that conflict with international law, particularly the CBD, and the laws of provider countries, then we should be able to accept that this is biopiracy too.

3.3 The disincentive effect

Industry commonly expresses the view that ethno-bioprospecting, and natural product research more generally, are scientifically and commercially unproven drug discovery strategies in the present era however effective they may been in the past. While nature used, before the emergence of synthetic chemistry, to provide all of the drugs on the market and traditional knowledge much of the inspiration, most pharmaceutical companies purport to have little if any interest in the “jungle pharmacy”. If they have to comply with complex TK protection regimes and benefit sharing, their scepticism about TK and bioprospecting could well increase further and alternative drug discovery strategies may look even more

promising. Again, evidence for such admittedly plausible assertions is lacking, and we should certainly not accept them as given. Indeed, the statistical evidence produced so far to support such a view is not at all credible making it hard to know whether concerns are genuine or are groundless scaremongering.²¹

A recent publication that deserves notoriety is one produced and aggressively publicised by the Pacific Research Institute. This paper purports to scientifically determine the losses to the pharmaceutical and biotechnology industries in 27 countries up to 2025 in terms of reduced capital stocks resulting

from declining research and development investments caused by the establishment of what the authors call - without any clarification whatsoever - a "patent-based ABS regime". Confidently, but in the absence of any persuasive evidence notwithstanding the generous quantity of complicated-looking statistical tables, the authors make the following claims:

By the year 2025, the patent-based ABS regime would reduce the biotechnological and pharmaceutical research and development capital stock by about \$144 billion (in year 2004 dollars), or almost 27 percent, for the 27 nations. This implies a loss of 150-200 new drugs. The cumulative loss to the 15 EU countries would be

\$79 billion between now and 2025. By comparison, the United States would lose \$21.6 billion.

The fact that the US government and its biotech industry lobby groups are so keen to promote such crude propaganda does them little credit.

Similarly, a new Washington-based organisation, the American BioIndustry Alliance, seems to be trying to scare industry and governments into thinking that a disclosure of origin system would create legal uncertainty in the patent system and drive industry away from biodiversity.²² Since the legal uncertainty inherent to the US patent system without disclosure of origin has become almost legendary,²³ many observers including ones from industry may find such claims amusing.

PART 2: TRADITIONAL KNOWLEDGE AND INTERNATIONAL DIPLOMACY: THE CURRENT STATE OF PLAY

4 THE CONVENTION ON BIOLOGICAL DIVERSITY

4.1 The Conference of the Parties, the Working Groups and the International Regime

The Convention on Biological Diversity (CBD), which entered into force in 1993²⁴, has as its three objectives “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources”. As should be well known to most readers of this paper, Article 8(j) requires parties to

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.

The international negotiations on the CBD that deal with legal solutions to TK protection have considered, inter alia, the following: (i) national and international sui generis regimes; (ii) legally and non-legally binding instruments and agreements including contracts, guidelines and codes of conduct; (iii) specific protection measures such as TK databases and disclosure of origin of genetic resources and associated TK in patent applications; (iv) principles such as prior informed consent and respect for customary law; and (v) the incorporation of TK protection provisions in the International Regime on Access and Benefit Sharing that is currently being debated.

To review implementation of the CBD, the Conference of the Parties meets biannually. IPRs are most frequently discussed in deliberations on such topics as access to genetic resources, benefit sharing, and the knowledge innovations and practices of indigenous and local communities.

At the Sixth Meeting of the Conference of the Parties (COP-6), which took place in The Hague in 2002, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization were officially adopted.²⁵ The Guidelines, which are intended to be used when developing and drafting legislative, administrative or policy measures on ABS and contracts, have a number of provisions relating to IPRs. Parties with genetic resource users under their jurisdiction are suggested to consider adopting “measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights”.²⁶ As means to implement the CBD provision that benefit sharing be upon mutually agreed terms, two elements to be considered as guiding parameters in contracts and as basic requirements for mutually agreed terms are (i) that “provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent”, and (ii) “the possibility of joint ownership of intellectual property rights according to the degree of contribution”.²⁷ COP Decision VI/24, to which the Bonn Guidelines were annexed, also called for further information gathering and analysis regarding several matters including:

- *Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;*
- *Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights application and the re-examination of intellectual property rights granted;*
- *Feasibility of an internationally recognized certification of origin system as evidence of prior informed consent and mutually agreed terms;*
- *Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.*

In addition, the Decision invited WIPO, which as we will see is actively engaged in these same issues,

to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia:

- (a) Genetic resources utilized in the development of the claimed inventions;
- (b) The country of origin of genetic resources utilized in the claimed inventions;
- (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
- (d) The source of associated traditional knowledge, innovations and practices; and
- (e) Evidence of prior informed consent.

Since then, a subsequent COP Decision (VII/7) requested WIPO and UNCTAD to analyse issues

relating to the implementation of disclosure or origin. Specifically, these issues were as follows:

- *Options for model provisions on proposed disclosure requirements;*
- *Practical options for IP application procedures with regard to the triggers of disclosure requirements;*
- *Options for incentive measures for applicants;*
- *Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties; and*
- *Intellectual property-related issues raised by proposed international certificates of origin/source/legal provenance.*

Both WIPO²⁸ and UNCTAD²⁹ have subsequently produced substantial documents on disclosure of origin.

In a separate COP-6 Decision on Article 8 (j) and related provisions, the COP invited

Parties and Governments, with the approval and involvement of indigenous and local communities representatives, to develop and implement strategies to protect traditional knowledge, innovations and practices based on a combination of appropriate approaches, respecting customary laws and practices, including the use of existing intellectual property mechanisms, sui generis systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice.

It also requested “the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity³⁰ to address the issue of *sui generis* systems for the protection of traditional knowledge”.

The Seventh Meeting of the COP (COP-7), which took place in Kuala Lumpur in 2004, adopted

Decision VII/16 on "Article 8(j) and Related Provisions". Section H of the Decision was on the development of elements of sui generis systems for the protection of traditional knowledge, innovations and practices. Drawing on the work of the Working Group on Article 8(j), its annex offered the following list of potential elements.

1. Statement of purpose, objectives and scope.
 2. Clarity with regard to ownership of traditional knowledge associated with biological and genetic resources.
 3. Set of relevant definitions.
 4. Recognition of elements of customary law relevant to the conservation and sustainable use of biological diversity with respect to: (i) customary rights in indigenous/traditional/local knowledge; (ii) customary rights regarding biological resources; and (iii) customary procedures governing access to and consent to use traditional knowledge, biological and genetic resources.
 5. A process and set of requirements governing prior informed consent, mutually agreed terms and equitable sharing of benefits with respect to traditional knowledge, innovations and practices associated with genetic resources and relevant for the conservation and sustainable use of biological diversity.
 6. Rights of traditional knowledge holders and conditions for the grant of rights.
 7. The rights conferred.
 8. A system for the registration of indigenous/local knowledge/Systems for the protection and preservation of indigenous/local knowledge.
 9. The competent authority to manage relevant procedural/administrative matters with regard to the protection of traditional knowledge and benefit-sharing arrangements.
 10. Provisions regarding enforcement and remedies.
 11. Relationship to other laws, including international law.
 12. Extra-territorial protections.
- Activities relating to TK are being carried out not just by the Working Group on Article 8(j) and Related Provisions (hereafter "8(j) Working Group"), but also by the Working Group on Access and Benefit Sharing (hereafter "ABS Working Group"), most importantly in the context of the International Regime on Access to Genetic Resources and Benefit Sharing. Agreement that there should be such a regime was reached at the 2002 World Summit on Sustainable Development, specifically "to negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources". The International Regime is currently under negotiation and the Conference of the Parties is the body mandated by the United Nations General Assembly to be the principle forum to develop the regime. As indicated in COP-7 decision VII/19 a number of elements relevant to TK protection are required to be considered by the Working Group on access and Benefit Sharing:
- (x) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j).
 - (xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights.
 - (xv) Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located.

- (xvi) Customary law and traditional cultural practices of indigenous and local communities,
- (xviii) Code of ethics/code of conduct/ models of prior informed consent or other instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities.

