



# GENDER DIMENSIONS OF INTELLECTUAL PROPERTY AND TRADITIONAL MEDICINAL KNOWLEDGE

E-DISCUSSION PAPER

Asia-Pacific Trade and Investment Initiative  
UNDP Regional Centre in Colombo  
April 2007

**GENDER DIMENSIONS OF INTELLECTUAL  
PROPERTY AND TRADITIONAL MEDICINAL  
KNOWLEDGE**

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First Edition

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This E-Discussion Paper is written by Heather Gibb at The North-South Institute, as a background study for the Gender and Trade Policy Paper. The paper had its origins in a bus conversation in Dhaka with a woman whose organization was working with rural women on a pilot project to cultivate an indigenous medicinal plant for local and, potentially, regional markets. She was unfamiliar with intellectual property rights issues and concerned that her association, which had a mandate to advise the government on trade policy, was also unfamiliar with trade regimes. It was not apparent that the funder was aware of national, regional or international IP regimes which might have a bearing on the long-term viability of their project.

No one seemed to be connecting the dots between a pilot project targeting women micro-entrepreneurs, Traditional Knowledge and intellectual property regimes on the one hand, and trade-related capacity building initiatives available for government officials and larger producers on the other. I am very grateful for the support, encouragement and patience of Yumiko Yamamoto and Bryn Gay at the UNDP Asia-Pacific Regional Centre in Colombo, and for helpful conversations with Russell Barsh, Philip Bird, Chantal Blouin, Tasmin Rajotte, and Ann Weston. All errors and omissions are entirely the responsibility of the author. Several Creative Commons-licensed photographs were taken from Flickr.com®; photographers are gratefully acknowledged.

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## ABBREVIATIONS AND ACRONYMS

AIDS	Acquired ImmunoDeficiency Syndrome
ASEAN	Association of Southeast Asian Nations
BIMSTEC	Bay of Bengal Initiative for MultiSectoral Technical and Economic Cooperation (Bangladesh, India, Myanmar, Sri Lanka, Thailand, Bhutan and Nepal)
CBD	Convention on Biological Diversity
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CENTAD	Centre for Trade and Development
CIPR	Commission on Intellectual Property Rights
COMTRADE	UN Commodity Trade Statistics Database (of United Nations)
COP	Conference of the Parties (the governing body of the CBD)
DEBTEC	Biotechnology and Environmental Conservation Centre, Bangladesh
FAO	Food and Agriculture Organization of the United Nations
FTA	Free Trade Agreement
HIV	Human Immunodeficiency Virus
ICG	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (of WIPO)
ICIMOD	International Centre for Integrated Mountain Development
IFC - SEDF	International Finance Corporation - The South Asia Enterprise Development Facility
IK	Indigenous Knowledge
ILO	International Labour Organization
IP	Intellectual Property
IPRs	Intellectual Property Rights
IUFRO	International Union of Forest Research Organizations
MAPs	Medicinal and Aromatic Plants
MAPPA	Medicinal and Aromatic Plants Program in Asia (International Centre for Integrated Mountain Development, Nepal)
NGOs	Non-Governmental Organizations
NTFP	Non-Timber Forest Product
PDCA	Provisional Committee for Proposals Related to a Development Agenda (WIPO)
PIC	Prior, Informed Consent
QUUNO	Quaker United Nations Office
SAARC	South Asian Association for Regional Cooperation (Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka)
SDT	Special and Differential Treatment
SEDF	South Asia Enterprise Development Facility
SME	Small and Medium Enterprise

TK	Traditional Knowledge
TM	Traditional Medicine
TMK	Traditional Medicinal Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIFEM	United Nations Development Fund for Women
UNU-IAS	United Nations University Institute of Advanced Studies
UPOV	International Union for the Protection of New Varieties of Plants
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WIPO-IGC	World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
WTO	World Trade Organization

## INTRODUCTION

World Trade Organization (WTO) trade ministers reached a breakthrough agreement in Doha, Qatar in 2001 that interprets and implements the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) “in a manner supportive of WTO members’ right to promote public health and...promote access to medicines for all.”<sup>1</sup> This agreement recognized the right of countries to make use of TRIPS flexibilities that would let public authorities issue compulsory licences to a third-party to produce or import a pharmaceutical drug that is still under patent. By 2003 WTO members had reached an agreement to allow countries that produce generic drugs to export them to poor countries that have no capacity to manufacture generics. The move responded to evidence (and strong civil society campaigning) that patent protection under TRIPS for essential pharmaceutical drugs was having the effect of increasing prices and reducing access to essential medicines, in particular, to drugs that treat Human Immunodeficiency Virus (HIV) and Acquired ImmunoDeficiency Syndrome (AIDS), tuberculosis and malaria (Blouin 2006).

