

PROTECTION AND PROMOTION OF TRADITIONAL MEDICINE
IMPLICATIONS FOR PUBLIC HEALTH
IN DEVELOPING COUNTRIES

Carlos M. Correa
University of Buenos Aires
August 2002

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PREFACE

This study has been prepared with the support of the Rockefeller Foundation. A first draft was extensively reviewed by Catherine Monagle, who also undertook the final editing of the study. The author is also thankful for the comments made on the first draft by Graham Dutfield, Kelly P. Bannister, Gerry Bodeker, Xiaouri Zhang, Anthony Taubman, Jo Render, Robert Lettington, and Russell Barsh.

A review was also conducted by a group of experts convened by WHO, which met in New York on October 23, 2001, composed of Jerome Reichman, Catherine Monagle, Trevor Cook, Robert Weissman, German Velasquez, Xiaorui Zhang, Russell Barsh, Anthony So and the co-ordinator of the project, Carolyn Deere. The author, however, is solely responsible for the opinions contained in the study.

INTRODUCTION

Traditional medicine (hereinafter “TRM”)¹ includes knowledge and practices either codified in writing or transmitted orally. Non-codified, orally transmitted knowledge is generally held and used only within a limited circle of people such as within specific indigenous or rural communities and falls within the sometimes used terms “indigenous” (or “tribal”), “farmers” (or “rural”), “popular” (or “folk”) knowledge (Koning, 1998, p. 263). Systems of TRM codified in writing are often sophisticated systems of medicine supported by theories and rich experience. Such TRM is often widely diffused on a national scale as well as beyond national borders, as in the case, for example, of Traditional Chinese Medicine (TCM), Ayurveda, Unani, Tibetan, Mongolian and Thai traditional medicine, Kampo and Korean traditional medicine (based on TCM).

In some cases, different TRM systems coexist within the same country. In India, for instance, the orally transmitted “folk” system practiced by village physicians/folk healers and tribal communities, coexists with “scientific” (*Sasthreeya*) systems such as Ayurveda, Sidha, Unani and Amchi that are based on organized, codified and synthesized medical wisdom with strong theoretical and conceptual foundations and philosophical explanations (Pushpangadan 2002, p. 5).

TRM serves the health needs of the vast majority of people in developing countries, where access to “modern” health care services

¹ For the purposes of the analysis in this study, the following definition of TRM has been adopted: “The sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing” (WHO Traditional Medicine Programme. *Sung*, 1998).

and medicine is limited by economic and cultural factors. TRM is broadly used in such countries,² often being the only affordable treatment available to poor people and those in remote communities. In a context of persisting poverty and marginalization³ and, in particular, in view of the high prices generally charged for patented medicines,⁴ the relevance of TRM in developing countries may, in the future, increase.

TRM also plays an important role in developed countries. Many pharmaceutical products produced and used there are based on, or consist of, biological materials sourced through reference to traditional medicine. These include compounds extracted from plants and algae, as well as from microbial sources and animals. Plants, in particular, are an indispensable source of pharmaceuticals.⁵ The demand for “herbal medicines”⁶ has grown dramatically in recent

² For instance, the per capita consumption of TRM products in Malaysia is more than double the consumption of modern pharmaceuticals. TRM is even significant in relatively advanced developing countries such as South Korea, where the per capita consumption of TRM products is about 36% more than modern drugs (Balasubramanian, 1997, *pii*).

³ See, e.g., UNDP, 2001; Hirst and Thompson, 1996; Khor, 2000.

⁴ The TRIPS Agreement has imposed the obligation to recognize product patents for pharmaceuticals in all Members to the World Trade Organization. On the impact of patents on access to medicines in developing countries, see, e.g. Oxfam, 2000; Kettler, 2002.

⁵ See, e.g., Lambert, Srivastava and Vietmeyer, 1997, p. 1; ten Kate and Laird, 1999.

⁶ “Herbal medicines” are defined by WHO as “finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines. Exceptionally, in some countries herbal medicines may also contain, by tradition, natu-

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years. The world market for such medicines has reached, according to one estimate, US\$60 billion, with annual growth rates of between 5 and 15 per cent.⁷

Public policies with regard to TRM vary significantly between countries. Different policies exist, in particular, in relation to the integration⁸ of TRM in national health care systems. Some countries, such as China, the Republic of Korea and Vietnam, have adopted measures to promote integration⁹ aimed at exploiting the complementarities of TRM and modern medicine.¹⁰ Measures have included procedures for the registration of traditional healers or herbalists,¹¹

ral organic or inorganic active ingredients which are not of plant origin” (WHO, 1996, p. 178). For definitions in national laws, see Jayasuriya and Jayasuriya, 2002, p. 198.

⁷ Estimates by the Secretariat of the Convention on Biological Diversity, 2000. See also WHO, 2000a, p. vi.

⁸ The concept of ‘integration’ in the ethnomedical literature often implies the incorporation of aspects of TRM into national healthcare in a way acceptable to modern medicine. Many TRM associations prefer the term ‘partnership’ as suggesting a more equal relationship.

⁹ In China, for instance, the Constitution promulgated in 1982 and the present Constitution declared that the State should “develop both modern medicine and traditional medicine”. The Constitution establishes that “traditional Chinese Medicine and Western medicine should unite and learn from each other, mutually complement each other and improve together, in order to promote the integration of traditional Chinese and Western medicine”. See Xie, 2002, p. 119.

¹⁰ It has been noted, for instance, that TRM has been more effective than modern medicine in addressing some diseases, such as certain viral diseases (Xie, 2002, p. 127)

¹¹ In the case of Kenya, for instance, the herbalists have been required to register with the Ministry of Culture, and to obtain a recognition certificate. They have also been required to submit samples of all the herbal medicines they use to a scientific institution for testing (Kenya Medical Research Institute -KEMRI- or University of Nairobi), as well as to provide information on the names of the plants, the parts used, the methods of preparation, administration and dosages (Muchae, 2000, p. 12). See also Chandra, 2002, p. 152.

the establishment of specialized hospitals, colleges and universities,¹² the development of research programs,¹³ the validation and certification of TRM products,¹⁴ the introduction of ‘Good Manufacturing Practices’¹⁵ and the incorporation of medical doctors who have graduated from traditional medical universities, into the staff of hospitals of modern medicine to promote the use of TRM in combination with the practice of Western medicine.¹⁶ In some countries, such as Zimbabwe and South Africa, the responsible authorities accord substantial recognition to healers through national efforts designed to integrate traditional and Western medical systems. In others, healers are afforded no substantive recognition, their status existing purely within the custom of local communities (Lettington, 2000, p. 5).

TRM has been recognized in western science as a valuable source of products and treatments for health care. It often provides leads for the development and commercialization of new pharmaceutical products. However, western intellectual property systems have regarded TRM, as well as other components of traditional knowledge (TK), as information in the “public domain”,¹⁷ freely available for

¹² In China, in 1995 there were 2371 TCM hospitals and 30 TCM colleges, some of which have been promoted to university level. See Xie, 2002, p. 120-123. In India, there are 2.854 TRM hospitals and more than 387 colleges specializing in TRM (Chandra, 2002, p. 139).

¹³ See e.g., on China Xie, 2002, p. 129; on India, Chandra, 2002, p. 140. Several African countries, such as Burundi, Guinea, Tanzania, Cameroon and Mali, have established research institutions with statutory responsibility for undertaking research relating to TRM (Ayasuriya and Ayasuriya, 2002, p. 202).

¹⁴ In India, for instance, pharmacopoeial standards for 158 drugs are available and 634 formulations have been published in the Ayurvedic Formulary of India. Thousands of Ayurvedic and Unani formulations are licensed for sale over the counter by the national and local governments (Chandra, 2002, p. 143 and 138).

¹⁵ Such as in India and Indonesia (Chandra, 2002, p. 139).

¹⁶ See, e.g., Xie, 2002, p. 119; Chandra, 2002, p. 143.

¹⁷ “Public domain” is generally understood in the IPRs field, as including any information that is not subject to IPRs or for which IPRs have expired. This means that, to the extent that some information is not covered under any of the

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use by anybody. This has meant that TRM and other traditional knowledge has been exploited in Western contexts without any recognition, moral or economic, to those who originated or held the relevant knowledge. Further, diverse components of TRM have been appropriated under intellectual property rights (IPRs) by researchers and commercial enterprises, without any compensation to the knowledge's creators or holders.

Due to such cases of appropriation, growing attention has been paid in the last ten years to the issue of "protection" of traditional knowledge, including TRM. However, "protection" has been used in the literature and advocated by many interested groups, with quite different conceptions and goals in mind.

Some (e.g. Downes, 1997) understand "protection" in the context of IPRs, where it essentially means to *exclude* the unauthorized use by third parties of protected knowledge. Under this approach, IPRs may constitute either an *offensive* mechanism to support the commercialization of TK and to ensure benefit sharing,¹⁸ or a *defensive* tool to prevent the *misappropriation* of traditional knowledge.

Others (e.g., Simpson, 1997) regard "protection" as a means to *preserve* traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. Protection here has a direct positive role in supporting TK based communities' livelihoods and cultures, and requires the application of mechanisms -- such as conservation projects -- where IPRs have little or no part to play.

IPRs modalities, it would belong to such domain and could be freely used. See, e.g., Fishman, 2000, p. 1/3.

¹⁸ "Benefit sharing" refers here to the fair and equitable participation of TK holders in the benefits arising from the commercial and other utilization of TK. See article 15 (7) of the Convention on Biological Diversity.

While all these forms of ‘protection’ are important, this paper focuses on issues relating to protection of TRM in the context of IPRs, both as a defensive and offensive strategy. Its main purpose is to try to clarify the extent to which IPRs may be used in relation to TRM, and what the implications of such use may be for public health.

Some aspects of TRM may be protected under existing IPRs, such as patents. There have also been proposals to develop *sui generis* systems of protection -- that is, systems specially suited to the characteristics of traditional knowledge, including TRM.¹⁹ While such proposals in general fail to clearly set out the *rationale* for their adoption²⁰, they are often, explicitly or implicitly, based on considerations of equity: if innovators in the “formal” system of innovation receive compensation through IPRs, justice requires that holders of traditional knowledge be similarly treated.

Though IPRs may, under some circumstances, help TRM holders to obtain a monetary compensation for their knowledge, by their very nature IPRs restrict the diffusion of the protected knowledge, thereby reducing static efficiency and imposing a cost on society. In the case of TRM in particular, the application of IPRs may benefit those who commercially exploit protected knowledge or who share in the benefits of such a commercialization, but at the cost of limiting access to TRM by those who need medicines and treatment. A tension, therefore, arises between different objectives: to compensate TRM holders and promote the commercialization of TMR, on the one hand, and to ensure the widest possible access to TRM, especially by the poor, on the other.

This study examines, first, some characteristics of TRM relevant to issues of IPRs protection. Second, it considers the rationale for the protection of TRM under IPRs, existing or to be created. Third, it discusses the extent to which existing modes of IPRs

¹⁹ See, e.g. Ruiz Müller, 2002.

²⁰ See, e.g. Girsberger, 2000, p. 1-3.

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(patents, trade secrets, trademarks and geographical indications) may be applied to TRM. Particular emphasis is given to the discussion of patents, with the other forms of IPRs being touched on more briefly. Fourth, in the light of the analysis presented in the preceding sections, policy options available for the protection and promotion of TRM in the context of health policies are discussed, with consideration given to both IPRs and non-IPRs modalities. Finally, some considerations are raised relating to the issue of IPRs protection of TRM in the context of public health policy.

I. INTELLECTUAL PROPERTY AND TRM

IPRs are granted to individuals or juridical persons who claim to be inventors or creators. Such rights may apply to a broad range of creative expressions, designs, products and processes, provided that certain requirements and conditions are met. Thus, in the case of patents, the claimed invention must be novel (that is, not publicly available or disclosed), convey an inventive activity and, in most jurisdictions, be capable of industrial application. Ornamental designs may be protected if original. Trade secrets law protects knowledge of actual or potential commercial value.

There is, *a priori*, no reason why such categories of rights may not apply to various expressions of traditional knowledge, including TRM. However, there are several characteristics of TRM that create barriers to protection through the use of existing forms of IPRs.

This section briefly presents some of the features of TRM that may determine the extent to which patents and other IPRs can be applied to its various expressions.²¹ The discussion in this section does not address the question of whether IPRs *can* or *should be applied* to TRM, but rather highlights peculiar characteristics of TRM that may be relevant to the potential application of such rights. Section III examines the use of patents and (to a lesser extent) other IPRs to protect TRM.

A. Components

²¹ With regard to enforcement issues, see section IV. f below.

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As defined above, TRM encompasses knowledge and practices used for diagnosis, prevention and cure. An important part of TRM knowledge refers to the properties of natural *materials* used in their wild form, or as part of a preparation or mixture. Such materials include plant based or “herbal medicines”,²² as well as animal parts and minerals.

“Folk” traditions as well as other systems of TRM use a large number of medicinal plants. As a result of this extensive use of plants,²³ the concept of TRM is more often known as being linked to plant-based medicines. However, animal-based medicines have played a significant role in healing practices, magic rituals, and religions of many societies. In fact, of the 252 essential medicines selected by the World Health Organization, 11,1 per cent come from plants and 8,7 per cent are derived from animals (Medeiros Costa Neto, 1999, p. 6).

In addition, TRM encompasses a great variety of *methods* of diagnosis and treatment, including physical, mental and spiritual therapies. The application of such methods is strongly influenced by the culture and beliefs dominant in a particular community,²⁴ to the extent that they may be ineffective when applied in a different context.

TRM includes, thus, knowledge concerning medicines and their use (appropriate dosage, particular forms of administration,

²² See definition above.

²³ In India, for instance, the codified systems of medicine utilize about 2000 plant species for medicinal purpose, while the tribal communities, who live in and around the forests, utilize over 8000 species of plants, most of which are otherwise not known to the outside world (Pushpangadan 2002, p. 5). See, also, Shankar, 1996, p. 170.

²⁴ Physical methods of treatment involve muscle manipulation and massage. Mental methods of treatment involve self discipline in the form, for instance, of a strict diet. Spiritual methods of treatment include, for instance, prayers and use of holy water (Koon, 1999, p. 167).

etc.), as well as the procedures and rituals applied by healers as part of their traditional healing methods. In some cases therapies are primarily applied without the use of medication, such as acupuncture, chiropractic, Qigong, T'ai Chi, yoga, naturopathy, thermal therapy, and other physical, mental, spiritual and mind-body therapies.

As discussed below, while some products used in the context of TRM, as well the processes for their preparation, may find protection under patents and other IPRs, methods of diagnosis and treatment generally would not, unless the protection of such methods is specifically provided for by national law.

B. Possession

In some cases, TRM knowledge is produced by individuals without any interface with the community or outsiders. It may, hence, be held by individuals ("individual knowledge").²⁵ For instance, healers use *rituals* as part of their traditional healing methods, often allowing them to monopolize their knowledge, despite disclosure of the phytochemical products or techniques used (Bhatti, 2000, p. 13).²⁶ In addition, individuals continuously improve or innovate on existing knowledge.

In other cases, knowledge is in the possession of some but not all members of a group ("distributed knowledge"). Knowledge is asymmetrically distributed among individuals within a group, even though such individuals may not be aware that others share the same

²⁵ A review of anthropological literature reveals that certain authors suggest that concepts close or equivalent to individual forms of IPRs are quite common in indigenous and traditional proprietary systems (see, e.g. Dutfield, 2000a, p. 69). According to one view, the right of an indigenous inventor or custodian of TK should not be sacrificed on the alter of collective ownership, since this would infringe fundamental human rights (Gupta, 2002a)

²⁶ Though the extent to which such *prima facie* individual knowledge can be truly classified as individual knowledge depends on other factors, as discussed below.

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knowledge (Bonabeau and Theraulaz, 1994). “Individual” and “distributed” knowledge are often interconnected. In some TRM systems healers compare notes and share remedies across quite wide geographic areas.²⁷

Finally, certain knowledge may be available to all the members of a group (“common knowledge”), such as where knowledge of herbal home remedies is held by millions of people, often concentrated among women and the elderly. This “common knowledge” may not be confined to one group or country, and may even be held across national boundaries.

The attitudes towards the appropriation and sharing of knowledge vary significantly among different local/indigenous cultures. In some cases a strong sharing ethos prevails, leading to the rejection of any form of individualistic, Western model of appropriation. In other cultures, the concept of property in knowledge exists in a manner comparable to IPRs, with some degree of sale or exchange of knowledge as a commodity (Dutfield, 2000a, p. 281-282; Dutfield, 2000b, p. 288). Even if that is the case, often there is no clear demarcation between personal and community ownership as exists in the Western worldview.

Possession of knowledge by individuals, in effect, does not mean that such knowledge is perceived by communities as not belonging to them. Though at any one time, the knowledge may only be held by a handful of people with special roles in the community, in the course of the history of that community it is essentially communally held knowledge. Those with the special knowledge do not “own” it as such, and many have obligations to share the knowledge within the community at different intervals. There may exist, for instance, community standards for when the information must be passed, such as during initiation rituals. These features indicate slight but important differences between the meaning of individual property in Western culture, and knowledge held by individuals within a non

²⁷ This is, e.g., the case in Burundi (Communication by Burlington of 27.8.01).

Western community context. For instance, a study on herbal knowledge in India concluded that

“There is no clear demarcation between what belongs to the general community, specific community, or individuals within the communities. Certainly for the herbalists, as indicated in the results of the case study, herbal knowledge is treated as personal property. However, some of the knowledge they possess is relatively available in the same form in the general community due to the older tradition of sharing knowledge. The herbalists have continuously innovated what is available in the general community and hence they possess special rights to their innovations. It is hard to determine how the benefits should be shared if there is no clarity in the ownership.” (Sharma, 2000, p. 5).

In cases where there is distributed and common possession of knowledge,²⁸ complex issues of entitlement to any possible intellectual property rights also arise, since Western IPRs systems do not provide for the granting of rights to communities as such. In many instances, in addition, the same knowledge may be held by more than one community, and an issue of geographical or historical priority arises (for instance, kava in various Pacific Cultures, and the use of neem derivatives throughout South and South East Asia).

The multiplicity of factual situations as to the possession of TRM makes it particularly hard to apply existing IPRs or to develop *sui generis* regimes, as discussed below.

C. Evolution

²⁸ For an alternative classification of modalities of knowledge possession based on the concept of “negative” and “positive” community domains, 1997, p. 185.

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Much TRM has been used for generations and has been passed on inter-generationally, as indicated in the WHO definition mentioned above.²⁹ However, TRM is not a static body of knowledge; it continues to evolve with the practices of the individuals/communities that hold and use it (Correa, 2000a, p. 242). TRM, like other bodies of knowledge, is built on incrementally by improvement on and additions to old knowledge.³⁰ Thus, TRM consists of knowledge received from the past and handed down from generation to generation but also includes recent knowledge that may be the product of deliberate experimentation and observation. Thus, healers in traditional/indigenous communities do contribute to the pool of existing knowledge. Moreover, formal and informal research takes place within codified TRM systems. The Canadian Indigenous peoples organization, the Four Directions Council, has suggested that

*“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 people acquire from settlers and industrialized societies”.*³¹

D. Disclosure

A significant part of TRM has been disclosed as a result of codification (that is, formalization in written form), wide use, or through collection and publication by anthropologists, historians, botanists or

²⁹ See footnote 1.

³⁰ It should be noted that the word “innovations” is used in article 8 (j) the Convention on Biological Diversity, thereby indicating that not all traditional knowledge is ancient or non-contemporary.