At COP-8, which took place in March 2006, two relevant decisions were adopted, Decision VIII/4 on Access and Benefit Sharing, and Decision VIII/5 on Article 8(j) and Related Provisions. Decision VIII/4 requested the ABS Working Group “to continue the elaboration and negotiation of the international regime” and instructed it “to complete its work at the earliest possible time before the tenth meeting of the Conference of the Parties”. COP-10 is likely to take place in 2010. This is somewhat later than many countries had been demanding.

Decision VIII/5 contains a sub-section titled “**Development of elements of sui generis systems for the protection of the knowledge, innovations and practices of indigenous and local communities**”. Among other provisions, the sub-section

Urges Parties and Governments to develop, adopt and/or recognize national and local sui generis models for the protection of traditional knowledge,

innovations and practices with the full and effective participation of indigenous and local communities.

Urges Parties and Governments to report on these initiatives to adopt local and national sui generis models and to share experiences through the clearing-house mechanism;

Invites Parties and Governments with transboundary distribution of some biological and genetic resources and associated traditional knowledge to consider the establishment of regional sui generis frameworks for the protection of traditional knowledge, innovations and practices, as appropriate, with the full and effective participation of indigenous and local communities;

Requests the Executive Secretary to continue gathering and analysing information, in consultation with Parties, Governments, indigenous and local communities, to further develop as a priority issue, the possible elements listed in the annex to decision VII/16 H for consideration by the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions at its fifth meeting, and further requests the Working Group on 8(j) to identify priority elements of sui generis systems;

4.2 Commentary

The COP appears to be serious about developing new legal norms for the international-level legal protection of TK in addition to the local, national and regional approaches that it is also encouraging. The question remains, in what form will such norms be delivered? Will they be integrated into the International Regime? Or will there be a stand-alone sui generis regime, perhaps an international treaty?

Taking the International Regime possibility first, it remains to be seen what the Regime will look like in terms of its form, its provisions,

and the extent to which they will be legally binding and enforceable. It is also unclear how far it will deal with TK. It is possible that it would merely reiterate the CBD’s provisions on TK without deviating much from the extant language. On the other hand, the International Regime could go far beyond the CBD’s language on TK and clarify and strengthen the rather vague and undeniably weak legal obligations placed on governments by Article 8(j). There is much to play for. While attaching provisions on TK protection to a multilateral access and benefit sharing system has the potential to

advance the cause of those supporting TK protection by “piggy-backing” on a cause that governments may consider to have greater economic and strategic importance, there are tensions between TK protection and ABS. For many of these countries, any effective access and benefit sharing regime must be founded on the principle of national sovereignty. It is to be hoped that this principle will not extend to TK. Unfortunately, historical and present-day practices justify some anxiety including a feeling that for many countries, the prior informed consent to be sought must come from a government body only, and not from traditional communities at all.

The view expressed here, and one justified, *inter alia*, on human rights grounds is that TK which can be traced to specific ethnic or cultural groups should not be treated as part of the national cultural or intellectual heritage *if* to do so would negate the rights of knowledge holders and customary owners. Indigenous peoples’ organisations are generally unhappy with the idea that TK rights should be vested in the state on behalf of the holders.

As for a stand-alone *sui generis* regime, as in other forums there is opposition that may make such a regime impossible to agree upon. Consequently, it is possible that the biggest achievement will be an international declaration, resolution or code of conduct.

5 THE WORLD INTELLECTUAL PROPERTY ORGANIZATION

For the 25th Session of WIPO's General Assembly in 2000, the Secretariat prepared a document which invited member states to consider the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The WIPO Secretariat suggested that the IGC constitute a forum for members to discuss three themes that it had identified during the consultations. These were "intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore."³¹ This suggestion was enthusiastically supported by a large number of developing countries and was approved without formal opposition from any member.

In the early years, most of the IGC's work on TK and on folklore (nowadays referred to more often as traditional cultural expressions) concentrated on defensive protection. More specifically, the Committee has been considering ways to improve the availability to patent examiners of traditional knowledge and of publications describing TK. In addition, much discussion has covered disclosure of origin of

genetic resources and/or related TK in patent applications, as at the CBD COP meetings and the WTO. This subject will be covered in greater depth in Part 3 below.

However, positive protection is increasingly being discussed in a substantive manner. The first shift in this direction came at the third session of the IGC in June 2002, for which WIPO prepared a paper called "Elements of a *sui generis* system for the protection of traditional knowledge".³² It was given further impetus in Autumn 2003 when the WIPO General Assembly decided that the IGC's new work would focus particularly on the international dimension of the relevant issues and agreed that "no outcome of its work is excluded, including the possible development of an international instrument or instruments."³³

The IGC has drafted two sets of provisions: the Provisions for the Protection of Traditional Knowledge,³⁴ and the Provisions for the Protection of Traditional Cultural Expressions.³⁵ Both of these were presented first at the eighth session of the IGC and will be further deliberated on at the ninth session. The objectives and principles are listed below in full.

5.1 Provisions for the Protection of Traditional Knowledge

The text of the Provisions is as follows:

I. POLICY OBJECTIVES

- | | |
|---|---|
| <ul style="list-style-type: none"> (i) <i>Recognize value</i> (ii) <i>Promote respect</i> (iii) <i>Meet the actual needs of traditional knowledge holders</i> (iv) <i>Promote conservation and preservation of traditional knowledge</i> (v) <i>Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems</i> | <ul style="list-style-type: none"> (vi) <i>Support traditional knowledge systems</i> (vii) <i>Contribute to safeguarding traditional knowledge</i> (viii) <i>Repress unfair and inequitable uses</i> (ix) <i>Concord with relevant international agreements and processes</i> (x) <i>Promote innovation and creativity</i> (xi) <i>Ensure prior informed consent and exchanges based on mutually agreed terms</i> |
|---|---|

- (xii) *Promote equitable benefit-sharing*
- (xiii) *Promote community development and legitimate trading activities*
- (xiv) *Preclude the grant of improper intellectual property rights to unauthorized parties*
- (xv) *Enhance transparency and mutual confidence*
- (xvi) *Complement protection of traditional cultural expressions*

CORE PRINCIPLES

II. GENERAL GUIDING PRINCIPLES

- (a) *Responsiveness to the needs and expectations of traditional knowledge holders*
- (b) *Recognition of rights*
- (c) *Effectiveness and accessibility of protection*
- (d) *Flexibility and comprehensiveness*
- (e) *Equity and benefit-sharing*
- (f) *Consistency with existing legal systems governing access to associated genetic resources*
- (g) *Respect for and cooperation with other international and regional instruments and processes*
- (h) *Respect for customary use and transmission of traditional knowledge*

- (i) *Recognition of the specific characteristics of traditional knowledge*
- (j) *Providing assistance to address the needs of traditional knowledge holders*

III. SUBSTANTIVE PRINCIPLES

1. *Protection Against Misappropriation*
2. *Legal Form of Protection*
3. *General Scope of Subject Matter*
4. *Eligibility for Protection*
5. *Beneficiaries of Protection*
6. *Fair and Equitable Benefit-sharing and Recognition of Knowledge Holders*
7. *Principle of Prior Informed Consent*
8. *Exceptions and Limitations*
9. *Duration of Protection*
10. *Transitional Measures*
11. *Formalities*
12. *Consistency with the General Legal Framework*
13. *Administration and Enforcement of Protection*
14. *International and Regional Protection*

5.2 Provisions for the Protection of Traditional Cultural Expressions

The text of the Provisions is as follows:

I. OBJECTIVES

- (i) *Recognize value*
- (ii) *Promote respect*
- (iii) *Meet the actual needs of communities*
- (iv) *Prevent the misappropriation of traditional cultural expressions/ expressions of folklore*
- (v) *Empower communities*

(vi) *Support customary practices and community cooperation*

(vii) *Contribute to safeguarding traditional cultures*

(viii) *Encourage community innovation and creativity*

(ix) *Promote intellectual and artistic freedom, research and cultural exchange on equitable terms*

(x) *Contribute to cultural diversity*

(xi) *Promote community development and legitimate trading activities*

(xii) *Preclude unauthorized IP rights*

(xiii) *Enhance certainty, transparency and mutual confidence*

II. GENERAL GUIDING PRINCIPLES

(a) *Responsiveness to aspirations and expectations of relevant communities*

(b) *Balance*

(c) *Respect for and consistency with international and regional agreements and instruments*

