UNCTAD-ICTSD Project on IPRs and Sustainable Development



Protecting Traditional Knowledge and Folklore

A review of progress in diplomacy and policy formulation

By Graham Dutfield Senior Research Associate, ICTSD and Academic Director of the UNCTAD - ICTSD Project on IPRs and Sustainable Development

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International Centre for Trade and Sustainable Development (ICTSD)
International Environment House
13 chemin des Anémones, 1219 Geneva, Switzerland
Tel: +41 22 917 8492 Fax: +41 22 917 8093
E-mail: ictsd@ictsd.ch Internet: www.ictsd.org

United Nations Conference on Trade and Development (UNCTAD)
Palais des Nations
8-14, Av. de la Paix, 1211 Geneva 10, Switzerland
Tel: +41 22 907 1234 Fax: +41 22 907 0043
E-mail: info@unctad.org Internet: www.unctad.org

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For details on the activities of the Project and all available material, see http://www.ictsd.org/iprsonline

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ABOUT THE AUTHOR

Graham Dutfield, Senior Research Associate at ICTSD and Academic Director of the ICTSD-UNCTAD project on IPRs and Sustainable Development, is a recognised international expert in the field of IPRs and traditional knowledge. He is also a Senior Research Fellow in Intellectual Property Law at the Queen Mary College, University of London

FOREWORD

The present paper dealing with Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation is one contribution of the joint UNCTAD-ICTSD Project on Intellectual Property Rights (IPRs) and Sustainable Development to the ongoing debate on the impact and relevance of intellectual property to development. It analyses the proposals made by developing countries in several international fora (WTO, CBD and WIPO) with respect to the protection of traditional knowledge (TK). These proposals refer to "defensive" protection on the one hand, and to "positive" protection on the other hand. The former kind of protection responds to developing countries' concerns about their knowledge or cultural expressions being subject to monopolization and commercialisation through IPRs to the advantage of unauthorized persons, without sufficient opportunity for their indigenous communities to obtain an equitable share in the resulting benefits. In the context of defensive protection, one major proposal relates to the introduction of a disclosure of origin requirement into patent law to assure a fair participation by the holders of TK in any benefits arising from the commercialisation of their knowledge. The study points out ways to design such a requirement in TRIPS-compatible forms. It then assesses critically the practical use of the second major proposal, relating to the establishment of TK prior art databases.

As to "positive" protection, the study discusses possibilities for TK holders themselves to obtain an IPR to make effective use of their knowledge. The author explains the advantage of a liability regime of protection over a property-based system in those countries where TK is already in wide circulation and may therefore only be subject to subsequent compensation rather than to a right of exclusivity. In order to assure the secrecy of certain TK and to protect it from unfair commercial use, positive protection of TK could also be achieved through the establishment of database rights, modelled after the protection of undisclosed information under Article 39.3 of the TRIPS Agreement. Finally, a proposed way of reducing transaction costs and improving the international enforcement of rights over TK is the establishment of global biocollecting societies that would, in addition to serving as a repository of TK registers, provide a range of other services.

The study concludes by making a number of strategic considerations as to how developing countries could possibly proceed in their efforts to protect TK on the international level. In essence, the author puts emphasis on the importance of concerted action between groups of like-minded developing countries. However, the paper also highlights the limitations of any harmonization effort, noting the need to respect the tremendous jurisprudential diversity of traditional societies.

Intellectual property rights (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, traditional knowledge, biodiversity, biotechnology, the Internet, the entertainment and media industries. In a knowledge-based economy, there is no doubt that an understanding of IPRs is indispensable to informed policy making in all areas of human development.

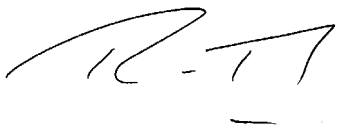
Intellectual Property was until recently the domain of specialists and producers of intellectual property rights. The TRIPS Agreement concluded during the Uruguay Round negotiations has signalled a major shift in this regard. The incorporation of intellectual property rights into the

multilateral trading system and its relationship with a wide area of key public policy issues has elicited great concern over its pervasive role in people's lives and in society in general. Developing country members of the World Trade Organization (WTO) no longer have the policy options and flexibilities developed countries had in using IPRs to support their national development. But, TRIPS is not the end of the story. Significant new developments are taking place at the international, regional and bilateral level that build on and strengthen the minimum TRIPS standards through the progressive harmonisation of policies along standards of technologically advanced countries. The challenges ahead in designing and implementing IP-policy at the national and international levels are considerable.

Empirical evidence on the role of IP protection in promoting innovation and growth in general remains limited and inconclusive. Conflicting views also persist on the impacts of IPRs in the development prospects. Some point out 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 stress that intellectual property, especially some of its elements, such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers.

It is urgent, therefore, to ask the question: How can developing countries use IP tools to advance their development strategy? What are the key concerns surrounding the issues of IPR 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 they have the capacity, especially the least developed among them, to formulate their negotiating positions and become well-informed negotiating partners? These are essential questions that policy makers need to address in order to design IPR laws and policies that best meet the needs of their people and negotiate effectively in future agreements.

It is to address some of these questions that the joint UNCTAD-ICTSD Project on Intellectual Property and Sustainable Development was launched in July 2001. 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 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.



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EXECUTIVE SUMMARY

Traditional knowledge (and to a certain but lesser extent folklore) and its relationship to the formal IPR system has emerged as a mainstream issue in international negotiations on the conservation of biological diversity, international trade, and intellectual property rights including the TRIPS Agreement. In the past few years, high-level discussions on the subject have been taking place at the WTO, the Conference of the Parties to the Convention on Biological Diversity (CBD), and at the World Intellectual Property Organization (WIPO) which has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Several developing country governments in these forums have adopted the view that TK and folklore need to be protected legally, and have criticised the formal IPR system for legitimising their misappropriation. The question that many seek answers to is what should be done?

Solutions to the protection of traditional knowledge in IPR law may be sought in terms 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. 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 and NGOs, 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.

Defensive Protection

Two important proposals have come out of international negotiations to provide defensive protection of TK through the patent system. The first is to require patent applicants to disclose the origin of genetic resources and associated TK relevant to the invention and, according to one variant of the proposal, to provide proof that regulations governing the transfer of the resources and associated TK were complied with. The second is to compile databases of published information on TK for patent examiners to identify potentially novelty-destroying prior art. In addition, a promising alternative approach may be to develop a misappropriation regime.

Disclosure of Origin

The compulsory disclosure of genetic resources and associated TK in patent applications was originally mooted by civil society organisations. The proposal is intended to help realise fair and equitable benefit sharing as required by the CBD. It is supposed to do this by ensuring that the resources and TK were acquired in accordance with biodiversity access and benefit sharing regulations in the source countries. Proposals relating to disclosure have weak, medium and strong forms. The weak form is that such disclosure would be encouraged or even expected but not required and its omission would not disqualify the patent from being granted. The medium form is that disclosure of origin would be mandatory.

The strong form goes beyond disclosure in the patent specification to require that patent applicants comply with the CBD's access and benefit sharing (ABS) provisions. One way to implement this is to establish a certification of origin system according to which applicants would have to submit 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 and benefit sharing. Applications unaccompanied by such documentation would automatically be returned to the applicants for re-submission with the relevant documentation.[1]

Two questions arise here. First, is compulsory disclosure of origin incompatible with TRIPS? Second, is it actually a good idea anyway? The answer to the first question depends upon whether we are talking about the weak, medium or strong versions. Clearly there is no problem whatsoever with the weak version. As for the medium version, it is difficult to accept the view that this establishes another substantive condition. One can easily argue that such disclosure of TK is essential for a full description of how the invention came about. In addition, by helping to describe the prior art against which the purported inventive step needs to be measured its disclosure ought to be required anyway. As for the source of the genetic material, it is difficult to see why inventors should not be required to indicate where they got it from and would hardly be burdensome in most cases.

The medium and strong versions would seem to conflict with TRIPS if failure to conform would result in a rejection of the application. To one legal expert, the main issue is what the consequences of non-compliance with a disclosure requirement would be for the patent holder. If the consequence would be a rejection of the application or a post-grant revocation, there would be a conflict. Consequently, the way to avoid a conflict with TRIPS is not to make the disclosure requirement a condition for granting the patent but a condition for its enforceability after it has been granted.[2] The expert suggests that framing the disclosure requirement as a condition for enforcement could be adopted multilaterally in the framework of WIPO and then, perhaps, incorporated into TRIPS.

However, a careful application of the strong version may provide a more satisfactory resolution. There is no compelling reason at all why the compulsory submission of a document

such as a certificate of origin would impose another substantive condition as long as it is not linked to determining the patentability of the invention. After all, examination and renewal fees normally have to be paid by patent applicants and owners, and TRIPS does not prevent them merely because they are not mentioned in the Agreement. Similarly, the submission of documentation attesting to the fact that the applicant had complied with the relevant ABS regulations, such as a certificate of origin, would be just another administrative requirement.

In short, the following interpretation seems plausible: it would not be a violation of TRIPS for countries to require patent applicants (i) to describe the relevant genetic material and TK in the specification and (ii) to submit documentary evidence that the ABS regulations were complied with. But it probably would be to require patent applicants also to disclose the geographical origin of the relevant genetic material and associated TK in the specification. Consequently, imposing such a requirement will entail a revision of TRIPS. Alternatively, these requirements could be introduced outside of the search and examination processes as administrative measures.

The problem is that a patent applicant may be tempted to omit disclosure of the relevant TK. There is no particular reason for an examiner to suppose that a given invention is based on TK unless the applicant discloses the fact. So in most cases his or her suspicions are unlikely to be aroused and the patent will then be granted assuming it is deemed to fulfil the normal requirements.

Turning to the second question, mandatory disclosure 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. 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.

But in the case of plant varieties, which can be patented in some countries, genetic material may come from numerous sources some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programmes. Since new varieties may be based on genetic material from many different sources, 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, the system may be unworkable and may not necessarily benefit developing countries if it were. The patent applicants may simply be unable to comply and the examiners would be unable to verify whether the identities of the countries and indigenous communities of origin have been fully disclosed and are the true ones. It is possible also that the requirement could reinforce the tendency for plant breeders to rely on material in existing collections rather than to

search for hitherto undiscovered resources from the countries of origin. This would have the effect of increasing the genetic uniformity of new plant varieties.

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture may offer a solution. This is 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). The MTA will require benefits to be shared from the use, including commercial use, of the resources acquired. Article 13(d) of the International Treaty requires that "a recipient who commercialises a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to [a financial mechanism to be established] an equitable share of the benefits arising from the commercialisation of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment".

In effect, this means that a recipient that sells a food or agricultural product incorporating material from the multilateral system *must* pay monetary or other benefits from commercialisation under the following circumstance: that he/she owns a patent on the product and – as is normally the case – there is no exemption in the patent law of the relevant jurisdiction that would freely allow others to use it for further research and breeding. If the product is a plant variety protected under an UPOV Convention-type system with such a research exemption, the recipient selling the product would be *encouraged* to pay benefits.

As for the certification of origin system, one of the practical complications 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?

In short, mandatory disclosure and certification of origin are promising ideas that can help enhance compatibility between the CBD and the patent system. But the practicalities still need to be thought out carefully.

TK Prior Art Databases

India has been a particularly strong demandeur on TK databases and has already begun to develop a Traditional Knowledge Digital Library (TKDL), which is a searchable database of already documented information related to traditional health knowledge of the ayurvedic system and to medicinal plants used by practitioners. The government wants to make the TKDL available to patent examiners in India and elsewhere. Clearly, the question of TRIPS

incompatibility does not arise. Such databases would simply be used to improve the efficiency of prior art searches.

But would TK databases actually be useful? They could certainly stop patents like the notorious turmeric one from being granted. It is by no means certain that they would have prevented other controversial patents. They may have narrowed their scope but even this is by no means certain. How would TK have to be described in order to constitute novelty-destroying prior art? Let us consider the example of a patented therapeutic compound isolated from a medicinal plant. Most likely, the examiner will treat the TK relating to the plant as being quite distinct from the chemical invention described in the specification.

In this context, it is important to note that national and regional patent laws vary with respect to how information or material in the public domain should be presented or described in order that they constitute novelty-defeating prior art. For example, the European Patent Convention considers an invention "to be new if it does not form part of the state of the art", which is "held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application". This indicates that articles which are publicly available may form the state of the art whether or not they have been described in writing or even orally. In this context, it is noteworthy that the European Patent Office Technical Board of Appeal has ruled that "the concept of novelty must not be given such a narrow interpretation that only what has already been described in the same terms is prejudicial to it … There are many ways of describing a substance". Furthermore, as two legal authorities explain, "the information disclosed by a product is not limited to the information that is immediately apparent from looking at the product. Importantly, the information available to the public also includes information that a skilled person would be able to derive from the product if they analysed or examined it".[3] This might suggest that patents on isolated therapeutic compounds from medicinal plants may be vulnerable to a challenge on the basis of lack of novelty. However, one should also be cautious about this because "any information that is obtained as a result of an analysis undertaken by a person skilled in the art must be obtained without undue burden or without the need to exercise any additional inventive effort".

This analysis of how Europe defines and assesses novelty-defeating prior art suggests that many so-called biopiracy cases could not be legally challenged there, and that TK databases will make little difference.

Misappropriation Regime

Professor Carlos Correa has proposed the development of a misappropriation regime. He recommends 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.

Arguably, such a misappropriation regime could and probably should incorporate: (i) the concept of unfair competition; (ii) moral rights; and (iii) cultural rights. Unfair competition would deal with situations in which TK holders engaged in commercial activities relating, 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 6bis of the Berne Convention, and 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).

Some might say that free-riding on the knowledge and cultural works and expressions of traditional communities who are not themselves interested in commercialising them does no direct harm. Consequently, misappropriation does not apply to such acts. But is it really the case that there are no victims? One could argue that such behaviour infringes on certain cultural rights that these communities are entitled to enjoy. So 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 misappropriation that the law should arguably provide remedies for.

Positive Protection

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. Ex-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.

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 is 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 in which 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 users and beneficiaries. They will not be interested in a system that does not accommodate their world views and customs but rather imposes other norms with which they feel uncomfortable and wish to have no part of. Clearly, TK holders and communities must be partners in the development of the sui generis system to avoid the development of an inappropriate and unworkable system.

There will of course be objections from those who would oppose a liability regime on the principle that we should not have to pay for public domain knowledge. One may counter this view by saying that 'the public domain' is an alien concept for 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 over that knowledge or its responsibilities to ensure that the knowledge is 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 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 be more effective with registration. In addition, 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 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.

Database Rights

Nuno Carvalho of WIPO has suggested that TK databases be protected under a special database right.[4] These days, there is tremendous interest in documenting TK and placing it in databases. But as Carvalho points out, traditional communities and TK holders are rarely the ones responsible for compiling or holding the databases. Moreover, one presumes they wish to control access to and use of the information held in the databases rather than the way this information is presented or expressed. For these reasons, copyright law does not provide an adequate solution. As Carvalho explains: "it is necessary to establish a mechanism of industrial property protection that ensures the exclusivity as to the use of the contents of the databases, rather than to their reproduction (copyright)".

The basis for his proposal may be found in Article 39.3 of TRIPS which deals with test or other data that must be submitted to government authorities as a condition of approving the marketing of pharmaceutical or agrochemical products, where the origination of such data involves considerable effort. The Article requires governments to protect such data against unfair commercial use. It also requires them to protect data against disclosure except where necessary to protect the public. This allows for the possibility that certain information will have to be protected against unfair commercial use even when that information has been disclosed to the public.

To Carvalho, such additional protection could be extended to TK in the form of a legal framework for a TK database system. The system would retain the following three features derived from Article 39.3 of TRIPS: (a) the establishment of rights in data; (b) the enforceability of rights in the data against their use by unauthorized third parties; and (c) the non-fixation of a predetermined term of protection.