³¹ Quoted by Dutfield, 2000, p. 3.

other researchers and observers (Koning, 1998, p. 270). The longer TRM knowledge has been around, the more likely it is to have been disclosed through use and publication.

The codified TRM tradition consists of medical knowledge with sophisticated theoretical foundations (Shankar, Hafeel and Suma, 1999, p. 10). The Ayurvedic system of medicine is a particularly good example, as it is codified in 54 authoritative books. Codified TRM has been made publicly available and, hence, under current IPRs rules, could not be appropriated, either by its traditional holders or third parties.

As indicated previously, non-codified systems include what have been termed “folk”, “rural”, “tribal” and “indigenous” TRM, which has been handed over orally from generation to generation. Such systems of medicine, are generally based on traditional beliefs, norms and practices based on centuries old experiences of trials and errors, successes and failures at the household and community level. These are passed through oral tradition and may be called ‘people’s health culture’ (Balasubramanian, 1997, p. 1)

However, there are cases in which TRM is and has always been kept secret. In specialized areas, such as knowledge dealt with by bone-setters, midwives or traditional birth attendants and herbalists, including knowledge of healing techniques and properties of plants and animal substances, access is restricted to certain classes of people (Koon, 1999, p. 158).

In Kenya, for instance, a study on herbal medicine showed that most of the herbalists interviewed maintained the secrecy of their knowledge:

“In Kenya, among the members of the Kikuyu community, indigenous knowledge in some fields was a well guarded secret. For instance a person who had acquired special skills as a black smith would not allow just anybody to walk into his workshop and watch him make such instruments as spears, pangas, diggings hoes, etc. The skills of making such

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instruments were carefully guarded. Such a person would only train his son or a very close relative. The same case applied to herbalists. An intruder was always heavily fined in order to deter any attempt to steal such knowledge. The problem with this type of system is that such important knowledge was owned by and confined to a few family members and rapid development on innovations was hampered by secrecy” (Muchae, 2000, p. 6).

While prior disclosure of TRM will in many cases prevent the acquisition of IPRs, notably patents, not all TRM may be deemed as disclosed and lacking novelty for the purpose of IPRs protection.

E. Commercial Value

Some TRM can be used and understood outside its local, traditional and/or communal context and acquire commercial value, but this is not always the case. There are spiritual components in the TRM peculiar to each community. Knowledge that cannot be utilized beyond its communal context has little or no commercial value, despite the value that such knowledge may have for communal life (Koning, 1998, p. 265).

The commercial value of TRM can be directly reaped by the knowledge holders or through transmission of knowledge to researchers and companies, domestic or foreign. TRM’s commercial value may derive from different activities, such as cultivation of medicinal plants for sale or production and distribution of TRM-based medicines. TRM can also be a signpost for the screening of natural products for therapeutic benefit,³² or useful to confirm research results produced in the laboratory and complement scientific testing, including safety and efficacy.

³² Biochemist Norman Farnsworth’s (1988) estimated that of the 119 plant-based compounds used in medicine worldwide, 74 per cent had the same or related uses as the medicinal plants from which they were derived (Duffield 2000, p. 10).

Cultivation of medicinal plants is one increasingly important component of the TRM value added chain. Although cultivation from the wild continues to provide the majority of plant material consumed by the herbal medicine industry, in Asia the trend is towards agriculturally cultivated materials that often better guarantee supplies, consistency, species identification, and high levels of post-harvest handling (ten Kate and Laird, 1999, p. 101; Chandra, 2002, 142).³³ In contrast, in Africa, whose population relies greatly on TRM, virtually no investment in such cultivation of medicinal plants has been made.³⁴

The production and commercialization (including internationally) of products based on codified TRM generates considerable value. For instance, the total Indian Ayurvedic market was estimated at Rs 1000 Crore in 1999 (Warrier, 1999, p. 14). TRM was estimated to generate for China -- the leading country in this field -- income for about US\$5 billion in 1999 from the international market and US\$1 billion from the domestic market. Europe's TRM market in 1999 was calculated to be US\$11.9 billion (Germany contributing 38 per cent, France 21 per cent and United Kingdom 12 per cent) (Pranoto, 2001, p. 2).

Attempts have been made to estimate the contribution of biodiversity related traditional knowledge to modern industry, particularly pharmaceuticals. Nevertheless, estimating the full value of traditional knowledge in monetary terms is difficult if not impossible,³⁵ and significant controversy exists about the value of TRM as a source of new products for pharmaceutical companies. It has been

³³ In India it has been noted, however, that less than 30 of the medicinal plants utilized by the industry are under commercial cultivation. 80,000 metric tones a year of certain plant varieties are being collected from the wild. At this rate of collection, the TRM industry may crash because of lack of suppliers in the short term (Shankar, 1996, p. 171).

³⁴ Personal communication Bodeker 2001.

³⁵ See, e.g. Dutfield 2000, p. 10

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pointed out that in some cases pharmaceutical companies have obtained considerable benefits from the exploitation of TRM.³⁶ Some have observed, however, a declining interest by pharmaceutical companies in bio-prospecting for new drugs,³⁷ especially in view of the opportunities opened by genomics, combinatorial chemistry and proteomics.³⁸ Others suspect that pharmaceuticals companies may wish to downplay their involvement in “biopiracy” and to de-emphasise the risk of appropriation, so that policy makers will create more advantageous policy measures for access and benefit sharing.

Established agreements for access and benefit sharing do not assist in providing a clear picture of the commercial value of non-codified TRM. A small number of publications in the ethno-botanical literature (Blum 1993; Carlson et al. 1997; King and Carlson 1995; Carlson, 2001; Nelson-Harrison et al, 2002) describe real life examples of how agreements for research and benefit sharing were established and implemented between northern researchers and communities.³⁹ An analysis of bio-prospecting undertaken since 1992 in developing countries by the International Cooperative Biodiversity Groups (ICBG) funded by the U.S. National Institutes of Health (National Cancer Institute), showed that four out of eight ICBG projects collected ethnomedical data, and three used ethnomedical data to select plants for testing. Three big pharmaceutical corporations and an emerging biotechnology company participated in ICBG projects,

³⁶ An often cited case is the use of the Madagascan rosy periwinkle plant by Eli Lilly for the treatment of Hodgkin’s disease (a type of lymph cancer) and childhoodleukemia.

³⁷ According to Greene, some imagine “that traditional medicinal knowledge of indigenous peoples is an object of great interest to drug companies and hence deserving of a high value (given its scarcity). Analysis of the case at hand and continuing trends away from research involving traditional plant remedies in the pharmaceutical industry cast great doubt on the dollar value of traditional knowledge to pharmaceutical companies (Greene, 2001, p. 31).

³⁸ See, e.g. Barsh, 2001.

³⁹ See also Laird, 2002, and BerDak, 1999.

along with six U.S. universities. Only one U.S. patent⁴⁰ resulted from the ICBG program, despite that 200,000 field specimens had been screened (Barsh, 2001). Examples of agreements for acquiring and developing TRM, include the agreement between Merck and the Instituto Nacional de Biodiversidad (INBio) of Costa Rica, and that between Extracta (a Brazilian company) and Glaxo-Wellcome, aimed at investigating natural compounds for use as antibiotics and treatment of tropical diseases, such as dengue fever.⁴¹ There is, however, no precise data available on the commercial benefits arising from these contracts, probably because it will take several years for them to be generated, if commercial benefits arise at all.

F. Role in Public Health

Whatever the commercial value of TRM may be, it is well established that TRM plays a crucial role in health care for a large part of the population living in developing countries. According to the World Health Organization,

“...up to 80 per cent of Africans –or more than a half billion people- visit traditional healers for some or all of their medical care. In Africa and in many developing nations, medical services are limited or unobtainable for the majority of the population. It is the traditional healers and birth attendants in rural and urban areas that have historically provided and continue to provide primary healthcare. They are the vital link to supplying the needed services in their communities, and yet their efforts must continue to expand as populations grow, and health concerns continue to increase

⁴⁰ U.S. Patent No. 5.591.770 on the use of extracts of the Sarawak tree (*Calophyllum lanigerum*) in chemotherapy, which is being worked by a joint venture between university scientists and the government of Sarawak.

⁴¹ *Journal do Brasil*, July 30, 1999.

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in complexity and case numbers" (Nelson-Harrison et al, 2002, p. 283).

The function that TRM plays in health care in developing countries has often been overlooked when considering the issue of IPRs protection. Attempts to realize the commercial value of TRM may conflict with the achievement of some public health objectives, particularly increasing access to medicines by the poor. Public health implications will be examined further in section V below.

II. RATIONALE FOR PROTECTION

The “protection” of TRM under IPRs - generally as part of “traditional knowledge”- has been advocated in many national, regional and international fora, documents and academic work⁴². The provision contained in article 8 (j) of the Convention on Biological Diversity (CBD), as adopted in 1992, triggered a number of proposals to deal with this issue at the national and international level⁴³. Most notably, in 2000, an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established under the auspices of WIPO.⁴⁴

The need for applying IPRs to TRM depends upon the type of objectives pursued, and the extent to which they can be fulfilled by different modalities of IPRs, existing or to be created. Since IPRs are not an end in themselves, the establishment of IPRs should be considered as a *means* to effectively reach well defined goals.⁴⁵

The main goals suggested or implied in various analyses for IPRs protection of traditional knowledge, including TRM, have been equity, the preservation of knowledge against erosion, preventing misappropriation, promoting self-determination and the right to de-

⁴² See, e.g. an annotated bibliography Dunfield, 2000a. See also Gorrea, 2001.

⁴³ See e.g. the Report of the UN Secretary General on the Intellectual Property of Indigenous Peoples, EICN.41 Sub.2/1992/30.

⁴⁴ This Committee (hereinafter the “WIPO Committee”) held its first meeting in Geneva, on April 30 to May 3, 2001.

⁴⁵ On the rationale for the granting of IPRs, see, e.g., Penrose, 1951; Gutterman, 1997; Bettig, 1996.

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velopment. In certain combinations these goals partially interconnect or overlap, while in others they are mutually incompatible.⁴⁶

All of these goals have some legitimacy. However, as examined below, IPRs in many cases, may *not* be a suitable tool to achieve the intended goals, and other effective instruments may have to be utilized. The following sub-sections briefly present the arguments advanced for the IPRs protection of traditional knowledge, as relevant to TRM.

A. Equity

Proposals for the protection of traditional knowledge (including codified and non-codified TRM) are often based, explicitly or implicitly, on *equity* considerations.⁴⁷ A main objective of protection would be to obtain recognition and some compensation for the commercial use of TRM outside the community or the society which generated it, either by excluding the unauthorized use by third parties, or by ensuring a right to remuneration (or benefit sharing) for such use.

Equity can also be understood, in this context, in the sense of allowing indigenous people to access a system (IPRs) that other peoples can access to gain reward for their own knowledge/innovations, so that they have the capacity to be rewarded through licensing or undertaking commercialisation themselves. This second interpretation of 'equity' is a common implicitly assumed rationale for expanding IPRs to cover traditional knowledge.

Though only applicable to biological resources and the knowledge associated to its conservation and sustainable use, the CBD offers a possible model, not necessarily based on the granting of IPRs,

⁴⁶ For instance, the type of measures required to prevent the granting of IPRs over TRM under a misappropriation approach, are essentially incompatible with those aimed at encouraging the commercialization of TRM through the acquisition of IPRs.

⁴⁷ See, e.g. Ekpere, 2002.

for bringing more justice into essentially asymmetric relationships. In implementing the CBD some countries have considered how to extend the principles of prior informed consent and benefit sharing to the knowledge associated to the use of biological diversity.⁴⁸ Such a model, however, would apply to cases of bio-prospecting rather than to the utilization of existing and publicly available knowledge under codified TRM systems, such as Chinese medicine or Ayurveda.

There is some experience with “bio-prospecting” of medicinal plants under agreements that provide for benefit sharing with the local/indigenous communities that supplied the relevant knowledge and/or materials (Grifo and Downes, 1996). Nevertheless, TRM knowledge holders should not be assumed to necessarily expect a monetary reward for the knowledge they supply (or is otherwise appropriated). While Western IPRs assume that the act of innovation or creation is largely motivated by financial gain, local/indigenous communities generally believe that knowledge is socially created, through interaction amongst humans and nature, and that individuals are obliged to put their knowledge to use to the benefit of the community without expecting a monetary compensation. Thus, the way most healers are paid, at least the traditional ones in Eastern and Southern Africa, is through a voluntary system including *pro bono* work and soft loans.⁴⁹ The voluntary aspect functions because of social aspects: fear of ancestors, spirits or whatever force is believed to be behind the medicine, makes people pay what they are able to because otherwise they believe the medicine will not work. The voluntary system is extremely important as it serves a social purpose, fitting what might be described as the healers’ Hippocratic Oath.⁵⁰

⁴⁸ Decision 391 of the Andean Group countries mandated the development of mechanisms to protect traditional knowledge (transitional provision 8). See on the experience of the Andean Group countries, Rigz Müller, 2000.

⁴⁹ Personal communication by Rettington, 27-8-01.

⁵⁰ *Ibidem*.

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Hence, equity-based claims of protection are not necessarily equivalent to demands of remuneration. Moreover, in some communities a monetary payment may be regarded as morally unacceptable, or custodians of knowledge may not be free to make money out of it, or to transmit it for use outside their cultural or spiritual context. In fact, to do so can cause a great deal of offence, resentment and even distress.⁵¹

A study on herbal medicines made in Kenya revealed that:

“Eighty per cent of those interviewed are well-informed about the commercial value of their knowledge and were quick to indicate that access to it can always be negotiated. Five of the herbalists indicated that futile attempts have been made by foreigners to obtain information on particular herbal remedies. Seven of the herbalists indicated that they have been approached by local scientists for information. Apparently the herbalists were aware that the information so given was to be used in research and the information was given in mutual trust and confidence. Surprisingly, none of the herbalists had entered into any agreement about the future of the results or final destiny of the information so given” (Muchae, 2000, p. 12).

In sum, while claims for justice seem well founded in cases of misappropriation, it may be wrong to assume that local/indigenous communities regard monetary payments as the most adequate means to find relief from the injuries suffered by them when knowledge is appropriated. In many instances, they may rather seek a moral recognition of their contribution to the development of the knowledge. The communities may not want to be ripped off but they also may not want some kind of IPR-type system to be imposed on them. In many cases, they may not be interested in an economic compensa-

⁵¹ Communication by G. Dutfeld to the electronic dialogue on traditional knowledge of the UK Commission on Intellectual Property Rights, 27-11-01 (www.iprcommission.org).

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tion, but just in respect for and recognition of their culture and beliefs.

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B. Preservation

The “protection” of TRM may also aim at its preservation,⁵² requiring actions of very different nature, such as avoiding uses that may erode TRM, addressing problems that negatively affect the life or culture of the communities that hold it, and documenting the relevant knowledge.

Most medicinal plants are gathered from the wild.⁵³ For instance, India and China reportedly harvest 90 per cent and 80 per cent of their medicinal plants respectively from uncultivated sources. A similar situation exists in Africa. Due to ever-expanding populations and the expansion of practices such as logging, the biodiversity-dependant communities are currently facing the degradation of the ecosystems on which they depend (Lettington, 2000, p.12). Wild populations of species like pygeum (*Prunus Africana*) and yohimbe (*Pausinystalia yohimbe*) are currently harvested in unsustainable and destructive ways in order to feed international markets. Around 200 medicinal plant species have been added to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) appendices (ten Kate and Laird, 1999, p. 102).

During the period 1990-1993, Africa lost 3.7 millions hectares of forest every year or an annual deforesting rate of 0.7 per cent (more than double the global average, which averages 0.3 per cent). African forest cover 520 millions hectares or close to 18 per cent of the area of the continent. Conservation of natural resources is crucial to an ecosystem capable of supporting the continued practice of TRM (Nelson-Harrison et al, 2002, p. 283). Direct measures to prevent

⁵² Preservation is not actually a rationale in and of itself, but a proxy for other possible rationales, normally either cultural integrity or the value of use (personal communication by Lettington, 27.8.01).

⁵³ The use of the term ‘wild’ for these areas of collection, however, may be inappropriate, since such areas are cared for/conserved as part of the indigenous management system, though this may not be an obvious conservation effort to Western observers.

overexploitation of medicinal plants and development of cultivation techniques to allow cultivation (and perhaps improvement) of the required plants (Pranoto, 2001, p. 3) may be crucial to the preservation of TRM.

Further, cultural erosion⁵⁴ may be a powerful factor in the loss of TRM. As youth move to urban areas and education de-emphasizes the value of traditional culture and knowledge, TRM loses its heirs.⁵⁵ Thus, it has been noted that in the Asian context:

“Urbanization and the advent of the nuclear family leading to the virtual disappearance of the grandmother, the mother-in-law, and the village elders, have led to a situation where common remedies which had been administered without any doctors for years have now become questionable for a new generation of Western-educated urban public exposed only to the allopathic system and allopathic drugs. The age-old practices of maintaining kitchen gardens and visits to the village grocer who stocked all the dried herbs have gone into disuse in the cities. Knowledge about which part of the plant is to be used, namely, the root, stem, bark or leaves, has been effaced. Yet, for centuries this had been the mainstay of entire populations, long before allopathy came on the scene, and continues to be so for tribal and village people in many developing countries even today” (Chandra, 2002, p. 138).

An obvious action to preserve TRM knowledge is to document it. India has pioneered initiatives for the documentation of traditional knowledge, including TRM. It launched an ‘All India Coordinated

⁵⁴ The crisis affecting the world’s diverse culture and languages is, according to some estimates, far greater than the biodiversity crisis. Around 90% of the 6000+ currently spoken languages (and the cultures expressed by them) may have gone extinct or face extinction in the next one hundred years (Oviedo, Gonzalez and Maffi, 2000, p. 6).

⁵⁵ Personal communication B. Bodeker, 13 August 2001.

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Research Project on Ethnobiology' (AICRPE) under the Man and the Biosphere Program in 1982. The overall objective of AICRPE was to make an in-depth study and analysis of the multidimensional perspectives of the life, culture, tradition and knowledge system of the tribal communities of India. Initially the project was administered under the Department of Science and Technology, but was later transferred to the Indian Ministry of Environment and Forests. It operated at 27 centers within India, utilized approximately 600 scientists drawn from botany, zoology, sociology, anthropology, ayurveda, chemistry and pharmacology and lasted for 16 years (1982-1998). The AICRPE project documented the use of over 10,000 wild plants used by tribal peoples to meet a variety of their needs (Pushpangadan 2002, p. 5).

The "Gene Campaign" project has also aimed at documenting the biodiversity and related knowledge of three tribal populations in India: the Munnars in South Bihar (in the Chotanagpur region); the Bhils of Madhya Pradesh; and the Tharus of the Terai region. Medicinal plants and related knowledge was sought and documented with the help of educated tribal youth. Elders in the village, medical practitioners and traditional healers were consulted in the collection and understanding of the information (Government of India, 2000).

Similar initiatives have been established in other countries. For example:

- In the Peoples Democratic Republic of Laos, the Traditional Medicines Resource Centre (TRMC) works with local healers to document details of all traditional medicine with a view to promoting a sharing of practices within Laos. The TRMC is also collaborating with the International Co-operative Biodiversity Group (ICBG) in efforts to discover prospective medicinal products. Any profits or royalties realized from plants and knowledge recovered during the collaboration will be shared with all the involved communities (Riley, 2000).