(d) *Flexibility and comprehensiveness*

(e) *Recognition of the specific nature and characteristics of cultural expression*

(f) *Complementarity with protection of traditional knowledge*

(g) *Respect for rights of and obligations towards indigenous peoples and other traditional communities*

(h) *Respect for customary use and transmission of TCEs/EoF*

(i) *Effectiveness and accessibility of measures for protection*

III. SUBSTANTIVE PRINCIPLES

1. *Subject Matter of Protection*

2. *Beneficiaries*

3. *Acts of Misappropriation (Scope of Protection)*

4. *Management of Rights*

5. *Exceptions and Limitations*

6. *Term of Protection*

7. *Formalities*

8. *Sanctions, Remedies and Exercise of Rights*

9. *Transitional Measures*

10. *Relationship with Intellectual Property Protection and Other Forms of Protection, Preservation and Promotion*

11. *International and Regional Protection*

5.3 Commentary

Both sets of draft Provisions are controversial. Norway has been seeking to push the process forward in a staged approach beginning with consensus on fundamental objectives and principles to be expressed in a non-binding declaration or recommendation.³⁶ The ultimate outcome could then be a treaty but that would presumably come several years down the road. Nonetheless, despite the efforts of countries

that would like to see meaningful results, there still remains a strong possibility that these texts and the processes which are pushing them forward will follow the Substantive Patent Law Treaty text and process in running into the sands of stalemate and recriminations.

For several developed countries, there is little for them to gain economically from a legal regime on TK or TCEs. Consequently, they

are not interested in participating positively in negotiations targeted at such an outcome even if they agree that the IGC to continue to exist. There are exceptions to this general observations. Some European countries that wish to maintain good relations with developing country governments are willing to go much further than, say, the United States. On the other, some developing countries are becoming rather negative about the IGC. They suspect two things. First, that they can never get the international treaty on TK that they seek through the IGC. Second, that the Committee's very existence serves as a justification for developed country opponents to actively keep

the subjects of TK and ABS out of negotiations on intellectual property at the WTO and other WIPO forums using the argument that these are matters exclusively for the IGC to deal with.

As for TK holders and their representatives, they have serious concerns that WIPO's mandate to promote intellectual property conflicts with their wish to roll back IP regimes they find intrusive, and that the IP focus of discussion on TK, inevitable perhaps for such an organisation, is too constraining since it reduces a highly complex issue to the technicalities of the formal IP rights of patents, copyright, trademarks, trade secrets and geographical indications.

6 THE WORLD TRADE ORGANIZATION

6.1 TK, the TRIPS Council and the Doha Development Agenda

TRIPS is of course silent on traditional knowledge. Nonetheless, discussions on TK have come up, mostly at the TRIPS Council. These initially took place in the context of the review of implementation of Article 27(b). The 2001 launching of the Doha Development Agenda has made traditional knowledge and folklore as well as the relationship between TRIPS and the CBD integral to the TRIPS Council's work.

Specifically, at the fourth meeting of the WTO Ministerial Conference which took place in Doha in November 2001, a Ministerial Declaration was adopted according to which the WTO member states instructed

the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension

As a contribution to this examination, Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe jointly submitted a paper to the Council for TRIPS in June 2002.³⁷ The paper, noting the relevant provisions of the Bonn Guidelines, proposed that TRIPS be amended to provide that WTO member states must require

that an applicant for a patent relating to biological materials or to traditional

knowledge shall provide, as a condition to acquiring patent rights: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.

As at the CBD COP and at WIPO, disclosure of origin has been debated at some length, and several follow-up proposals have been tabled.³⁸ The most recent of these, in May 2006 was submitted by Brazil, Pakistan, Peru, Thailand and Tanzania.³⁹ Annexed to this document is text that would form an additional section of TRIPS, namely Article 29 bis ("Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge"). The most substantial part is paragraph 2, which states as follows:

Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

6.2 Commentary

The WTO may not be the most appropriate venue for establishing new norms on positive traditional knowledge protection that would require the insertion of additional text to the TRIPS Agreement or the possible deletion of existing text. A modest amendment aimed at improving access to medicines involved a considerable amount of effort and it is hard

to imagine the achievement of the more substantial revisions that positive TK protection would entail. However, this is not to suggest that disclosure of origin need not be discussed at the WTO. Indeed, the TRIPS Council has a clear mandate to do so and, compared to positive TK protection, the measures required are comparatively uncomplicated.

PART 3: FROM THEORY TO PRACTICE IN LEGAL PROTECTION OF TK

7 POSSIBLE APPROACHES TO TRADITIONAL KNOWLEDGE PROTECTION

7.1 General approaches

Solutions to the protection of traditional knowledge in IPR law are being sought in the forms of “positive protection” and “defensive protection”. Positive protection refers to the acquisition by the TK holders themselves of an IPR such as a patent or an alternative right provided in a *sui generis* system. Defensive protection refers to provisions adopted in the law or by the regulatory authorities to prevent IPR claims to knowledge, a cultural expression or a product being granted to unauthorised persons or organisations. It is important to mention here that positive protection measures may also serve to provide defensive protection and vice versa. The distinction between the two, then, is not always clear-cut.

To many countries, non-governmental organisations and others, defensive protection is necessary because the intellectual property system, and especially patents, is considered defective in certain ways and allows companies to unfairly exploit TK. It may also be true that defensive protection may be more achievable than positive protection. This is because some of the most commonly-discussed defensive protection measures are basically enhancements to or modifications of existing IPRs. Effective positive protection is likely to require a completely new system whose development will require the very active and committed participation of many governments.

7.2 Positive protection

Property rights and liability rules

Entitlement theory and experience to date both suggest that extant legal systems for protecting knowledge and intellectual works tend to operate as either property regimes, liability regimes, or as combined systems containing elements of both. Perhaps a consideration of these is a good way to start.

What is the difference between property and liability regimes? A property regime vests exclusive rights in owners, of which the right to refuse, authorise and determine conditions for access to the property in question are the most fundamental. For these rights to mean anything, it must of course be possible for holders to enforce them.

A liability regime is a “use now pay later” system according to which use is allowed without the authorisation of the right

holders. But it is not free access because post compensation is still required. A *sui generis* system based on such a principle has certain advantages in countries where much of the TK is already in wide circulation but may still be subject to the claims of the original holders. Asserting a property right over knowledge is insufficient to prevent abuses when so much traditional knowledge has fallen into the public domain and can no longer be controlled by the original TK holders. A pragmatic response is to allow the use of such knowledge but to require that its original producers or providers be compensated.⁴⁰ Interestingly, this approach has been adopted by Peru through a law passed in 2002, known as the Regime of Protection of the Collective Knowledge of Indigenous Peoples. In the case of use of public domain traditional knowledge, an indigenous group may be entitled to compensation from outside parties in the form of 0.5 percent of the value

of sales of any product developed from the knowledge. The money is paid into the Fund for the Development of Indigenous Peoples.

There are different ways the compensation payments could be handled. The government could determine the rights by law. Alternatively, a private collective management institution could be established, which would monitor use of TK, issue licenses to users, and distribute fees to right holders in proportion to the extent to which their knowledge was used by others. They could also collect and distribute royalties where commercial applications are developed by users and the licenses require such benefits to go back to the holders. Such organisations exist in many countries for the benefit of musicians, performers and artists. Alternatively, in jurisdictions where TK holders are prepared to place their trust in a state or government-created competent authority to perform the same function, a public institution could be created instead.

While such organisations have the potential to reduce transaction and enforcement costs, considerations of economic efficiency should not be the only criteria for designing an effective and appropriate *sui generis* system. TK holders and communities will be its principal users and beneficiaries. They will not endorse a system that fails to accommodate their world views and customs but rather imposes other norms with which they feel uncomfortable and wish to avoid. Clearly, TK holders and communities must be partners in the development of a *sui generis* system lest it become an inappropriate and unworkable system.