Carvalho suggests that such databases be registered with national patent offices and that to avoid the appropriation of public domain knowledge, enforcement rights be confined to knowledge that complies with a certain definition of novelty. Novelty need not be defined in any absolute sense but as commercial novelty (as with the TRIPS provisions on layout-designs of integrated circuits and the UPOV Convention). In other words, knowledge disclosed in the past could be treated as 'novel' if the innovation based upon it has not yet reached the market.

Global Biocollecting Society

Professor Peter Drahos has suggested the creation of a Global Biocollecting Society (GBS).[5] This is a property rights-based institution that would reduce transactions costs while improving the international enforcement of rights over traditional knowledge associated with biodiversity. It would also generate trust in the market between holders and commercial users of TK. The GBS would be a kind of private collective management organisation as is common in the area of copyright and related rights. These operate at the national level. One key difference is that the GBS would be an international institution. Another is that its mandate would be to implement the objectives of the CBD, particularly those relating to traditional knowledge. Membership of the GBS would be open to traditional groups and communities and companies anywhere in the world. The GBS would be a repository of community knowledge registers voluntarily submitted by member groups and communities. These would be confidential except that the identities of the groups or communities submitting registers would be made known. In doing so, it would trigger a dialogue between a community known to have submitted a register and a company interested in gaining access to information in this register. The result would be an arrangement to access TK in exchange for certain benefits.

To improve the chances for successful transactions of benefit to traditional communities, the GBS could provide a range of services in addition to serving as a repository of TK registers. It could, for example, assist in contractual negotiations and maintain a register of independent legal advisors willing to assist traditional communities. It could monitor the commercial use of traditional knowledge including by checking patent applications. The GBS could also have an impartial and independent dispute settlement function. Its recommendations would not be legally binding but there would still be incentives to adhere to them. For example, failure to do so could result in expulsion from the GBS, in which case the excluded party, if a company, might face negative publicity that would be well worth avoiding.

Compensatory Liability Regime

The compensatory liability regime idea proposed by Professor Jerome Reichman differs from the previous proposals in that it is – as its name indicates – a liability regime rather than a property-based system. It adopts a conception of TK as know-how, or at least it aims to protect certain TK that may be characterised as know-how. Know-how is taken to refer to knowledge that has practical applications but is insufficiently inventive to be patentable.

For such knowledge, a property regime is considered likely to afford excessively strong protection in the sense that it will create barriers for follow-on innovators. Such a regime will also intrude on the public domain. Reverse engineering ought to be permitted, but not improper means of discovering the know-how such as bribery or industrial espionage. However, know-how holders face the problem of shortening lead time as reverse engineering

becomes ever-more sophisticated. So what is to be done? In the interests of striking the right balance between the reasonable interests of creators of sub-patentable innovations and follow-on innovators, a liability regime is needed to ensure that for a limited period of time, users should be required to compensate the holders of know-how they wish to acquire. Such a regime would apply to know-how for which lead times are especially short and which do not therefore lend themselves to trade secret protection. Compensation would not be paid directly but through a collecting society. Misappropriation regime could apply to old knowledge, CLR to new knowledge. Trade secrecy could also be allowed. The CLR would require know-how to be registered. Short-term legal protection during which all uses by second comers should be compensated. Royalty rates low – standard form agreements. In some cases blanket licenses.

Strategic Considerations

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 principle.

An April 2002 International Seminar on Traditional Knowledge organised by the Government of India in co-operation with UNCTAD implicitly addressed the questions posed at the start of this section. At the Seminar, in which representatives from Brazil, Cambodia, Chile, China, Colombia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela and India

participated, a communiqué was issued which noted that national sui generis systems "provide the means for protection and growth of TK within national jurisdictions", these were inadequate to fully protect and preserve TK. But as the participants went on to explain: "the ability of patent offices in a national jurisdiction to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to TK holders, does not ipso facto lead to similar action on the patent application in other countries. A need was therefore expressed for an international framework for protecting TK." The following components of "a framework for international recognition of various sui generis systems, customary law and others for protection of TK" were suggested:

1. local protection to the rights of TK holders through national level sui generis regimes including customary laws as well as others and its effective enforcement inter alia through systems such as positive comity of protection systems for TK
2. protection of traditional knowledge through registers of TK databases in order to avoid misappropriation
3. a procedure whereby the use of TK from one country is allowed, particularly for seeking IPR protection or commercialization, only after the competent national authority of the country of origin gives a certificate that source of origin is disclosed and prior informed consent, including acceptance of benefit sharing conditions, obtained
4. an internationally agreed instrument that recognizes such national level protection. This would not only prevent misappropriation but also ensure that national level benefit sharing mechanisms and laws are respected worldwide.

This seems like a good way to move forward. Nonetheless, harmonising national TK protection standards can only go so far. 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 tremendous jurisprudential diversity of traditional societies. 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.

1. A SURVEY OF THE RELEVANT INTERNATIONAL FORUMS AND THE STATE OF PLAY IN THE NEGOTIATIONS

In the past few years, high-level discussions have been taking place at the Conference of the Parties (COP) to the CBD and the World Intellectual Property Organization (WIPO) that aim, among other things, to explore ways to make the IPR system and the CBD's provisions traditional knowledge and on access to genetic resources and benefit sharing (ABS) more mutually supportive. The WTO has also held negotiations on the same subject. The discussions, proposals and outcomes – which are actually rather similar to each other – are briefly described below.

1.1 The CBD Conference of the Parties

The Convention on Biological Diversity (CBD), which entered into force in 1993[6], 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". 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".

To review implementation of the CBD, the Conference of the Parties (composed of all Contracting Parties) meets periodically (usually 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. The COP has become a forum in which IPRs and the TRIPS Agreement are debated, critiqued (and defended) in a fairly open way.

At the Sixth Meeting of the Conference of the Parties, which took place in The Hague in May 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.[7] 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".[8] 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".[9] 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:

1. Genetic resources utilized in the development of the claimed inventions;
2. The country of origin of genetic resources utilized in the claimed inventions;
3. Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
4. The source of associated traditional knowledge, innovations and practices; and
5. Evidence of prior informed consent."

In a separate 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 Diversity[10] to address the issue of sui generis systems for the protection of traditional knowledge, focusing in particular on the following issues:

(a) Clarification of relevant terminology;
(b) Compiling and assessing existing indigenous, local, national and regional sui generis systems;
(d) Studying existing systems for handling and managing innovations at the local level and their relation to existing national and international systems of intellectual property rights, with a view to ensure their complementarity;
(f) Identifying the main elements to be taken into consideration in the development of sui generis systems;
(g) The equitable sharing of benefits arising from the utilization of traditional knowledge, innovations and practices of indigenous and local communities."

1.2 WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

In September 1999, WIPO's Standing Committee on the Law of Patents (SCP) held its third session, which was to be devoted mainly to discussing a draft Patent Law Treaty (PLT). The PLT was intended to harmonise certain patent procedures while steering clear of matters relating to substantive patent law. The Colombian delegation at the session submitted a brief document entitled *Protection of biological and genetic resources*[11] that turned out to be quite controversial. The delegation proposed that the PLT include an article based on the two proposals that the document comprised. The first was that "all industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally".

The second was that: "Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin."

This idea of linking patent filing with access and benefit sharing regulations gained the support of Bolivia, Paraguay, China, Namibia, Cameroon, Mexico, South Africa, Chile, Cuba, India, Kenya, Costa Rica and Barbados. Predictably it did not go down well with some of the other delegations, including the United States, the European Union, Japan and South Korea, all of which argued that the proposed article related to substantive patent law and therefore had no place in the Patent Law Treaty. As things turned out, Colombia's proposal did not fail completely in that the concerns behind it were given other opportunities for expression within WIPO.

As a compromise, the SCP invited WIPO's International Bureau to do two things. The first was to include the issue of protection of biological and genetic resources on the agenda of that November's meeting of the Working Group on Biotechnological Inventions. The second was to arrange another meeting specifically on that issue. This Meeting on Intellectual Property and Genetic Resources took place in April 2000 and reached a consensus that "WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work."[12]

Two months later the Diplomatic Conference for the Adoption of the Patent Law Treaty took place. While the main purpose was of course to agree upon and formally adopt the PLT, there were also consultations on genetic resources. Based upon these consultations, WIPO's Director-General Kamil Idris read out an agreed statement announcing that "Member State discussions concerning genetic resources will continue at WIPO. The format of such discussions will be left to the Director General's discretion, in consultation with WIPO Member States."[13] After the Conference, he continued to consult with member states on how such discussions could continue.

For the 25th Session of WIPO's General Assembly, also 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."[14] This suggestion was enthusiastically supported by a large number of developing countries and was approved without formal opposition from any member.

The first three sessions of the IGC convened in April and December 2001, and in June of the following year. At the third IGC, substantive discussion relating to how patent law might more effectively promote benefit sharing and prevent the misappropriation of TK focused mainly on two possible approaches. The first was to require patent applicants to disclose the origin of genetic resources and/or associated TK in related patent applications. Some delegations believe such applicants should also provide documentary evidence of prior informed consent and compliance with the ABS regulations of provider countries. The US delegation stated that such requirements would conflict with TRIPS by creating another substantive condition on patentability beyond those already provided by the latter. Countries like India and Brazil have repeatedly stated that such a measure is necessary to make patents supportive of the CBD. They claim that mandatory disclosure of origin would do this by preventing private monopoly rights from extending to illegally acquired genetic resources.[15]

The second approach was to improve the availability of public domain traditional knowledge to patent examiners to prevent cases where patents whose claims extend to traditional knowledge are improperly awarded. Two possible ways to do this are to provide an inventory of publications that regularly document TK, and to compile databases of public domain traditional knowledge. India is a very keen proponent of such databases and is already setting up its own Traditional Knowledge Digital Library. The specifics of these proposals and their feasibility are considered in Chapter 3.

1.3 Traditional Knowledge and Folklore at the WTO

TRIPS is silent on TK, and makes no reference to the CBD. But this has not prevented developing countries from referring to the TRIPS-CBD relationship and portraying it in a negative light. In October 1999, twelve developing countries from Asia, Africa and Latin America submitted two joint papers to the General Council detailing the implementation issues they were seeking solutions to.[16]

The two papers put forward several TRIPS-related proposals. One of these argued that TRIPS is incompatible with the CBD and sought a clear understanding that patents inconsistent with Article 15

of the CBD, which vests the authority to determine access to genetic resources in national governments, should not be granted. Several other proposals were directed to Article 27.3(b) and the review of its substantive provisions. One proposal was that the subparagraph should be amended in light of the provisions of the CBD taking fully into account the conservation and sustainable use of biological diversity, and the protection of the rights and knowledge of indigenous and local communities.

Traditional knowledge has become an especially important element of the debate. On 6 August, 1999, the African Group of countries[17] proposed to the WTO General Council that in the sentence on plant variety protection in Article 27.3(b) "a footnote should be inserted stating that any sui generis law for plant variety protection can provide for [inter alia]: (i) the protection of the innovations of indigenous farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources".

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".

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.[18] 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".

This proposal is discussed in the third part of this case study.

1.4 The FAO International Treaty on Plant Genetic Resources for Food and Agriculture

In November 2001, the Food and Agriculture Organization of the United Nations adopted a new international agreement called the International Treaty on Plant Genetic Resources for Food and Agriculture.

Recognising both the sovereign rights and the inter-dependence of countries over their plant genetic resources, the International Treaty establishes a multilateral system that aims to facilitate access and benefit sharing (ABS). ABS is to be regulated principally by means of a standard material transfer agreement (MTA), which will apply also to transfers to third parties and to all subsequent transfers.

Article 9, which deals with the concept of Farmers' Rights, is especially relevant to the present Study. The Treaty refers to three measures that governments should take to protect and promote Farmers' Rights. These are:

"(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture."

The final paragraph of Article 9 points out that "Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate".

The International Treaty is not yet in force, but it seems likely that because of these provisions, the FAO will become an important forum for discussions on TK.

1.5 Other Institutions and Forums

The United Nations Conference on Trade and Development

In 2000, the United Nations Conference on Trade and Development (UNCTAD) began its work on TK by holding an Expert Meeting on National Experiences and Systems for the Protection of Traditional Knowledge, Innovations and Practices. The Meeting, which was requested by the member states, resulted in a Report intended to reflect the diversity of views of experts.[19] The Report was taken up in February 2001 by UNCTAD's Commission on Trade in Goods and Services, and Commodities. Based upon this report, the Commission adopted recommendations directed to governments, the international community, and to UNCTAD.[20] The recommendations to the international community are as follows:

"The issue of protection of TK has many aspects and is being discussed in several forums, in particular the CBD Working Group on the Implementation of Article 8(j) and Related Provisions, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and the WTO (both the TRIPS Council and the Committee on Trade and Environment). Therefore, continued coordination and cooperation between intergovernmental organizations working in the field of protection of TK should be promoted. The Commission makes the following recommendations at the international level:

(a) Promote training and capacity-building to effectively implement protection regimes for TK in developing countries, in particular in the least developed among them;
(b) Promote fair and equitable sharing of benefits derived from TK in favour of local and traditional communities;
(c) Encourage the WTO to continue the discussions on the protection of TK;
(d) Exchange information on national systems to protect TK and to explore minimum standards for internationally recognized sui generis system for TK protection."

The United Nations Commission on Human Rights

In August 2000, the Sub-Commission on the Promotion and Protection on Human Rights of the United Nations Commission on Human Rights adopted a resolution on "Intellectual Property Rights and Human Rights".[21] While the resolution has no legal status it has attracted a great deal of attention to this issue. The resolution referred to a number of 'actual or potential conflicts' between IPRs and human rights including the consequences of plant breeder's rights and the patenting of genetically modified organisms for the enjoyment of the basic right to food, and the reduction of control by communities (especially indigenous communities) over their own genetic and natural resources and cultural values, leading to accusations of 'biopiracy'. The resolution requested that the WTO take fully into account the obligations of member states under the international human rights conventions to which they are parties during its ongoing review of TRIPS.

In August 2001, the Sub-Commission considered two official reports on the relationship between intellectual property rights and human rights in general, and on the impact of TRIPS on human rights.[22] In response, another resolution was adopted which essentially reiterated the Sub-Commission's view that actual or potential conflict exists between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights. It requested that the UN High Commissioner for Human Rights seek observer status with the WTO for the ongoing review of TRIPS. The resolution also stressed the need for adequate protection of the traditional knowledge and cultural values of indigenous peoples, and emphasized the Sub-Commission's concern for the protection of the heritage of indigenous peoples.[23]

The World Health Organization

The World Health Organization's involvement in TK relates to the organisation's work on traditional medicine and in response to requests from its members to cooperate with WIPO, UNCTAD and other international organisations to support countries in improving their awareness and capacity to protect knowledge of traditional medicine and medicinal plants, and securing fair and equitable sharing of benefits derived from them. Pursuant to this undertaking, WHO held an Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine in Bangkok in December 2000. The Workshop produced a list of recommendations including the following:

- "Ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge of the community from biopiracy.
- Traditional knowledge which is in the public domain needs to be documented in the form of traditional knowledge digital libraries in the respective countries with the help of WHO to WIPO's work in this area. Such information needs to be exchanged and disseminated through systems or mechanisms relating to intellectual property rights.
- Governments should develop and use all possible systems including the sui generis model for traditional medicine protection and equitable benefit sharing.
- Countries should develop guidelines or laws and enforce them to ensure benefit sharing with the community for commercial use of traditional knowledge.
- Efforts should be made to utilize the flexibility provided under the TRIPS Agreement with a view to promoting easy access to traditional medicine for the health care needs of developing countries".

2.TRADITIONAL KNOWLEDGE AND FOLKLORE: CLARIFYING THE TERMS

The purpose of this section is to investigate the terms 'traditional knowledge' and 'folklore' as they are used by governments, non-governmental advocates and experts, and to clarify their meanings so that policy makers may have a better understanding of what traditional knowledge and folklore are, who traditional knowledge and folklore holders and practitioners are, and the various ways by which they produce, acquire and control their knowledge and cultural works and expressions. This is necessary for the development of workable policy solutions at the international level. In addition, effective national policy making is likely to be stymied without such an understanding and an appreciation of the tremendous diversity of traditional systems of knowledge production and regulation.