- In the Ivory Coast a TRM program was set up by Ministry of Health in 1978. In order to protect traditional medicinal knowledge and promote proper use of traditional medicine. This program conducted surveys of traditional health practitioners in 7 out of 19 regions of the Ivory Coast and has recorded more than 1,000 medicinal plants, used traditionally used by traditional health practitioners.
- In the United Arab Emirates, there is a long history in the use of traditional medicine. The Zayed Complex for Herbal Research & Traditional Medicine (ZCHRTM) was established in 1996. One of its basic missions is to collect, record and analyze the traditional medicine knowledge from traditional practitioners.
- The Government of Iran has, since 1990, supported the development of a national inventory of medicinal plants. Up to now, 2.500 flora of 8.000 plants have been listed, classified and divided into 20 volumes. The National Academy of Traditional Medicine in Iran and Islam was established in 1991. One of its objectives is to study the history of Iranian traditional medicine and preserve Iran's traditional medicine.

While these efforts are valuable and should be continued, the question to be addressed here is what role can intellectual property play in preserving TRM. The Crucible Group has considered with some detail the arguments for and against a possible function of IPRs in the preservation of traditional knowledge. The Group identified general reasons that may, if the cause and effect assumptions within the arguments can be substantiated, justify a system of IPR protection as a means to ensure the preservation of such knowledge. According to one of such arguments,

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“Vesting legally recognized ownership of knowledge in communities through sui generis IPRs will raise the profile of that knowledge and encourage respect for it both inside and outside the knowledge holding communities. This will make the learning and development of such knowledge a more attractive prospect for the younger members of such communities, thus perpetuating its existence.

The possibility of economic returns for the use of that knowledge by third parties acts as a further incentive for community members to respect their knowledge and continue to engage in practices in which that knowledge is used and generated.

Indigenous and local knowledge holders will be more willing to disclose otherwise secret knowledge once they know sui generis laws can give them control over how their knowledge gets used. In this way, IP laws encourage the disclosure, use and proliferation of knowledge that might otherwise be lost” (The Crucible Group, 2001).

The Group also noted, however, that merely using a law to make something into property that was previously part of the public domain

“does not suddenly save it, conserve it, make people respect it or want to use it...Fencing off their knowledge does nothing to protect it from being even more eroded, undermined, or ignored or at risk of being lost” (The Crucible Group, 2001).

Some indigenous people may find the suggestion that recognition through a Western system will mean that they have any more respect for and tendency to preserve their own traditional knowledge insulting. The inclination to preserve knowledge may well relate more to an understanding of and pride in their own culture and beliefs relating to ownership and distribution of knowledge than in acceptance within and validation by an alien framework. Communities may be more inclined to preserve and transmit their TRM knowledge to future generations if their rights are respected, for example, under

mainstream recognition of their own customary laws, rather than through creating and applying new IPRs systems alien to their culture and beliefs.

IPRs may have little or no impact on the preservation of TRM knowledge, if other critical conditions are not met, such as the continuous interaction of the communities with the natural environment in which their cultures and lifestyles have developed and evolve. TRM is unique to a given culture or society and is developed as a result of the co-evolution and co-existence of both the indigenous cultures and their traditional practices of resource use and ecosystem management (Pushpangadan, 2002).

As mentioned above, TRM is not static, but continuously evolves through incremental innovation. Policies for the “preservation” of such knowledge should ensure the maintenance of the sources of such evolution. While commercial interests may provide incentives for that purpose in certain contexts, notably in the case of codified TRM systems, in other contexts, such as small communities or tribes, the key factor may be the protection of their cultural integrity, which may be threatened rather than enhanced by prospects (sometimes not realistic or achievable) of monetary returns.

In conclusion, the protection of TRM as a means for the preservation of relevant knowledge, requires as a fundamental condition the maintenance of the traditional lifestyles and cultures, and of the ecosystems where the TRM has developed and continues to evolve. It is likely that IPRs can do little, if anything, to effectively preserve TRM and the sources of materials used for the preparation of medicinal products, or to ensure that such knowledge continues to be improved over time, if such other conditions are not met. An excessive focus on IPRs may deviate attention from the most crucial factors on which the preservation of TRM depends.

C. Preventing Misappropriation

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As mentioned, the need to protect TRM has arisen in many instances in the context of claims relating to the unauthorized appropriation of TRM-based products, processes and the biological resources on which they are based.

For example, patents have been obtained by applicants from developed countries on the production, processes and/or therapeutic uses relating to caraway (*Carum carvi*), amaltas (*Cassia fistula*) and Indian mustard (*Brassica campestris*) (Sharma, 2000, p. 5). A patent (US patent No. 5.401.504) was also granted to the University of Mississippi Medical Center, in March 1995, over the “Use of Turmeric in Wound Healing”. The claim covered “a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound”, such wounds including surgical wounds and body ulcers. The powder of the turmeric plant is a classic “grandmother’s remedy” in India. It has been applied to the scrapes and cuts of generations of children (Dutfield, 2000a, p. 65). On 14 August 1997, the US Patent and Trademark Office invalidated the patent upon request by India’s Council for Scientific and Industrial Research (CSIR), after ascertaining that there was no novelty.⁵⁶

A further example is the patent - regarded as outrageous by indigenous communities in Amazonia - that relates to a variety of the ayahuasca⁵⁷ vine (*Banisteriopsis caapi*). In 1986, after research in Ecuadorian Amazonia, a US citizen was granted US plant patent No. 5.751 (Garí, 2000, p. 8 p. 9). Ayahuasca is used for many medicinal and ritual purposes and is a sacred plant for many of the indigenous peoples of Amazonia. The patent was challenged by several NGOs and was re-examined and revoked in 1999. However, it was re-instated by the US Patent and Trademark Office in 2001. Another

⁵⁶ See, e.g., SUNS No. 4050, 8 August, 1997. The lack of novelty was held on the basis of a 1953 article in the Journal of the Indian Medical Association and on Ayurvedic texts (Hansen, 2002).

⁵⁷ “Ayahuasca” is the vernacular name among the Amazon Quechua people, in whose language ayahuasca means “vine of the spirits”.

publicized case in Latin America was the grant of US patent No. 5.304.718 to researchers of the Colorado State University on a variety of the important South American food plant quinoa. Other significant examples, although many could be mentioned, include the more than one hundred patents obtained on derivatives of the neem tree (which indigenous communities have used traditionally in India for multiple purposes)⁵⁸ and the patent held by the University of Lausanne that relate to the Madagascan plant *Swartzier Madagascariensis*.⁵⁹

The reaction generated by these kind of patent grants, illustrate the deep differences that often exist between the Western concept of the private/public domain and the constructions of knowledge held by traditional/indigenous peoples.

Under the Western paradigm of IPRs, any information not covered by a specific form of IPRs, is a *res nullius* and belongs to the “public domain”. The concept of the public domain, though technically correct in the context of the IPRs legal paradigm, ignores that knowledge may be subject to special rules of appropriation under

⁵⁸ In early 2000 a patent granted to W.R. Grace Company and US Department of Agriculture on neem oil extract used as fungicide and insecticide (EPO patent No. 436257) was revoked by the European Patent Office. However, other neem-related patents have remained active, such as a patent obtained by the same company in 1992 covering specific storage-stable pesticide compositions and methods for making them, which retained at least 80% of the active ingredient after one year when stored at a room temperature of 25 degrees Celsius. On the neem-based patents in the U.S. and India, ~~Karki~~, 2001.

⁵⁹ The Panafrican News Agency reported on November 11, 2000, that “a bitter row has erupted between Zimbabwe’s traditional healers and a Swiss university over the latter’s move to patent a drug the former had submitted for trial under a research agreement. The Zimbabwe National Healers’ Association, a group of witch doctors, had submitted a plant known as *Swartzier Madagascariensis* to the University of Zimbabwe for medical trial on patients suffering from candida, footrot and oral thrush. But the drug was later sent to the University of Lausanne in Switzerland which patented it jointly with a US drugs company....”.

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customary laws,⁶⁰ that sometimes recognize certain forms of ownership or possession rights.⁶¹ According to evidence collected by WIPO, in some cases such laws include elements comparable to IPRs⁶². Whenever IPRs are granted over traditional knowledge components, tensions with the conceptual framework of local and indigenous communities becomes more acute. Certain communities view knowledge as an integral part of their natural environment or of their religious system and worldview. Even where there is a notion of property within the worldviews of local/indigenous communities, certain peoples do not view knowledge as a subject over which property rights can be held. In these cases, the Western concept of IPRs may violate the communities' value systems and explain why - as in the case of *ayahuasca*- the communities were outraged by the granting of patent rights.

The debate about misappropriation often confuses at least four distinct situations:

(a) Knowledge that is disclosed and firmly in the public domain (at least in a Western framework) becomes patented due to failing to identify relevant prior art in the examination of the patent application. If such prior art were brought to the attention of the respective patent office or of a court -- as in the *turmeric* case -- the patent could be revoked. The US delegation to the WIPO Committee dealing with TK mentioned above, has argued that

“if information is not written down, that information is completely inaccessible to patent examiners everywhere as prior art when they are examining patent applications. It is possible, therefore, for a patent to be issued claiming as an invention technology that is known to a particular indigenous community. The fault lies not with the patent system, however, but with the inaccessibility of the knowledge involved

⁶⁰ See, e.g. Dutfield, 2000b, p. 285.

⁶¹ See also section IV.j below.

⁶² See WIPO, 2001; see also Valencia, 1998.

beyond the indigenous community” (US Statement to the First Meeting of the WIPO Committee May 1, 2001).

While this statement acknowledges the ramifications of limitations in the examination process, it puts the burden on traditional/indigenous communities to prove their knowledge is in the public domain, rather than on patent offices to properly establish the lack of prior art.

A large part of TRM knowledge in codified TRM systems may give rise to cases of this kind. Reaction against IPRs protection is based on the public availability of the relevant knowledge, which should remain available to all. The patent system is intended to reward contributions to the state of the art, not the appropriation of pre-existing knowledge. A possible solution to this problem, as discussed below,⁶³ lies in gathering and publishing data on disclosed TRM so as to prevent the granting of IPRs thereon.

(b) There are cases where certain knowledge, which is *not* publicly available (e.g. held by a small indigenous community), is acquired by an individual or a company and protected, *as received*, without authorization from and/or compensation to the community who held and developed the knowledge. To the extent that the community had no specific right over such knowledge recognized under the applicable national law, there is no infringement of any right, though customary law may have been violated. Moreover, since the knowledge was not technically part of the prior art, patents granted may be held valid (if an inventive step is also present). This problem thus cannot be simply addressed by challenging the patent on the basis of lack of novelty. The prior consent and benefit sharing principles enshrined in the CBD may provide, as discussed below, a possible model to deal with this situation. It may also be possible to challenge the patent on the basis of rules relating to invention, since the patent owner cannot be legally deemed the inventor.⁶⁴

⁶³ See section IV.c below.

⁶⁴ See section IV.g below.

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(c) Received TRM is improved on or modified, and the outcome subject to IPRs (e.g. a synthetically produced active ingredient found in a plant or a more stable form of a known substance). In these cases, something new has been created that represents an addition to but that derives from the previously available pool of knowledge.

No significant legal questions arise when the derivative has built upon previously disclosed knowledge, as the inventor has added value to the preexisting prior art. When derivatives have been based on non-publicly available knowledge possessed by traditional/indigenous communities, the same issues as in point (b) above emerge in relation to benefit sharing.

There may be questions in such cases concerning the extent of the technical contribution made by patent holders. In some instances, the degree of inventive activity involved may be minimal, for instance, when a researcher or company claims protection over a useful characteristic of a plant that was familiar to a traditional/indigenous community, but which the latter were unable to describe in appropriate technical terms.⁶⁵ In order to avoid objections to patentability, claims may be made on a purified extract or a synthetic version of the compound, but this would not dissipate doubts about the legitimacy of the appropriation (Dutfield, 2000 p.12).

(d) In some cases commercial companies profitably exploit TRM knowledge, which is publicly available, *without* acquiring IPRs, and without any benefit sharing with traditional knowledge holders or cultures of origin. Examples include kava-kava from the Pacific Islands, tea tree oil from Aboriginal Australian medicine, Devil's Claw from Namibia and South Africa, *Prunus Africana* from equatorial

⁶⁵ An example could be the appetite-suppressing element found in a plant (*hoodia cactus*) known to the San community in South Africa, which was patented by the South African Council for Scientific and Industrial Research, and licensed to a British company. An agreement between the CSIR and the San has since been reached.

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Africa and many other herbal medicines popular in western markets. By definition, no IPRs issues are involved in these cases.

The following table summarizes the different cases described above in the light of principles of patent law.

Table 1
Typology of TRM misappropriation

Status of TRM knowledge	Appropriation	Legal situation
1. Publicly available	As received	Invalid patent (lack of novelty)
2. Undisclosed	As received	Questionable inventor-ship
3. Publicly available/ undisclosed	Derivatives	Valid patents, if an inventive step proven
4. Publicly available	Commercially exploited	No patents granted

In the first three cases there is appropriation of knowledge under IPRs, but in the third case such appropriation takes place with regard to a “derivative” or modified form of the received knowledge. Cases 1 and 2, and certain IPRs granted under case 3 are often termed “bio-piracy”. The third column of the Table suggests that in the first two cases, patents could be invalidated. In these cases the “protection” of TRM is not necessarily linked to demands of benefit sharing, but aims mainly at *preventing* the acquisition of IPRs that should be invalid given the appropriate application of IPRs standards of novelty and invention.

Finally, there are cases in which there is merely disclosure, rather than misappropriation of TRM through publication without the consent of knowledge holders, which puts such knowledge into the public domain. Over recent years, there has been a growing trend of surveying medicinal plants, conducting screenings of their chemical constituents, and developing inventories of their traditional use in healthcare. The data has been then compiled in databases, often available for public use and, in some cases for commercial gain. The CABI medicinal plant database in Wallingford, UK, with over 3 million entries of scientific studies on medicinal plants, and the NAPRALERT database at the University of Illinois are two large commercial examples. There are many smaller databases located in national research centers around the world as well as in international and national NGO's.⁶⁶

A recent survey indicates that publications in scientific journals generally leading to the transfer of TRM to the public domain are made both by academics in developed and in developing countries. Table 2 presents articles in 25 journals in English, French and Chinese where explicitly reference is made to ethnomedical uses of the substances described.⁶⁷

University-based authors account for an overwhelming 81 per cent of the publications. Amongst the developing countries, the leading producers of ethnomedical publications are India (20 publications), Brazil (19), Mexico (10), Argentina (10), South Africa (9), Turkey (9) and Nigeria (6). Another 37 countries from all regions are also represented.

While those opposing IPRs over traditional knowledge may welcome the fact that publication will prevent appropriation, ques-

⁶⁶Communication from Bodeker, 13 August 2001.

⁶⁷The largest number of articles were found in the *Journal of Ethnopharmacology* (128 articles or 51% of the total), *Pharmaceutical Biology* (50 articles or 19%), *Economic Botany* (14 article or 6%), and *Phytomedicine* (12 articles or 5%).

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tions obviously arise as to the legitimacy of publishing knowledge without the consent of the knowledge holders, as is often the case. Publication without such consent certainly denies an important component of the right to self-determination (see next section). Unlike the potential invalidation of a wrongly granted patent, once publication is made there is no means to reverse or remedy the situation, unless a patent is promptly applied for by the original holders of the knowledge and fraud in the publication may be proven, certainly a too heavy burden for most TRM holders, especially those in developing countries.

Table 2
Ethnomedical Publications 1996-2001

		First Identification	First Confirmation	Totals
Source	Tribal	73	39	112
	Folk	55	85	140
Institution	University	106	98	204
	Government	16	15	31
	Corporation	4	5	9
	NGO	3	5	8
Region	North	50	57	107
	South	77	68	145
Totals		128	124	252

Source: Barsh, 2001.

D. Promoting Self- Determination ⁶⁸

The right to self-determination essentially recognizes the right of peoples to define their own way of life, in all its many facets. This right, though applying to 'all peoples' in international law,⁶⁹ is seen by indigenous scholars, leaders and communities as particularly important for the advancement of the interests of indigenous peoples.⁷⁰ It is implicitly cognizant of the history of indigenous peoples (as, generally speaking, previously autonomous peoples who, while being forcibly subject to colonization, have maintained a distinct identity), while providing a conceptual framework for the achievement of their aspirations.

The protection of traditional knowledge, including TRM could be used, according to some, to provide indigenous communities with a measure of control over their relations with the rest of the community. Such control may be an element of self-determination⁷¹ and collective cultural sovereignty (The Crucible Group, 2001). Particularly, the application of IPRs to TRM enables indigenous peoples to choose to participate in a system that they have been previously ex-

⁶⁸ This subsection (and partially the next one) is substantially based on a personal communication by ~~Cherine~~Cherine Monagle (November 2001).

⁶⁹ See Article 1 of the International Covenant on Civil and Political Rights .

⁷⁰ See ILO Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries, adopted 27 June 1989. While the Draft Declaration on the Rights of Indigenous Peoples explicitly denotes the right to self-determination as applying to indigenous peoples (no other instruments do, and the right has never been specifically interpreted as applying to indigenous peoples in any interpretive body), the declaration remains in draft form. See ~~Alcay~~Alcay, 1996.

⁷¹ The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples and the Draft Declaration on the Rights of Indigenous Peoples both allude to the legal recognition of indigenous communities' intellectual property rights as elements of indigenous peoples' self-determination.

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cluded from, thus giving them the choice to gain IPRs and engage in commercialization if they so desire.

The IPRs protection of TRM will, arguably, be consistent with the spirit of the right to self-determination, and various specific rights in international law (both binding and non-binding),⁷² only if indigenous peoples desire, or at least do not object to, the availability of such protection.⁷³ Protection that is incompatible with the values of indigenous peoples, or inappropriate for other reasons as determined by them, is unlikely to meet such criteria.

Given the likelihood of diverging opinions among indigenous peoples regarding the IPRs protection of TRM,⁷⁴ the establishment of rules at the international level including a single *sui generis* form of protection may, at least for some indigenous peoples, be inconsistent with the right to self-determination. Laws at a national level may or may not be consistent with self-determination depending upon the opinions of the indigenous peoples within that particular jurisdiction and the process by which the decision to give IPR protection to traditional knowledge was reached.⁷⁵

⁷² See, ILO Convention 169, ILO Convention 107, adopted 1957, the Draft Declaration on the Rights of Indigenous Peoples, the International Covenant on Civil and Political Rights, the UN Charter, The Declaration on the Right to Development and the International Covenant on Economic, Social and Cultural Rights.

⁷³ See, for example, Article 7, ILO Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries, and Articles 3, 4, 12, 19, 29, 30 available at <http://www.ilo.org/public/english/employment/strat/poldev/papers/1998/169guide/169guide.htm#C1>. and Article 31 of the Draft Declaration on the Rights of Indigenous Peoples.

⁷⁴ See various perspectives submitted to the United Nations Conference for Trade and Development (UNCTAD) seminar on 'Systems and National Experiences for Protecting Knowledge, Innovation and Practices', Geneva, 30 October-1 November (2000).

⁷⁵ See Article 7, ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries (1989).

The existence of laws that fail to prevent the misappropriation of TRM fail to support the achievement of self-determination and specific rights in ILO Convention 169 and the Draft Declaration on the Rights of Indigenous Peoples, as misappropriation can reduce the ability of indigenous peoples to exercise control over resources and culture by limiting their ability to define and carry out their own development priorities,⁷⁶ and by removing the opportunity to choose to either utilize IPRs and commercialize knowledge, or to ensure that knowledge does not become subject to IPRs.

E. Promoting Development

Another goal that has been suggested as a rationale for the protection of TRM is based on its potential contribution to economic development, particularly development that would benefit local/indigenous communities.