Those who would oppose a liability regime may object on the ground that we should not have to pay for public domain knowledge. One may counter this view by observing that “the public domain” is an alien concept to many indigenous groups. Just because an ethnobiologist described a community’s use of a medicinal plant in an academic journal without asking permission, this does not mean that the community has abandoned its property rights in that knowledge or its interest in ensuring that the knowledge be used in a culturally appropriate manner.

Seen this way, a liability regime should not be considered an alternative to a property regime but as a means to ensure that TK holders and communities can exercise their property rights more effectively.

Whichever approach is selected - and a combination of both is probably essential - the question arises of whether rights must be claimed through registration, or whether the rights should exist in law irrespective of whether they are filed with a government agency. It seems only fair that the rights should exist regardless of whether they are declared to the government, and that these rights should not be exhausted by publication unless the holders have agreed to renounce their claims. Yet, protection and enforcement would probably become more effective with registration, and knowledge transactions would become much easier to conduct if claims over TK were registered. Consequently, the *sui generis* system should encourage the registration of right claims but not make this a legal requirement for protection.

Finally, it must be cautioned that devising the most sophisticated and elaborate system is useless if the potential users and beneficiaries remain unaware of its existence or have more immediate concerns, such as extreme poverty, deprivation and societal breakdown caused by the insufficient recognition of their basic rights. It will also fail if it does not take their world views and customary norms into account.

A customary law based regime?

Traditional societies may be governed by a set of formal or informal juridical and administrative institutions such as councils of the elders, spiritual leaders, chiefs, courts, and widely accepted and enforced customary norms including those relating to property rights. Indeed, according to the Four Directions Council, a Canadian indigenous peoples organization: “Indigenous peoples possess their own locally-specific systems of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights

and responsibilities which attach to possessing knowledge, all of which are embedded uniquely in each culture and its language.”⁴¹

In traditional societies customs are often of major importance in regulating social and economic behaviour. Customs are established modes of behaviour within a cultural community that may have the force of law. Customary norms and rules exist in all cultures, although not all cultural communities have dedicated judicial institutions to enforce them and to resolve disputes.

How is customary law different from state law? First, generally speaking customary laws are unwritten while state law is codified or at least is founded upon a tradition of documented case law augmented by statutes. Second, for many traditional societies, customary law is not a subject for legal specialists; neither is it at all divorced from people’s everyday lives. On the contrary, a customary law system may be regarded as “a living law, a law activated and modified not by specialised practitioners but by those who in their daily lives, practice the law, living out their traditional customs in everyday contacts - and occasional confrontation with neighbours, rivals, partners, relatives.”⁴² Third, customary laws tend to be unwritten.

In some countries there has been much discussion concerning recognition and the question of whether or not customary law should be codified. Whether or not to codify customary law is a genuine dilemma. It can be argued that codifying customary laws will freeze them in time and prevent them from evolving. On the other hand, integrating them into the national legal system may require in depth understanding and analyses that only codification would make possible. Nonetheless, recognition of customary law need not require codification. Moreover, stipulating precise definitions is not desirable unless strictly necessary. After all, few patent laws provide a definition of “invention”.

While it is important to be pragmatic, traditional communities in their dealings with industry normally have to accept that Western legal forms and instruments including patents and contracts are the basic rules of the game. TK holders and communities are understandably concerned that one type of IPR system is being universalised and prioritised to the exclusion of all others, including their counterpart customary systems. This does not seem fair. After all, if indigenous peoples in WTO member states are required to accept the existence of patents that they are economically prevented from availing themselves of and contracts that they are cannot realistically enforce in the courts, why should their own knowledge-related customary regimes including property rules not be respected by others?

Securing the protection of traditional knowledge, technologies and resources according to the local regulations requires the existence of effective local governance structures and customary law, including property regimes, and respect for these structures and regimes from outsiders. This is easiest to achieve in countries where customary law systems can operate with relative freedom and where rights are enforceable. In such cases, the possibility arises for traditional rules and norms to be asserted with as much (or as little) legal effect within that country as, say, patent rights, trade marks and copyrights. But whether customary laws regulating cultural, intellectual and physical property are fully incorporated into national legal systems, are enforceable in local courts alone, or are just given some minimal recognition at the state level, the common assumption that traditional knowledge and resources are by definition part of the public domain becomes much more open to challenge than if customary law has no recognition at all. This is extremely important since so much of what TK holders apparently want to protect *is* considered to be in the public domain.

7.3 Defensive protection

The prevention of misappropriation

Carlos Correa initially proposed a misappropriation regime. According to his proposal:

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.⁴³

He recommended that, in view of the lack of experiences to date in developing such a regime, a step-by-step approach may be necessary. In the first instance, such a regime should contain three elements: documentation of TK, proof of origin or materials, and prior informed consent.

Correa refers to two United Nations documents that implicitly support his proposal. The first of these is Decision V/16 of the CBD's Conference of the Parties, which states

Request[ed] Parties to support the development of registers of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity through participatory programmes and consultations with indigenous and local communities, taking into account strengthening legislation, customary practices and traditional systems of resource management, such as the protection of traditional knowledge against unauthorized use.⁴⁴

The second is the "Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples," which were elaborated in 1995 by Erica-Irene Daes, then Special Rapporteur of the UN Subcommission on Prevention of Discrimination and Protection of Minorities.⁴⁵

Paragraphs 26 and 27 state the following:

National laws should 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 to an arrangement for the sharing of ownership, control, use and benefits.

National laws should ensure the labelling and correct attribution of indigenous peoples' artistic, literary and cultural works whenever they are offered for public display or sale. Attribution should be in the form of a trademark or an appellation of origin, authorized by the peoples or communities concerned.

The WIPO IGC's draft Provisions for the Protection of Traditional Knowledge contains an article on protection against misappropriation.⁴⁶ It states as follows:

ARTICLE 1 PROTECTION AGAINST MISAPPROPRIATION

1. Traditional knowledge shall be protected against misappropriation.
2. Any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge.
3. In particular, legal means should be provided to prevent:
 - (i) acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach or inducement

of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means;

(ii) acquisition of traditional knowledge or exercising control over it in violation of legal measures that require prior informed consent as a condition of access to the knowledge, and use of traditional knowledge that violates terms that were mutually agreed as a condition of prior informed consent concerning access to that knowledge;

(iii) false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over traditional knowledge-related subject matter when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access;

(iv) if traditional knowledge has been accessed, commercial or industrial use of traditional knowledge without just and appropriate compensation to the recognized holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on its user, and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge; and

(v) willful offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge and is contrary to ordre public or morality.

4. Traditional knowledge holders should also be effectively protected against other acts of unfair competition, including acts specified in Article 10bis of the Paris Convention. This includes false or misleading representations that a product or service is produced or provided with the involvement or endorsement of traditional knowledge holders, or that the commercial exploitation of products or services benefits holders of traditional knowledge. It also includes acts of such a nature as to create confusion with a product or service of traditional knowledge holders; and false allegations in the course of trade which discredit the products or services of traditional knowledge holders.
5. *The application, interpretation and enforcement of protection against misappropriation of traditional knowledge, including determination of equitable sharing and distribution of benefits, should be guided, as far as possible and appropriate, by respect for the customary practices, norms, laws and understandings of the holder of the knowledge, including the spiritual, sacred or ceremonial characteristics of the traditional origin of the knowledge.*

Paragraph 1 of the following article states that:

1. *The protection of traditional knowledge against misappropriation may be implemented through a range of legal measures, including: a special law on traditional knowledge; laws on intellectual property, including laws governing unfair competition and unjust enrichment; the law of contracts; the law of civil liability, including torts and liability for compensation; criminal law; laws concerning the interests of indigenous peoples; fisheries laws and environmental laws; regimes governing access and benefit-sharing; or any other law or any combination of those laws. This paragraph is subject to Article 11(1).⁴⁷*

Arguably, such a misappropriation regime could and probably should incorporate: (1) the concept of unfair competition; (2) moral rights; and (3) cultural rights. Unfair competition would deal with situations in which TK holders engaged in commercial activities pertaining, for example, to know-how, medicinal plants, artworks or handicrafts, had their trade affected by certain unfair commercial practices committed by others. According to Article 10*bis* of the Paris Convention for the Protection of Intellectual Property, the following acts are prohibited on the grounds of constituting unfair competition:

1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

The TRIPS Agreement incorporates the substantive provisions of the Paris Convention by reference and explicitly mentions Article 10*bis* in the sections dealing with geographical indications and undisclosed information.⁴⁸ Specifically, WTO members must provide legal means to prevent any use of geographical indications that would constitute unfair competition. Also, members must ensure effective protection against unfair competition with respect to undisclosed information.