2.1 What are Traditional Knowledge and Folklore?

The terms 'traditional knowledge' (TK) and 'folklore' are frequently used as if they are discrete categories of culturally-specific knowledge. Since 'folk' means people and 'lore' is defined in the Oxford English Dictionary as "a body of traditions and knowledge on a subject or held by a particular group", the two are not obviously different in meaning (see Box 1). And yet, for certain reasons the two are differentiated, as should soon become clear.

Box 1 : Categories and embodiments of traditional knowledge and folklore

Posey and Dutfield have summarised a range of categories and embodiments of TK and folklore. It is noteworthy that most of these are related to the environment:[24]

1. knowledge of current use, previous use, or potential use of plant and animal species, as well as soils and minerals;
2. knowledge of preparation, processing, or storage of useful species;
3. knowledge of formulations involving more than one ingredient;
4. knowledge of individual species (planting methods, care, selection criteria, etc.);
5. knowledge of ecosystem conservation (methods of protecting or preserving a resource that may be found to have commercial value, although not specifically used for that purpose or other practical purposes by the local community or the culture); and
6. classification systems of knowledge, such as traditional plant taxonomies.
7. renewable biological resources (e.g., plants, animals, and other organisms) that originate (or originated) in indigenous lands and territories;
8. cultural landscapes, including sacred sites;
9. nonrenewable resources (e.g., rocks and minerals);
10. handicrafts, works of art, and performances;
11. traces of past cultures (e.g., ancient ruins, manufactured objects, human remains);
12. images perceived as 'exotic', such as the appearance of indigenous people, their homes and villages, and the landscape; and
13. cultural property (i.e., culturally or spiritually significant material culture, such as important cultural artifacts, that may be deemed sacred and, therefore, not commodifiable by the local people

The categories presented in Box 1 are unlikely to provoke controversy or to provoke much debate. But as the discussion below shows, traditional knowledge and folklore are understood, misunderstood and applied in a variety of ways, some of which are based on assumptions that conflict with those held by other advocates and commentators.

These assumptions relate to the following areas:

1. The identity and nature of TK and folklore holding societies
2. The relationship between TK and folklore and other forms of knowledge
3. The extent to which TK and folklore can (or cannot) be new and innovative
4. Property rights in TK holding societies
5. Authorship in traditional societies
6. TK and folklore and the public domain

This part of the chapter will investigate some of the common assumptions falling under each of these particular areas, and identity those which are most plausible and susceptible to general application. But first, we need to come up with some generally accepted definitions of traditional knowledge and of folklore.

Traditional knowledge commonly refers to knowledge associated with the environment rather than knowledge related to, for example, artworks, handicrafts and other cultural works and expressions (which tend to be considered as elements of folklore). According to one expert, traditional knowledge (or what she calls 'traditional environmental knowledge') is "a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use".[25]

As for folklore, it is worth noting first that folklore predates traditional knowledge as a subject for discussion at the international level, going back to the 1970s, when it was soon as a copyright-related matter. According to Michael Blakeney, "the expression 'Traditional Knowledge' . . . accommodates the concerns of those observers who criticize the narrowness of 'folklore'. However, it significantly changes the discourse. Folklore was typically discussed in copyright, or copyright-plus terms. Traditional knowledge would be broad enough to embrace traditional knowledge of plants and animals in medical treatment and as food, for example. In this circumstance the discourse would shift from the environs of copyright to those of patent law and biodiversity rights". [26]

UNESCO and WIPO were the two institutions where discussions on folklore protection took place. UNESCO's involvement is of course due to its interest in culture. This is very evident in UNESCO's definition provided in the Recommendations on the Safeguarding of Traditional Culture and Folklore, which were adopted by the organisation's members in 1989: "folklore (or traditional and popular culture) is the totality of tradition-based creations of a cultural community, expressed by a group of individuals and recognised as reflecting its cultural and social identity; its standards and values are transmitted orally, by imitation or by other means. Its forms are, among others, language, literature, music, dance, games, mythology, rituals, customs, handicrafts, architecture and other arts".

Folklore thus understood is tradition based, collectively held, is orally transmitted, and a source of cultural identity. In the West folklore is understood differently, because traditional knowledge and art forms no longer constitute an integral part of most people's lives, and may even be considered as archaic.[27] This view may well prevail not only among people in developed countries, but also among urban elites in developing countries.[28] It may be difficult, then, for members of western (and westernised) cultures to appreciate the importance of folklore in the lives of indigenous peoples. In these latter societies, in contrast, folklore is not a historical phenomenon, but, as UNESCO recognises, is living and evolving, handed down from generation to generation orally rather than in fixed form, and is an essential aspect of cultural identity in many countries. Thus, folklore in traditional societies may take various forms including the following: (i) music, dance and other performing arts; (ii) history and mythology; (iii) designs and symbols; and (iv) traditional skills, handicrafts and artworks.

Music, dance and other performing arts are, in traditional communities, vital expressions of a living culture. Performances may be purely for entertainment or they may be carried out for religious or other reasons. Some performances may be open to the whole community, whereas others may be restricted, with initiated people only permitted to enact, listen to or see them.

Myths, legends, songs and stories may all be used to transmit cultural history from one generation to the next. It is knowledge about origins which may be the most highly valued and which a people is least willing to disclose to outsiders.[29] Knowledge that enables people and groups to perform ceremonies and rituals is likely also to be seen as a valuable form of intellectual property. It may provide individuals and groups with

status, respect and cultural identity, and may even constitute a claim to legal title to sacred sites and other places.

Traditional designs and symbols may be located on a rock that is part of a landscape[30], on a pot, wall, clothing, or even on a human body.[31] They can be transferred to a whole range of objects, conferring artistic, functional, or decorative value on an object.

Traditional handicrafts and artworks can be important sources of income. They are not mass-produced objects made in accordance with precise, inflexible guidelines established by the ancestors. Instead, they are the products of individual artisans and artists steeped in the culture of the society to which they belong.

2.2 In what Types of Society may TK and Folklore be found?

One may validly respond to this question in a very inclusive way or take a much more restrictive view of what a TK-holding society should look like. Starting with the inclusive view, one could reasonably argue that the existence of TK is not limited to certain types of society but on the contrary may be found in all societies no matter how modern they might appear to be and how *un*traditional much of the knowledge in circulation within them is. This is not to suggest that TK is easy to find in every society, but that the urbanisation and westernisation processes that have transformed many of the world's societies are unlikely to have resulted in the complete eradication of TK even in those countries which have experienced these phenomena the most comprehensively.

Many people tend to apply the term more narrowly to the knowledge held by tribal populations that are outside the cultural mainstream of the country in which these peoples live and whose material cultures are assumed to have changed relatively little over centuries or even millennia. Those who use the term this way consider traditional knowledge as referring primarily to the knowledge of indigenous and tribal peoples as defined under the International Labour Organization Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries. According to the Convention 'tribal peoples' refers to those "whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations".

'Indigenous peoples' refers to those peoples "who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions".

Because it is so common to characterise TK holders as being members of such societies, the term 'indigenous knowledge' is sometimes used instead of, interchangeably with, or as a sub-set of, traditional knowledge.

However, to make matters still more complicated, 'indigenous knowledge' is used also by others – often academics – in a slightly different way to express the localised nature of the knowledge they are referring to. Holders of indigenous knowledge, according to this view, may come from a diverse range of (indigenous and non-indigenous) populations and occupational groups, such as traditional farmers, pastoralists, fishers and nomads whose knowledge is linked to a specific place and is likely to be based on a long period of occupancy spanning several generations. Often, this knowledge is differentiated with more generally held knowledge and with the knowledge of urbanised and western (or westernised) societies.

Others would claim that such conceptual approaches are unnecessarily narrow in the sense that traditional knowledge is not necessarily local and informal, and that to assume they are would exclude formalised traditional systems of knowledge that are well documented in ancient texts and are part of the cultural mainstream of some countries, such as the Ayurvedic, Siddha and Unani health systems of the South Asian countries. In some countries, these systems are formalised to such an extent that they are studied at universities and have just as high a status as western

biomedicine. In India, some commentators differentiate these knowledge systems from local folk knowledge which still tends to be orally transmitted, even though they consider all these kinds of knowledge to be traditional.

TK-holding individuals, groups and communities, then, may be members of culturally-distinct tribal peoples as well as traditional rural communities that are not necessarily removed from the cultural mainstream of a country. TK-holding societies may inhabit areas of both the developing and the developed world, although they are more likely to be found in culturally (and biologically) diverse developing countries where indigenous groups continue to – in the terminology of the Convention on Biological Diversity – embody traditional lifestyles. But while TK holders tend to inhabit rural areas including very remote ones, members of such peoples and communities may live in urban areas yet continue to hold TK. TK may also be held and used by individuals in urbanised and westernised societies that have no other connection with the societies from which the TK may originated.

Evidently, we should avoid a fixed and dogmatic idea of what TK holders and their communities look like. But at the same time, it is important not to conflate the differing concerns and interests of the various types of TK-holding society. For indigenous and tribal groups facing cultural extinction, preserving their knowledge may take on a special importance (even if respect for their land rights could be more crucial still).

2.3 False Dichotomies? Traditional Knowledge and its 'Opposites'

Because TK is difficult to define, some experts have tried to clarify its meaning either by describing what it is not rather than what it is, or by identifying various features that make it completely opposite to scientific knowledge as the latter term is understood in urban, western, westernised or secular societies. Leaving aside the point made earlier that traditional knowledge also persists in the latter types of society, albeit to a limited extent, such a dichotomy seems at first to be quite plausible (see Box 2).

Box 2: Traditional knowledge and western scientific knowledge: can they be distinguished?

A Canadian anthropologist called Martha Johnson identified several ways that TK is generated, recorded, and transmitted, which the relevant academic literature considers makes TK completely different to western scientific knowledge.[32]

Thus, traditional knowledge:

1. is recorded and transmitted orally;
2. is learned through observation and hands-on experience;
3. is based on the understanding that the elements of matter have a life force;
4. does not view human life as superior to other animate and inanimate elements but that all life-forms have kinship and are interdependent;
5. is holistic rather than reductionist;
6. is intuitive rather than analytical; is mainly qualitative rather than quantitative;
7. is based on data generated by resource users themselves rather than specialised group of researchers;
8. is based on diachronic rather than synchronic data;
9. is rooted in a social context that sees the world in terms of social and spiritual relations between all life-forms; and
10. derives its explanations of environmental phenomena from cumulative, collective and often spiritual experiences. Such explanations are checked, validated, and revised daily and seasonally through the annual cycle of activities.
11. cultural property (i.e., culturally or spiritually significant material culture, such as important cultural artifacts, that may be deemed sacred and, therefore, not commodifiable by the local people

Is this dichotomy simplistic or even false? It seems credible, based as it is on a thorough review of the literature. Yet it needs at least to be qualified. Few if any populations are completely isolated or have been for a long time. Cross-cultural transfers of knowledge and consequent hybridisation and cross-fertilisation between different systems of knowledge are thus likely to be the norm rather than the exception. One should thus be cautious in assuming that traditional knowledge systems are discrete, pristine and susceptible to generalisations of the kind made by Johnson. As another anthropologist has argued, the same may be said for scientific knowledge, which "is indisputably anchored culturally in western society, where it largely originated, although with the contemporary communications revolution and cultural globalization, hybridization is occurring and blurring distinctions between scientific and other knowledge on socio-cultural grounds".[33]

It is worth adding that even if these differentiations are completely reliable, one should not conclude that TK is inherently unscientific. Johnson's findings confirm that a great deal of traditional environmental knowledge is empirical and systematic, and therefore scientific. Further support for the view that TK is scientific comes from anthropologists and other academics that use the ethnoscience approach to studying TK relating to nature,[34] and treat this knowledge as being divisible into western scientific fields. Accordingly, we have ethnobiology, ethnozoology, and ethnomedicine, for example. Of course, not all TK would fall into these categories. After all, nowhere in the world is all knowledge associated with nature scientific. But it seems reasonable to claim that some TK *is*, at least to some degree, scientific even if the form of expression may seem highly *un*scientific to most of us. For example, an indigenous person and a scientist may both know that quinine bark extract can cure malaria. But they are likely to describe what they know in very different ways that may be mutually unintelligible (even when communicated in the same language).[35]

2.4 Old and Fossilised, or New and Dynamic?

To some, traditional knowledge is by definition age-old knowledge, and creativity and innovation are generally lacking. Otherwise it would not be traditional. But recent empirical studies of traditional communities have discredited this view. As Russel Barsh, a noted scholar and commentator on the rights of indigenous peoples argues:

"What is 'traditional' about traditional knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is unique to each indigenous culture, lies at the very heart of its 'traditionality'. Much of this knowledge is actually quite new, but it has a social meaning, and legal character, entirely unlike the knowledge indigenous peoples acquire from settlers and industrialized societies".[36]

In short, knowledge held and generated within 'traditional' societies can be new as well as old. People who point this out are likely to emphasise that TK has always been adaptive because adaptation is the key to survival in precarious environments. Consequently, while TK is handed down from one generation to another, this does not mean that what each generation inherits is what it passes on. TK develops incrementally with each generation adding to the stock of knowledge.

Similarly, while the traditional classical health systems of China, India, Japan and Korea are based upon ancient texts, these systems continue to evolve and many present-day innovations take place. This is demonstrated by the existence of many Chinese patents on refinements of 'traditional' medical formulations (see below).

2.5 Intellectual Property in Traditional Societies

Who owns knowledge in traditional societies? Is it the individual creator or holder? the leader or leaders of a community? the whole community? a group of people within a nation, tribe or community such as a clan or lineage group? Or alternatively, is traditional knowledge shared freely because traditional societies do not have concepts of property or at least do not apply them to knowledge?

Discussions on these questions are often characterised by tendentious and misleading generalisations. Even if we narrow the scope of our discussion to indigenous peoples such as those of the Amazon, Siberia or the Pacific, these questions defy easy answers. Many traditional communities have a strong sharing ethos, but this does not mean that every*thing* is shared with every*body*. This is confirmed by a wealth of anthropological literature which reveals that such concepts as 'ownership' and 'property' – or at least close equivalents to them – also exist in most, if not all, traditional societies.[37] In fact, many traditional societies have their own custom-based 'intellectual property' systems, which are sometimes very 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. They also differ widely from each other. Therefore, to assume that there is a generic form of collective / community IPRs would be misleading since it would ignore the tremendous diversity of traditional proprietary systems, many of which are highly complex.

Despite this, it is often assumed that traditional knowledge is shared freely and that where property rights do exist, they are always collective in nature rather than individual as in the West. In some ways this view may do a disservice to traditional societies concerned about the misappropriation of TK. TK that has been disclosed to non-members of a small community or group of people is usually considered to be in the public domain unless its disclosure arose through illegal or deceptive behaviour by the recipient such as a breach of confidence. If no property rights exist, then whose rights are being infringed by somebody's publishing this knowledge, commercially exploiting it or otherwise appropriating it? Arguably nobody's.

Of course, one may consider such behaviour to be unjust whether or not the knowledge is the property of the TK creator, holder or community. But it may become harder to justify this view if we overstate the case that TK is shared without restrictions.

Having made this point, though, other arguments may still be deployed. One such argument derives from the problematic nature of the public domain concept, at least from the view of many traditional societies in which TK holders or others, such as tribal elders, have permanent responsibilities with respect to the use of knowledge irrespective of whether the knowledge in question is secret, is known to just a few people, or is known to thousands of people throughout the world. Custodianship responsibilities do not necessarily cease to exist just because the knowledge has been placed in the so-called public domain. And there is no doubt that a tremendous amount of TK has been disclosed and disseminated over the years without the authorisation of the holders. In this context, the following observation about indigenous peoples by Barsh is revealing:

"Indigenous peoples generally think in terms of the freedom of individuals to be what they were created to be, rather than being free from certain kinds of state encroachments. Along with this highly individualized notion of 'rights' is a sense of unique personal responsibilities to kin, clan and nation. Each individual's 'rights', then, consists of freedom to exercise responsibilities towards others, as she or he understands them, without interference." [38]

In short, indigenous societies often consider each member as having *individual* rights and *collective* responsibilities that are linked inextricably. Indeed, the persistence of these responsibilities is probably more of a reason why the formal IPR system is inappropriate than the supposedly collective nature of customary rights over TK. Besides, individual property rights over knowledge are not necessarily absent from many traditional societies but these will often be accompanied by certain duties.