The role of IPRs as instruments to promote and support commercialization - and thereby economic development - may be significantly different in the case of codified as compared to non-codified TRM systems. The commercial exploitation of herbal medicines, for instance, has opened up important business opportunities for Chinese⁷⁷ and Indian⁷⁸ companies, both domestically and internationally.

Such exploitation, whether in regard to codified or non-codified TRM involves several steps - from procurement and authentication of raw materials to packaging and distribution. With

⁷⁶ See Articles 7 and 23, ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries (1989), Articles 4,12,21,29,20 of the Draft Declaration on the Rights of Indigenous Peoples.

⁷⁷ The total 1996 output of the finished TCM sector was US\$ 3,7 billion. Thirteen out of the top fifty TCM producing companies were listed publicly on the domestic stock exchange (ten Kate *ibid*, 1999, p. 80).

⁷⁸ See, e.g. Agarwal, 2000; Rao, 2002.

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increased demands for safety, efficacy and quality control, greater investments are required in research and development, plant capacity and compliance with good manufacturing practices.⁷⁹ Such investments may in some cases, be significant, in particular, for the scientific validation of medicines through pre-clinical and clinical studies,⁸⁰ as well as for the development of appropriate dosage forms. The size of these investments may pose an insurmountable barrier to poor local/indigenous communities willing to commercialize their knowledge.

The granting of IPRs may stimulate the referred to investments, in that they may reduce the risk of free-riding by third parties. However, as discussed, in most cases the products, as well as their therapeutic uses, would be known and not patentable.⁸¹ Patents, if inventive, (as examined further in the following section) may be applied for and obtained for processes of extraction or manufacture, combinations and formulations. Some countries may also consider providing some form of exclusive protection over the test data developed in relation to a particular product, so as to allow for the recovery of investments made, but at the price of creating barriers to access.⁸²

It may also be argued that the availability of IPRs protection could act as an incentive for local/indigenous communities to *transmit* to third parties knowledge kept under their control, thereby making commercial exploitation possible. IPRs may help to build the

⁷⁹ In India, for instance, collaborative research programs have been established between industry and the Council for Scientific and Industrial Research (CSIR) in relation to raw materials, processing and formulation (see, e.g., Warriar, 1999, p. 14).

⁸⁰ See, however, section IV.h below.

⁸¹ It is possible that trademarks and geographical indications rather than patents, prove in many cases to be the most useful tools for the commercialization of TRM. See section III.C below.

⁸² See also section IV.h below.

confidence necessary for that communication to take place.⁸³ Though this is a plausible argument, it may overlook that IPRs are on the whole alien to local/indigenous cultures, and that it may be difficult to create trust on the basis of an instrument that is unfamiliar to them and based on values that are not shared. This argument may also overlook the difficulties that communities may face in acquiring and, particularly, licensing, any rights they obtain. As mentioned below, acquiring patent rights is generally complex and costly and enforcement costs through litigation are extremely high.

There may also be cases where local/indigenous communities desire to not only gain intellectual property rights, but to take on the commercialization of their TRM knowledge themselves, provided that they have the capital and managerial capacity to do so. IPRs may strengthen the communities' market position in these cases.

The exercise of the right to development by indigenous peoples⁸⁴ requires participatory and decision-making arrangements that are consistent with the concept of self-determination⁸⁵ and specific rights in international law, and thus has implications for the appropriate development of policy in this area. For example, Article 7.1 of the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries states that

⁸³ See, e.g., Drahos, 1997.

⁸⁴ See Declaration on the Right to Development, adopted by United Nations General Assembly resolution 41/128 of 4 December 1986. Article 1.1 states: *"The right to development is an inalienable human right by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized"*.

⁸⁵ As discussed previously, the right to self-determination applies only to indigenous peoples if they are 'peoples' for the meaning of the International Covenant on Civil and Political Rights and other such instruments. Instruments such as ILO Convention 169 that apply directly to indigenous peoples, are compatible with the right to self-determination and give form to many of its ramifications.

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*“the peoples concerned shall have the right to decide their own priorities for the process of development as it affects their lives, beliefs, institutions and spiritual well-being and the lands they occupy or otherwise use, and to exercise control, to the extent possible, over their economic, social and cultural development. In addition, they shall participate in the formulation, implementation and evaluation of plans and programs for national and regional development which may affect them directly”.*⁸⁶

Where States wish to encourage the availability of protection for the purpose of economic development more generally, the benefits from such activities should be fairly distributed⁸⁷. By common measures of fairness, some benefits should in some way be channeled back into the indigenous community/ies in which the TRM originated.

F. Summary: What Can Protection Achieve?

The preceding analysis has shown that proposals for the protection of TRM may be informed by quite different objectives. The following table attempts to indicate the possible relevance of IPRs and other

⁸⁶ Article 7.2 goes on to require that “Governments shall ensure that, whenever appropriate, studies are carried out, in cooperation with the peoples concerned, to assess the social, spiritual, cultural and environmental impact on them of planned development activities. The results of these studies shall be considered as fundamental criteria for the implementation of these activities”. Thus, if States party to this Convention consider legislation or measures to protect TRM, or intend to support the development of international law on the matter, such a study should be undertaken and its results must be considered a ‘fundamental criteria’ for the implementation of that protection.

⁸⁷ The preamble to the Declaration on the Right to Development recognizes the distribution of benefits as an essential component of development (note that the preamble does not have the legal force of the Declaration itself).

tools to achieve various objectives. In the light of such analysis, IPRs are marked in the second column with “3” when they seem very relevant to attain the goals described in the first column; with “2” when IPRs may be somehow relevant, but their efficacy questionable as compared to other options: and with “1” when the described tools are irrelevant in attaining the proposed objectives. The third column indicates other, non-IPRs tools that might be considered as alternatives in meeting the relevant objective.

Table 3
Protection of TRM : how relevant IPRs are?

Objectives⁸⁸	IPRs	Other tools
Saving data (conservation)	1	Registries, data bases
Collecting data	1	Contract-based benefit sharing Registries, data bases
Preventing erosion of knowledge	1	Recognition of land rights, cultural integrity, customary laws, preservation of natural environment
Ensuring continuous improvement/innovation	1	Recognition of land rights, cultural integrity, customary laws, preservation of natural environment
Benefit sharing	2	Access legislation, contracts, application and recognition of customary laws
Self-determination	1	Recognition of various rights in international law -- including participatory decision making, recognition of customary law
Development/commercial	3	Recognition of land rights, preservation

⁸⁸ The objective relating to misappropriation is not mentioned in this Table, since in that case the aim is to *exclude* rather than to ensure IPRs protection.

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exploitation		tion of conditions necessary for cultural integrity, recognition of customary laws
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This Table suggests that IPRs may be relevant to promote the commercialization of TRM, but not very relevant or completely irrelevant in relation to other possible objectives often mentioned in the literature and examined above. Commercialization may contribute to economic development where the use of IPRs generates value added products resulting in an increase in income. The size of such a contribution may significantly vary, but is likely to represent only a tiny fraction of GNP in the case of community based TRM. While that small contribution may benefit economies in general (albeit to a small degree), many or even most local/indigenous communities will, for reasons such as disclosure already discussed, have no opportunity to directly benefit from the possibility of protection of TRM through IPRs.

Although it is not at all clear that IPRs provide the most appropriate tool for attaining many of the objectives described above, the debate concerning the protection of TRM has been triggered by a number of proposals to apply IPRs to traditional knowledge. For this reason, examining the application of existing modes of IPRs in the field of TRM is a useful place to begin to explore the relevance of protection under IPRs. This analysis follows.

III. APPLYING EXISTING IPRS

The application of existing IPRs to traditional knowledge in general has been extensively examined in the literature⁸⁹ and debated in some fora.⁹⁰ Considerable attention has also been paid to the possibility of developing *sui generis* regimes.⁹¹ In this section the use of some forms of IPRs to protect TRM is examined. Special attention is given to patent protection, given that it enables the exercise of exclusive rights over TRM knowledge or over its possible uses.⁹²

A. Patents

This sub-section illustrates how the patent system may be applied to different components of knowledge, based on, or related to, the medicinal use of plants and other natural products. Though, as shown below, applicants from developed countries have been the main users of the patent system in the field of TRM, applications from local companies and researchers from developing countries are reportedly⁹³ growing, particularly in the context of codified TRM systems.

Patents protect inventions, that is, new, non-obvious technical solutions. Patents are granted by a government authority and confer the exclusive right to make, use or sell an invention generally for a period of 20 years (counted from the date on which the application for the patent was filed). In order to be patentable, an invention usu-

⁸⁹ See, e.g. Dutfield, 2000a.

⁹⁰ See, e.g. GRULAC, 2001.

⁹¹ See section IV.e below.

⁹² In contrast, trademarks and geographical indications only protect signs used to identify products, not the underlying knowledge as such.

⁹³ See, e.g., Karki, 2001; Yongfeng, 2002.

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ally needs to meet the requirements of absolute novelty (previously unknown to the public), inventive step or non-obviousness, and be capable of industrial application (or useful). Patents may be granted for all types of processes and products, including those related to primary production, namely agriculture, fishing or mining.

Patents may be conferred to protect inventions based on or consisting of natural substances (including genetic materials), plants and animals. As discussed below, they can also be granted in some countries in respect of the *use* of a product and of methods of diagnostics, surgical and therapeutic treatment. Though there are important differences among national laws on the subject matter of patent protection, at least in principle, patents may be applied to different components of TRM, provided that the above mentioned patentability requirements are met.

There are, however, several major obstacles to affording patent protection to existing TRM knowledge. Some such obstacles stem from the legal standards established to acquire patent rights in national laws.

A.1. Novelty

The universal novelty requirement, as applied in most countries, prevents the patenting of information in the “prior art”, that is, information that has been published in a written form or has otherwise been made available to the public, for instance, through public use, *in any country* before the date of filing of a patent.

The novelty requirement will generally impede the patenting of TRM knowledge that has been published or openly used before the filing date of the patent application.⁹⁴ Hence, a large portion of TRM

⁹⁴ In the *Delgamuukw* case (December 1997) the Supreme Court of Canada rejected the court’s usual approach of attributing little if any weight to the oral evidence of elders. That is, oral testimony was given status as legal evidence.

held by local/indigenous communities, and codified TRM, is likely to be deemed not to be novel and therefore not patentable.

In order to destroy novelty, however, the prior use must generally be such that access to the information would have allowed a third party to execute the invention, without significant further research. Thus, there may be situations in which novelty may not be lost, despite the relevant TRM knowledge having been previously used, even for long periods. An example would be the case of TRM knowledge used in a small community, when the information has not diffused beyond the community's members. Cases in which the traditional healers have kept confidential⁹⁵ certain aspects of their treatment and associated medicines may be another example. In short, it would be incorrect to assume that all TMR, because it may be old and previously used, has necessarily lost its novelty for the purposes of patent law.

An important issue is whether novelty should be deemed to exist in cases where the chemical structure of the active substance responsible for the therapeutic effect of an openly used product was not known. For instance, a UK court held in the case *Merrill Dow Pharmaceuticals v. Norton & Co.* (1996) that it was not necessary for an active substance to be identifiable or reproducible for it to

Presumably, in Canada at least, this precedent provides an argument for non-written knowledge (oral history) to invalidate novelty on a patent claim (personal communication from KBannister, 22.8.01). See also Gupta, 2002b.

⁹⁵ In the Mobil case, for instance, the Enlarged Board of Appeal of the European Patent Office decided that the word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection. Under the European Patent Convention, a hidden or secret use, because it has not been made available to the public, is not a ground for objection to validity of a European patent (*Mobil/Friction-Reducing Additive*, 1990) (see Koon, 1999, p. 166).

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have been made available to the public.⁹⁶ Applied in the context of TRM, this doctrine would mean that the fact that local/indigenous communities were unable to scientifically describe the structure of a useful compound, would not prevent it from entering the public domain. Further, disclosure in a non-written form may not be an obstacle to obtain patents on TRM in countries where a *relative* novelty standard is applied. In the United States, for instance, according to article 102 of the Patent Law (35 United States Code),

A person shall be entitled to a patent unless 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 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...

This means that TRM knowledge that has been published in a written form in the United States or in any other country is not patentable. However, if such knowledge was publicly used but not documented in a foreign country, novelty is not lost and patenting remains a possibility.

As a result of the relative novelty requirement of the U.S., as mentioned above, several patents relating to or consisting of genetic materials or traditional knowledge acquired in developing countries, have been granted to researchers or firms by the US Patent and Trademark Office (Correa, 1999; The Crucible Group, 2000).

⁹⁶ Lord Hoffmann explained this situation by reference to the case of Amazonian Indians, who believed that the effect of the cinchona bark on malaria was due to “the spirit of the bark”. The Indians, however, should be said to have known about quinine even though they did not know its chemical structure (Koon, 1999, p. 166).

A.2. Inventive step

When certain TRM knowledge has remained undisclosed -- and, thus, the novelty of the information preserved -- an additional standard of patentability must be met in order to acquire patent rights: “inventive-step” or “non-obviousness”. This standard requires that the claimed invention be non-obvious for a person with ordinary skills in a given technical field. Even if novel, knowledge will not be patentable if it is proven obvious or lacking an inventive step.

“A person with ordinary skills” is a legal fiction. Patent offices and courts may apply different standards, according to the technical field concerned.⁹⁷ Thus, something that may be obvious to a healer or professional trained in TRM may not be so for somebody trained in the Western medical tradition (the reverse may also be true, of course), thereby allowing for the granting of a patent (assuming other standards are met). It is likely that patents and courts tend to assess obviousness under the crystal of Western knowledge, as long as they do not recognize TRM as a valid system of knowledge. Hence, uses of plants and other knowledge that may be obvious within a TRM system may be deemed “inventive” and patentable.⁹⁸

Non-obviousness is judged in the United States on the basis of the determination of a) the scope and content of the “prior art”; b) the differences between the claimed invention versus the prior art; and c) the level of ordinary skill in the relevant field of technology (Wegner, 1994, p. 224). Under the US standards, inventions may result from painstaking research, slow trial and error, or serendipity.⁹⁹ In Europe and other countries, emphasis is given to the extent

⁹⁷ See, e.g. Reid, 1999, p. 42-50.

⁹⁸ This increases the possibility of TK holders obtaining patents but, given their limited resources and lack of familiarity with the patent system, it is likely that others (researchers and companies) will benefit the most from this limitation in the examination process.

⁹⁹ See, e.g., Dratler., 1999, §2.03[3].

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that the invention solves a technical problem. This “problem-and-solution” approach makes the inquiry on inventive step more objective than in the United States (Merges, 1992, p. 505). In some cases, commercial success where others have failed is regarded as an indicator of inventive step.¹⁰⁰

Thousands of patents are granted each year in the major countries for minor, sometimes trivial developments (Barton, 2000, p. 1933). In 1999, for instance, the United States Patent Office granted over 160 000 patents, twice the number granted ten years before. This is probably the combined result of the quite broad non-obviousness and utility standard applied, as well as of shortcomings in the examination procedures.¹⁰¹

In this context, the patentability of TRM knowledge, or minor variants around it, may be more likely than expected by many, as illustrated by the already referred to cases of several questionable patents based on traditional knowledge. Whether this is the right policy or not in the case of TRM depends on the philosophy underpinning the patent system in each country, and on the objectives pursued.

Quite clearly, the loose application of the inventive step/non-obviousness standard allows for the patenting of minor advancements, if any, in relation to previously available information.¹⁰² This is clearly undesirable from the point of view of public policy and the preservation of the freedom to use knowledge within the public domain. There is little society may gain by extending legal monopolies to holders of TRM, or to those that obtained knowledge from them, where no genuine invention can be claimed.

¹⁰⁰ See, e.g. Reid, 1999, p. 53.

¹⁰¹ For example, less than 50% of the examinations conducted by the Office refer to the relevant background bibliography; the examination is by and large limited to analyzing previous patents. See, e.g. Aharonian, 2000.

¹⁰² See, e.g. Correa, 2001.

A.3. What can be patented?

The range of possible TRM-based inventions is wide. This section illustrates - without being exhaustive - some of the possible areas of patenting, and describes the modalities under which patents are granted in some jurisdictions. In examining the scope of patentability, it should be remembered that the granting of patents is dependent on each national law, and that a patent is only effective in the country of grant. Therefore the patentability in one country does not mean that certain TRM could be not patented in another country, and vice-versa. It is also important to note that neither the TRIPS Agreement nor any other international instrument in force, requires the granting of patents over certain natural materials as such (including genes). The Agreement specifically allows Members not to patent plants and animals, except microorganisms (article 27.3 (b)). There is, hence, considerable leeway to nationally specify the patent policy on this matter¹⁰³. Some developing countries have expressed the view that the patentability of living materials is contrary to basic cultural and ethical values, and have suggested that the Agreement should be amended to allow Members not grant patents on living materials if they so decide.¹⁰⁴

(i) Natural products

¹⁰³ The Agreement only requires (Article 27.3 (b)) the patentability of microorganisms, that is of organisms not visible with the naked eye. Even in this case, there is no obligation on the WTO Members to grant patents on microorganisms which, according to the national law are not “invented”, but merely found in nature.

¹⁰⁴ See, the proposal for review of article 27.3 b of the TRIPS Agreement submitted by Kenya on behalf of the African countries (WT/GC/W/302, of August 6, 1999). See also IP/C/W/206 of 20 September 2000.

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Traditional medicines include plants, animal and mineral materials, extracts, mixtures and herbal preparations. Obstacles for the patentability of such medicines may arise when they consist of or are based on *natural* materials that have not been processed or modified.

One of the basic problems is the extent to which a substance existing in nature for which a certain use has been identified, may be deemed to be an “invention” or a mere “discovery”. Such use may have been identified with regard to a product whose properties were not known, or in respect of products whose properties were known, the “invention” eventually being the determination of its chemical or genetic structure.

Patent protection of biological materials, including cells and genes, has been accepted in many countries. This remains, however, a controversial issue, particularly with regard to the patentability of materials existing in nature that have just been isolated, purified, or slightly altered. In some countries (e.g. the United States) an isolated or purified form of a natural product, including genes, is patentable. The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) adopted a similar approach. The Directive, essentially declaratory of long standing law throughout much of Europe,¹⁰⁵ establishes that “biological material” and substances isolated from nature are patentable.¹⁰⁶

In some countries, however, the patenting of existing biological materials, unless they have been genetically altered, has been contested and denied. For example, in United Kingdom -- before the adoption of the referred to European Directive -- the High Court of Appeal had held that the isolation of gene sequences constituted a mere discovery and, hence, was not patentable. The Court argued that although the amino acid sequence of t-PA had not previously been determined, one cannot patent a known substance just by being

¹⁰⁵ See, e.g. Grubb, 1999, p. 213.

¹⁰⁶ “Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature” (article 3.2).

the first to determine its structure (Thurston and Hall, 1988) It is uncertain the extent to which this doctrine can be maintained after the adoption of the European Directive on Biological Inventions.

Some laws do not allow the patenting of genetic materials. The Mexican patent law (1991, as amended in 1994) excludes the patentability of all genetic materials. The Argentine patent law (1995) and the Andean Group Decision 486 (2000), do not allow the patentability of materials existing in nature. The Brazilian patent law (1996), stipulates that no patents shall be granted with respect to living beings or “biological materials found in nature”, even if isolated, including the “genome or germplasm” of any living being.

Despite the possible exclusion of certain natural products from the patent domain, patents may still be granted for the processes used to produce them in a medicinal form. Since process patents do not prevent third parties from using alternative processes to obtain the same product, patenting processes (and not the products as such) may be the preferred option for countries sensitive to the problems of affordability of medicines.