Norway is proposing that Article 10*bis* be used as the model for an international misappropriation regime that would go beyond just unfair competition. Accordingly, further discussion on such a regime could start off on the following bases:⁴⁹

1. *The members of the Paris Union for the Protection of Industrial Property*

and the World Intellectual Property Organization should assure nationals of member countries adequate and effective protection against misappropriation and unfair use of Traditional Knowledge (TK)

2. *Any use of TK against honest practices in cultural, industrial or commercial matters should be considered as actions in breach of paragraph one.*
3. *TK holders should in particular be provided with effective means to ensure that:*
 - (i) *the principle of prior informed consent applies to access to TK, benefits arising from certain uses of TK are fair and equitable shared,*
 - (ii) *all acts of such a nature as to create confusion by any means whatever with the origin of the TK are repressed, and*
 - (iii) *all acts of such a nature that would be offensive for the holder of the TK are repressed.*

Moral rights are provided in Article 6*bis* of the Berne Convention for the Protection of Literary and Artistic Works. Moral rights usually consist of the right of authors to be identified as such (sometimes referred to as the right of paternity), and to object to having their works altered in ways that would prejudice their honour or reputation (the right of integrity).⁵⁰

It could be argued that free-riding on the knowledge, cultural works, and expressions of traditional communities who are not themselves interested in commercialising them does no direct harm. Consequently, the doctrine of misappropriation does not apply to such acts. But is it really the case that there are no victims? One could reply that such behaviour infringes on certain cultural rights that these communities are entitled to enjoy. Lyndel Prott, formerly of UNESCO, identified a set of individual and collective rights that could be described as "cultural rights," and which are supported to a greater or lesser extent by international law.⁵¹ Of these, the following (of which only the first is an individual right) stand out in light of the present discussion:

- *the right to protection of artistic, literary and scientific works*
- *the right to develop a culture*
- *the right to respect of cultural identity*
- *the right of minority peoples to respect for identity, traditions, language, and cultural heritage;*
- *the right of a people to its own artistic, historical, and cultural wealth*
- *the right of a people not to have an alien culture imposed on it.*

To the extent that unauthorised or improper use of a cultural group's artefacts and expressions imbued with cultural, spiritual or aesthetic value erodes the integrity of the culture of origin, it is reasonable to treat such uses as manifestations of a form of misappropriation that the law should arguably provide remedies for.

Disclosure of origin

"Disclosure of origin" has become a collective term for certain requirements to be incorporated into patent law. A great deal of work has been carried out in intergovernmental organisations and forums. These requirements vary widely in terms of the weight and nature of the legal, administrative or informational burdens placed on patent applicants and owners. Accordingly, it is convenient to describe three types of disclosure requirement.

Version one – "voluntary disclosure"

The least burdensome of these types is to encourage the disclosure of genetic resources and/or traditional knowledge relevant to an invention being patented. Its omission would not disqualify the patent application from being accepted, being granted, or being subsequently enforced. In other words non-compliance gives rise to no legal consequences. Such disclosure aims to serve the purpose of enhancing transparency in terms of international commercial transfers of genetic resources and traditional knowledge.

Version two – "mandatory disclosure"

A closely related incarnation of disclosure of origin would be to make this requirement mandatory, with failure to disclose or dishonest disclosure having one or some of the following consequences: the patent application would not be accepted; it would be rejected during the prosecution stage; if granted it would not be enforceable; or if granted it would be revoked with possible criminal sanctions for wrongdoers.

The burden of compliance is placed on the patent applicants and the patent granting offices. The role of provider country governments would be to monitor compliance and take legal action in cases of alleged non-compliance.

In the case of both types of disclosure requirement, what is being proposed, one presumes, is that the country providing the resource should be disclosed whether or not it is the country of origin. In other words, it is the country of *source* that should be disclosed.

Version three – "proof of legal acquisition"

A somewhat different version of the disclosure of origin requirement would tie the patent system more closely to the CBD's ABS provisions, in particular to the ABS regimes operating in those countries *directly* providing the genetic resources and/or traditional knowledge. One way to implement this is to require patent applicants to submit with their application official documentation from provider countries proving that genetic resources and - where appropriate - associated TK were acquired in accordance with the ABS regulations including conformity with such obligations as prior informed consent, with the terms mutually agreed between providers and the recipients, and with the need to comply with CBD Article 8(j) on the knowledge, innovations and practices of indigenous and local communities.

To harmonise the rule and make the requirement operate more effectively, there could be an international certification of origin system. The Bonn Guidelines on Access to Genetic Resources

and Fair and Equitable Sharing of the Benefits Arising out of their Utilization refer to “a legally recognized certification of origin system as evidence of prior informed consent and mutually agreed terms”. The idea here is that if provider countries were to agree on some common requirements and procedures, standardised certificates of origin could be used which all national and regional patent offices would recognise. The COP and the ABS Working Group is discussing ways to incorporate a certification of origin system in the International Regime.

Which is better?

Personally, I feel sceptical about the first two types of disclosure requirement, and, *with certain qualifications* would advocate the third. On the basis of past experiences, imposing an obligation on patentees to disclose in the specification the origin of genetic resources and/or traditional knowledge relevant to the invention would produce modest results in terms of (i) improving patent quality, and of (ii) preventing the unauthorised appropriation and commercialisation of biodiversity.

One reason is that so many resources and so much traditional knowledge related to patents are acquired or is learned about without having to go to any of the countries of origin or source. Therefore, the measure would apply to quite a small number of patents.

More seriously (in the sense that the first problem is common to all three types), the inclusion of such information may not be very relevant to the standard criteria of novelty and inventive step and so their absence may not be noticeable to patent examiners or to anybody else including NGOs. Besides, it may prove difficult to agree on what exactly should be the relationship between the invention and the biogenetic resource and/or associated traditional knowledge for disclosure of origin to apply. In many cases, knowledge and material relevant to an invention may be manifold. Should all sources of knowledge and material be compensated no matter how distant and tangential? This might be hard to justify and to achieve a consensus upon.

It may be worth noting too that if all countries of origin had to be disclosed this might require access to biogeographical information that may not be readily available. Aside from this practical issue, one may reasonably wonder, if we are dealing with *origin* as opposed to *source*, how several countries that could legitimately claim to be countries of origin of the same resource might wish to respond to the patenting of an invention based upon it.

Proof of legal acquisition seems to have more promise as an effective measure in terms of encouraging equitable processes and outcomes to the economic benefit of both providers and users. Admittedly, the fact that so many resources and so much traditional knowledge related to patents are acquired or is learned about without having to go to any of the countries of origin or source would also limit its application. But linking the patent right to the legality of the acquisition of the relevant resources or knowledge appears to have some practical advantages.

First, as a legal requirement implemented as an administrative measure rather than as part of the substantive examination it leaves examiners to apply the standard tests of patentability (i.e. novelty, inventive step and industrial applicability) in the normal way. As recent complaints about low patent quality in the United States tend to indicate, this is difficult enough. It is true that improving access to information about traditional knowledge could certainly help improve patent quality. But it is less clear to me that the *geographical origin* of a chemical substance that was subsequently modified by an inventor has anything necessarily to do with determinations of novelty or inventive step. Therefore, expecting a patent examiner to heed such a consideration as part of his work adds to his workload without making his job easier in any other way.

Second, proof of legal acquisition avoids the difficult technical, and arguably somewhat philosophical, question of how closely related the genetic resource and/or traditional knowledge should be to the invention which is the subject of the patent application for the requirement

to apply. Bioprospecting and genetic resource export permits issued by governments under their ABS regulations should simply require that *all* patent applications submitted within say 10-20 years of the permit being granted for inventions resulting from the material and information acquired be accompanied by: (i) a declaration from the applicant stating that the relevant ABS rules of the provider country were complied with; and (ii) a copy of the bioprospecting/export permit. Provider countries might wish to consider amending their ABS rules to impose such an obligation (or to make it more explicit).