2.6 Authorship in Traditional Societies

Attribution is far from being a simple matter in many traditional societies. Many commentators, especially those supporting the rights of traditional peoples and communities in the developing world, emphasise the collective nature of creative processes in traditional societies, which they contrast with the individualistic view of creativity (and of ownership in the end-product of that creativity) that prevails in western societies. Such generalisations have some truth to them, but it is important not to exaggerate the differences either. The

sources of much TK are difficult to trace, either because two or more peoples or communities share the knowledge, or because the author is simply unknown.

What of the perceptions of indigenous peoples and other traditional communities? Again, views vary widely. Some indigenous groups actually consider it presumptuous to attribute authorship to a human being or a group of people. According to the late ethnoecologist Darrell Posey, who spent many years studying and working with the Kayapó people of the Amazon, "indigenous singers. . . may attribute songs to the creator spirit"[39] Australian lawyer Michael Blakeney states, "if the beliefs and practices of Australian indigenous peoples are any guide, authorship may reside in pre-human creator ancestors … Authorship is replaced by a concept of interpretation through initiation."[40] But for other groups, this may not be true at all. For example, many of the 10,000 'grassroots innovations' documented by the India-based Honeybee Network are attributed to *and claimed by* individuals.[41]

2.7 The Stakes Involved

While the misappropriation of TK and folklore are serious matters demanding attention, the most urgent concern is probably their alarmingly rapid disappearance. At a time when TK especially is enjoying a measure of mainstream acceptance it has not had before, human cultural diversity is eroding at an accelerating rate as the world steadily becomes more biologically and culturally uniform. According to the IUCN Inter-Commission Task Force on Indigenous Peoples: "cultures are dying out faster than the peoples associated with them. It has been estimated that half the world's languages – the storehouses of peoples' intellectual heritages and the framework for their unique understandings of life – will disappear within a century".[42]

According to the Task Force, the main threats include genocide, uncontrolled frontier aggression, military intimidation, extension of government control, unjust land policies, cultural modification policies, and inappropriate conservation management. This suggests that measures to protect TK and folklore and the rights of the holders, custodians and communities need to be implemented with some urgency. As the late Darrell Posey so poignantly expressed it: "With the extinction of each indigenous groups, the world loses millennia of accumulated knowledge about life in and adaptation to tropical ecosystems. This priceless information is forfeited with hardly a blink of the eye: the march of development cannot wait long enough to even find out what it is about to destroy." [43]

Yet this tragedy is not inevitable. As Posey explained, "if technological civilization begins to realize the richness and complexity of indigenous knowledge, then Indians can be viewed as intelligent, valuable people, rather than just exotic footnotes to history".[44]

Folkloric works and expressions are also threatened with actual disappearance. When peoples are forced to struggle for survival amidst intrusions on their traditional ways of life from outside, knowledge of and ability to perform cultural expressions may be among the first casualties. Often people cease to practice their traditional performing arts, and learning to perform them may no longer be major concerns of younger members exposed increasingly to outside cultural influences. In this context, it is important to understand that in many traditional societies certain categories of knowledge have a significance that goes well beyond any practical or commercial applications they may have. According to a statement that came out of a February 2000 conference called *Protecting knowledge: traditional resource rights in the new millennium* organised and hosted by the Union of British Columbia Indian Chiefs:[45]

1. "Indigenous Peoples' own languages, knowledge systems and laws are indispensable to their identity, and are a foundation for self-determination.
2. Indigenous Peoples' knowledge systems are inextricably and inalienably connected with their ancestry and ancestral territories.
3. Indigenous Peoples' heritage is not a commodity, nor the property of the nation-state. The material and intellectual heritage of each Indigenous People is a sacred gift and a responsibility that must be honoured and held for the benefit of future generations."

In communities undergoing rapid social change, traditional knowledge may no longer be seen as valuable. As it dies out an important source of a peoples' cultural identity disappears with it.

But there are other concerns. Most of these relate to inappropriate or exploitative use by others. Biopiracy generally refers either to the unauthorized commercial use of biological resources and/or associated TK from developing countries, or to the patenting of spurious inventions based on such knowledge or resources without compensation. Critics of such practices argue that if patent, copyright and trademark infringements are acts of intellectual piracy, then so is the failure to recognise and compensate the intellectual contributions of traditional peoples and communities. For many people biopiracy is a serious problem and is becoming increasingly common.

Some concerns have more to do with folklore than with traditional knowledge. One of the most important is the threats to the livelihoods of many traditional artisans from the copying and mass production of handicrafts by outsiders, who thereby deprive artisans of a source of income. Another concern is the misrepresentation and distortion of cultural expressions. For example, when people are paid to do performances on television or in front of tourists, the cultural context is often lost and the performance becomes a 'show'. It may well be shortened to conform to a schedule. In such ways a traditional performing art can be distorted, devalued and perverted. Traditional performers may consent to this because they are poor and need the income. But folklore practitioners and producers also complain of unauthorised performances, recording and dissemination.

The popularity of traditional music can generate a good income for traditional musicians and performers but there can also be severe exploitation. Unfixed traditional music is generally considered to be in the public domain, meaning that other musicians may be able to adapt it and copyright the result. Also, recordings can be made of a collection of songs and the compilation can then be copyrighted.[46] An indigenous group may be willing to let a researcher or somebody else write a description of a song or dance, or make a tape or film recording. However, unless a traditional performance is known to a very small number of people, it is treated as being part of the public domain. As a result, there may be an absence of legal remedies to prevent others from freely trading in recordings of their performance, omitting to acknowledge the source, and presenting it in a distorted form. In the case of music, a compilation of recordings of songs on audio or videotape can be copyrighted and a musician can include elements of a traditional song in his own song and copyright the result. There is probably no legal requirement for the musician to acknowledge or compensate the community or group from which the song was copied unless an individual composer can be identified.

With respect to designs and symbols, it is very difficult for traditional communities to use legal means to prevent these from being copied and used for commercial purposes by others if they are not kept secret. This is because the right to use and reproduce designs may be determined by customary laws that are not recognised outside the community.

The importance of TK and folklore for the holders, practitioners and their communities should be clear. What about the governments? Not surprisingly, governments vary in how much importance they attach to TK and folklore. In much of Asia, Africa and Latin America, biopiracy seems to be a dominant concern. But there are also differences reflecting in part a fundamentally different view among governments about whose interests they are advancing. In countries like India, the predominant view is that the nation itself is the 'victim' of biopiracy. For Africa, the perception seems to be that the continent as a whole is prey to the biopirates. But in the Americas, Australia and New Zealand, the victims are seen generally as indigenous peoples who usually – though not always – represent minority populations. It is important to be aware of these differing perceptions and the reasons for them. Some countries feel quite nationalistic about this issue and consider biopiracy as a manifestation of neo-colonialism. For them, TK is national (or perhaps continental) knowledge, and while some of it may rightfully belong to minority groups, most of it does not. For the New World countries established by European settlers, TK belongs to certain discrete communities and falls outside the dominant culture. For them, dealing with this issue in forums like WIPO is, one presumes, a matter of doing the right thing by their indigenous groups, who they admit have been subjected to oppression in the past and continue to be marginalised.

In other parts of the world, folklore is treated as being more important. This appears to be the case for many

Middle Eastern countries where biopiracy is not treated as a significant matter, but which have rich cultural traditions and whose economies may benefit significantly from the export of traditional products such as carpets (as with Iran), or where considerable economic activity may be generated locally and perhaps regionally from the recording, broadcasting and performance of intangible cultural expressions, especially music.

2.8 Defensive and Positive Protection

Solutions to the protection of traditional knowledge in IPR law may be sought in terms 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.

3. PROPOSALS FOR PROTECTING TRADITIONAL KNOWLEDGE AND FOLKLORE: INVENTORY AND ANALYSIS

The first part of the chapter clarifies what the current international patent standards are in relation to biochemical compounds, genetic resources and life-forms, and details the TK-related controversies surrounding the extension of patenting to these types of subject matter. This is important because several proposals presented and analysed in this chapter, particularly the defensive measures, are deemed necessary because of the alleged negative consequences arising from this development in the law of patents. In short, the rights of holders and practitioners of TK and folklore and the interests of interested governments are to be defended not *by* the patent system but *from* it.

The second part discusses and evaluates the three most important proposals so far to have come out of international negotiations to provide defensive protection of TK through the patent system. The first is to require patent applicants to disclose the origin of genetic resources and associated TK relevant to the invention and, according to one variant of the proposal, to provide proof that regulations governing the transfer of the resources and associated TK were complied with. The second is to compile databases of published information on TK for patent examiners to identify potentially novelty-destroying prior art. The third is to ban the patenting of natural substances and life-forms, thereby precluding the kinds of patents that would misappropriate TK associated with biological resources from being granted. In addition, the idea of a misappropriation regime, as suggested by Professor Carlos Correa of the University of Buenos Aires, is discussed.

The third part discusses and evaluates a range of positive protection measures described in the literature.

Table 1: Summary of defensive and positive protection measures

Defensive protection measures	**Positive protection measures**
1. Disclosure of origin of genetic resources and associated traditional knowledge and compliance with ABS regulations • Certification of origin/prior informed consent ('strong disclosure') • Compulsory disclosure ('medium disclosure') • Voluntary disclosure ('weak disclosure') 2. TK databases 3. Banning patents on life 4. Misappropriation regime	1. UNESCO-WIPO Model Provisions on National Law and Illicit of Expressions of Folklore 2. The Tunis Model Law on Copyrights in Developing Countries 3. Database rights 4. Global biocollecting society 5. Compensatory liability regime

3.1 Patent Controversies

The TRIPS Agreement requires WTO Members to allow patents to "be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…" But Article 27.3(b) allows members to exclude from patentability the following:

"plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof."

In terms of products, then, micro-organisms must be patentable and plant variety rights must come under some kind of IPR system (see Table 2, which summarises what Article 27.3(b) requires members to do and allows them not to do). But what about genetic and biochemical resources? Must these also be patentable? Since they are not expressly excluded, patents must in principle be made available for these subject to the conditions that they be new, involve an inventive step and be capable of industrial application. Do these requirements mean that resources existing in nature cannot be patented? As I will explain below, they do not in the United States and Europe.

Table 2: Article 27.3(b) – a summary of its provisions

WTO members must provide protection for:	**WTO Members may exclude from patent protection:**
▪ Micro-organisms ▪ Non-biological processes ▪ Microbiological processes ▪ Plant varieties (by an IPR system which may be patents, a sui generis alternative, or a combination)	▪ Plants ▪ Animals ▪ Essentially biological processes for the production of plants or animals ▪ Plant varieties

Three closely related issues have focused critical attention on the patent system. These are the extension of patents to substances discovered in nature, and the problem of patents being granted that would not be if the novelty and inventive step criteria were properly applied. The third issue is the opportunity that the system provides for businesses and researchers to acquire sole patent rights for inventions that could not have been achieved without their having first accessed traditional knowledge. Let us now consider these issues in some detail.

In Europe and North America, which have the most experience in the patenting of such apparently natural substances, there has never been any kind of blanket exclusion of inventions on the basis that because they were not 100 per cent human-made they cannot be inventions. For example, adrenaline was first patented in 1903[47], and insulin in 1923.[48] Shortly after the Second World War Merck was granted patents on two products extracted from a micro-organism called Streptomyces griseus: the antibiotic streptomycin and vitamin B_{12}.[49] While there was a general assumption that living things could not be patented, patents were occasionally granted in some countries on plants and micro-organisms. The United States even had a plant patent system from as early as 1930. But for most of the twentieth century the legal situation in Europe and North America was uncertain. From the 1970s, though, things became clearer as the scope of patent protection was extended not just to micro-organism products but micro-organisms themselves followed later on by plants and animals. As for DNA sequences they started appearing in patent applications in about 1980.

How can such products, some of which are obviously discoveries, be protected by patents as if they are inventions? The technical explanation is that patent law treats them as if they are chemical substances, and these have been patentable for at least 150 years. It is well established in the patent laws of Europe and North America that while you cannot claim as an invention something as it occurs in nature, it is possible to do so if you extract it from nature and thereby make it available for industrial utilisation for the first time. This argument may not always convince a patent examiner or a court, though. But you almost certainly will if you change the substance or life-form in some way such as by adding something to it (e.g. a gene), subtracting something from it (i.e. purifying it), mixing it with something else to create a new or synergistic effect, or structurally modifying it so that it differs in an identifiable manner from what it was before.[50] It also appears to be possible in some jurisdictions to get a patent on a natural substance by simply being the first to describe it in the language of biochemistry.

Thus the South African Council for Scientific and Industrial Research (CSIR) has in several countries patented certain compounds found in a plant called hoodia, which has traditionally been used by certain groups of Bushmen people known as Xhomani as an appetite suppressant. The patent specification may well provide the first biochemical description of how the

plant produces its commercially promising effect.[51] But the intended use of the plant would hardly be considered as novel by the Bushmen groups who are not mentioned at all in the patent.[52] According to the European Patent Convention's standards, though, the CSIR has a legitimate claim. The European Patent Office Guidelines for Examination state that: "if a substance found in nature has first to be isolated from its surrounding and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which is it obtained or by other parameters … and it is 'new' in the absolute sense of having no previously recognised existence, then the substance per se may be patentable." [53]

To be fair, the CSIR has agreed to share benefits with the Bushmen (although it only agreed to do so after being heavily criticised for initially failing to make such a commitment). The patents certainly place the institution in a better position to do this (Box 3).

Box 3: The hoodia patent

For years, perhaps even centuries, the Xhomani San (Bushman) people of the Kalahari Desert have eaten parts of a local plant called hoodia to stave off hunger and thirst. Yet when South African scientists working at South Africa's Council for Scientific and Industrial Research (CSIR) learned about the Xhomani people's use of the plant and did some experiments, they claimed this use of the plant as their own invention. In fact, the CSIR has filed patent applications in numerous countries claiming ownership of the process of obtaining the active ingredient of this plant and its analogues and derivatives, as well as their use 'for the manufacture of medicaments having appetite suppressant activity'. Nowhere in the patent documents are the Xhomani people mentioned.

CSIR has high hopes that its 'invention' will become Africa's first blockbuster drug, helping to reduce obesity in the developed world while generating millions of dollars a year in sales. A British company called Phytopharm, which is carrying out the development work, and Pfizer, which has an exclusive license to sell the drug, also stand to benefit should the drug be commercialised. The Xhomani was excluded from each of these deals and stood to gain nothing. This was especially unfortunate given that the San people are facing the total destruction of their culture and a way of life that has enabled them to survive in a difficult environment for centuries. But in 2002, the CSIR responded to widespread criticism by agreeing to share future profits with the Xhomani

As the volume of patent applications rapidly increases each year and the ability of national and regional patent offices to process them properly becomes an ever more acute concern, the granting of patents for 'inventions' that privatise parts of the public domain has become a huge controversy that has brought the whole patent system into serious disrepute. So the problem caused by patent rules allowing discovered natural substance to be protected is compounded by the increasing numbers of patents being granted for 'inventions' that lack novelty and inventive step and are essentially reformulations of existing knowledge with claims covering products that differ minimally if at all from those that already exist. The United States Patent and Trademark Office in particular has been severely condemned for its granting of patents that should have been rejected and for turning the patent system into what to the outsider appears almost to be a quasi-registration system. In addition, the law is that undocumented knowledge held only in foreign countries does not form the state of the relevant art.[54] Although an applicant is not allowed to receive a patent if "he did not himself invent the subject matter sought to be patented"[55], there are concerns that this loophole sometimes allows people to copy such undocumented foreign knowledge and claim they have come up with a new invention.