The extent to which substances found in nature may be patented is of particular importance for TRM since, as mentioned, TRM extensively relies on such substances, often in an unmodified form. Countries wishing to promote access to traditional medicines should draw a clear dividing line between products existing in nature, which are not patentable (even if isolated or subject to standard procedures of purification), and products which have been modified or combined in a manner that gives rise to a genuine invention.

(ii) Extracts and formulations

While, as mentioned, the patentability of natural products may be limited by patent rules, it may be possible to claim protection on extracts or formulations (i.e. a mixture of an active ingredient with certain excipients) of natural products.

Examples of patents of this type include US 4178372 on hypoallergenic stabilized aloe vera gel: US 4725438 on an aloe vera

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ointment; US 4696819 on material extracted from coca leaves; and EP 0513671 on “*commiphora mukul*” extracts.

Of course, the granting of these kind of patents depends on the extent to which the patentability requirements are met, a debatable issue when relatively common processes of extraction or simple formulations are claimed. Claims of this type may be used, in some instances, to bypass the prohibition on the patentability of substances found in nature, or to overcome objections based on lack of novelty. A patent granted on a formulation, however, would not prevent communities or other parties from using and commercializing the same product, in its natural form or with a different (not infringing) formulation.

(iii) Combinations and preparations

Patents may be obtained, if the patentability requirements are met, for combinations and preparations. This is normally the case with modern pharmaceuticals, both in cases where a composition is a simple mixture of diverse components and where there is some chemical reaction between them (Grubb, 1999, p. 208).

Traditional medicines often consist of combinations of several ingredients¹⁰⁷ or of preparations, such as fatty or essential oils, expressed juices, etc. Many examples of patents granted on combinations of plants for therapeutic purposes can be identified, for instance, EP 0519777 relating to formulations made out of a variety of fresh plants; and WO 93/11780 on a skin therapeutic mixture containing cold-processed aloe-vera extract (with yellow sap and aloin removed).

As in the case of extracts and formulations, claims on combinations or preparations may be used to overcome patentability objections. Similarly, the use or commercialization of any of the components of

¹⁰⁷ In Ayurvedic and Unani formulations, for instance, sometimes a single medication has over 50 ingredients. The simplest formulations have 6-10 ingredients involving the use of different parts of several plants (Chandra, 2002, p. 143)

a combination or preparation (isolated or in different combinations or preparations) would not constitute infringement.

(iv) Production and extraction processes

Many traditional medicines are obtained through fractional distillation,¹⁰⁸ purification or concentration. The processes for obtaining such products, if novel and non-obvious, may be patented.

There are numerous examples of patents relating to extraction and other processes for the preparation of medicines based on natural products, such as ES 475.812 on a process for the extraction of organic compounds with therapeutic activity from plants; ES 2010127 for the preparation of a medicine for skin reparation; EP 0530833 on a process to prepare hard gelatine capsules containing Chinese herbal extracts; ES 8801986 for preparation of a juice or gel of aloe; ES 393347 on a process for the extraction of an active ingredient from *anacardium occidentale*; and US 4956429 on a method of making a coca leaf flavor extract.

As mentioned, process patents confer less market power than product patents, because alternative, non-infringing processes, may be sometimes utilized to obtain the same product. The TRIPS Agreement, however, obliges Members to extend the protection conferred over a process to the product directly obtained by the patented process.¹⁰⁹ Hence, if the patented process is unique, or the alternative processes are difficult to apply or not economically viable, process patents may effectively be used to block the commercialization of the product obtained.

(v) Methods for treatment and diagnostics

Traditional treatment methods are usually specific to a particular country or to a particular community, although some of them, such

¹⁰⁸ The process of separating components that have different boiling points from a volatile liquid, by first heating the liquid and then condensing and collecting the components as they vaporize.

¹⁰⁹ See article 28.1 (b) of the TRIPS Agreement.

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as acupuncture, are used worldwide. Many methods of TRM have proven to be efficient and cost-effective in the provision of primary healthcare in the community, without causing harm to the human body. Such methods are generally accessible and affordable to people of all strata, particularly those living in poor and isolated regions (Ma'at, 2001, p. 2).

The patent protection of treatment and diagnostic methods faces important obstacles and limitations. First, such methods -- which are applied to the human body -- do not comply with the requirement of industrial applicability, imposed in most countries as a condition of patentability.¹¹⁰ A noticeable exception is the U.S., where "usefulness" and not industrial applicability is required, thereby broadening the room for such patenting to occur. Second, at least in the case of codified TRM, treatment methods, would be non patentable due to lack of novelty. Third, the enforcement of these kind of patents is problematic, since monitoring the use of treatments and prosecuting infringement is extremely difficult and costly.

Most national patent laws exclude the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals, for legal, ethical or practical reasons. Article 27.3.a of the TRIPS Agreement explicitly allows Members not to grant patents for such methods. However, in the United States, patent practice increasingly favors the protection of medical methods, although a bill enacted in 1996 (amending US patent law, 35 USC 287.c) determined that the use of patented surgical methods can not be subjected to infringement suits.¹¹¹ An illustration of such patents was the controversial (and finally revoked) US patent relating to turmeric mentioned above, which claimed a method of healing wounds and not the substance as such.

¹¹⁰ In a few countries where this rule applies, the patentability of said methods has been allowed on the basis of courts' interpretation or legal exceptions. See, e.g. Correa, 2000b, p. 26.

¹¹¹ See, e.g. Grubb, 1999, p. 220.

In sum, because of their non-industrial applicability, or of their outright exclusion, treatment methods are generally not appropriable under patent laws. This means that TRM methods of treatment, whether codified or not, do not face the same risk of misappropriation by third parties as biological materials of medicinal use,¹¹² being the U.S. -- and a few other countries -- a noticeable exception.

(vi) Uses of known products

An important issue in relation to the protection of TRM is the extent to which the “use” of a known product can be subject to patent protection. This issue may arise, for instance, when the therapeutic properties of a natural product are identified and claimed.

The patenting of use inventions, where admitted, depends on whether the purpose of the use is novel and non-obvious. In countries that permit the protection of use inventions, claims may be either *product* or *process* claims, depending on the context.¹¹³ Some national laws treat the new use as a *process* patent claim of one of two kinds: “use” claims (such as “the use of X as an antihistamine”) or claims on one or more actual process steps (e.g. “a method of preventing...”).¹¹⁴ In the United States, patents on uses are confined to a particular “method-of-use”, which does not encompass protection of the product as such (Merges, 1992, p. 489).¹¹⁵

¹¹² This also means, of course, that TRM holders will be unable to obtain patent protection over such methods.

¹¹³ Thus, in Europe, *first medical indications* (that is, a medical use for a product previously not used for that purpose) have been dealt with as a product claim, whereas the *second medical indication* (that is, when a new use is discovered for a product that already had pharmaceutical use) as a process claim.

¹¹³ See, e.g. Grubb, 1999, p. 208.

¹¹⁴ Ibidem.

¹¹⁵ Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods. See, e.g. Hansen and Hirsch, 1997, p. 120.

Title

In contrast, the European Patent Convention allows for the patentability of a known product for a new specific purpose (Stieger, 1982). Under article 54(5) of the European Patent Convention, the identification of the first medical indication of a known product may suffice to allow patenting of the product.¹¹⁶

In the case where the application refers to the second medical indication of a known pharmaceutical product, however, an obstacle to patentability arises. Patent applications over the therapeutic use of a known product are written as instructions to the physician on how to employ a certain substance to treat a particular disease. Such a new use, hence, is equivalent to a *method of therapeutic treatment*, which is deemed non-patentable under European law.¹¹⁷

Many patent laws recently adopted in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether the protection for processes covers “uses” or “methods of use”.

The TRIPS Agreement seems to leave freedom to Members to decide whether or not to protect new uses, since it only obliges them to grant patents for products and processes (article 27.1). They also are free to adopt or not the “Swiss formula” approach.

¹¹⁶ The Technical Board of Appeal of the European Patent Office has ruled that such claims should be deemed as covering all therapeutic uses of the product as in the case of claims on a pharmaceutical composition. Infringement of such claims would only take place when the product is commercialized for direct therapeutic use, and not in bulk (Grubb, 1999, p. 218).

¹¹⁷ In order to overcome this barrier, the European Patent Office admitted since 1984 (under a legal fiction), claims on the second medical indication of a known pharmaceutical product when framed under the so-called “Swiss formula”, that is, “Use of X for the manufacture of a medicine to treat Y”. However, the “Swiss formula” suffers from “the logical objection that it lacks novelty, since it claims the use of the compound for preparation of a medicament, and normally the medicament itself will be the same as that already used for the first pharmaceutical indication” (Grubb, 1999, p. 221).

(d) Patenting of TRM in practice

The previous section has indicated various approaches that can be followed for the patent protection of TRM, and suggested that countries have, under current international rules, considerable freedom to determine the scope of such patenting. In section IV.C below, the implications of different policy options are discussed in more detail. Little is known as to the extent to which patenting of TRM-related inventions occurs in practice. Such patenting has steadily increased in China, with more than 12,000 patents applied in relation to TCM during 1999-2001 (Yongfeng, 2002).

A recent study by Barsh (2001) presents interesting information on the US record with regard to patents derived from ethnomedicine (see Table 4). Fifty-five such patents were granted during the period 1995-2001,¹¹⁸ most of them originating from “tribal” knowledge, followed by Chinese, Euro-folk and Ayurvedic medicine.

The majority of patents (58 per cent) claim a new therapeutic application or form of delivery of a known active component of a traditional medicinal plant or compound, while in other cases claims apparently cover the already customary use of plants, or an isolated or synthesized form of certain compounds. This suggests that patent claims tend to concentrate on the *use* of certain compounds, rather than on the latter as such. In any case, and though more detailed analysis would be necessary, these data seem to confirm the expressed concerns regarding the appropriation of TRM knowledge under the patent system.

Other interesting observations provided by Table 4 is that most patents (50 of 55) were obtained by small pharmaceutical companies, small producers of botanicals and herbal supplements, universities, and individual researchers. However, only 7 were granted to applicants from developing countries (5 to individuals or universi-

¹¹⁸ During the same period, nearly 50,000 patents were granted for pharmaceuticals in the U.S..

Title

ties and one to a large company in India). Big pharmaceutical and cosmetic companies accounted for nine percent of the identified patents. A majority of the patents of traditional/indigenous origin built upon research in Amazonia (7 of 24), tropical Africa (5 of 24), and Central America (3 of 24). Two originated in Australia and only one in North America. No more than three or four of the 55 patents in Table 4 were based on the applicant's own field research; the rest had drawn their inspiration from articles by others in academic journals, which they cited.

Table 4
U.S. Patents Derived from Ethnomedicine, 1995-2001

Sources		Tribal	Chinese	Ayurvedic	Euro-folk	Totals
Assignee	BigPharma	1	-	1	-	2
	Big Cosmetic	3	-	-	-	3
	Smallpharma	6	2	3	1	12
	Botanical	2	3	-	8	13
	University	7	5	-	1	13
	Individual	5	3	3	1	12
Claims	Customary use	6	2	3	-	11
	Isolation/synthesis	7	4	-	1	12
	Novel use/ delivery	11	7	4	10	32
Totals		24	13	7	11	55

Source: Barsh, 2001.

Title

A comparison with data in Table 2 suggests that while academics and institutions from developing countries are active in publishing information about TRM, they are much less active than their counterparts in developed countries in applying for patents on TRM-related products and uses.

It is also interesting to note that in many cases a large variety of patents were obtained in relation to the same natural product, as illustrated by the one hundred-plus patents relating to the neem tree. Another telling example is provided by patents concerning taxol (*taxus brevifolia*), which include different product and processes, as well as uses (see Table 5).

Table 5
Patents over taxol in the U.S.

Subject matter	No. of Patents
Synthesis/semi-synthesis/preparation/process of production of taxol its derivatives	106
Taxol products- formulations/compounds/derivatives/composition and intermediates	3
Extraction/isolation/purification	21
New uses/ methods of treatments/ method of administration/doses	16
Structure-activity relationship	2
Other miscellaneous areas including plant patent or patents on agents for drug resistance	6

Source: Karki, 2000, p. 209.

In sum, while much of TRM is not novel, a significant number of patents have been obtained on TRM knowledge and related products, both on TRM that can accurately and not so accurately be described as truly novel in the sense demanded by an appropriate application of novelty standards. Typically, several patents are applied for and obtained around a single commercially promising TRM-based product (including processes and uses). Applicants are generally companies or researchers from developed countries. While a growing number of patents is being acquired by applicants from developing countries, they still lag significantly behind their counterparts in the developed world in their propensity to patent.

B. Trade Secrets

Trade secrets may be applied for the protection of some components of TRM, if the information is kept secret and is of actual or potential commercial value. Trade secrets are commonly protected under the doctrine of unfair competition,¹¹⁹ which provides legal protection against commercially dishonest practices, provided that the knowledge holder takes reasonable steps, under the circumstances, to keep the knowledge secret.¹²⁰

In some cases, traditional knowledge, including healing practices and materials, are deliberately kept secret by the few individuals in the community privy to the knowledge. Often the knowledge is kept secret because of the place it holds in cultural concepts and practices - such as rituals and magic.

Trade secrets law may be suitable for the protection of TRM knowledge, due to a number of its characteristics.

¹¹⁹ See, e.g. article 39.1 of the TRIPS Agreement.

¹²⁰ See article 39.2 of the TRIPS Agreement.

Title

First, conceptually, the protection of trade secrets does not presuppose the granting of property rights, but simply the right to take actions against whoever has acquired commercially valuable secret knowledge through unfair commercial practices. This approach may be compatible with the view prevailing in many communities, that any form of appropriation of their members' knowledge is inappropriate.

Second, *registration* is not needed in order to acquire the rights conferred under trade secrets law. This is particularly important for TRM holders, since in many cases they are neither equipped for, nor inclined to comply with registration formalities, and/or unable to bear the ensuing costs.

Third, though the protected knowledge should be commercially valuable, trade secrets law does not require establishment that the knowledge is "new" or involves an "inventive step" as required under patent law. In some jurisdictions,¹²¹ trade secrets protection may be extended to knowledge of *potential* commercial value.¹²² This extension may permit the protection of TRM which currently has no commercial application, but which may become used for such purposes in the future.

Fourth, unlike other forms of IPRs, trade secrets protection lasts as long as the protected knowledge is not divulged. This feature is especially appropriate to the nature of TRM that has remained secret and must remain so if cultural norms are not to be violated.

Finally, in the case of TRM, the possession of knowledge is often of a collective nature. While communities do not generally fall under the category of "legal persons", nothing would prevent a

¹²¹ See, e.g. the North-American Free Trade Agreement (NAFTA), article 1771 (1).

¹²² See, e.g., NAFTA article 1711.1 (b).

Member country from extending trade secrets protection to information held by such communities. As noted by GRULAC,

“Acknowledgement of the fact that secret traditional knowledge may be protected by means of unfair competition law will make it possible for access to that knowledge, its exploitation and its communication to third parties to be monitored. Control over the knowledge, and regulation of the manner in which it may be acquired, used and passed on, will in turn make possible to arrange contracts for the licensing of secret traditional knowledge and derive pro from its commercial exploitation” (GRULAC, 2001, p. 4).

Of course, as in the case of other IPRs, trade secret holders need the capacity, including financial, to enforce their rights through generally costly and lengthy court procedures. This is not, a minor point when considering not only the availability of protection but its possible efficacy in protecting the interests of TRM holders.¹²³

C. Trademarks

Trademarks protect visually perceptible signs¹²⁴ (including colors, numbers, images, letters, and product shapes) that distinguish the goods or services of different undertakings. Depending on the applicable national law, trademarks may be acquired through use or by registration.

Trademarks do not protect the knowledge or technology incorporated in a trademarked product and, hence, do not impede the commercialization by a third party of an imitative product under a different trademark, or without a trademark. In addition, since the

¹²³ See also Section IV.f below.

¹²⁴ Some countries also admit the protection of signs that cannot be captured by the eye, like sounds and smells.

Title

basic function of a trademark is to distinguish the products (or services) of one enterprise from those of other enterprises, the protected sign must be different from the generic denomination of the product.

Local/indigenous communities could acquire trademarks subject to compliance with national rules on ownership and representation. Given the collective nature of a good part of TRM knowledge, “collective marks” or “certification” marks may be particularly suitable. Such marks are used by a group of producers -- generally the members of an association - and may serve to distinguish the geographical origin or other common characteristics or quality of certain products. The acquisition of a collective or certification mark normally requires the submission of approval of regulations for the use of the mark.¹²⁵

Trade marks may be as important for the marketing of TRM-based products¹²⁶ as for any other medicine, depending on the strength of the mark, the particular conditions of the relevant market and the prevailing prescription practices of healers and physicians. Domestic companies may benefit from trademarks identifying medicines derived from TRM systems. Trademarks can also be useful to local/indigenous communities if they decide to commercialize themselves certain products, provided that they are able to monitor its use and enforce their rights in cases of violation. The use of collective marks or certification may have the benefit of providing a specific

¹²⁵ A “collective” mark is generally owned by an association that does not use it. Use is done by the members of the association. The owner should ensure that the relevant standards are complied with by the authorized users. The main difference between “collective” and “certification” marks is that the former can only be used by the members of the association, while the latter can be used by any undertaking, even if not belonging to a particular association, that complies with specified standards. See, e.g., WIPO, 1997, p. 185.

¹²⁶ An example, in other area of traditional knowledge, is provided by Aboriginal and Torres Strait Islander artists in Australia, who have obtained a national certification trademark.

title

badge of approval of a local or indigenous community, in addition to give an indication of geographically dependent qualities of products.

As with other IPRs, as discussed below, the effectiveness of trademarks as a means of promoting the commercialization of TRM will depend on the title-holders' capacity to exercise their rights, so as to deter the commercialization of infringing products. Moreover, the value of trademarks, as well as of geographical indications, depends on the capacity to establish and preserve product homogeneity and quality standards, and on investments, sometimes substantial, in promotion and marketing. In other words, protection by such signs does not automatically guarantee that they would generate added value for the right holders.

D. Geographical Indications

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation due to that place of origin.¹²⁷ Most commonly, a geographical indication consists of the name of the place of origin of the goods. Some products have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Such indications may provide a competitive advantage, both domestically and in foreign markets, when a TRM product is associated by the public with its geographical origin.

An essential condition for the recognition of a geographical indication is that specific characteristics of a product must be attributable to its geographical origin.

In accordance with GRULAC,

¹²⁷ The TRIPS Agreement defines in Article 22.1 a geographical indication as an indication which identifies a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

Title

“Geographical indications, especially appellations of origin, may be used to enhance the commercial value of natural, traditional and craft products of all kinds in so far as their particular characteristics may be attributed to their geographical origin. A number of products that come from various regions are the result of traditional processes and knowledge implemented by one or more communities in a given region. The special characteristics of those products are appreciated by the public, and may be symbolized by the indication of source used to identify the products. Better exploitation and promotion of traditional geographical indications would make it possible to afford better protection to the economic interests of the communities and regions of origin of the products” (GRULAC, 2001, p. 3).

Like in the case of trademarks, geographical indications may be useful to enhance the commercial value of TRM, whenever the consumer can establish an association between the geographical origin and the characteristics or quality of certain products. While such indications can not be legally used in the country of registration by parties not belonging to the relevant region or locality, procedures for the international recognition of such indications are still under negotiation in the framework of WTO¹²⁸. Several developing countries have strongly advocated the strengthening of protection of geographical indications for products other than wines and spirits, which already receive an enhanced protection under the TRIPS Agreement.¹²⁹

There are some examples of geographical indications linked to traditional knowledge used in the Andean Group countries, which illustrate the potential use of such indications to protect TRM.¹³⁰

¹²⁸ See the WTO Doha Ministerial Declaration para. 18 (WT/MIN(01)/DEC/1).