The patent granting office would record receipt of the application *and* items (i) and (ii). The patent examiner would not even need to be aware of the declaration or permit copy and would be left to examine the application in the normal way. The granting office would notify the competent authority of the provider country that the patent application had been received. It is submitted that such a procedure would not be burdensome for the patent granting office. Again, the country where the patent granting office is located may need to amend its relevant legislation, although it may only require modest reform of the office's internal regulations. However, to be truly effective, the legal means should be made available to allow governments who consider a foreign patent they were not notified about may have been for an invention resulting from resources or traditional knowledge acquired under their ABS regulations to challenge the patent's legality in the jurisdiction in which it was granted.

The third advantage of proof of legal acquisition is that it can respond to but at the same time move beyond concerns about misappropriation and encourage the kinds of scientific research partnerships that can benefit developing countries rich in biological and genetic resources but still lacking the technological capacity to exploit them effectively. The CBD seeks among other things to encourage fair, transparent and mutually beneficial partnerships between providers and users of benefit to all parties. If life science and biotechnology businesses want

access to genetic resources and traditional knowledge they must understand they have to accept the rules of the provider countries. Proof of legal acquisition is hardly an unreasonable or difficult to comply with part of the deal. It may well be a lot easier to comply with than version 2 may on occasions turn out to be. And complying with it may be very good for the image of the companies concerned who in doing so will show that they are a business to be trusted.

Admittedly, there are drawbacks with version 3. One of these is that it would not apply to cases of patenting where genetic material and traditional knowledge were acquired not through bioprospecting but *ex situ* collections and literature searches. On the other hand, mandatory disclosure of origin could still require the source of genetic resources and traditional knowledge to be indicated even if only by citing the relevant journal articles or books. Of course, *versions 2 and 3 are not mutually exclusive and may in fact be mutually reinforcing*. Another drawback is that proof of legal acquisition is less appropriate for patents claiming new plant varieties. ABS regulations tend to be targeted towards pharmaceutical bioprospecting and are not sensitive to the specificities of plant breeding. On the other hand, most seed companies appear to be comfortable with version 2.

Is it a good idea anyway?

Versions 2 and 3 could probably operate quite well for resources with health applications, especially pharmaceuticals. The pharmaceutical industry generally bases its new drugs on single compounds. Tracing and declaring the sources of these should not normally be a particularly onerous task if version 2 were the chosen option. For version 3, the task of compliance would be even simpler. The measure would still need to determine the extent to which the obligation would extend to synthetic compounds derived from or inspired by lead compounds discovered in nature. It should be noted that the industry is not favourable to disclosure of origin, whereas the seed industry, with the possible exception of the bigger firms, is better disposed towards the requirement and is confident that compliance

would not present great difficulties. Having made that point, though, the latter industry is not much interested in bioprospecting. And the little interest it has may evaporate if it has to comply with ABS regulations in the same way that pharmaceutical firms have to.

But in the case of plant varieties, which can be patented in some countries, genetic material may come from numerous sources. Consequently, the value of individual resources is relatively low. In addition, the seed industry is much smaller than the pharmaceutical industry and will never generate as many benefits to share anyway. So for plant varieties developed through conventional breeding methods, any version of disclosure of origin may produce little benefit to developing countries. But in any case, patenting of plant varieties is bad policy. Plant variety protection should be left to UPOV and other sui generis IPR systems.

So perhaps version 3 should apply to genetic resources and traditional knowledge for all applications and business sectors other than food and agriculture. Resources and knowledge in the latter categories should be dealt with under the multilateral system of facilitated access established by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Why? because facilitated access to plant genetic resources for food and agriculture of those crop species covered under the multilateral system is to be subject to a standard material transfer agreement (MTA), which will require benefits to be shared from the use, including commercial use, of the resources acquired, and is far more appropriate

7.4 Some words of caution

A poorly designed international sui generis system may turn out to be useless or even dysfunctional. Consider that indigenous peoples and traditional communities make up most of the world's cultural, intellectual and jurisprudential diversity. A legal system that works for a group inhabiting a valley in the Upper Amazon may be totally inappropriate for another group in Siberia or even in a neighbouring valley. But for a common international regime to provide

for scientific, commercial and food security reasons.

One of the practical complications in the version 3 context is that many countries still do not have ABS regulations. If the patent must be accompanied by official documentation from the source country, no authority may exist to provide it. In this case, presumably the requirement for a certification would have to be waived. But if so, what is to stop a company from claiming that a resource was obtained from such a country when it was actually collected illegally from another country with ABS regulations?

Clearly, none of the above proposals is going to prevent all misappropriation of genetic resources and traditional knowledge. And neither is a substitute for competent substantive examinations of patent applications. However, countries that are net exporters (whether voluntarily or otherwise!) of genetic resources and traditional knowledge probably have more important things to think about than trying to eradicate inappropriate patenting. Such efforts should be no more than a means to such higher ends as technological capacity building, local and national economic development and poverty alleviation. How can disclosure of origin pursue such ends? Proof of legal acquisition, in my view, is the best option first and foremost because it has the potential to link the acquisition and deployment of important business assets (i.e. patents) to sustainable development in a way that versions 1 or 2 can do only in a very indirect way.

effective international legal protection in foreign jurisdictions, a certain degree of harmonisation would probably be necessary. And a harmonised system cannot easily accommodate diversity. The result may be a regime that is appropriate to no culture and is therefore useless.

On the other hand, a legal system tailored to the specificities of a few prominent ethnic groups may well alienate other indigenous peoples,

constituting another case of “globalised localism” to be added to intellectual property rights, which are really just European legal models that have been exported around the world including to countries of the world and cultures that may actually have little use for most of them.

It must also be cautioned that devising the most sophisticated and elaborate IPR system will have little or no impact if the potential users and beneficiaries are unaware of its existence and/or have more immediate concerns such as extreme poverty, deprivation and societal breakdown caused by the insufficient recognition of their basic rights. It will also fail if it does not take their world views and customary norms into account.

Principally, traditional knowledge and technology protection for many indigenous groups is likely to work only with secure land rights. Groups empowered with rights to control access to their lands and communities are far better placed to benefit from legal protection of their

knowledge. In fact, it is probably indispensable. In many parts of the world, indigenous groups are being expelled from their ancestral lands. Demanding legal protection of their knowledge without doing anything about this problem is futile if not perverse.

But even this may not be enough. Groups and individuals that have control over their own destinies are far better placed to benefit from legal protection of their knowledge. For example, indigenous groups empowered with rights to control access to their lands and communities have a better chance of preventing misappropriation of their knowledge and negotiating favourable bioprospecting arrangements. But in all too many cases, indigenous groups and TK holders suffer from extreme poverty, ill health, unemployment, lack of access to land and essential resources, and human rights violations. With so many immediate problems awaiting a solution, there are serious limits to what can be achieved in Geneva.

PART 4: PATHWAYS TO THE FUTURE

8 TOWARDS A POSITIVE AGENDA ON TK PROTECTION

8.1 What should we negotiate ...?

In concluding this study, two important questions arise in international negotiations that need to be considered carefully. First, should efforts be devoted to developing a national *sui generis* system first in order to gain experience that makes it easier to determine what a workable international solution should look like, or is a multilateral settlement a pre-condition for the effective protection of the rights of TK holders in any country? Second, how might concerned countries overcome the limitation with national *sui generis* systems to protect TK, which is that they will have no extra-territorial effect?

Should efforts be devoted to developing a national *sui generis* system first in order to gain experience that makes it easier to determine what a workable international solution should look like? Or is a multilateral settlement a pre-condition for the effective protection of the rights of TK holders in any country? And what kind of a multilateral settlement is feasible anyway?

While each country will no doubt come up with good reasons to answer these questions differently, there seems to be a consensus among countries supporting *sui generis* systems of positive protection and groups representing TK holding people and communities that the problem with having a national system in a world where few such systems exist is that no matter how effective it may be at the domestic level, it would have no extra-territorial effect. Consequently, TK right holders would not be able to secure similar protection abroad, and exploitative behaviour in other countries would go on as before.