The now notorious patent on the use of turmeric powder for wound healing[56] granted to the University of Mississippi Medical Center may be an example of this.[57] The patent provoked considerable anger in India because such use of turmeric was common knowledge there. Yet the Indian government agency that challenged the patent had to do more than persuade the US Patent and Trademark Office that this was true. It had to provide published documentation. Because it was able to do so the patent was revoked.[58] Yet the patent should never have been granted in the first place.

Many such patents do not really do any harm except to waste the time of patent examiners. But some are potentially harmful and others are actually harmful. Two potentially harmful patents relate to a plant related to mustard called maca (Lepidium meyenii). Maca, sometimes dubbed 'natural viagra', is a traditional crop that Andean populations have cultivated for centuries for use as a food and as the basis for several medicinal formulations. One of the US patents, owned by Pure World Botanicals Inc., is for an isolated maca extract which, it is claimed, can be used to treat cancer and sexual dysfunction, as well as the process of preparing it.[59] The latter use is already well known. Indeed, the company has for several years been importing maca into the United States and selling it for this very purpose.[60] The other patent, which Biotics Research Corporation owns[61], covers a mixture of powdered maca and antler and the process of increasing testosterone levels in men by administering this mixture in various forms. The consumption of both maca and antler is already known to be associated with increased testosterone levels. This casts doubt on whether the company has a genuinely patentable invention.

While suggestions that Peruvian maca farmers depending on exports could be affected by these patents are purely speculative, some may well be harmful. A good example appears to be a US patent on a field bean cultivar called 'Enola' (Box 4).

Box 4: The 'Enola' bean patent

In 1999, the US Patent and Trademark Office granted a patent on a field bean cultivar dubbed 'Enola' by the inventor, an entrepreneur called Larry Proctor. Controversially, Proctor's Colorado USA-based company Pod-Ners has been using the patent to block the sale of imported beans with the same colour as the ones described in the patent. This would include various traditional bean varieties. The patent claims not only a certain yellow-coloured *Phaseolus vulgaris* bean seed, plants produced by growing the seed as well as all other plants with the same physiological and morphological characteristics include, but also the breeding methods employed. Two things are extraordinary about this patent. The first is many bean cultivars exist and the specification provides no evidence that none of these cultivars possess the same characteristics falling within the patent's rather broad claims.[62] The second is that Mr Proctor employed conventional crossing and selecting breeding methods that are in no way novel. This prevents others from using the bean *and* other beans with similar characteristics in their own breeding programmes. None of this would necessarily matter if the owner had not decided to assert the patent aggressively. Soon after receiving the patent, Proctor sued a company called Tutuli that had been importing Mexican yellow bean cultivars called mayocoba and peruano from that country since 1994, and with customs inspectors disrupting supplies Tutuli began to suffer financially as did Mexican farmers that had been selling their beans to this firm. His company has since then filed lawsuits against various other small bean companies and farmers.[63] The patent is being challenged by the International Center for Tropical Agriculture (CIAT), which holds the largest collection of bean varieties and claims that six of its 260 yellow bean accessions very closely resemble enola and may well fall within its claims. CIAT's Director, Dr Joachim Voss reportedly called the patent "both legally and morally wrong" and claimed to have "solid scientific evidence that Andean peasant farmers developed this bean first, together with Mexico." [64] The Mexican government has also condemned the patent. But according to one report, the patent owner will get his revenge on Mexico if he loses: "Proctor warns that if his patent is reversed he'll flood the Mexican market with beans, depressing an already-weak bean price".[65]

In short, it seems to be easier than it should be to receive a patent. This is because in many countries the examination process is not as thorough as it should be. The main reason is that too few examiners are handling too many applications with the result that a lot of bad quality patents are being issued.

As is well known, patents are supposed to protect only those inventions that are new. Yet, novelty is to some extent a relative rather than absolute term, especially when viewed from a cross-cultural perspective. This was nicely explained by Lord Hoffman of the British House of Lords in a 1995 patent case: "There is an infinite variety of descriptions under which the same thing maybe known. Things may be described according to what they look like, how they are made, what they do and in many other ways. Under what description must it be known in order to justify the statement that one knows that it exists?" [66]

He went on to use the example of quinine: "The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule ($C^{20}H^{24}N^2O^2$) was discovered . . . . Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine. On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills. And he certainly would not know about the artificially synthesised alkaloid." [67]

The hoodia patent case exemplifies this point, as do the patents relating to maca, and another one based upon Phyllanthus niruri, a medicinal plant used in India for treating various ailments including jaundice, which was discovered in tests to show effectiveness against viral hepatitis-B and E. The Fox Chase Cancer Center, which had carried out these tests, was awarded a US patent[68] for a pharmaceutical preparation comprising an extract of the plant. While the invention was sufficiently new, useful and non-obvious to be patentable, Indian Ayurvedic healers are unlikely to be as impressed as the Patent and Trademark Office examiner who granted the patent.

It seems that while a plant or animal extract or mixture of extracts known by an indigenous group to have a useful characteristic cannot be patented due to its lack of novelty, the achievement of being first to explain the extract's effectiveness by way of some tests, by describing its mode of action in the language of chemistry, or even by just modifying the mixture in some modest way seems to be sufficient in some jurisdictions to merit the award of a patent. Often such patents make no reference to the relevant traditional knowledge (e.g. the hoodia patent) or merely mention it in a cursory manner as if it is of little importance (e.g. the turmeric patent). Under these circumstances, it is hardly surprising that indigenous groups believe the patent system to be exploitative and predatory. This is hardly an ideal state of affairs for industry. Such patents make it so much harder for trusting relationships to be developed between indigenous groups and researchers and businesses that could benefit all parties.

3.2 Defensive Protection

Disclosure of Origin

The compulsory disclosure of genetic resources and associated TK in patent applications was originally mooted by civil society organisations. The proposal is intended to help realise fair and equitable benefit sharing as required by the CBD. It is supposed to do this by ensuring that the resources and TK were acquired in accordance with biodiversity access and benefit sharing regulations in the source countries.[69]

Proposals relating to disclosure have weak, medium and strong forms. The weak form is that such disclosure would be encouraged or even expected but not required and its omission would not disqualify the patent from being granted. The medium form is that disclosure of origin would be mandatory. The International Chamber of Commerce supports the weak version[70], which was adopted in the 1998 European Union Directive on the Legal Protection of Biotechnological Inventions. Recital 27 states that: "Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents." [71]

It is interesting to note that Belgium is seeking to implement Recital 27 by linking compliance with the CBD to requirements that exploitation of an invention not be contrary to ordre public and morality. In 2000, a draft proposal to modify the 1984 Belgian Patent Act was prepared which "stipulates that the exploitation of an invention is contrary to ordre public and morality

when the invention is developed on the basis of biological material that was collected or exported in breach of Articles 3[72], 8(j), 15 and 16 of the CBD".[73] In addition, "a patent application should contain, not only a formal request, a description, one or more claims, drawings and an abstract, *but also the geographical origin of the plant or animal material on the basis of which the invention was developed*".[74]

India has actually introduced the medium form into the Patents (Amendment) Act, 2002, which adds two new grounds for revocation, which are that patents may be revoked on the grounds "that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention", and "that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere". In addition, a significant new item is added to the list of things that are not inventions within the meaning of the Act: "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components".

The strong form goes beyond disclosure in the patent specification to require – like the first of the new provisions being considered in Belgium – that patent applicants comply with the CBD's ABS provisions. One way to implement this is to require applicants to submit 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 and benefit sharing. Applications unaccompanied by such documentation would automatically be returned to the applicants for re-submission with the relevant documentation. The Bonn Guidelines 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.[75]

Three questions arise here. First, is compulsory disclosure of origin incompatible with TRIPS? Second, if it is, is an amendment of TRIPS to incorporate it feasible and desirable? Third, could disclosure of origin work in practice? In other words, is it actually a good idea anyway?

The answer to the first question depends upon whether we are talking about the weak, medium or strong versions. Clearly there is no problem whatsoever with the weak version. As for the medium version, it is difficult to accept the view that this establishes another substantive condition. One can easily argue that such disclosure of TK is essential for a full description of how the invention came about. In addition, by helping to describe the prior art against which the purported inventive step needs to be measured its disclosure ought to be required anyway. As for the source of the genetic material, it is difficult to see why inventors should not be required to indicate where they got it from and would hardly be burdensome in most cases.

The medium and strong versions would seem to conflict with TRIPS if failure to conform would result in a rejection of the application. But according to one expert, the solution to the problem may be not to make the disclosure requirement a condition for granting the patent but a condition for its enforceability after it has been granted.[76] This interpretation is somewhat questionable. As suggested earlier, it seems reasonable to argue that a proper description of an invention should include a detailed disclosure of how it was achieved including a statement of how the genetic material was required and a description of the state of the art at the time. And as for the submission of a document such as a certificate of origin, there is no reason why it should not be allowable to make this a requirement for granting the patent as long as it is not linked to determining the patentability of the invention. After all, examination and renewal fees normally have to be paid by patent applicants and owners, and TRIPS does not prevent them merely because they are not mentioned in the Agreement.

It is noteworthy that some countries have decided not to wait for the WTO to determine the legality of these kinds of measure. For example, the Andean Community's Common Intellectual Property Regime (Decision 486), which took effect in December 2000, requires that patent applications must contain:

"a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or

by-products originating in one of the Member Countries; [and] if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries." [77]

On the feasibility and desirability of revising TRIPS, one possibility is to amend Article 29 of TRIPS, which deals with conditions on patent applications, and which the Indian government has proposed in the past.[78] Brazil favours amending Article 27.3(b).[79] Given the subject of Article 29, the Indian proposal seems more logical, but the Brazilian one may be more strategic. This is because a review of Article 27.3(b) is currently on-going, and also because the Doha Ministerial Declaration refers to the CBD-TRIPS relationship in the context of this review. But it is difficult to be certain that either proposal is realistic or advantageous. Ideally, the demandeurs need to examine the practical complexities as presented here and their implications[80] and then to reflect on the economic advantages that could be gained from a successful outcome, and to balance such advantages with the disadvantages from the concessions that would need to be made in exchange. No doubt, this is much easier said than done. But it is important to try to gain a reasonably clear idea of how much is at stake economically as well as politically just in case the demand succeeds and something has to be given up in return.

Turning to the third question (i.e. could disclosure of origin work in practice?), mandatory disclosure 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. 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.

But in the case of plant varieties, which can be patented in some countries, genetic material may come from numerous sources some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programmes. Since new varieties may be based on genetic material from many different sources, 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. Besides, it is by no means certain that provider countries are the actual countries of origin or if not had themselves acquired the resources in conformity with the CBD. One might add also that many of these countries are likely not to be developing countries. So for plant varieties developed through conventional breeding methods, the system may be unworkable and may not necessarily benefit developing countries if it were. The patent applicants may simply be unable to comply and the examiners would be unable to verify whether the identities of the countries and indigenous communities of origin have been fully disclosed and are the true ones. It is possible also that the requirement could reinforce the tendency for plant breeders to rely on material in existing collections rather than to search for hitherto undiscovered resources from the countries of origin. This would have the effect of increasing the genetic uniformity of new plant varieties. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture may offer a solution. This is 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). The MTA will require benefits to be shared from the use, including commercial use, of the resources acquired. Article 13(d) of the International Treaty requires that "a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to [a financial mechanism to be established] an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment".

In effect, this means that a recipient that sells a food or agricultural product incorporating material from the multilateral system *must* pay monetary or other benefits from commercialisation under the following circumstance: that he/she owns a patent on the product and – as is normally the case – there is no exemption in the patent law of the relevant jurisdiction that would

freely allow others to use it for further research and breeding. If the product is a plant variety protected under an UPOV Convention-type system with such a research exemption, the recipient selling the product would be *encouraged* to pay benefits.

As for the certification of origin system, one of the practical complications, as the International Chamber of Commerce has correctly noted, is that many countries still do not have ABS regulations.[81] In fact, one country has even decided not to have any such regulations, though it must be said that the country in question (Denmark) is not exactly noted for its biodiversity-richness.[82] 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?

In short, mandatory disclosure and certification of origin are promising ideas that can help enhance compatibility between the CBD and the patent system. But the practicalities still need to be thought out carefully.[83]

TK Prior Art Databases

India has been a particularly strong demandeur on TK databases and has already begun to develop a Traditional Knowledge Digital Library (TKDL), which is a searchable database of already documented information related to traditional health knowledge of the ayurvedic system and to medicinal plants used by practitioners. The government wants to make the TKDL available to patent examiners in India and elsewhere. Clearly, the question of TRIPS incompatibility does not arise. Such databases would simply be used to improve the efficiency of prior art searches. Moreover, no country involved in the WIPO IGC has opposed the idea in principle, although there have been some differences of opinion on whether TK databases should be made publicly available only or provided for the exclusive use of patent offices (see below).[84]

But would TK databases actually be useful? They could certainly stop patents like the turmeric one from being granted. It is by no means certain that they would have prevented the other controversial patents described above. They may have narrowed their scope but even this is by no means certain. Take the hoodia patent. The problem here is that the relevant TK was known about but was apparently unrecorded in any published document. Therefore it would not be in the database anyway. But let us suppose for a moment it was. How would it have had to be described in order to constitute novelty-destroying prior art? If the published description came, say, from an anthropologist untrained in chemistry, it is possible that the examiner would have treated the TK relating to the hoodia so described as being quite distinct from the CSIR's patent specification.

In this context, it is important to note that national and regional patent laws vary with respect to how information or material in the public domain should be presented or described in order that they constitute novelty-defeating prior art.[85] In Japan, for example, industrially applicable inventions are patentable except for:

- "inventions which were publicly known in Japan or elsewhere prior to the filing of the patent application;
- inventions which were publicly worked in Japan or elsewhere prior to the filing of the patent application; [and]
- inventions which were described in a distributed publication or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the patent application." [86]

According to the examiners' guidelines, "'an invention described in a publication' means an invention which a person skilled in the art can identify on the basis of matters both described and essentially described, though not literally, in a publication."[87] In practice, this means that "novelty-defeating disclosure … has to be enabling, i.e. it teaches those skilled in the art how to make and use the claimed invention. If novelty-defeating disclosure fails to provide such information, the disclosure will not be a novelty-defeating bar".[88] This "enabling disclosure" requirement also operates in the UK and Germany among other countries.[89] It appears to imply that if published TK is not disclosed in a way that would teach someone to come up with an invention similar to or exactly as described in the specification of

the actual patent, the latter's validity would not be threatened.

As for Europe, the European Patent Convention considers an invention "to be new if it does not form part of the state of the art", which is "held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application".[90] This indicates that articles which are publicly available may form the state of the art whether or not they have been described in writing or even orally. In this context, it is noteworthy that the European Patent Office Technical Board of Appeal has ruled that "the concept of novelty must not be given such a narrow interpretation that only what has already been described in the same terms is prejudicial to it … There are many ways of describing a substance".[91] Furthermore, "the information disclosed by a product is not limited to the information that is immediately apparent from looking at the product. Importantly, the information available to the public also includes information that a skilled person would be able to derive from the product if they analysed or examined it".[92] This might suggest that the European patent on the hoodia compounds[93] may be vulnerable to a challenge on the basis of lack of novelty. However, one should also be cautious about this because "any information that is obtained as a result of an analysis undertaken by a person skilled in the art must be obtained without undue burden or without the need to exercise any additional inventive effort".[94]

This analysis of how Japan and Europe define and assess novelty-defeating prior art suggests that many so-called biopiracy cases could not be legally challenged in those parts of the world (despite the promising European legal interpretations that I cited), and that TK databases will make little difference. But what about patents covering traditional plant varieties like the Pod-Ners one (see Box 4) as is allowed in certain countries like the United States? Preventing these patents would require the database to provide descriptions of all existing landraces. This may not be feasible, which reinforces my scepticism that while TK databases would prevent some of the really bad patents, many would not be affected. This is not to deny their usefulness, but to caution that without other reforms to the patent system they would only deal with the most egregious cases of TK misappropriation, and not even all of these.