¹²⁹ See, e.g. Rangnekar, 2002.

¹³⁰ The “Chuaao Cacao” (from the native cacao varieties found in the Chuaao locality of the

It should be noted that the commercial value of geographical indications depends on adequate management practices and quality controls and marketing capabilities. Thus, legitimate users of a geographical indication must establish the standards to be applied, and the monitoring mechanisms (e.g. inspection of production facilities, testing of samples) to ensure that the characteristics and quality of products conform to such standards. They must also enforce their rights domestically and internationally. All this may not be possible for TRM holders, in most cases, without significant State or other support.

Venezuelan coastal region) is produced under particular climate conditions and using the traditional drying and fermentation procedures of the Afro-American communities living within this area. The Chuao Cacao is highly aromatic and has an excellent lasting favor. It is exported to the high quality chocolate producers of Switzerland, Belgium, France and the United Kingdom. "Cocuy Pecayero" is a spirited drink produced with green agaves from the State of Lara (Venezuela), similar to the Mexican tequila. The Cocuy, which is basically a product consumed domestically, is currently produced by the region's local communities, based on traditional procedures inherited from the indigenous communities. See Vivas Eugui and Ruiz Müller, 2001, p. 14.

IV. POLICY OPTIONS: PROTECTING AND PROMOTING TRM

The previous sections have indicated different objectives and the scope available for the protection of TRM under IPRs. This section discusses some of the problems to be faced in order to implement different forms of IPRs-based protection. Such problems include -- but are not limited to -- the boundaries of the public domain, the attribution of rights, and enforcement issues. This section also discusses a number of policy options relating to the IPRs protection of TRM.

It must be acknowledged from the outset that the vast literature available on this subject exhibits a great variety of opinions on the desirability of extending IPRs protection to traditional knowledge, ranging from rejection of such possibility as inappropriate or likely to distort, rather than support, indigenous systems, to the belief that IPRs may benefit both knowledge holders and the society as a whole.¹³¹ These different views arise from multiple philosophical, legal and ethical perceptions of the status of such knowledge and the role of local/indigenous communities, as well as from diverging opinions and expectations as to the socio-economic implications of IPRs protection. The discussion that follows is essentially underpinned by concerns about the possible implications of IPRs in the area of public health.

A. Defining Public Domain

“Public domain” encompasses, under standard IPRs law, knowledge that is not subject to IPRs currently in force, whether registered or

¹³¹ See, e.g. Blakeney, 2000.

Title

not.¹³² Knowledge in the public domain is free for use by anybody, without consent of or remuneration to its holder. But the freedom to use knowledge in the public domain also means that nobody can appropriate it, unless modified in a way that permits legitimate claims of IPRs. There are, of course, communication channels between the “private” and the “public” domains, since the former draws on the latter and, once IPRs expire, protected knowledge falls into the public domain.

Public domain and public availability of knowledge are not equivalent concepts. Thus, knowledge published in a patent is available to the public, but it cannot be used without the consent of the patent owner. Conversely, knowledge held secret but ineligible for protection under trade secrets law (for instance, because of lack of actual commercial value) belongs to the public domain.

One important implication of the concept of public domain in the context of traditional knowledge is that, unless protected by an existing modality of IPRs, knowledge even if not publicly available (for instance, when held by a small community or a few individuals) would be deemed to belong to the public domain. Hence, under current IPRs law, anybody may use such knowledge, without prior consent or compensation.

As examined above, much of the debate on traditional knowledge has been triggered by cases in which knowledge that was publicly available has been appropriated under patent rights. As illustrated by the *turmeric* case, such patents, if challenged, may be revoked and become legally void, because the claimed invention does not comply with the novelty requirement. An additional reason (that has often been overlooked) is that in such cases of “bio-piracy” there is also a violation of the inventorship rules generally provided for under patent laws. Though a patent should be granted (according to the

¹³² Patents, utility models, designs and (in some jurisdictions) trademarks, are acquired through registration, while copyright and trade secrets do not require such a formality.

“first to file” system) to the first person to apply for it, he/she should be entitled to the patent on the basis of an act of invention, or as a legitimate successor in right to the inventor.¹³³

The main problem, however, arises when certain traditional knowledge is neither publicly available nor subject to a specific modality of IPRs and, hence, only technically in the public domain. Different strategies may be followed to deal with this problem.

One strategy would aim at ensuring that the true holders of such knowledge claim and obtain protection under IPRs, so as to effectively remove such knowledge from the public domain. Efforts to apply trade secret law to traditional knowledge are essentially based on this approach.¹³⁴ Though this strategy may be successful in some cases, in others the holders of knowledge may be unwilling or unable to comply with the complex procedures necessary to acquire and exercise IPRs.

An alternative approach would be to redefine the concept of public domain, by ensuring recognition to *customary laws* as part of the “private” domain, as long as such laws provide for some form of ownership over knowledge. This approach would address the problems associated with appropriation and lack of compensation for traditional knowledge, although would not be applicable to some local/indigenous peoples and has delicate political implications that may be difficult to tackle in many countries.¹³⁵

¹³³ See a further analysis of this issue in section IV below.

¹³⁴ For instance, the “BIOZULUA” database established by the Venezuelan *Fundación para el Desarrollo de las Ciencias Físicas, Matemáticas y Naturales* (FUDECI) stores information held by different ethnic groups regarding plants and animals deemed useful for food and medicinal use, as well as the associated knowledge. The collected information is handled as a trade secret in order to avoid undue appropriation and use (see Vivas and Ruiz Müller, 2001, p. 15-16).

¹³⁵ See section IV.J below.

Title

It may also be possible to consider that knowledge that is known to a community but which is not used (or presumably known) outside of that community has not been made available to the public. The presence of customary laws or practices within a community limiting or prohibiting use and dissemination of such knowledge outside of the community, might be taken into account to demonstrate that unfettered disclosure, as recognized by modern IP systems, might not have occurred.¹³⁶

B. Title

Another delicate issue is determining the attribution of rights, especially when certain knowledge is held by more than one community. IPRs are conferred to individuals and legal entities (juridical or legal persons). Communities are not generally accorded such a legal *status*. It is difficult to identify not only the communities to whom certain knowledge should be attributed, but also who legitimately represents them (Greene, 2001, p. 32).

In some countries, organizational structures (often structures imported from the West) such as associations, corporations, councils and cooperatives have been formed in order to address the communities' representation problem. Some legislation has sought to provide for the recognition of indigenous groups and communities in general -- e.g. Australia's Aboriginal Councils and Associations Act - - or of land-owning groups in particular -- e. g. Papua New Guinea's Land Groups Incorporation Act. Attempts have also been made to tailor the legislation to the particular nature, functions and powers of the indigenous body concerned, as in the case of Anangu Pitjantjatjara, the corporate body established in South Australia to hold and

¹³⁶ See the Report on the Traditional Knowledge Workshop, 24 January 2002, Commission on Intellectual Property Rights, available at www.iprcommission.org

manage the ancestral lands of the Pitjantjatjara people¹³⁷ (Fingleton, 1998, p. 34).

The issue of title-hood of TRM and representation poses complex legal and practical problems. It should be left to the local or indigenous communities to decide whether rights in the knowledge they hold are assigned to the community or to individual holders (e.g. healers). The answer may be different, for example, for African and Amer-indian cultural groups, depending on their spiritual and social conceptions. The same applies to the problem of representation. As noted by Fingleton,

“the more the legislative regime allows groups to incorporate their own cultural concepts and processes into their formal legal structures, the more likely those structures are to be effective in meeting their members’ needs and wishes. The recognizing law must, in other words, be culturally appropriate if it is to serve a useful purpose” (Fingleton, 1998, p.34).

C. Applying Patent Laws

As mentioned, certain elements of TRM may be protected under patents. There are, however, several aspects of patent systems that are likely to discourage, if not make impossible, their effective use by domestic companies in developing countries willing to commercialize TRM, as well as by healers or local/indigenous communities. Some such aspects may be tackled -- though not necessarily solved -- by introducing changes in patent laws and regulations, as described be-

¹³⁷ A review of this law, however, found in 1996 that the Act gave almost no room for local cultural variation in corporate structures and decision-making processes, and in fact caused groups to lose control over their affairs (Fingleton, 1998, p. 33).

Title

low. Adjustments in patent law and practice would also be required to curb misappropriation of TRM.

C.1. Subject matter

As mentioned, WTO Members have a certain leeway to determine what is patentable, notably with regard to the patentability of natural products and therapeutic methods.

Countries concerned with “bio-piracy” may wish to exclude from patentability substances found in nature, as well as the use of known products, in order to prevent misappropriation. In addition, it would seem logical that a country that broadly excludes methods of medical treatment, also broadly exclude new therapeutic uses for known products. Nevertheless, given the territoriality of the patent system, a country that prevents the patenting of uses under its national law cannot force other countries to follow the same approach. In the absence of international rules on the matter, nothing will prevent a country from declaring patentable (if the legal requirements are met) what is not deemed patentable in another country.

From the perspective of public health, the granting of patents over methods of therapeutic treatment seems undesirable, since it would reduce access to health care, particularly for the poor, while it is unlikely to promote in any manner the development of new TRM-based therapeutic methods.

Though WTO Members may limit the scope of patentability, some developing countries may worry that it could hinder investment in local bio-prospecting or research activities that may lead to patents on TRM-based products and successful commercialization. It must be borne in mind, however, that developing countries possessing TRM knowledge often lack the financial resources and the research and industrial capabilities to scientifically identify and isolate the compounds that explain the therapeutic effects of certain traditional medicines. In addition, TRM healers and local/indigenous communi-

ties generally lack the skills and resources necessary to follow the complex patent procedures and, in particular, to face the costs of registration and enforcement of IPRs both locally and abroad. Even with a wide scope of patentability, these factors seriously limit the practical utility of such an approach.

C.2 Patentability requirements

There is also some flexibility for the determination of the novelty and inventiveness standards in national laws, in ways that may expand or restrict the patenting of TRM. There are no restrictions in the TRIPS Agreement¹³⁸ or in other international instruments, that limit countries' freedom to determine such standards, provided that they do not discriminate on the basis of the place of the invention or the field of technology.¹³⁹ The stricter those standards are, the narrower the scope for holders of TRM knowledge (and for those acquiring rights over it) to obtain patent protection.

What the standards of patentability should be is a matter of national policy. Low standards may increase the possibility of local/indigenous communities to obtain patents, should they wish to do so, but the society will bear the cost of recognizing patents over knowledge that is and should remain in the public domain. In addition, acquiring patents and enforcing them are complex and costly endeavors, and there is nothing suggesting that such communities will become in the near future more interested in or able to use the patent system than they are today.

It is conceivable, however, that -- particularly in the case of codified TRM systems -- some research institutions and local companies take advantage of such low standards in order to protect and commercially exploit products with already known properties. This

¹³⁸ See, e.g. Correa and Yusuf, 1998, p. 200-201.

¹³⁹ See article 27.1 of the TRIPS Agreement.

Title

may favor the development of a domestic industry based on TRM. The counter point is, however, that knowledge that could be publicly available would become subject to monopolistic rights, in turn reducing access to medical treatment, all that without any real contribution to the advancement of knowledge.

In addition, should a country opt to favor the patentability of TRM via low standards, given the national treatment principle, both national and foreigners would enjoy equal rights to apply for and obtain patents under such standards. Who would benefit the most may be an open question until the experience shows what the outcome is, but there is a great chance that, because of greater technological and financial resources, foreign companies could take advantage in exploiting lax standards. A collateral but significant problem is that, given the non-discrimination principle contained in article 27.1 of the TRIPS Agreement, the same low standards should be applied to any other field of technology, including pharmaceuticals, possibly leading to a wide number of patents on marginal developments, aimed mainly at blocking competition or extending *de facto* the life time of a patent on certain active ingredients.¹⁴⁰ As a result, the costs to be supported in the area of public health (and other sectors) by an unnecessary restriction of competition, may significantly exceed the benefits (if any) of that policy.

C.3. Novelty

The way in which the novelty requirement is defined, particularly with regard to non-written disclosure, has important implications for the possible misappropriation of TRM. As mentioned, the exclusion of non-written disclosures made outside the U.S. as a ground for the loss of novelty, as provided for under US law, allows for the patenting of knowledge that would be deemed part of the prior art in most other countries in the world. An amendment to such law aligning it

¹⁴⁰ See, on these practices, often known as *evergreening*, Correa, 2001.

with the standards applied elsewhere, would make a great contribution to reducing tensions in this area.

There have been initiatives to develop proper written documentation of traditional knowledge. They essentially aim at reducing the room for the patentability of codified TRM. These initiatives document knowledge, making it available to patent examiners throughout the world, so that “prior art” is readily identifiable.

These documentation efforts have been facilitated in the last years by the application of digital technology:

“In the recent past, there have been several cases of bio-piracy of traditional knowledge (TK) from India. For preventing such instances in the future there is a need for developing digital databases of prior art related to herbs already in the public domain. Following patents on brinjal, etc., in India, an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as TK Digital Library (TKDL). Such digital databases would enable Patent Offices all over the world to search and examine any prevalent use/prior art. And thereby prevent grant of such patents and bio-piracy” (Government of India, 2000).

The documentation of traditional knowledge, in the view of the Indian government, fosters not only the prevention of ‘bio-piracy’. It may also provide a basis for the sharing of benefits arising from the use of such knowledge, though documentation *per se* will not ensure benefit sharing with the holders of such knowledge (Government of India, 2000). A clear effect of such libraries is that both local/indigenous communities and third parties will be prevented from obtaining patents over documented knowledge.

The issue of traditional knowledge digital libraries (TKDL) has also been addressed by WIPO with the aim of not only detailing in

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writing traditional knowledge already in the public domain, but of improving the WIPO International Patent Classification (IPC) so that the data is easily accessible to patent examiners. Ideally, as these TKDL come into being, they will be incorporated in the minimum search documentation list of the Patent Cooperation Treaty (PCT), therefore ensuring that the data in these libraries will be considered during the processing of patent applications filed under the PCT system. It has also been suggested that search and examination guidelines in patent examining authorities be updated to ensure that TKDLs are consulted.¹⁴¹

Concerns have been expressed about the extent to which documentation programs may expedite “bio-piracy”, rather than preventing it, by facilitating the work of those who wish to appropriate the benefits of the knowledge which is being documented. Since this may occur, the development of TKDL does not exclude the need for regulations to prevent misappropriation. A related issue -- which is beyond the remit of this study -- is the protection conferred to the data bases containing that information.¹⁴²

If the policy goal were to facilitate the patentability of TRM, rather than to limit it, a possible option would be to establish an extended grace period for inventions pertaining to this field whenever claimed by the communities or individuals that legitimately developed or hold them (Bhatti, 2000, p. 10). This would certainly expand the

¹⁴¹ See the Report on the Traditional Knowledge Workshop, 24 January 2002, Commission on Intellectual Property Rights, available at www.iprcommission.org.

¹⁴² Article 10.2 of the TRIPS Agreement establishes that “compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself”. Specific legislation introducing a *sui generis* type of protection (including an “extraction right”) has been adopted in Europe, but in most countries original data bases are protected under the general rules of copyright law.

scope of patentability in cases where it would have been excluded by loss of novelty.¹⁴³

C.4. Inventive step

Countries wishing to limit patentability, as much as possible, in order to prevent misappropriation in the area of TRM, may apply a strict standard of inventive step. As mentioned above, if the role of a “skilled average person” is played by persons trained in TRM, some applications that would otherwise have been accepted, may well be rejected. It may also be the case that concepts familiar to anyone trained in Western chemistry, are deemed non-obvious by the TRM specialist. Examiners and judges, therefore, will face the difficult task of determining the body of knowledge under which inventiveness is to be evaluated. The patent system being a Western concept, however, an inclination to apply Western science is predictable, unless different policies on the matter are established.

In contrast, in countries that wish to promote patenting in the field of TRM, the inventive step may be defined so as to allow patentability of improved variants of existing products, for instance, better bio-availability or higher stability. Higher purity would normally not be enough to justify an inventive step, though purification processes may be patentable.

D. Utility Models

¹⁴³ In some countries (such as the United States, Argentina, Mexico) any publication made by the inventor within one year prior to the date of application for a patent does not destroy novelty. This grace period is particularly useful for the protection of research results obtained in universities and other public institutions, where researchers are usually under pressure to promptly publish their findings

Title

It has been suggested¹⁴⁴ that utility models or “petty patents” may provide an alternative way of protecting TRM.

The requirements for acquiring a utility model are less stringent than for patents. While the requirement of “novelty” is always to be met, that of “inventive step” or “non-obviousness” may be much lower or absent altogether. In practice, protection for utility models is often sought for innovations of a rather incremental nature that otherwise may not meet the patentability criteria.

The term of protection for utility models is shorter than for patents and varies from country to country (usually between 7 and 10 years without the possibility of extension or renewal). In most countries where utility model protection is available,¹⁴⁵ patent offices do not examine applications as to substance prior to registration. This means that the registration process is significantly simpler and faster. Utility models are much cheaper to obtain and to maintain than patents.¹⁴⁶

Utility models are generally intended to protect minor or incremental innovations in the mechanical field. One noticeable exception is Germany, where utility models protection is conferred since 1891. In 1987 the scope of protection was broadened to include inventions concerning chemicals and polymers, in addition to mechani-

¹⁴⁴ For instance, by the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) of India.

¹⁴⁵ Currently, utility model protection is granted in Australia, Argentina, Armenia, Austria, Belarus, Belgium, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, members of the African Organization of Intellectual Property (OAPI), Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.

¹⁴⁶ See, e.g., WIPO at www.wipo.org/sme/en/ip_business/utility_models/

cal devices.¹⁴⁷ The European Commission has prepared a proposal for the adoption of a Directive harmonizing the utility model protection in Europe,¹⁴⁸ to enable small to medium enterprises (SMEs) to attain IPRs protection in a less complicated and cheaper way than through the patent system. Though, upon a proposal by the European Parliament, the scope of the Directive was revised in order to cover software, chemical substances or processes would not be covered.¹⁴⁹ Developing countries willing to apply utility models to TRM should ensure that the laws are designed so as to include medicinal products.

Some studies suggest that utility models have played an important role in promoting incremental innovation and productivity growth. Thus, the World Bank reports that in Brazil utility models helped domestic producers gain a significant share of the farm-machinery market by encouraging adaptation of foreign technologies to local conditions. Utility models in the Philippines encouraged successful adaptive invention of rice threshers. In Japan,¹⁵⁰ utility models had a strongly positive impact on real total factor productivity (TFP) growth over the period because they were an important

¹⁴⁷ Whereas the German Patent Act requires an “inventive activity”, a utility model requires an “inventive step”. However, it often turns out that this difference is of more academic than practical relevance (Schuster and Hess, 1997, p. 27). This allows applicants to simultaneously file and obtain patents *and* utility models in parallel, since both can co-exist. The registration of the utility model grants the applicant immediate protection, since examination is not necessary and the average time to register an utility model is about two months (Schuster and Hess, 1997, p. 26), while under patent law an injunction against infringers can only be obtained after the issuance of the patent.

¹⁴⁸ See COM (1999) 309, 12.7.99.

¹⁴⁹ The chemical industry was unhappy with the idea of utility models, because the value of patents could be undermined by the proliferation of unexamined utility models. See, e.g., Leith, 2000.

¹⁵⁰ The substantive examination of utility models was abolished in Japan in 1994, thereby dramatically shortening the time required from application to registration.

Title

source of technical change and information diffusion (World Bank, 2001, p. 123).