There may be a way out of this problem. If a group of concerned countries decided to act strategically as a group, some interesting

possibilities could emerge. Members of such a group could agree upon harmonised standards and then apply the reciprocity principle so that protection of TK would only be extended to nationals of other members. Of course, the group should not be an exclusive club. Other interested countries should also be able to join subject to their enactment of similar legislation. As a new category of intellectual property not specifically provided in TRIPS, the members would presumably not have to comply with the most-favoured nation (MFN) principle. In other words, the preferential treatment afforded to nationals of group members would not have to be extended to non-group members who might then feel encouraged to sign up to the same standards and thereby enjoy the same treatment.

This seems like a good way to move forward. Concerned countries should not wait for solutions to emerge from Geneva. Rather they should also collaborate among themselves.

There are precedents for adopting the reciprocity principle in place of MFN. In fact, the developed countries have been the main precedent-setters. The United States successfully used the reciprocity principle in its Semiconductor Chip Protection Act to encourage other countries to enact similar legislation. The European Union is doing the same with its 1996 Directive on the Legal Protection of Databases, which is quite controversial in this regard. To own the rights defined under the Directive, database makers or right holders must be nationals or residents of an EU member state, or in the case of a company, it must have offices in a member state and be genuinely linked with the economy of a member. Non-qualifying makers such as foreigners who produce their databases in another part of the world will only acquire protection if there is an

agreement between the European Union and the relevant country to extend protection to their nationals. This is likely to require the country also to establish a similar system and to allow nationals of EU members to secure protection in return. The 1978 Act of the UPOV Convention even more explicitly allows members to apply the reciprocity principle. According to Article 3, any UPOV member “applying this Convention to a given genus or species shall be entitled to limit the benefit of the protection to the nationals of those member States of the Union which apply this Convention to that genus or species and to natural and legal persons resident or having their registered office in any of those States.”

In conclusion, the following list of key points is provided for the consideration of negotiators and policy makers:

- Act on the understanding that different countries have varied interests and concerns in respect of traditional knowledge and technologies and also that their positions may be based on quite different assumptions and ideological standpoints concerning traditional knowledge (TK) and technologies and TK-holding groups.
- Urgent as it is to respond to the loss of TK, do not expect early solutions to this issue. Devising workable measures and achieving consensus on their adoption will take a long time given the complexity of the issue, the stakes involved and the conflicting interests of the various “stakeholders”.
- Avoid or discourage protracted discussions on the applicability of existing IPRs to traditional knowledge, technologies and cultural works and expressions, and on the “need” to define traditional knowledge and technologies first before solutions may be formulated.
- Conduct studies to estimate the costs of implementing proposals or measures to protect traditional knowledge and technologies and weigh these against the benefits that can realistically be gained *before* deciding to actively pursue them in international forums.
- Ensure that national policies and multilateral-level negotiating positions and strategies are consistent, coherent and mutually supporting.
- Encourage the active participation of traditional knowledge and technology holders and traditional communities in both the formulation of national policies and of multilateral negotiating positions.
- Place the interests of indigenous peoples and traditional communities at the centre of all negotiating strategies on traditional knowledge and technologies.
- Be aware that many otherwise sympathetic people oppose the creation of new property regimes on the grounds that they will shrink the public domain. Therefore, it may be necessary to emphasise that a *sui generis* system based upon customary law would not enclose part of the knowledge commons but would merely recognise property rights that already exist but which are not respected.

8.2 ... and where should we do it? the case for better forum management

The fact that TK and (albeit to a lesser extent) TCEs are now being discussed in so many different international forums means there are both opportunities and challenges. Opportunities arise from the fact that these topics are now the subject of substantive proposals in various forums which have the broad support of many countries. On the other hand, handling the TK issue is complicated by the number of forums

in which it is being discussed and by the need to be consistent, far-sighted and aware of the stakes involved. Consistency is important because government representatives can sometime express contradictory positions on the same subject in different forums. Some of these positions may be ill-informed and inimical to the national interest. The more forums there are, the greater is the danger of this happening.

Adopting a long-term vision is essential. When it comes to TK, clear and realistic goals must be formulated based on an informed calculation of what is necessary and feasible. As for the stakes involved, these are very high in the case of the WTO, where a diverse range of trade-related complaints and demands are bartered between different countries.

Each interested country needs to calculate how important a settlement on TK is as compared with the counter-demands from other countries in exchange for a deal on TK, and whether a compromise would be worthwhile or not. It seems that the WTO is not the most promising place to achieve meaningful gains on TK though it is of course *the* appropriate forum to register specific concerns about the intellectual property rules of the multilateral trading system, of which the failure to protect TK is an important example of their lack of balance. But the price of victory may be very heavy in terms of what interested countries might have to concede in return.

The Conference of the Parties to the CBD has already proved to be quite a fruitful forum for generating progressive decisions and proposals. It is probably not coincidental that it is a relatively open forum where non-governmental organisations including those representing indigenous peoples and local communities can communicate their views directly to delegates, who are in many cases very receptive to their suggestions and proposals. However, these decisions and proposals are not legally binding and it remains doubtful whether the parties will adopt any substantive binding norms on TK. But it is important to bear in mind that while COP decisions are not legally binding, they represent the consensus of participating contracting parties. As such, they may be used to support demands made in other forums such as the Council for TRIPS and WIPO, which is to some extent collaborating with the COP, and perhaps may have some limited effect.

To achieve genuine solutions on TK, though not necessarily on related issues, the WIPO IGC seems at the present time to be the most promising place. It is not as open as the COP

to non-governmental stakeholders including TK holders, a situation that needs to be resolved urgently for the sake of its credibility. Moreover, its long-term future is very uncertain. However, the IGC's discussions so far have been substantial and constructive. The possibility exists for some legally binding norms to be adopted if enough developing countries can agree on what these norms should be and are willing to act together. Because evaluating proposals for such norms may be difficult and will probably take quite a lot of time including domestic consultations with stakeholders and experts, this may involve a lengthy process. This is no bad thing. While the loss of TK is an urgent problem, it is still better to spend time developing effective norms than to rush into the adoption of ones that seem attractive on paper but turn out to be ineffective or even counterproductive.

Finally, a warning seems in order concerning bilateral and regional free trade and investment agreements. These have proved to be a useful way for the United States and the European Union to get individual, or sometimes groups of, developing countries seeking enhanced access to developed countries markets to introduce provisions that go beyond what TRIPS requires. The United States and the European Community both use this strategy, but the USA has been the more aggressive. Such TRIPS plus provisions include: (i) extending patents and copyright to new kinds of subject matter; (ii) eliminating or narrowing permitted exceptions including those still provided in US and European IP laws; (iii) extending protection terms; and (iv) ratifying new WIPO treaties containing TRIPS plus measures.

While such agreements make it theoretically possible for developing country negotiators to bind the US and Europe to measures that further their interests, they seldom achieve any concessions at all in IP. Consequently, the danger exists that the US in particular will use these trade agreements to get developing countries to abandon their demands concerning traditional knowledge and genetic resources in exchange for advantages in other areas of trade.

Some might consider a case in point to be the 2006 Peru-US Trade Promotion Agreement. The Agreement was accompanied by a document called the “Understanding regarding biodiversity and traditional knowledge”. According to the Understanding, “the Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development.” They also recognise the importance of

- (1) obtaining informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority;
- (2) equitably sharing the benefits arising from the use of traditional knowledge and genetic resources; and
- (3) promoting quality patent examination to ensure the conditions of patentability are satisfied.

These are important concessions on the part of the United States. However, “recognising the importance of” is hardly the language of a legally binding commitment. Moreover, the Understanding goes on to state that “the Parties recognize that access to genetic resources or traditional knowledge, as well as the equitable sharing of benefits that may result from use of those resources or that knowledge, can be adequately addressed through contracts that reflect mutually agreed terms between users and providers.” This indicates agreement that contracts are sufficient to meet the needs of genetic resource provider countries and TK holding communities.⁵² Not surprisingly, the US has consistently argued that the use of contracts makes it unnecessary to adopt new multilateral norms and reforms to the international IP regime aimed at regulating access and benefit sharing. But at least there is nothing in the Understanding that prevents Peru from taking the measures it has already undertaken domestically and regionally and is proposing at the multilateral level.