The discussion so far should make it evident (among other things) that a definite cultural bias is inherent to patent law. And as long as patent systems privilege certain sources of knowledge and forms of expression over others,[95] databases will go only so far in preventing behaviour that indigenous groups find exploitative. In fact, they may even be counter-productive since they could also provide opportunities for further biopiracy.

This latter concern is certainly a valid one if the TK databases are to be made available not only to patent offices but to the general public. Then they would become a valuable resource for industry, which would otherwise have to conduct far more time-consuming literature searches to acquire the same quantity of information. It is even more valid if the decision were also made to document hitherto unrecorded TK and place it in the databases. Indeed, in the last few decades many thousand of patents have been granted in China for formulations based on medicinal plants used for centuries in Chinese traditional medicine.

As yet, there is no consensus among delegates at the WIPO IGC that only published TK should be entered and that the databases should be available only to patent examiners. It seems fair that TK holders should have the right to veto the inclusion of their knowledge in a database and to have their views respected on how or whether access to it should be regulated. But before any decision is made, it is important to bear in mind that if *the* purpose of the database is to present published information to examiners so they do not grant patents in error, then unrestricted access is likely to give rise to further abuses.

Banning Patents on Life

Beginning as a campaign by activists and NGOs, opposition to the patenting of life forms including plants, animals, micro-organisms, cells, proteins and genes has been adopted as a negotiating position by some developing countries including – as we saw earlier – the African Group, which in its 1999 WTO submission referred to earlier warned that "by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities". On this basis, the paper proposed that:

The review process [of Article 27.3(b)] should clarify that plants and animals as well as microorganisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organisms should also not be patentable.

This would constitute a very broad exception indeed and while there may be some strategic advantage in adopting such a position, it has no chance whatsoever of being adopted at least for the time being. The economic power and political influence of businesses that gain from patenting in these areas is irresistible. In any case, for Europe and the United States, a century of patent law evolution and jurisprudence underpinning the extension of patent law to these kinds of substance would have to be reversed. It is not realistic to suppose that the US and European governments would all agree to such a reversal through a revision of TRIPS. A more debatable question is whether a more modest widening of the Article 27.3(b) exceptions either in an optional or mandatory form would have more chance of success. In the mandatory form, again, the chance of success seems virtually non-existent. But for those countries that feel strongly about this, they could consider drawing the line between the patentable and the unpatentable in the biotechnology field as they see fit, whether or not this is TRIPS compliant and sticking to their guns as a matter of principle. A dispute settlement panel is unlikely to find in their favour, but the developed countries are becoming keener not to be seen as bullies on TRIPS and may choose not to make a challenge that will provoke widespread condemnation. But even in this case, the kinds of patent that the developing countries object to would still be granted in the US, Europe or Japan.

The 'no patents on life' position of course assumes that patents cannot or will not shield the collective interests of bioprospecting partners including indigenous peoples, and that in consequence the best that can be done is too keep patents out of bioprospecting transactions and natural product-based research, development and commercialisation more generally. This position may be too negative. But whether or not patents can only be a problem and never a solution in the ABS context, decisions on where to draw the patentability line need to take many other factors into account including science and technology capacity-building, foreign direct investment and technology transfer. The interests of individual developing countries in this respect are likely to vary, but further discussion about this would fall outside the scope of this study, and will therefore not be pursued.

Misappropriation Regime

Professor Carlos Correa has proposed the development of 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 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."

He recommends 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 CBD-COP Decision V/16, which: "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."

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. 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 labeling 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."

Arguably, such a misappropriation regime could and probably should incorporate: (i) the concept of unfair competition; (ii) moral rights; and (iii) cultural rights.

Unfair competition would deal with situations in which TK holders engaged in commercial activities relating, 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 10bis of the Paris Convention, 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."

It is noteworthy that the TRIPS Agreement explicitly mentions Article 10bis in the sections dealing with geographical indications and undisclosed information. 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.

Moral rights are provided in Article 6bis of the Berne Convention, and 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).[96]

It could be argued that free-riding on the knowledge and cultural works and expressions of traditional communities who are not themselves interested in commercialising them does no direct harm. Consequently, misappropriation does not apply to such acts. But is it really the case that there are no victims? One could argue 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.[97] 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.

A useful comment on cultural rights is provided by Cohen, who conceives them as a collective right to maintain cultural integrity[98]:

"Culture is a characteristic of groups, not of individuals. Hence, when we speak of cultural rights – which I take to mean the right to maintain the integrity of the culture – we are speaking of group rights, the privilege

that a group enjoys vis-à-vis others to maintain its style and strategy of living."

So 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 misappropriation that the law should arguably provide remedies for.

3.3 Positive Protection

Basic Approaches of an International Sui Generis System

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.[99] But it is not free access. Ex-post compensation is still required. A sui generis system based on such a principle has certain advantages in countries where much of the traditional knowledge is already in wide circulation but may still be subject to the claims of the original holders. In Britain, people sometimes say that "it is no use shutting the barn door after the horse has bolted" when, for example, security measures are being considered to prevent the loss of things that have already been stolen. Similarly, 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.

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 is 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 in which 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 users and beneficiaries. They will not be interested in a system that does not accommodate their world views and customs but rather imposes other norms with which they feel uncomfortable and wish to have no part of. Clearly, TK holders and communities must be partners in the development of the sui generis system to avoid the development of an inappropriate and unworkable system.

There will of course be objections from those who would oppose a liability regime on the principle that we should not have to pay for public domain knowledge. One may counter this view by saying that 'the public domain' is an alien concept for many indigenous groups. Just because an ethnobiologist described a community's use of a medicinal plant in an academic journal without asking permission (which is a normal practice), this does not mean that the community has abandoned its property rights over that knowledge or its responsibilities to ensure that the knowledge is 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 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 be more effective with registration. In addition, 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 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.

WIPO-UNESCO Model Provisions for National Laws on Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions

In 1982, a Committee of Governmental Experts convened by WIPO and UNESCO adopted the Model Provisions for National Laws on Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions, which the secretariats of the two organisations had jointly drafted. The intention was to go beyond conventional copyright by protecting intangible expressions as well as fixed works. The document avoids a definition of folklore, but provides a list of 'expressions of folklore' that merit particular attention:

- "verbal expressions, such as folk tales, folk poetry and riddles;
- musical expressions, such as folk songs and instrumental music;
- expressions by action, such as folk dances, plays and artistic forms or rituals: whether or not reduced to a material form; and
- tangible expressions, such as:
  - productions of folk art, in particular, drawings, paintings, carvings, sculptures, pottery, terracotta, mosaic, woodwork, metalware, jewellery, basket weaving, needlework, textiles, carpets, costumes;
  - musical instruments;
  - [architectural forms]."

This list is not intended to be definitive. Interested countries are free to come up with their own list which could conceivably include many of the categories and embodiments of TK and folklore presented in Box 1.

Certain uses of expressions of folklore are subject to prior authorisation by a competent authority or the community itself if they are: "made both with gainful intent and outside their traditional or customary context", and would therefore constitute 'illicit exploitation' if used without this authorisation. According to WIPO, the two terms have a different meaning:

"'Traditional Context' is understood as the way of using an expression of folklore in its proper artistic framework based on continuous usage by the community. For instance, to use a ritual dance in its traditional context means to perform it in the actual framework of the respective rite. On the other hand, the term 'customary context' refers rather to the utilization of expressions of folklore in accordance with the practices of everyday life of the community, such as usual ways of selling copies of tangible expressions of folklore by local craftsmen. A customary context may develop and change more rapidly than the traditional ones."

These uses are twofold:

- "any publication, reproduction and any distribution of copies of expressions of folklore;
- any public recitation or performance, any transmission by wireless means or by wire, and any other form of communication to the public, of expressions of folklore."

In addition, four types of 'prejudicial action' are specified that offenders may be liable or punished for committing:

- "failure to indicate the community and/or geographic source of an expression of folklore in printed publications and other communications to
- the public;
  unauthorized use of an expression of folklore where authorisation is required;
- deliberately deceiving the public about the ethnic source of a production;
- any kind of public use that distorts the production in a manner 'prejudicial to the cultural interests of the community concerned'."

A 'competent authority', which could be the communities themselves, an organisation representing them, or a government entity would be set up to deal with applications for use of expressions of folklore, and perhaps to fix and collect authorisation fees.

The rights covered in the model provisions have some of the characteristics of copyright law in that they protect the (community) creators of artistic expressions, and neighbouring rights in that they can protect performances. However, compared with both these mechanisms, the Model Provisions have some advantages:

- They protect both fixed and unfixed expressions of folklore, which is rare in national copyright laws.
- The period of protection is indefinite.
- The protection goes beyond neighbouring rights, which only prevent performing, recording, and broadcasting works, and includes rights similar to the moral rights that exist in some copyright laws and even geographical indications.
- The provisions recognise the need to balance protection from abuses of folklore against the need to provide space for the further development and dissemination of folkloric expressions.

There is no reason to suppose that the Model Provisions conflict with the TRIPS Agreement. But are they workable in practice? This is difficult to answer. While a few African countries have enacted legislation based partly on them, experiences in applying them are lacking.

The Tunis Model Law on Copyright in Developing Countries

The 1976 Tunis Model Law on Copyright was adopted by a Committee of Governmental Experts convened by the Tunisian government with the support of UNESCO and WIPO. 'Folklore' is considered to mean "all literary, artistic and scientific works created on national territory by authors presumed to be nationals of such countries or by ethnic communities, passed from generation to generation and constituting one of the basic elements of the traditional cultural heritage". Several features of the Model Law are particularly interesting.

First, works of national folklore can be protected without time limit. The possibility of an indefinite copyright term in theory makes this legal model more appropriate for folklore. Moreover, use of works that have fallen into the public domain may still be subject to remuneration. This is because the Model Law introduces the concept of the paid public domain (domaine public payant). Works that have fallen into the public domain may be used without restriction subject to the payment of a fee to be paid to the competent authority. The latter institution would be required to use moneys collected for benefiting authors and societies representing authors and promoting and disseminating national folklore.

Second, the Model Law recognises that the conventional fixation requirement of copyright law cannot be applied to expressions of folklore. Thus, an optional provision is included which states that "with the exception of folklore, a literary, artistic or scientific work shall not be protected unless the work has been fixed in some material form".

Third, moral rights are asserted. Since the concerns of traditional communities regarding the use of a folkloric expression by others may have as much to do with distortion and a failure to acknowledge the source as its commercial exploitation, moral rights are very important. Given the 'perpetual, inalienable and imprescriptable' nature of moral rights as asserted in the Model Law, the right to use folkloric works without restriction except for payment of a fee cannot be assumed automatically.

Some African countries have copyright laws based at least in part on the Model Law.[100] Also, the Bolivian copyright law of 1992 contains some of the innovative elements of the Model Law, including the paid public domain idea and the fact that there is a 'competent authority', which is a State agency.

As with the Model Provisions, there is no obvious conflict with TRIPS. As for their appropriateness, the moral and economic rights provided do not really reflect the whole community interest in the representation and use of folkloric works, but only that of the author. The domaine public payant is also somewhat controversial. Some are concerned that a creative society depends upon a freely accessible public domain. If fees are charged to use public domain information and cultural works and expression, the effect may be to stifle further creativity and innovation. On the other hand, it is sometimes argued that "the public domain" is an inappropriate western concept anyway. This is because is tends to be applied in ways that fail to acknowledge the customary property rights and claims of traditional societies.

Database Rights

Nuno Carvalho of the World Intellectual Property Organization has suggested that TK databases be protected under a special database right.[101] These days, there is tremendous interest in documenting TK and placing it in databases. But as Carvalho points out, traditional communities and TK holders are rarely the ones responsible for compiling or holding the databases. Moreover, one presumes they wish to control access to and use of the information held in the databases rather than the way this information is presented or expressed. For these reasons, copyright law does not provide an adequate solution. As Carvalho explains: "it is necessary to establish a mechanism of industrial property protection that ensures the exclusivity as to the use of the contents of the databases, rather than to their reproduction (copyright)".

The basis for his proposal may be found in Article 39.3 of TRIPS which deals with test or other data that must be submitted to government authorities as a condition of approving the marketing of pharmaceutical or agrochemical products, where the origination of such data involves considerable effort. The Article requires governments to protect such data against unfair commercial use. It also requires them to protect data against disclosure except where necessary to protect the public. This allows for the possibility that certain information will have to be protected against unfair commercial use even when that information has been disclosed to the public.

To Carvalho, such additional protection could be extended to TK in the form of a legal framework for a TK database system. The system would retain the following three features derived from Article 39.3 of TRIPS:

- "the establishment of rights in data;
- the enforceability of rights in the data against their use by unauthorized third parties;
- and the non-fixation of a predetermined term of protection."

Carvalho suggests that such databases be registered with national patent offices and that to avoid the appropriation of public domain knowledge, enforcement rights be confined to knowledge that complies with a certain definition of novelty. Novelty need not be defined in any absolute sense but as commercial novelty (as with the TRIPS provisions on layout-designs of integrated circuits and the UPOV Convention). In other words, knowledge disclosed in the past could be treated as 'novel' if the innovation based upon it has not yet reached the market.

Global Biocollecting Society

Peter Drahos of the Australian National University has suggested the creation of a Global Biocollecting Society (GBS). This is a property rights-based institution that would reduce transactions costs while improving the international enforcement of rights over traditional knowledge associated with biodiversity. It would also generate trust in the market between holders and commercial users of TK.

The GBS would be a kind of private collective management organisation as is common in the area of copyright and related rights. These operate at the national level. One key difference is that the GBS would be an international institution. Another is that its mandate would be to implement the objectives of the CBD, particularly those relating to traditional knowledge. Membership of the GBS would be open to traditional groups and communities and companies anywhere in the world. The GBS would be a repository of community knowledge registers voluntarily submitted by member groups and communities. These would be confidential except that the identities of the groups or communities submitting registers would be made known. In doing so, it would trigger a dialogue between a community known to have submitted a register and a company interested in gaining access to information in this register. The result would be an arrangement to access traditional knowledge in exchange for certain benefits.

To improve the chances for successful transactions of benefit to traditional communities, the GBS could provide a range of services in addition to serving as a repository of TK registers. It could, for example, assist in contractual negotiations and maintain a register of independent legal advisors willing to assist traditional communities. It could monitor the commercial use of traditional knowledge including by checking patent applications. The GBS could also have an impartial and independent dispute settlement function. Its recommendations would not be legally binding but there would still be incentives to adhere to them. For example, failure to do so could result in expulsion from the GBS, in which case the excluded party, if a company, might face negative publicity that would be well worth avoiding.

Compensatory Liability Regime

The compensatory liability regime idea proposed by Professor Jerome Reichman of Duke University differs from the previous proposals in that it is – as its name indicates – a liability regime rather than a property-based system. It adopts a conception of TK as know-how, or at least it aims to protect certain TK that may be characterised as know-how. Know-how is taken to refer to knowledge that has practical applications but is insufficiently inventive to be patentable.

For such knowledge, a property regime is considered likely to afford excessively strong protection in the sense that it will create barriers for follow-on innovators. Such a regime will also intrude on the public domain. Reverse engineering ought to be permitted, but not improper means of discovering the know-how such as bribery or industrial espionage. However, know-how holders face the problem of shortening lead time as reverse engineering becomes ever-more sophisticated. So what is to be done? In the interests of striking the right balance between the reasonable interests of creators of sub-patentable innovations and follow-on innovators, a liability regime is needed to ensure that for a limited period of time, users should be required to compensate the holders of know-how they wish to acquire. Such a regime would apply to know-how for which lead times are especially short and which do not therefore lend themselves to trade secret protection. Compensation would not be paid directly but through a collecting society. Misappropriation regime could apply to old knowledge, CLR to new knowledge. Trade secrecy could also be allowed. The CLR would require know-how to be registered. Short-term legal protection during which all uses by second comers should be compensated. Royalty rates low – standard form agreements. In some cases blanket licenses.