However, there is some evidence indicating that in those countries where utility model protection has been available, SMEs have not been the primary users of that system. One of the shortcomings of the system lies in one of its main advantages: the lack of examination to grant the rights means that title-holders must be careful in asserting their rights against potential infringers, since infringement claims may trigger off counterclaims of damages against the title-holder (Leith, 2000). This experience suggests that resource-constrained communities and other TRM holders are likely to face similar if not more significant difficulties to exercise their rights.

The role that utility models might play in the field of TRM is uncertain. First, in order to be applicable, legislation should specifically allow for the protection of non-mechanical inventions, particularly chemical substances of biological origin, something that most laws do not allow today.

Second, even if easier to obtain, acquiring utility models requires the compliance of administrative procedures and, above all, the capacity to enforce the rights against potential infringers which, as noted, is costly and poses a major barrier for communities, as it does for SMEs even in developed countries.

Third, granting utility models in relation to TRM domestically will not ensure their protection in foreign countries, where a similar protection may not be accorded.

Fourth, the advantages of this approach for the protection of TRM will depend on the specific design of the national legislation, particularly with regard to the level of inventive step required. If similar to the one applied to patents, the only significant advantage would be of procedural nature, not irrelevant but perhaps insufficient to make a real difference for potential applicants.

Fifth, the granting of utility models would face the same problems relating to determination of title-hood and representation noted above for other modes of IPRs, and would require the establishment of disclosure obligations of the type described in the preceding sub-section.

The TRIPS Agreement neither obliges nor limit Members' right to legislate on utility models, subject only to the national treatment obligation established by the Paris Convention (article 1 (2)). However, the question remains whether an easier means to get protection in the form of utility models would actually benefit TRM holders, since most of the obstacles regarding registration and enforcement common to other forms of IPRs remain. Utility models may become, as suggested by the German experience, a practical complement to patent protection for those that have access to the patent system anyway.

E. Designing a *sui generis* Regime

Given the difficulties in applying existing modes of IPRs protection, even if modified, to address some of the problems raised by traditional knowledge, several proposals have been made to develop *sui generis* regimes for the protection of such knowledge through international or national *sui generis* regimes.¹⁵¹ Little progress has been made, however, in actually designing them.

Proposals for the recognition of "tribal", "communal" or "community intellectual rights",¹⁵² and "traditional resource rights",¹⁵³ among others, essentially advocate such a *sui generis* approach. In many cases, however, the rationale for the proposed pro-

¹⁵¹ For a review of literature on the matter, see Dutfield, 2000a.

¹⁵² See, e.g. Berhan and Egziabher, 1996, p. 38.

¹⁵³ See, e.g. Posey and Dutfield, 1996; Koon, 1999.

Title

tection is unclear in terms of the specific objectives to be reached (Correa, 2000a).

A few countries have started to address the complex conceptual and operational problems involved in the recognition of communities' rights over traditional knowledge. For instance, "collective" intellectual property rights have been recognized by the Constitution of Ecuador (1998). The Biodiversity law of Costa Rica (1998) protects 'sui generis community rights' (article 82). The Provisional Measure No. 2.052 of Brazil (21.12.00) recognizes the rights of local communities to benefit from their knowledge and to be compensated for its economic exploitation. They can prevent third parties from disclosing or transferring such knowledge without their authorization. In the Philippines, the "Act to Recognize, Protect and Promote the Rights of Indigenous Cultural Communities/Indigenous Peoples" (No. 837, of 28 July, 1997), stipulates that:

"Indigenous Cultural Communities/Indigenous Peoples are entitled to the recognition of the full ownership and control and protection of their cultural and intellectual rights. They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts" (Section 34).

At the international level, the Council for TRIPS has under its consideration the review of article 27.3(b) of the TRIPS Agreement. The Doha WTO Ministerial Declaration also highlighted the need for further work in this area¹⁵⁴. The review of article 27.3 (b) has been re-

¹⁵⁴ See paragraph 19 of the Doha WTO Ministerial Declaration (WT/MIN(01)/DEC/1) adopted on 14 November 2001, which calls for the

garded by many developing countries as an opportunity to harmonize the TRIPS Agreement with the Convention on Biological Diversity (the CBD),¹⁵⁵ and to develop rules for the protection of traditional knowledge.¹⁵⁶ The approaches proposed by different countries however, differ.

For the African Group, such a review should preserve the room existing at the national level to develop specific modalities of protection for traditional knowledge. Venezuela¹⁵⁷ has gone a step further and proposed the development of binding *international* rules on the matter. It has suggested

“to establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders” (WT/GC/W/282).

Though the viability of this latter proposal in the framework of the TRIPS Agreement is still uncertain, it addresses one of the problems that countries opting for the protection of traditional knowledge under a *sui generis* regime would face: due to the principle of territoriality, protection at home would neither prevent the misappropriation of the protected knowledge in other countries, nor allow the TK holders to obtain any type of protection abroad. Hence, an international agreement would be necessary in order to obtain legal recognition of such holders' rights on an international scale.

Council for TRIPS to examine the issue of protection of traditional knowledge and folklore.

¹⁵⁵ See, e.g., the submission by Egypt, WT/GC/W/136.

¹⁵⁶ See, in particular, the submissions by India (WT/GC/W/147) and by the African Group (WT/GC/W/302).

¹⁵⁷ Under Decision 391 of the Andean Pact, the Member countries thereof are bound to develop legal regimes for the protection of communities' knowledge. A constitutional provision to that effect has been adopted in Ecuador. None of the Andean countries, however, have so far developed such regimes.

Title

Some developing countries (notably from Latin American and the Caribbean) have also actively promoted the increased involvement of the World Intellectual Property Organization (WIPO) in the discussion and development of a *sui generis* regime for traditional knowledge.¹⁵⁸

The establishment of *sui generis* regimes pose many complex conceptual and practical issues (Correa, 2000a; Correa, 2000c). Such problems include the determination of:

- who the title-holders are and how are they represented;
- the subject matter of protection;
- the eligibility requirements and modes of acquisition, possibly including registration;
- the kind of rights to be granted (exclusive rights, or merely remuneration or moral rights);
- the duration of protection and its possible retroactive application;
- sanctions in case of infringement; and
- enforcement mechanisms.

There are two important additional problems to be faced. First, as mentioned, there is a great variety of codified TRM systems, while local/indigenous communities utilize various forms of TRM knowledge (which in many cases may be shared by more than one community). In order to be consistent with the very concept of *sui generis*, such systems should be tailored to the diverse cultures and environments in which they would be applied. In fact, certain communities could be said to have developed their own *sui generis* systems under their own customary laws. The idea (quite popular in certain circles) that a single *sui generis* regime may fit all, and that Western experts (including this author) are better equipped than the

¹⁵⁸ As mentioned, an Inter-Governmental Committee to deal with these issues was established by WIPO in September 2000.

communities themselves to design systems suitable to their conceptions and needs is thus highly debatable.

Second, should a *sui generis* regime be established in a particular country, the territoriality principle deems that such a regime would not get recognition in other countries, unless bilateral, regional or international agreements were adopted. While it may take some time to develop an acceptable international regime, bilateral or regional agreements may be more rapidly agreed upon and implemented. In any case, unless an international standard is developed, the value of new forms of IPRs protection will be limited to within national borders. In this sense at least, the use of established IPRs forms, if possible at all, and if consistent with a clearly articulated and appropriate rationale for protection (and especially if actually enforceable by their holders) present more advantages than newly established, but territoriality limited, *sui generis* forms of protection.

It has been suggested that the mutual recognition, on an international basis, of *sui generis* regimes established on the national level should be promoted (Department of Commerce, Government of India, 2002). This approach essentially advocates for an extraterritorial application of national laws on the matter, something that many countries may be very reluctant to accept. An alternative approach could be based on the global enforcement of private judgments and injunctive relief in commercial litigation as proposed in the draft “Hague Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters” (which is being negotiated under the Hague Conference on Private International Law).¹⁵⁹

Thailand is possibly the only country that has so far developed a comprehensive *sui generis* regime for TRM medicine (*see Box 1*). One important feature of the Thai law is that all three types of formulae can continue to be freely used domestically by traditional healers or Thai communities in limited quantities. The law also provides for measures aimed at the conservation and sustainable utilization of

¹⁵⁹ See Love, 2001.

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the medicinal plants, especially those at high risk of extinction. In addition, the Institute of Thai Traditional Medicine¹⁶⁰ was formally established (after having been in operation for seven years), and a Thai Traditional Knowledge Development Fund was created.

The Thai regulations have permitted the registration of over 700 licensed local manufacturers producing traditional medicine. In 1998, there were already 4,300 formulations registered with Thai FDA. These numbers are still increasing. The total value of production in 1999-2000 was around 320 million bahts¹⁶¹, without including traditional medicines produced individually by healers (Subcharoen *et al*, 2000).

The Thai Act provides a model of a special regime for the “protection” and the “promotion” of TRM which does not prevent the traditional healers from continuing to produce preparations for individual use. It contains, however, some questionable elements. In particular, the very long period of protection may create an “unnecessary burden on society” and provide “unreasonable profits to the owners of the traditional knowledge” (Kuanpoth, 2001, p. 6-7). In addition, there have been implementation problems, since no “national formulae” have been announced, and it has been difficult to establish title to “private formulae”.

Box 1

The Thai *sui generis* TRM regime

The “Thai Traditional Medicinal Intelligence Act” distinguishes different categories of “Traditional Formulations”:

“*National Formulae*” are formulations which are crucial for human health and are held by the State.

¹⁶⁰ The Institute is governed by a committee composed of equal numbers of NGO’s and governmental officials. Registration and other activities are distributed among 75 provincial offices throughout Thailand.

¹⁶¹ Approx. US\$ 7,5 million.

The Act stipulates that the ministry of Public Health has authority to decree a certain formula of traditional Thai medicine as a “national formula”. To be eligible, the traditional formula must be of significant benefit or have special medical value. After the announcement, the rights of such a formula belong to the State.

The commercial use of a national formula, for the production of drugs or for research and development, is subject to permission from the government (criminal sanctions are provided for in the case of infringement).

“*Private Formulae*” can be freely used by the owner. Third parties must obtain permission from the owner to use the formula. The request for the registration of a “private formula” can be submitted by an inventor or developer of the formula, or an inheritor of the inventor or developer of such a formula.

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

“*General formulae*”, finally, are well known traditional formula that may be used freely by anybody.

Source: Kuanpoth, 2001, p. 6-7.

In addition, the patent-like rights conferred under this system may allow title-holders to charge high prices, thereby reducing affordability to medicines essential to a large part of the population. Though it is arguable that the *sui generis* regime, as described, is necessary to promote investment in testing and validating TRM-based products, there is no analysis supporting this hypothesis, or examining other possible, less restrictive, options. The establishment of a *sui generis* regime of this kind would only seem to be justified if it were proven that benefits to society outweigh the deleterious effects on public health that such regimes may create.

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F. Enforcement

While, as described, TRM may be subject to a variety of IPRs, in most cases the costs of acquiring and exercising them are not only prohibitive for TRM holders because of registration fees but, because of high costs of enforcement.

For instance, the process of acquiring a patent includes drafting the patent specification and claims (a complex task that generally cannot be undertaken without expert advice), and payments for filing, examination, and actual receipt of the IPRs grant. Furthermore, in most countries maintenance fees need to be paid periodically to keep the patent in force. These expenses are far beyond the means of most local/indigenous communities and TRM healers.

Needless to say, it is only worth investing in obtaining a patent if it can be effectively used to prevent infringement. Monitoring whether the patent rights are respected is difficult, and bringing an action in court to stop infringement very costly. Of course, patents may be licensed and a licensee may bear these costs, depending, on the terms of the licensing agreement. But licensees would usually require the patent owner to defend the patent, should it be challenged on grounds of invalidity. Even if a case does go to court, a third party may well succeed in convincing the judge that its product, use or process is sufficiently different from the original traditional knowledge to constitute an invention of its own, or at least not to constitute an infringement (Dutfield, 2000, p. 15-16).

Similarly, the use of trade secrets raises complex issues of proof in a traditional context, including about possession of the relevant knowledge, its secret character and the adoption of reasonable measures to keep it confidential. Issues relating to the 'commercial value' of knowledge may also arise. The use of trade secret law therefore, poses questions of effective documentation and capacity to act in courts.

Comparable problems would emerge in cases where third parties falsely claimed ownership in respect of TRM. Challenging the validity of a patent, or the undue use of an indigenous symbol¹⁶² or geographical indication, also requires sound legal advice and entails significant costs.

Finally, things are complicated further by the territorial nature of IPRs protection. While it may difficult for local/traditional communities to acquire and enforce rights in their own country, it may be actually impossible to do it internationally. Registering a patent in the U.S. may cost at least US\$5.000 to US\$10.000, and quite a lot more in Europe,¹⁶³ where the largest markets are. In addition, in the U.S. the costs of a typical infringement suit¹⁶⁴ are estimated to run to US\$1 million to US\$3 million, while they are also substantial in other developed countries.

Given the high barrier posed by enforcement costs and procedures, States must be called to support their local/indigenous communities in order to allow them to make an effective use of IPRs. Without such support, protection through IPRs will have minimal practical relevance. Developed countries may also support such a-

¹⁶² See, e.g. the native people's opposition in the U.S. to the use as trademarks of Indian symbols (Coombs, 1998, p. 186-187). A proposed amendment to the trademark law in New Zealand would prevent the registration of a trademark where its use would offend a significant part of the community, including the Maori people. <http://www.ruddwatts.com/newsroom/publications/ip/newtrademarksbill2001.asp>

¹⁶³ The costs for the international protection of an invention are somewhere in the range of US\$40.000-US\$50.000, including registration and maintenance fees (Hofinger, 1996, p. 88).

¹⁶⁴ In some countries, administrative actions are also available. For instance, post grant opposition procedures are available before the European Patent Office, which have resulted in the invalidation of roughly 30% of the opposed patents (Merges, 1999). In the U.S., re-examination can be conducted by the US Patent and Trademark Office.

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tions as part of their development aid, by providing legal assistance to developing countries in this matter.

E. Misappropriation Regime

Despite wide agreement among developing countries about the importance of obtaining recognition for traditional knowledge, the main concern of some countries has been to avoid the “bio-piracy” of traditional knowledge, rather than the creation of positive rights for their potential benefits. A misappropriation regime aimed at avoiding the monopolization of TRM and related biological materials may be based on a number of measures (legal and otherwise), not requiring the granting of exclusive rights. The adoption of some elements of an international misappropriation system seems more feasible to achieve in the short term than an internationally accepted *sui generis* regime providing for positive protection.

Possible measures include changes in some key elements of the patent laws (of developed and developing countries), such as applying a consistent novelty requirement that ensures non-written disclosure outside the country of registration is deemed destructive of novelty.

Patent laws may also be amended in order to introduce an obligation to disclose the origin of resources covered by IPRs claims, as well as compliance with access legislation, where appropriate.

The disclosure of the country of origin of a biological product may facilitate claims of benefit sharing by these countries, as well as challenges to the validity of wrongly granted IPRs. This goal may be better achieved if the country where the application was made, notified the country of origin of the material as to the existence of such an application.

Some national laws have already taken some steps in relation to this matter (*see Box 2*). The European Directive on Biotechnologi-

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cal Inventions¹⁶⁵ also refers to the disclosure of information as to the origin of biological materials, but within preambular provision rather than as a substantive obligation.

The proposal for the implementation of the European Directive in Belgium stipulates in Article 4(3) that the exploitation of an invention is contrary to *ordre public* and morality, when an invention was developed on the basis of human tissue removal without the consent of the donor, or when an invention is developed on the basis of plant or animal material which was imported in violation of the law of the country of origin of these materials. In these cases, a patent could be revoked on the basis of Art. 49(1)(1) of the Belgian Patent Act 1984 (Van Overwalle, 2000, p. 282).

The disclosure obligation, as illustrated by the above mentioned legislation, may refer to the country where the applicant has obtained the material, and also require information about compliance with national access laws, if in existence and applicable¹⁶⁶, in that country.

Box 2

Disclosure Obligations Under National Laws



¹⁶⁵ No 96/9/EC of 11 March 1996.

¹⁶⁶ It is to be noted that only a few countries have so far adopted access legislation (Petit et al, 2000) and, therefore, there are no mechanisms in place in most countries to determine conditions for access. This is quite paradoxical in view of the importance attributed by developing countries to the principles of the CBD, and of their demand in WTO to reconcile the TRIPS Agreement with said Convention. See para. 19 of the WTO Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

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Costa Rica

Pursuant to Biodiversity Law 7788, Article 80, both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting intellectual or industrial property protection to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. Justified opposition from the Technical Office would prevent granting of a patent. Failure to provide the necessary information could lead to the rejection of the application or revocation of the patent.

India

The Patents Second Amendment Act (adopted in 2002) provides that the applicant must disclose in their patent application the source of origin of the biological material used in the invention (section 10). It also allows for opposition to be filed on the ground that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used in the invention. The grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application, and prior disclosure of knowledge, oral or written.

In addition, according to section 6 of the Indian Biodiversity Bill, anybody seeking any kind of intellectual property rights on a biological resource or knowledge obtained from India, needs to obtain prior approval of the NBA. The NBA will determine benefit-sharing conditions. Section 18 (iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

Box 2 (continued)

Andean Group

The Andean Group Decision 391 establishes that any IPRs or other claims to biological resources shall not be considered valid, if they were obtained or used in violation of the conditions for access to biological resources residing in any

of the Andean countries, as regulated under that Decision. Andean Decision 486 provides in Article 26 (h) that applications for patents shall be filed with the competent national office and shall 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. If appropriate, the applicant shall also submit a copy of the document that certifies the authorization to use the traditional knowledge by indigenous, African American, or local communities in the Member country where the products or processes whose protection is being requested were obtained or developed.

The possible establishment of a disclosure obligation has been controversial. Certain governments and experts suggest it would impose an additional requirement, inconsistent with article 27.1 of the TRIPS Agreement which lays down the three requirements for patentability (novelty, inventive step, industrial applicability), and with article 29 that provides for the conditions to obtain a patent grant. It has also been argued that applicants may lack the information necessary to comply with such an obligation, and that it would increase the costs of patent applications.

The disclosure obligation would not create an additional patentability requirement. As a matter of principle, a patent should not be granted to a person who has not made an “inventive contribution”. Inventorship is a basic element in patent law and there are no limitations under the TRIPS Agreement with regard to the means to determine it.¹⁶⁷ Applicants may be required to summarily show, in the

¹⁶⁷ See the Report of the WTO case *United States-Section 211 Omnibus Appropriations Act of 1998* (WT/DS176/AB/R) where the Appellate Body (supporting the panel’s view) held that neither the TRIPS Agreement nor the Paris Convention addresses the question how the ownership of a trademark is determined, and that is an issue to be determined by national law (para. 188-189). The same doctrine is arguably valid for patents and other

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case of inventions relating to the use of plants, etc., whether they have effectively arrived at the invention. Such an obligation would permit patent offices to obtain better information on the “prior art”, which may be deemed as inclusive of precedents that have not been divulged before the filing date, but that demonstrate that somebody has previously arrived at the same invention.¹⁶⁸

The applicant may be obliged to submit, on a *bona fide* basis, whatever information he or she has obtained without necessarily obliging him or her to make a costly and time consuming search of information not available or difficult to obtain. He or she should certainly be in a position to inform whether he/she has complied with existing access legislation.

The consequences of the failure to disclose the origin of material (and compliance with access legislation) may include invalidation of the grant, if the applicant is unable to prove inventorship. A lack of candor in providing information may also be deemed to have occurred and may be sanctioned with the non-enforceability of the granted rights,¹⁶⁹ as practised under US law.¹⁷⁰

H. Investment Incentives

One of the arguments for seeking IPRs protection in the area is TRM is, as mentioned above, the desire to promote the development of a TRM-based industry, particularly by stimulating investments to undertake the tests necessary to validate TRM-based products.