ENDNOTES

- 1 University of London Press, Limited v. University Tutorial Press, Limited [1916], 2 Ch 601.
- 2 World Health Organization, International Union for Conservation of Nature, and World Wide Fund for Nature (1993) *Guidelines for Conservation of Medicinal Plants*, Gland: IUCN.
- 3 E.g. Richards, P. (1999) "Casting seeds to the four winds: a modest proposal for plant genetic diversity management", in Posey, D.A. (ed) *Cultural and Spiritual Values of Biodiversity*, Nairobi & London: UNEP & IT Publications, 315-16.
- 4 United Nations Conference on Trade and Development (2000) Systems and national experiences for protecting traditional knowledge, innovations and practices. Background note by the UNCTAD Secretariat, UNCTAD, Geneva.
- 5 Genomics refers to the mapping, sequencing and analysis of the full set of genes (i.e. the genome) of different organisms or species. The human genome has always been the most interesting for governments and foundations, as well as for companies seeking to identify commercial applications.
- 6 The proteome is the 'protein complement encoded by a genome', and consists of three activities: 'identifying all the proteins made in a given cell, tissue or organism; determining how these proteins join forces to form networks akin to electrical circuits; and outlining the precise three-dimensional structures of the proteins in an effort to find their Achilles heel - that is, where drugs might turn their activity off or on'. Ezzell, C (2002) "Proteins rule". *Scientific American*, 286(4), pp 26-33, 28.
- 7 RNA (ribonucleic acid) interference ('RNAi'), or 'gene silencing', is a method of disrupting the body's production of proteins associated with diseases.
- 8 Dutfield, G. (2004) *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, London: Earthscan Publications.
- 9 Ten Kate, K and Laird, S A (1999) *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing*, Earthscan, London, at 50, 57.
- 10 Gupta, A.K. (1999) "Making Indian agriculture more knowledge intensive and competitive: the case of intellectual property rights". *Indian Journal of Agricultural Economics*, 54(3), pp 342-369.
- 11 See <http://www.nifindia.org>.
- 12 Fowler, B.J. (2004) "Preventing counterfeit craft designs", in Finger, J.M. and Schuler, P. (eds), *Poor People's Knowledge: Promoting Intellectual Property in Developing Countries*, Washington DC: The World Bank, pp.113-131.
- 13 Dutfield, G. [lead author] (2003) *Intellectual Property Rights: Implications for Development*, Geneva: UNCTAD & ICTSD.
- 14 Business Day (Johannesburg), 21 November 2002; Daily News (Harare), May 14, 2003.
- 15 The distinction I seek to draw between misappropriation and unfair free-riding is that with misappropriation, there must be victims as well as beneficiaries for the word to apply. However free-riding is not necessarily harmful to anybody, and there is likely to be considerable disagreement about where to draw the line between fair and unfair free-riding.
- 16 It may be able to if it can describe a specific formulation, even in fairly non-technical terms.
- 17 In some circumstances this may be allowable under the US patent system.
- 18 See Chen, J.(2005) "There's no such thing as biopiracy ... and it's a good thing too". 36 *McGeorge Law Review*.
- 19 See Posey, D.A. (2002) "Selling Grandma: commodification of the sacred through intellectual property rights", in Barkan, E. and R. Bush (eds), *Claiming the Stones/Naming the Bones: Cultural Property and the Negotiation of National and Ethnic Identity*, Los Angeles: Getty Research Institute.

- 20 Most recently see WIPO (2005) "Patent system and the fight against biopiracy: the Peruvian experience. Document submitted by Peru" [WIPO/GRTFK/IC/8/12].
- 21 Wolfe, T.A. & B. Zycher (2005) *Biotechnological and Pharmaceutical Research and Development Investment under a Patent-based Access and Benefit Sharing Regime*. San Francisco: Pacific Research Institute. <http://www.pacificresearch.org/pub/sab/health/2005/ABS.pdf>
- 22 "Biotech industry fights disclosure in patents on three IP policy fronts". *Intellectual Property Watch*. 2 March 2006. <http://www.ip-watch.org/weblog/index.php?p=235&print=1&res=1280&print=1>
- 23 There have been complaints from many quarters that the US patent system is becoming a de facto registration system that filters out very little in the way of the old and the blindingly obvious. Furthermore, the inequitable conduct doctrine, which can lead to judgments making patents unenforceable, is another potential source of uncertainty for patent holders that is specific to the US patent system.
- 24 As of March 2006, the CBD has 188 state parties including the European Union.
- 25 In Secretariat of the Convention on Biological Diversity (2002), "Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity" [UNEP/CBD/COP/6/20].
- 26 Paragraph 16(d)(ii).
- 27 Paragraph 43(c) and (d).
- 28 WIPO, "Examination of issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications." Transmitted by the General Assembly of the World Intellectual Property Organization (WIPO) to the Conference of the Parties of the Convention on Biological Diversity by the decision of the General Assembly at its Thirty-Second Session, September 26 to October 5, 2005. This third draft of the technical study is annexed to document WO/GA/32/8.
- 29 See Sarnoff, J.D. and Correa, C.M. (2006) *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, Geneva & New York: United Nations.
- 30 This body was established by the COP in 1998.
- 31 Ibid.
- 32 WIPO/GRTKF/IC/3/8. An updated version was prepared for the following IGC: WIPO/GRTKF/IC/4/8.
- 33 WO/GA/30/8, 2003.
- 34 As revised for the eighth session of the IGC. See annex to document WIPO/GRTKF/IC/8/5, 2005 and reproduced in annex to document WIPO/GRTKF/IC/9/5, 2006.
- 35 As revised for the eighth session of the IGC. See annex to document WIPO/GRTKF/IC/8/4, 2005 and reproduced in annex to document WIPO/GRTKF/IC/9/4, 2006.
- 36 WIPO/GRTKF/IC/9/12, 2006.
- 37 IP/C/W/356.
- 38 These are summarised and listed in IP/C/W/368/Rev.1, 2006. Also, see <http://www.iprsonline.org/submissions/article273.htm>.
- 39 WT/GC/W/564.
- 40 For economic analysis and a detailed blueprint for applying a compensatory liability regime to applications of traditional knowledge, see Lewis, T. & J.H. Reichman (2005) "Using liability rules to stimulate local innovation in developing countries", in K.E. Maskus and J.H. Reichman, *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge: Cambridge University Press.
- 41 Four Directions Council (1996) "Forests, indigenous peoples and biodiversity. Contribution of the Four Directions Council to the Secretariat of the Convention on Biological Diversity", Lethbridge: FDC.

- 42 Sheleff, L. (1999) *The Future of Tradition: Customary Law, Common Law and Legal Pluralism*, London & Portland: Frank Cass.
- 43 Correa, C.M. (2001) "Traditional knowledge and intellectual property: issues and options surrounding the protection of traditional knowledge". Quaker United Nations Office Discussion Paper 18.
- 44 Convention on Biological Diversity—Conference of the Parties, Decision V/16 (2000), available at <http://www.biodiv.org/convention/cops.asp#>.
- 45 United Nations Economic and Social Council, Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples, U.N. Doc. No. E/CN.4/Sub.2/1995/26, annex 1 (21 June 1995).
- 46 As revised for the eighth session of the IGC. See annex to document WIPO/GRTKF/IC/8/5, 2005.
- 47 "Eligibility for protection of traditional knowledge against acts of misappropriation should not require any formalities."
- 48 Arts. 22.2(b), 39.1.
- 49 Norway (WIPO/GRTKF/IC/9/12, para. 38).
- 50 Berne Convention, *id.* art. 6*bis*(1) provides:
"Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honour or reputation."
- 51 Prott, L.V. (1998) "Cultural rights as peoples' rights in international law", in Crawford, J. (ed), *The Rights of Peoples*, Oxford: Clarendon Press.
- 52 For a more positive opinion on the Understanding than the one expressed here, see Ruiz, M. (2006) "The not-so-bad US/Peru side letter on biodiversity". *Bridges* 10(1), 18-20.

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