National Sui Generis Systems

A number of countries have decided to develop legislation to protect TK and/or folklore. In addition, inter-governmental and non-governmental organisations have produced model legislation for interested countries to adopt. Several of these have already been reviewed in the literature, so the present study will deal with the new sui generis laws that have been passed in Panama and Peru:

- **Panama's Special System for Registering the Collective Rights of Indigenous Peoples, for the Protection and Defense of their Cultural identity and Traditional Knowledge, and Setting out other Provisions**

This legislation passed into law in Panama in June 2000. According to WIPO "the sui generis system of Panama actually constitutes the first comprehensive system of protection of traditional knowledge ever adopted in the world".[102]

Its aim is to protect the collective intellectual property rights and the traditional knowledge of the indigenous peoples over their creations. Such creations include "inventions, models, patterns and designs, innovations contained in images, figures, symbols, diagrams and petroglyphs". Also included are "the cultural elements of their history, music, art and traditional artistic expressions capable of a commercial use". These collective rights also extend to "musical instruments, music, dances and forms of performance, oral and written expressions contained in their traditions, which conform to their historical, cosmological and cultural expression"; and "instruments of work and traditional art, as well as the techniques for their preparation". Thus, the law is aimed at protecting not just tangible works of indigenous peoples but their intangible cultural expressions as well.

Requests for protection are to be made by indigenous peoples represented by their general congresses or other traditional authorities to a government agency known as the Department of Collective Rights and Folkloric Expressions, situated within the General Office of Registration of Industrial Property of the Ministry of Trade and Industry (DIGERPE), or to the National Office of Author's Rights of the Ministry of Education. Such requests – which can be made without charge nor services of a lawyer – will be examined and once granted will be without time limit.

Rights by others to use and commercialise the traditional art, crafts and other cultural manifestations of the indigenous peoples must conform to the regulations of the indigenous group concerned. Excepted from this provision are the folkloric dance ensembles which perform artistic representations at the national and international levels. Even so, natural or legal persons organising such representations which an portray indigenous culture in entire or partial form must include members of the group concerned in the performance. If this is not possible, authorisation will still be needed from the respective general congress or traditional authority.

The IPR system cannot be used by third parties without the authorisation of the indigenous peoples to acquire exclusive rights over elements of their cultural patrimony, which include the "customs, traditions, beliefs, spirituality, religiosity, cosmovision, folkloric expressions, artistic manifestations, traditional knowledge and any other form of traditional expression of the indigenous peoples".

The Law also seeks to promote indigenous arts, crafts, costumes and other traditional cultural expressions through the General Office of National Crafts of the Ministry of Trade and Industry, which inter alia will provide a certification mark on such products, and seek to ensure the participation of indigenous craftspeople in national and international trade fairs.

By an Executive Decree no. 12, of 2001, the regime now explicitly covers biodiversity-associated traditional knowledge.

- **Peru's Regime of Protection of the Collective Knowledge of Indigenous Peoples**

The Law of Protection of the Collective Knowledge of Indigenous Peoples was passed in August 2002.[103] It is a draft legislation developed by the National Institute for the Defence of Competition and Intellectual Property (INDECOPI) to protect the collective knowledge of indigenous peoples of that country.

The law aims to protect the *collective* knowledge of indigenous peoples relating to the properties of biological resources. All other categories of TK are excluded, as are traditional exchanges of knowledge among and between indigenous peoples, and use of knowledge associated with biological resources for the domestic market that have not been processed industrially.

Among the law's key provisions are that it:

- "obliges interested parties to obtain the prior informed consent of communities providing the biodiversity-related knowledge;
- promotes mutually agreed terms by recognising the need to sign licenses (contracts) for the use of the knowledge when a commercial or industrial application is intended (whether or not in the public domain);
- includes unfair competition procedures to defend the rights recognised in the regime (in the case of misappropriation or unauthorised use);
- calls for the establishment of different types of registers to document collective knowledge and make it more or less (depending on the type of register) available to third parties;
- creates a Fund for the Development of Indigenous Peoples; and
- associates the protection of traditional knowledge with intellectual property regimes by imposing the obligation of presenting a license when applying for a patent."[104]

Those who wish to access TK for scientific, commercial, or industrial application must acquire a non-exclusive license to be signed by interested parties and representatives of the communities concerned. Among the compulsory provisions of the license are that for commercial use or industrial application, 5 percent of the value of future sales must go to a Fund for the Development of Indigenous Peoples. The Fund is intended to contribute to the development of indigenous peoples by funding community projects, and will be administered *inter alia* by individuals representing indigenous peoples' organisations. Those wishing to access TK are also required to secure the prior informed consent of the communities holding the knowledge.

The law sets up three types of register: the National Public Register, the national Confidential Register, and Local Register. All are intended to safeguard the interests of indigenous communities with respect to their knowledge. One of the main functions of the Public Register is to prevent the patenting of traditional knowledge that has already been publicly disclosed. The other two types would not be publicly accessible.

Legal rights over knowledge are not dependent upon its existence in a register. But by including knowledge in the registers, communities will be in a better position to assert their rights to it.

4. STRATEGIC CONSIDERATIONS

The fact that TK and (albeit to a lesser extent) folklore 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. Some of the developed countries may only be prepared to cooperate on this issue in forums like the WIPO IGC if they can secure agreement from the developing countries to support other processes that may not be in their economic interests.

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 is unlikely that the parties will adopt any binding norms on TK. This is because the IPR-relatedness of the subject renders the COP an inappropriate forum to negotiate such norms, at least as far as the developed countries are concerned. And even if the COP were to adopt a protocol on TK, the likelihood is that no developed countries would sign up to it unless its terms were weak, in which case it probably would not be worthwhile anyway. 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, the WIPO IGC seems at the present time to be the most promising place. While regrettably 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, 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.

In concluding this study, five important questions arise in international negotiations that need to be considered carefully. First, what is the relationship between TK and folklore? Second, are they susceptible to a single legal or policy solution, or should they be treated as separate topics? Third, which should be given priority? Fourth, 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? Fifth, 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?

As we have seen, it is quite different to distinguish between the meanings of the terms. But they do have different connotations, at least for policy makers and lawyers if not to TK holders and traditional communities who are bound to find such distinctions artificial and somewhat alien. Their hitherto separate legal treatment has much to do with the fact that folklore has generally been treated as a subject for copyright lawyers (among others) to discuss, while TK came into international negotiations as a patent-related and environmental issue because of its association with the discovery of new drugs, biopiracy, and with the conservation and sustainable use of biodiversity. While UNESCO and WIPO were dealing with folklore as far back as the early 1980s, traditional knowledge only became a subject for international negotiation in 1992 when the Convention on Biological Diversity was opened for signature at the Earth Summit. At the present time, rightly or wrongly, traditional knowledge is generally treated as being more important than folklore. And traditional knowledge associated with biodiversity has been given priority treatment in international negotiations. Even then, the term 'traditional knowledge' is understood in different ways by diplomats and policymakers.

Can we reconcile the different ways traditional knowledge is understood and prioritised without harming the interests of individuals and groups whose knowledge diplomats, policy makers and NGOs say they wish to protect when they talk about "traditional knowledge"? This is not at all easy. And as long as it continues to be such a nebulous and misunderstood term, it is reasonable to wonder whether there can ever be an international consensus on how to protect it. This is not to say that a definition is needed to develop a legal system to protect it. After all, most patent laws do not define what an invention is. But a common understanding of what TK is and is not is essential for effective policy making. To date, progress in achieving this common understanding has not got very far.

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.

Peter Drahos[105], an intellectual property lawyer, describes how such a strategy could work:

"The key idea would be to devise an all-embracing model of protection for the physical, cultural and social resources of indigenous peoples…. It would then be possible to link the national statutory regimes of developing countries that were participating in the process. … Ideally, developing countries would have developed a common set of standards for the protection of indigenous knowledge through a process of consultation and co-operation. … Once a significant number of developing countries agreed to participate in such an arrangement and had demonstrated its feasibility, some Western countries would be likely to join. In this way, a regulatory model for the protection of indigenous knowledge could be networked and globalised.

The real power of this proposal comes from the possibility of a strategic alliance on the issue of indigenous knowledge between key developing countries. Imagine the power of a reciprocal arrangement between, say, India, China and Indonesia. Unity of attitude and approach would be absolutely crucial to this proposal. The United States was not able to succeed in its TRIPS objectives without the assistance of Japan and Europe. The strategy being outlined here would only succeed if developing countries were prepared to co-operate in the creation of a standardised statutory regime for indigenous knowledge. In the longer term, developing countries could work towards the creation of a multilateral treaty on indigenous knowledge. If it suited their purposes, they could contemplate incorporating such a treaty into the TRIPS Agreement."

An April 2002 International Seminar on Traditional Knowledge organised by the Government of India in co-operation with UNCTAD implicitly addressed the questions posed at the start of this section. At the Seminar, in which representatives from Brazil, Cambodia, Chile, China, Colombia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela and India participated, a communiqué was issued which noted that national sui generis systems "provide the means for protection and growth of TK within national jurisdictions", these were inadequate to fully protect and preserve TK. But as the participants went on to explain: "the ability of patent offices in a national jurisdiction to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to TK holders, does not ipso facto lead to similar action on the patent application in other countries. A need was therefore expressed for an international framework for protecting TK."

The following components of 'a framework for international recognition of various sui generis systems, customary law and others for protection of TK' were suggested:

1. "local protection to the rights of TK holders through national level sui generis regimes including customary laws as well as others and its effective enforcement inter alia through systems such as positive comity of protection systems for TK
2. protection of traditional knowledge through registers of TK databases in order to avoid misappropriation
3. a procedure whereby the use of TK from one country is allowed, particularly for seeking IPR protection or commercialization, only after the competent national authority of the country of origin gives a certificate that source of origin is disclosed and prior informed consent, including acceptance of benefit sharing conditions, obtained
4. an internationally agreed instrument that recognizes such national level protection. This would not only prevent misappropriation but also ensure that national level benefit sharing mechanisms and laws are respected worldwide."

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."

But harmonising national TK protection standards can only go so far. In 1996, a Canadian indigenous peoples' organisation called the Four Directions Council submitted a paper to the Secretariat of the Convention on Biological Diversity, which pointed out that: "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."[106]

For this reason, as the Four Directions Council expressed it: "Any attempt to devise uniform guidelines for the recognition and protection of indigenous peoples' knowledge runs the risk of collapsing this rich jurisprudential diversity into a single "model" that will not fit the values, conceptions or laws of any indigenous society."

It is therefore 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 this 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.

END NOTES

[1] The certification of origin idea was devised by Brendan Tobin. See Tobin, B. (1997), "Certificates of origin: a role for IPR regimes in securing prior informed consent", in J. Mugabe et al (eds), Access to Genetic Resources: Strategies for Sharing Benefits, ACTS Press.

[2] Carvalho, N.P. de (2000), "Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: the problem and the solution", Washington University Journal of Law and Policy 2: 371-401.

[3] Bently, L., and B. Sherman (2001), Intellectual Property Law, Oxford University Press, at 420.

[4] Carvalho, N.P. de (n.d.), "From the shaman's hut to the patent office: how long and winding is the road?"

[5] Drahos, P. (2000), "Indigenous knowledge, intellectual property and biopiracy: is a global bio-collecting society the answer?", European Intellectual Property Review 6: 245-250.

[6] As of August 20, 2002, the CBD has 183 state parties plus the European Union.

[7] 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].

[8] Paragraph 16(d)(ii).

[9] Paragraph 43(c) and (d).

[10] This body was established by the COP in 1998.

[11] World Intellectual Property Organization - Standing Committee on the Law of Patents (1999), "Protection of biological and genetic resources. Proposal by the Delegation of Colombia" [SCP/3/10].

[12] In World Intellectual Property Organization (2000), "Matters concerning intellectual property and genetic resources, traditional knowledge and folklore. Document prepared by the Secretariat" [WO/GA/26/6].

[13] Ibid.

[14] Ibid.

[15] See World Intellectual Property Organization (2002), "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Third Session. Geneva, June 13 to 21, 2002. Draft report prepared by the Secretariat" [WIPO/GRTKF/IC/3/17 Prov.].

[16] See World Trade Organization - General Council (1999), "Preparations for the 1999 Ministerial Conference. Implementation issues to be addressed before/at Seattle. Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda" [WT/GC/W/354]; World Trade Organization - General Council (1999), "Preparations for the 1999 Ministerial Conference. Implementation issues to be addressed in the first year of negotiations. Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda" [WT/GC/W/355].

[17] World Trade Organization - General Council (1999), "Preparations for the 1999 Ministerial Conference. The TRIPS Agreement. Communication from Kenya on behalf of the African Group" [WT/GC/W/302].

[18] World Trade Organization - TRIPS Council (2002), "The relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge". Communication from Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe [IP/C/W/356].

[19] UNCTAD (2000), *Report of the Expert Meeting on National Experiences and Systems for the Protection of Traditional Knowledge, Innovations and Practices* [TD/B/COM.1/33; TD/B/COM.1/EM.13/3].

[20] See http://www.unctad.org/en/special/c1dos5.htm

[21] United Nations Commission on Human Rights - Sub-Commission on the Promotion and Protection of Human Rights (2000), 'Intellectual property and human rights' - Resolution 2001/21. [E/CN.4/SUB.2/RES/2000/7].

[22] United Nations Commission on Human Rights - Sub-Commission on the Promotion and Protection of Human Rights (2001), 'Intellectual property rights and human rights. Report of the Secretary-General' [E/CN.4/Sub.2/2001/12]; United Nations Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights (2001), 'The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. Report of the High Commissioner' [E/CN.4/Sub.2/2001/13].

[23] United Nations Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights (2001), 'Intellectual property and human rights' - Resolution 2001/21 [E/CN.4/SUB.2/RES/2001/21].

[24] Posey, D.A., and G. Dutfield (1996), *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, Ottawa: International Development Research Centre, at 12-13.

[25] Johnson, M. (1992), "Research on traditional environmental knowledge: its development and its role", in M. Johnson (ed.), *Lore: Capturing Traditional Environmental Knowledge*, Ottawa: IDRC, at 3-4.

[26] Blakeney, M. (1999), "What is traditional knowledge? why should it be protected? who should protect it? for whom?: understanding the value chain", 3 WIPO Doc. WIPO/IPTK/RT/99/3, available at http://www.wipo.int/eng/meetings/1999/folklore/index_rt.htm.

[27] According to Widdowson, "all too often, the word has something of a pejorative connotation in England, and is associated primarily with the old, the rural and the uneducated". Widdowson, J.D.A. (1990), "English language and folklore: a national resource", *Folklore* 101(ii): 209-220. To avoid pejorative connotations "folklore" is sometimes replaced by "folklife" in the United States.

[28] For example, Professor John Murra, who was involved in the campaign to return some traditional textiles to indigenous communities in Bolivia recounted that (pers. comm., 1994): "When the cultural attaché of the Bolivian government called me to inquire about all the fuss and I told him that the textiles had magic and other religious meanings, he reminded me that Bolivia was a civilized country."

[29] Griffiths, T. (1993), *Indigenous Knowledge and Intellectual Property: A Preliminary Review of the Anthropological Literature*. Oxford: Working Group on Traditional Resource Rights, Oxford, UK (unpublished commissioned paper), at 23.

[30] Pinel, S.L., and M.J. Evans (1994), "Tribal sovereignty and the control of knowledge", in T. Greaves (ed.), *Intellectual Property Rights For Indigenous Peoples: A Sourcebook*, Oklahoma City: Society for Applied Anthropology.

[31] Maddock, K. (1989), "Copyright and traditional designs - an Aboriginal dilemma", *Intellectual Property* 2(1): 7-9.

[32] Johnson, op cit., at 7-8.

[33] Sillitoe, op cit., at 205.

[34] See Sillitoe, P. (1998), "What, know natives? local knowledge in development", *Social Anthropology* 6: 203, 207-09 (1998).