¹⁶⁸ This concept was applied in some US decisions, based on *Corona Cord Tire Co. vs. Dovan Chem. Corp.* (US Supreme Court, 1928), where a prior invention of another party, not publicly known, was deemed as destructive of the novelty of a second invention (Merges, 1992, p.504).

¹⁶⁹ See, e.g. Pires deCarvalho, 2000, p. 394.

¹⁷⁰ The US Supreme Court has declared that “A court of equity acts only when and as conscience commands; and if the conduct of the plaintiff be offensive to the dictates of natural justice, then, whatever may be the rights he possesses, and whatever use he may make of them in a court of law, he will be held remediless in a court of equity” (290 US 240 quoting *Deweese v Reinhard* 165 US 386).

However, traditional medicines are not subject, in many cases, to regulatory controls, or are subject to specific regulations that are less stringent than those applicable to modern medicines¹⁷¹. From a public health perspective, the past use (even if ancestral) of a medicine, may not be sufficient reason to obviate pre-clinical and clinical tests needed to establish toxicity and safety. The WHO has warned that, though, in general, prolonged use of a traditional medicine offers testimony of its safety, in a few instances

“investigation of the potential toxicity of naturally occurring substances widely used as ingredients in these preparations has revealed previously unsuspected potential for systematic toxicity, carcinogenicity and teratogenicity“ (WHO, 1996, p. 180).

The need for clinical trials under standard scientific procedures is the same as in the case of modern medicines. However, the regulatory authorities of many countries –including India- and the WHO have accepted much shorter preclinical animal tests for traditional medicines.¹⁷² According to WHO, if adequate study of the published literature demonstrates lack of harmful effects of a herbal remedy, clinical evaluation can be undertaken without previous animal toxicology studies (WHO, 1996).

The development of appropriate formulations may require some investment, more or less significant depending on the product’s characteristics and the targeted form of presentation,¹⁷³ but generally the size of investment required would not be high.

¹⁷¹ See, e.g. Jayasuriya and Jayasuriya, 2002, p. 200.

¹⁷² See, e.g. Chaudhury and Chaudhury, 2002, p. 213.

¹⁷³ TRM may also be used to investigate possible new therapeutic products or treatments, though this is rare for the plant medicines industry (ten Kate and Laird, p. 93).

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The granting of exclusive rights under IPRs and other schemes¹⁷⁴ may contribute to encourage investment in scientific validation and development of pharmaceutically acceptable formulations of traditional medicines, but important questions arise as to the justification of such rights for this purpose. The investments required are relative small -- as compared to those necessary for the development of new drugs -- and public support may be more easily available.¹⁷⁵ Exclusive rights restrain competition and reduce access to the protected medicines. Should the promotion of investment be desirable, States have many options (such as tax breaks) outside the IPRs system to provide the needed incentives without negatively affecting public health.

I. Benefit Sharing

The application of IPRs over TRM may facilitate sharing in the benefits derived from the commercial exploitation of such knowledge. However, if the protection of knowledge is through IPRs held by third parties (as opposed to healers/communities who have developed such knowledge), legally binding mechanisms to ensure benefit

¹⁷⁴ One possibility would be, for instance, to confer a limited period of exclusivity (shorter than patents) as applied under “orphan drug” legislation in the U.S. and other countries. The goal of this legislation is to provide incentives to pharmaceutical companies to invest in diseases where the small number of patients and, thus, total market expectations, are too small to warrant investing in the costly R&D process. An attractive feature of the orphan drug act is that it combines “push” and “pull” incentives (Kettler, 2002).

¹⁷⁵ Some countries have established extensive public supported programs to undertake clinical trials of traditional medicines. For instance, the Indian Council for Medical Research set up a network of more than 25 clinical research centres to carry out controlled clinical trials (Chaudhury and Chaudhury, 2002, p. 2120-221). In China the government began establishing in the late 1950s research institutes to establish the value of TCM and develop it further (Xie, 2002, p. 129).

sharing need to be established. Otherwise such a sharing would be exclusively based on the will of the IPRs owner. Mechanisms of that kind may be incorporated in IPRs law.

For instance, the Indian Plant Variety Protection law, passed in August 2001, has established that in order to ensure equitable sharing of benefits, the use of farmers' varieties to breed new varieties will have to be paid for. Revenue is to flow into a National Gene Fund. This money is to be collectively, rather than individually, accessed by farming communities (exceptions can be made where individuals are clearly identified as breeders of specific varieties). Further, sections 19 and 21 of the Indian Biodiversity Bill mandate the approval of the National Biodiversity Authority (NBA) before access to genetic resources takes place. While granting approval, the NBA could impose terms and conditions to secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of intellectual property rights on research based upon biological resource or knowledge obtained from India, needs to obtain the prior approval of the NBA.

A benefit-sharing regime needs not to be grounded on the existence and enforcement of IPRs. It may rather operate according to the model established by the CBD with regard to the access and use of biological resources¹⁷⁶, or to other specific arrangements. An example of benefit sharing carried out outside IPRs is provided by the AICRPE project in India, in relation to a plant identified as *Trichopus zeylanicus travancoricus* (and called 'Arogyapacha', or "evergreener of health"). This plant has been, traditionally used by the Kani tribe¹⁷⁷, with antifatigue and immuno-enhancing properties. Based on the lead from the Kani tribe, a scientifically validated and standardised herbal formulation ('Jeevani') was developed. The technology was transferred to a pharmaceutical company for commercial production. The Kani tribe will receive 50 per cent of the royalties paid by the company (Pushpangadan, 2002).

¹⁷⁶ It should be noted, however that, in principle, benefits under the CBD accrue to the States supplying genetic resources, not communities.

¹⁷⁷ The Kanis are a semi nomadic tribal people who inhabit the forests of the southern part of the Western Ghats in Kerala, India.

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j. *Customary law*

Customary laws may play an important role in preserving and regulating the use of traditional knowledge in certain local/indigenous communities. Such laws are generally based on the principles of collective right and free flow of knowledge. Seeking to extend existing modern systems of IPRs protection to such communities might undermine their existing customary systems, and defeat many of the objectives that IPRs are supposed to contribute to.

The protection of TRM could potentially be addressed through the enforcement of the customary laws of local/indigenous communities, rather than by the application of the current IPRs models¹⁷⁸. The success of a customary law approach would depend on the its formal recognition, accompanied by adequate legal arrangements concerning matters such as self-determination, land rights and biodiversity protection. The recognition of communities' customary law, hence, raises delicate political issues in the framework of the modern nation state, the relationship between indigenous peoples and national governments being problematic in many countries¹⁷⁹.

An important limitation of the customary law approach is that, if adopted at the national level, it would not encompass –very much like in the case of *sui generis* regimes discussed above- recognition of the rights conferred in foreign countries, unless specific agreements on the matter are put in practice under international agreements or unilaterally under national laws.

Under the current UK patent law, for instance, the presumption of inventorship in favour of the applicant can be overridden when another person was entitled by virtue of “any foreign law,

¹⁷⁸ The Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, requested further consideration of the role of customary laws and practices in relation to the protection of genetic resources and TK, innovations and practices, and their relationship with intellectual property rights (Decision VI/24 C 3(b)The Hague, 7 - 19 April 2002)

¹⁷⁹ “Some indigenous peoples understand themselves to be a nation within a nation or a nation whose peoples cross the borders of two or more nations. Some governments consider themselves to be the sole and entirely sufficient voice of all the peoples within their sovereign territory (The Crucible Group, 2000, p. 77).

treaty, or international convention” (Section 7.2.b.ii). Thus, if customary law were recognised in the country where the traditional knowledge originated, this provision might result in protection of the original holders of knowledge (who may get the transfer of ownership of the patent obtained by a third party or request its invalidation).

V. IPRs and public health

The exclusive rights conferred by IPRs enable the charging of prices above marginal costs. This creates a difficult dilemma for policy makers¹⁸⁰: how to reconcile the aims of intellectual property, which provides incentives by restricting the use of the protected products or processes, thereby guaranteeing extraordinary gains, with society’s interest in allowing the maximum use of knowledge through low prices, in ensuring diffusion and in facilitating continuous improvement of innovations. As noted by David (1992),

“Intellectual property inherently entails restricting the extent of useful application of the new knowledge by permitting the imposition of license and royalty charges upon the users. The more secure is the patent monopolist (even though it has been publicly disclosed), the higher the charges that can be levied. This reduces the benefits that would have accrued to society at large, and to consumers in particular, had the information been made available for competitors to exploit in the form of new products or production processes” (p. 16).

This dilemma is particularly serious in the area of public health, as increased prices mean reduced access to medicines which in some cases determines life or death. Proposals to protect TRM often overlook this crucial aspect: protection may benefit the few who may be able to commercialize TRM, but may hurt all those who need access to the protected products.

A basic question is, therefore, the extent to which IPRs should be granted over TRM, in view of the costs to society that the exercise of such rights may entail. Though this issue needs to be

¹⁸⁰ See, e.g. OECD, 1992, p. 50.

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more systematically examined, some considerations can be made here.

Patents (and to some extent, other IPRs) are justified, according to the prevailing economic theory¹⁸¹, to stimulate investments for research and development. Since much TRM already exists or is continually improved as a result of traditional practices, IPRs protection is unlikely to play a significant role, if any, in stimulating the development of such knowledge.

In many cases, herbs are sold as dietary supplements and, therefore, they fall outside the regulations on medicines, which are generally stricter than those related to such supplements (Balasubramanian, 1997,p.iii). In other cases, commercialization is subject to compliance with marketing approval, and investments are necessary to scientifically validate medicines. However, the tests required to validate any particular traditional medicine are, as indicated above, more limited than for non-TRM medicines, and often supported by public funding.

Despite that in the last twenty years the emphasis of the IPRs paradigm has shifted in some countries from the protection of *invention* to the protection of *investment* as such (Correa, 2002), IPRs are essentially granted to reward inventive or creative contributions rather than just any investment related to the generation of information. As also mentioned above¹⁸², governments may stimulate investment in validation of medicines used in TRM systems by non-IPRs means, for instance, by public funding and the granting of exclusive marketing rights for a limited period.

The recognition or establishment of new types of IPRs on TRM may reduce, rather than enhance, access to medicines and health treatment, particularly by the poor¹⁸³. In dealing with TRM, developing countries should very carefully balance the expected

¹⁸¹ See, e.g. Penrose, 1951; Gutterman, 1997, p. 36-70.

¹⁸² See section IV.h.

¹⁸³ The likely negative impact on access to health care of the strengthening of IPRs in developing countries, has been stressed in recent analyses, including some studies by the World Health Organization. See, e.g. Velásquez and Boulet, 1999.

benefits to be derived from IPRs protection, with the costs likely to arise from the limitations on access to TRM treatment that the exercise of such rights would entail. The basic question is to decide whether priority should be given to protect or rather to promote the use of TRM.

The promotion of the use of TRM calls for an integrated policy comprising, *inter alia*, the assessment of known herbal medicines¹⁸⁴, the exploration of potential medicinal plants, the training, certification and registration, where appropriate, of traditional healers and practitioners (Balasubramanian, 1997, p. *iii*), as well as standardization and improvement of the of TRM products that are industrially produced (Pranoto, 2001, p. 1). An example of this promotional approach is provided by Act No. 8423 (1997) of the Philippines, which aims “to accelerate the development of traditional and alternative health care” by improving the manufacture, quality control and marketing of traditional health care materials (Section 3.d). Policies for the promotion of TRM should also include educational and community extension programs, as well as the development of greater interaction with modern medicine. Particular attention should also be paid to R&D needed to establish the safety and efficacy of TRM, including to test TRM used to treat common diseases such as malaria.

Finally, it should be noted that the promotion and commercial success of TRM may have positive effects, but also some deleterious consequences. The increase in the demand for medicinal plants may raise their cost for the local population, for whom TRM is often the only affordable medical treatment. Moreover, many medicinal plants face extinction or severe genetic loss. Hence, governments should control trade in medicinal plants in the framework of broader policies for the conservation and sustainable use of such plants, with an understanding that the loss of biodiversity may also have implications for public health¹⁸⁵.

¹⁸⁴ WHO has developed Guidelines for this purpose (see WHO, 1996).

¹⁸⁵ Peru, for instance, passed a law in July 1999 which bans the non value-added export of some botanical species with known healing properties, which had become the target of massive extraction by foreign laboratories. The law covers the

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VI. Conclusions

TRM has particular characteristics influencing the extent to which IPRs may be applied. TRM includes materials, processes and methods of treatment, individually or collectively held, constituted by old and recently developed knowledge, largely but not totally disclosed and capable of generating commercial value at different points of the value added chain. Most importantly, TRM has great value in many developing countries where it plays a crucial role in the health care systems.

Some governments, scholars and NGOs have voiced the need to protect TRM under existing or new forms of IPRs, in order to recognize and compensate the creators and possessors of such knowledge. Others object to that possibility for ethical, economic or other reasons, while demanding measures to prevent “biopiracy”, that is, the unauthorized appropriation of TRM under Western IPRs systems.

Discussions concerning the protection of TRM under IPRs, have generally focused on the injustice generated by third parties’ misappropriation, and on the benefits that some forms of IPRs (existing or to be created) may generate for TRM holders. Little attention has been paid to the costs associated to the establishment of IPRs, as they may limit access to medicines and treatment. This issue is particularly important, since TRM serves the health care needs of millions of people in developing countries.

Developing a policy on TRM and IPRs is a very complex matter and presents difficult dilemmas, for a variety of reasons.

First, the scope and content of such policy would logically depend on the pursued objectives. A great diversity of views exists on the objectives that IPRs may foster in the field of TRM. The analysis made above reveals that tensions exist between some possible objectives of IPRs protection, notably between conferring exclusive rights over TRM and ensuring access to health care, especially by the poor. Moreover, the role that IPRs may play in attaining some of the intended objectives (such as preservation) does not seem to

two best-known medicinal plants in Peru’s indigenous pharmacopoeia: *cat’s claw* and *maca*.

have been carefully examined, and the potential of such protection is often overstated. Many of the objectives mentioned as justifying protection, such as benefit sharing, may be best attained by other, non-IPRs means.

Second, there are important differences among TRM systems in use, and any generalization about means for their protection is inappropriate. In particular, IPRs can play a quite different role with regard to codified and non codified TRM. In the case of codified TRM systems, the main problems to be addressed include the misappropriation by third parties and how to encourage investment for the validation of existing medicines. Misappropriation is also a concern in the case of non-codified systems, the main issues being in the context of IPRs the recognition of communities' contributions and benefit sharing.

Third, the concept of TRM embraces different categories of knowledge that may be subject to existing forms of IPRs, if the conditions for protection are met in particular cases. Several components of TRM, including products and processes and, in some countries, uses and methods of treatment, can be validly covered by patent rights. In fact, a large number of patents have been granted in relation to natural products, combinations, extracts and preparations thereof, as well as processes of production. The use of patents to protect TRM, however, face important obstacles, due to the need to meet the patentability requirements and to the costs and complexity of procedures before patent offices and, most importantly, of enforcement in courts. Management capacity and investments are necessary to get value out of the use of such rights. Other modalities of IPRs, such as trademarks and geographical indications, may also be applied, but they do not protect the knowledge as such and similar obstacles are faced with regard to the acquisition and enforcement of rights.

Fourth, while developing *sui generis* regimes for the protection of TRM (or, more generally, traditional knowledge) is an open option, many conceptual and practical difficulties need to be addressed. By definition, such regimes should be adapted to the object to be protected and to the context where it would be applied. Suggesting one single model of *sui generis* regime may defeat the very

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concept that it purportedly promotes. In addition to difficulties in determining who owns and what kind of rights are to be conferred, in the absence of an international regime the establishment of a *sui generis* system at the national level would not solve the problems of misappropriation and lack of benefit sharing with regard to commercial exploitation of TRM made abroad.

Last, and perhaps most importantly, TRM plays a very important role in the health care systems of developing countries, particularly of the poor. The diffusion of TRM-based products is also significant in developed countries. The granting of IPRs-forms of protection on medicines used in TRM systems may have high social costs via a reduction in access to medicines and treatment essential to millions of people. It is unlikely that such costs be offset by the benefits that may possibly accrue from validation or the improvement on such medicines that IPRs protection would encourage. Therefore, when designing national policies on TRM, a careful assessment of the possible implications of IPRs protection of TRM on public health should be made.

As noted, misappropriation is one of the main problems perceived in this area. There are a number of changes in patent laws that may be introduced and actions that may be taken, nationally and internationally, in order to prevent misappropriation of TRM, namely: establishment of a universal standard of novelty for patent grants; disclosure of the origin of biological materials in patent applications; clarification and strict application of inventorship rules; and development of data bases to establish prior art.

Such changes and actions may help to address, if not completely solve, one of the most thorny issues in this field, and would constitute an important step towards a better legal treatment of this issue. Action may also be taken for a rational and effective implementation of the benefit sharing principles of the CBD which, paradoxically, very few developing countries have incorporated into national policies and regulations.

When identifying rationales and mechanisms for the protection of TRM held by local/indigenous communities, it is important that the perspectives, opinions and rights of indigenous peoples be considered, and that indigenous representatives participate in relevant

decision-making processes. Such inclusion is not only a moral imperative but is, for some States, necessary for the satisfaction of their obligations under international law. A basic decision must be made as to whether any attempt to protect TRM will seek to impose Western standards and principles or face the more difficult task of accepting traditional concepts and finding ways to reconcile Western interests with them.

Some have suggested that the number of local/indigenous communities that would be likely to benefit from the availability of IPR protection may be small. Whether that is reason or not to go ahead with the creation of protection for TRM is a matter for local/indigenous peoples themselves to determine, in line with their own development and other priorities, including the effect of such measures, negative or positive, on their social and cultural development and rights.

While governments should recognize the contributions of local/indigenous communities and healers, and should condemn the misappropriation of their knowledge, they should not succumb, however, to the simplistic idea that the solution to the current problems of inequity and knowledge erosion can be solved by the adoption of existing or new forms of IPRs. Any solution to the problems associated to the protection of TRM requires a holistic approach.

Debates on IPRs protection have often overlooked that the existence of local/indigenous communities and, therefore, the preservation and further development of TRM, is indivisible from their cultural and natural environment. The principal threat to TRM knowledge is likely to originate not from the lack of legal recognition of IPRs, but from the continuous erosion of their cultures and the ecosystems in which local/indigenous communities live.

In light of public health priorities, governments may adopt several measures to *promote* the use of TRM for the affordable treatment of national and regional priority diseases, such as encouraging the validation, registration and quality control of TRM-based products.

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IPRs should not run counter to but should support public health¹⁸⁶. Developing countries may gain little and lose a lot if achieving the protection of TRM leads, in fact, to limiting access to TRM treatment and products. After the full implementation of the TRIPS Agreement, developing countries will be bound to pay more for needed medicines. TRM may become a critical component in the public health strategy of many of such countries. The benefits to society of safe and wide use of TRM may be substantial, while the granting of exclusionary IPRs may only benefit a few, if any.










Policies on TRM should aim at balancing considerations of equity and public health. While it is fair that TRM holders receive, when appropriate, a moral or economic reward for the knowledge they contribute, such reward should not be at the price of reducing access to TRM by people in need, particularly the poor.

¹⁸⁶ See the “Doha Ministerial Declaration on the TRIPS Agreement and Public Health”, WT/MIN(01)/DEC/W/2, 14 November 2001 .










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