[35] It might be countered that since the indigenous peoples of western Amazonia do not really understand why quinine works, their quinine-based treatment is a technology that is not science-based. If that is so, however, one could infer that many western "scientific" applications ought likewise to be "downgraded" to technologies, since they are not based on a complete understanding of why they work.

[36] Barsh, R.L. (1999), "Indigenous knowledge and biodiversity, in indigenous peoples, their environments and territories", in D.A. Posey (ed.), *Cultural and Spiritual Values of Biodiversity*, London and Nairobi: IT Publications and UNEP, at 73.

[37] See generally Cleveland, D.A., and S.C. Murray (1997), "The world's crop genetic resources and the rights of indigenous farmers", *Current Anthropology* 38(4): 477-496 (discussing aspects of the debate over the protection of indigenous farmers' rights); Griffiths, op cit. (discussing the concept of exclusive rights as it is inherent in indigenous communities regarding magical knowledge). Shamans and other TK holder specialists may wish to restrict access to their knowledge for reasons other than because they consider it to be their property. For example, sacred knowledge – which may include knowledge of the therapeutic properties of plants – is often considered dangerous if it gets into the hands of the uninitiated. In other words, they may be concerned for the welfare of those who acquire the knowledge and try to use it. The author of this Study is grateful to the late Darrell Posey for this insight. See also Hendricks, J.W. (1988), "Power and knowledge: discourse and ideological transformation among the Shuar", *American Ethnologist* 15(2): 216-238 (discussing the importance of the completion of an apprenticeship for shamans).

[38] Barsh, R.L. (1995), "Indigenous peoples and the idea of individual human rights", *Native Studies Review*, 10(2).

[39] Posey, D.A. (1995), *Indigenous Peoples and Traditional Resource Rights: A Basis for Equitable Relationships?*, Oxford: Green College Centre for Environmental Policy and Understanding, at 17.

[40] Blakeney, M. (2000), "The protection of traditional knowledge under intellectual property law", *European Intellectual Property Review* 22, at 251-252.

[41] For a discussion by the Director of the Honeybee Network regarding the origin of the knowledge leading to such "grass roots innovations," see Gupta, A.K. (1999), "Making Indian agriculture more knowledge intensive and competitive: the case of intellectual property rights", *Indian Journal of Agricultural Economics* 54, at 346-52.

[42] Inter-Commission Task Force on Indigenous Peoples (1997), *Indigenous Peoples and Sustainability: Cases and Actions*, Utrecht: IUCN and International Books, at 60.

[43] Posey, D.A. (2002), "Indigenous knowledge and development: an ideological bridge to the future", in D.A. Posey (K. Plenderleith, ed.), *Kayapó Ethnoecology and Culture*, London and New York: Routledge, at 59.

[44] Ibid.

[45] http://www.ubcic.bc.ca/protect.htm

[46] Seeger, in reference to United States copyright law, explains that "there are two aspects of music that may be separately copyrighted. One is the song, its melody and text. Thus Woody Guthrie can copyright 'This Land is Your Land' and certain uses of the song are controlled by the publishing company, which normally collects payment for personal use. The second stage is the singing itself. If I record the song 'This Land is Your Land' on a record, the company can copyright my singing, but it will have to pay a royalty to the publishing company for the song." Seeger, A. (1992), "Ethnomusicology and music law", *Ethnomusicology* 36(3): 345-359.

[47] H.K. Mulford and Co. actually held two patents for a glandular extractive product in the form of a purified form of adrenaline, and for this compound in a solution with salt and a preservative. In a 1911 court case, Parke Davis and Co., which was accused by H.K. Mulford of infringing its patents, defended itself on a number of grounds, one of which was that the inventions were mere products of nature and that this made the patents invalid. The judge, ruling in favour of Mulford, held that "Takamine [i.e. the inventor] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically." See Parke Davis and Co. v. H.K. Mulford and Co., 189 Fed. 95 (S.D.N.Y. 1911), affirmed, 196 Fed. 496 (2nd Circuit 1912).

[48] US Patent No. 1,469,994 (issued October 9, 1923) (Extract obtainable from the mammalian pancreas or from the related glands in fishes, useful in the treatment of diabetes mellitus, and a method of separating it).

[49] US Patent No. 2,446,102 (issued July 27, 1948) (Complex salts of streptomycin and process for preparing same; US Patent No. 2,563,794 (issued August 7, 1951) (Vitamin B_{12}).

[50] Dutfield, G. (in press), *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Aldershot: Ashgate; see also Bozicevic, K. (1987), "Distinguishing 'products of nature' from products derived from nature", *Journal of the Patent and Trademark Office Society* 69 (8): 415-426, at 422-423.

[51] See WIPO/PCT International Publication No. WO 98/46243 (Pharmaceutical compositions having appetite suppressant activity).

[52] Ironically, the head of Phytopharm, which is developing hoodia as an anti-obesity drug, was reported as saying that "the evidence seems to show that they [i.e. the Xhomani] used the plant as a food supplement and didn't even think about obesity." See Kapner, F. (2002), "Finding an answer to the west's big problem", *Financial Times* January 4: 18; also see Barnett, A. (2002), "Bushmen victory over drug firms", *The Observer* March 31: 19. The latter article notes that "although the details of the agreement have to be hammered out, the San are likely to be involved in farming and cultivating hoodia and to be offered scholarships to study so that their ancient botanical knowledge may lead to other commercial products". If the drug turns out to fulfil its commercial promise, the Xhomani would certainly deserve much more than this.

[53] European Patent Office (n.d.), *Guidelines for Examination in the European Patent Office*, Munich: EPO, at Part C-IV, 2.3. It is worth comparing this with the rather different Article 15(b) of the Andean Community's Common Intellectual Property Regime (Decision 486), which entered into effect in December 2000. The following (among others) are not considered to be inventions: "Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing".

[54] A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . 35 USC §102.

[55] See 35 USC §102(f).

[56] US Patent No. 5,401,504 (issued March 28, 1995) (Use of turmeric in wound healing).

[57] It is worth emphasising the words "may be". Many patents are granted that should not be and the problem seems largely due to the failure of the system to more efficiently enable examiners to identify novelty-destroying prior art published even in the US.

[58] Ganguli, P. (2001), *Intellectual Property Rights: Unleashing the Knowledge Economy*, New Delhi, Tata McGraw Hill, at 156.

[59] US Patent No. 6,267,995 (issued July 31, 2001) (Extract of *Lepidium meyenii* roots for pharmaceutical applications).

[60] ETC Group (2002), "Peruvian farmers and indigenous people denounce maca patents", ETC Group, 3 July (http://www.etcgroup.org/documents/macafinal1.pdf).

[61]US Patent No. 6,093,421 (issued June 25, 2000) (Maca and antler for augmenting testosterone levels).

[62] In fact, Proctor indicated in his application for a Plant Variety Protection certificate on Enola (that was subsequently granted) that 'the yellow bean, Enola variety, is most likely a landrace from the [Mexican] azufrado-type varieties'. ETC Group (2001), 'Proctor's gamble', News Release: 17 December 2001.

[63] ETC Group (2001), 'Proctor's gamble', News Release: 17 December.

[64] In Pratt, T. (2001), 'Small yellow bean sets off international patent dispute, *New York Times* 20 March.

[65] In Carlsen, L. (2001), 'Little, yellow … different?', www.latintrade.com/newsite/content/archives.cfm?TopicID=3&StoryID=1385.

[66] Merrell Dow v. HN Norton (1996), *Intellectual Property Reports* 33: 1-14, at 10.

[67] Ibid.

[68] US Patent No. 4,673,575 (issued June 16, 1987) (A pharmaceutical preparation comprising the methanol extractable components of *Phyllanthus niruri L*, administered to patients suffering from hepatitis B virus infection to inhibit the growth of the virus).

[69] This idea appears first to have been suggested in print by Frédéric Hendrickx, Veit Koester and Christian Prip (see Hendrickx, F., V. Koester, and C. Prip (1993), "Access to genetic resources: a legal analysis", *Environmental Policy and Law* 23 (6): 250-258). See also Gadgil, M., and P. Devasia (1995), "Intellectual property rights and biological resources: specifying geographical origins and prior knowledge of uses", *Current Science* 69(8): 637-639. The Danish government with the support of some activist groups sought unsuccessfully to have the EU biotechnology inventions directive incorporate the mandatory disclosure idea.

[70] See ICC (2002), "Policy statement: should patent applicants disclose the origin of biological materials on which they file patents? Should they demonstrate Prior Informed Consent (PIC) for their use? Prepared by the Commission on Intellectual Property" (http://www.iccwbo.org/home/statements_rules/statements/2002/should_patent_applicants.asp).

[71] Legal opinion differs as to whether recitals of EU directives are legally binding or not. Whichever is the case, the word "should" does not suggest an absolute legal requirement. See Van Overwalle, G. (2002), "Belgium goes its own way on biodiversity and patents", *European Intellectual Property Review* 5: 233-236, at 233.

[72] Article 3 states that "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.".

[73] Van Overwalle, G. op cit., at 234. This approach has been criticised on the basis of both legality and practicality. With respect to the former, Van Overwalle (Ibid., at 234-235) notes that the legal basis for such an application of the ordre public and morality concepts is very weak. She argues that there is no precedent in Belgium or in civil law countries more generally for construing ordre public and morality concepts so broadly or for applying them to acts such as these which, wrong as they may seem to many people, would not be considered as extreme examples of intolerable or publicly unacceptable behaviour.

[74] Ibid. (emphasis added).

[75] The certification of origin idea was devised by Brendan Tobin, then of the Peruvian Society for Environmental Law. See Tobin, B. (1997), "Certificates of origin: a role for IPR regimes in securing prior informed consent", in J. Mugabe, C.V. Barber, G. Henne, L. Glowka, and A. La Viña (eds), *Access to Genetic Resources: Strategies for Sharing Benefits*, Nairobi: ACTS Press.

[76] Carvalho, N.P. de (2000), "Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: the problem and the solution", *Washington University Journal of Law and Policy* 2: 371-401.

[77] Article 26(h) and (i).

[78] World Trade Organization - General Council (1999), "Preparations for the 1999 Ministerial Conference. Proposals on IPR issues. Communication from India" [WT/GC/W/147].

[79] World Trade Organization – TRIPS Council (2000), "Review of Article 27.3(b). Communication from Brazil" [IP/C/W/228].

[80] Given the possibility that small and medium-sized businesses could conceivably find these measures burdensome, it may be a good idea for demandeur governments to consult with their domestic SMEs if they have not already done so.

[81] ICC (2002), op cit.

[82] Ibid. This is not to suggest that bioprospecting would necessarily be a waste of time in a country like Denmark. Several valuable antibiotic producing micro-organisms were discovered in temperate-zone countries, including penicillin, cephalosporin, Neomycin, Nystatin, Novobiocin and Lincomycin. See Le Fanu, J. (1999), *The Rise and Fall of Modern Medicine*, London: Little, Brown and Co., at 13.

[83] It is noteworthy that CBD-COP Decision VI/24 invited WIPO to prepare a technical study and to report its findings to COP 7 "on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia:

-Genetic resources utilized in the development of the claimed inventions;

-The country of origin of genetic resources utilized in the claimed inventions;

-Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;

-The source of associated traditional knowledge, innovations and practices; and

-Evidence of prior informed consent."

[84] See World Intellectual Property Organization (2002), op cit [note 10].

[85] This matter was the subject of a questionnaire carried out by WIPO's Standing Committee on the Law of Patents that was sent to governments and regional patent offices (World Intellectual Property Organization - Standing Committee on the Law of Patents (2001), "Information provided by members of the Standing Committee on the Law of Patents (SCP) concerning the definition of prior art. Brief summary. Prepared by the International Bureau" [SCP/6/INF/2]). One of the questions was as follows: "A ship is displayed at a quay for sale. Does a screw propeller of the ship, which is under water, constitute prior art?" This is somewhat analogous to the question whether a patented chemical substance with a therapeutic effect is anticipated by public use of a plant-based treatment whose effectiveness derives from the chemical's existence. WIPO summarised the responses thus:

Some of the countries that responded positively indicated that the screw propeller formed part of the prior art provided the visitors were able to see the screw propeller or they could be given any explanation about the screw propeller. Three countries that responded negatively expressly mentioned that it was not considered prior art because of the concealed feature of the object. Three countries considered that the fact that the ship was for sale would satisfy the requirement of "accessibility to the public." Further, two countries replied that if the quay was accessible to the public, for example in a public harbor, the screw propeller would constitute prior art. One country explained that, even if the screw propeller was hidden from view, as long as its use was without limitation, restriction or obligation of secrecy, it would be considered public use.

[86] Article 29 of the Patent Law of 1959 as amended by Law No. 220 of December 22, 1999.

[87] Japan Patent Office (2001), *Examination Guidelines for Patent and Utility Model in Japan*, Tokyo: JPO Examination Standard Office (Part II – "Requirements for patentability"), at 10.

[88] Morneault, M.A., and B.F. Rademaker (2001), "A maze of laws and exceptions: examples of novelty around the world", *Journal of World Intellectual Property* 4(1): 27-32, at 28.

[89] Bently, L., and B. Sherman (2001), *Intellectual Property Law*, Oxford: Oxford University Press, at 422.

[90] Article 54.

[91] In Bently and Sherman op cit., at 421.

[92] Ibid., at 419-420.

[93] UK Patent No. 2,338,235 and EP No. 1,222,927.

[94] Bently and Sherman op cit., at 420.

[95] There are of course very sound reasons for privileging certain forms of expression over others. In fact, we all do it and we can hardly expect patent examiners to be any different. Yet favouring the discourse of synthetic chemists over traditional healers is bound to seem grossly unfair to the latter. There is also a cultural bias in treating TK as part of the public domain for businesses to derive legal and economic monopolies from without having to compensate the TK holders. Somehow we need to recognise this and do something about it.

[96] According to Article 6bis paragraph 1:

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.

[97] Prott, L.V. (1988), "Cultural rights as peoples' rights in international law", in J.Crawford (ed.), *The Rights of Peoples*, Oxford: Clarendon Press.

[98] Cohen 1977, at 77. [add full ref.]

[99] According to conventional entitlement theory as developed by Calabresi and Melamed, all legal entitlements may be assigned "to one of two rules, 'property rules' and 'liability rules'. The former are best described as 'absolute permission rules': one cannot take these entitlements without prior permission of the owner. The rightholder, acting individually, thus sets the price … By contrast, liability rules are best described as 'take now, pay later'. They allow for non-owners to take the entitlement without permission of the owner, so long as they adequately compensate the owner later." Merges, R.P. (2001), "Institutions for intellectual property transactions: the case of patent pools", in R. Dreyfuss, D.L. Zimmerman, and H. First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, Oxford: Oxford University Press, at 131.

[100] Kuruk, P. (1999), Protecting folklore under modern intellectual property regimes: a reappraisal of the tensions between individual and communal rights in Africa and the United States, *American University Law Review* 48: 769-849.

[101] This proposal is described in: Carvalho, N.P. (n.d.), "From the shaman's hut to the patent office: how long and winding is the road?"

[102] World Intellectual Property Organization (2002), "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Third Session. Geneva, June 13 to 21, 2002. Review of existing intellectual property protection of traditional knowledge. Prepared by the Secretariat" [WIPO/GRTKF/IC/3/7]

[103] Text available (in Spanish) from http://www.indecopi.gob.pe

[104] Ruiz, M., and I. Lapeña (2002), "New Peruvian law protects indigenous peoples' collective knowledge", *Bridges* 6(6), at 15

[105] Drahos, P. (1997), "States and intellectual property: the past, the present and the future", in D. Saunders, and B. Sherman (eds), *From Berne to Geneva: Recent Developments in Copyright and Neighbouring Rights*, Brisbane: Australian Key Centre for Cultural and Media Policy and Impart Corporation.

[106] Four Directions Council (1996) *Forests, Indigenous Peoples and Biodiversity: Contribution of the Four Directions Council*.