There has been less progress in international discussions on a TRIPS issue affecting another public health question of particular concern to developing countries: intellectual property (IP) on traditional medicinal knowledge<sup>2</sup> (TMK) or “traditional medicine”.<sup>3</sup> Traditional medicine, which relies heavily on natural remedies based on natural products, provides an important kind of primary

healthcare system in poor countries, particularly in rural areas, where access to Western biomedicine<sup>4</sup> is limited or prohibitively expensive. Medicinal and aromatic plants (MAPs) are an essential part of traditional healthcare systems, constituting an accessible, affordable and culturally appropriate source of primary healthcare for more than 80 percent of Asia’s population (WHO 2003). In China, traditional herbal preparations account for 30-50 percent of the total medicinal consumption (*ibid.*). Traditional medicine is widely used in India, particularly in rural areas; Ayurveda, Unani, Siddha, naturopathy, homeopathy and yoga are recognized by the Government of India under the Central Council of Indian Medicine Act (1970) (WHO 2001, p. 132). Seventy percent of Indonesia’s rural population relies on traditional medicine; more births are attended by traditional birth attendants than by allopathic practitioners. Indonesia also has an important traditional medicine industry: At the end of 1999, there were 723 manufacturers of traditional medicine, 92 of which were large-scale industries (*ibid.*, p. 134). In Bangladesh, almost 80 percent of the rural population is dependent on medicinal plants for their primary healthcare.<sup>5</sup> Traditional medicine dates as far back as 500 AD in Nepal, and Ayurvedic medicine is widely practiced: More than 75 percent of the population uses traditional medicine (WHO 2001, p. 137). Seventy percent of Sri Lanka’s rural population relies on traditional and natural medicine for their primary healthcare (*ibid.*, 139). The Republic of Korea and



Viet Nam have integrated traditional medicine into all areas of healthcare provision; India, Indonesia and Sri Lanka have national policies on traditional medicine (WHO 2002, pp. 8-10).

Medicinal plants are also important sources of livelihoods for millions of rural people in South and Southeast Asia, particularly women, indigenous peoples and people living in poverty. Traditional knowledge (TK) associated with medicinal herbs and cultivation, innovation and preservation of medicinal herbs is a highly gendered activity in most countries. In many cultures, women and men take on complementary roles and responsibilities in TMK, roles that are not presently well reflected in mainstream policy discussions. While there is considerable debate on the merit of including intellectual property rights (IPRs) at all in the WTO<sup>6</sup>, at present, members are obligated under their commitments to TRIPS to provide minimum standards of protection for intellectual property rights either by enacting new legislation or amending existing national laws. In this way, governance of “rights” to knowledge and resources traditionally managed by rural and indigenous populations has been moved away from local communities to multilateral trade forums, and, increasingly, into regional and bilateral trade agreements.

Initiatives in trade discussions at the international, regional and bilateral levels on intellectual property associated with traditional medicine have implications for the wellbeing of rural and indigenous populations, where maternal healthcare is often delivered by female traditional healers. The plants and traditional medicinal knowledge also have

important commercial applications of interest to pharmaceutical companies in both developed and developing economies. In addition, there is a growing recognition of the role that traditional medicinal knowledge can play in treating global diseases, and that traditional knowledge can be a good investment for pharmaceutical companies. While demand has risen, inequitable trade practices have meant that only a small portion of the profits trickle down to collectors and harvesters. Concerns include recognition of the intellectual property rights of traditional users and biopiracy<sup>7</sup> (illegal or unethical “bioprospecting”<sup>8</sup>). Thus, unresolved intellectual property issues may present an access problem for the historical holders of traditional medicinal knowledge: “increasingly, it appears that knowledge of traditional medicine (TM) is being appropriated, adapted and patented by scientists and industry, with little or no compensation to its original custodians, and without their informed consent” (UNCTAD 2000).

There are two key, related concerns: (1) people who depend on traditional medicine may lose access to medicinal plants and the associated knowledge if the plants are patented by pharmaceutical companies; (2) over-harvesting of commercially valuable medicinal plants in their natural environment could result in their extinction<sup>9</sup>, with both healthcare and livelihoods impacts for indigenous and rural peoples. Loss of plant biodiversity also jeopardizes traditional knowledge: If there is no habitat to support plants and indigenous or rural populations, the cultural and traditional medicinal knowledge will disappear.

There is a fairly extensive and diverse literature on IPRs and traditional knowledge, reflecting the many debates about the role IPRs might play in the preservation or commercial exploitation of TK, conservation of biodiversity, protection of indigenous peoples' rights, and public health systems. IP issues are discussed in many international forums with overlapping interests (see Box 3). This paper examines the discussion on intellectual property rights for traditional knowledge in medicine from a gender perspective. The growing literature on gender and trade has identified how trade policies can have different implications for men and women that are linked to gender-based differences in social and economic activities, access to productive resources and decision-making. Worldwide, women and men tend to be employed in different sectors (e.g., women are more likely than men to be employed in producing handicrafts and garments) or in different activities in similar sectors (e.g., women in some developing countries are more likely to grow staple foods for local markets than crops for export).<sup>10</sup> A gender analysis adds to our understanding of how trade decisions can have important and unintended impacts on the lives of disempowered peoples. Trade institutions and trade policy-making processes are rarely inclusive of the interests of small economic players, including rural, indigenous or ethnic groups, and gender concerns are even less well understood and addressed. Governments have international obligations to protect and advance women's economic activities under CEDAW<sup>11</sup>, the International Covenant on Economic, Social, Cultural and Political Rights, the Beijing Platform for Action, the Millennium Development

Goals and other human rights conventions as well as trade commitments; however, these obligations rarely factor in national trade policy discussions.

The paper draws on the limited literature on gender dimensions of IP and TK, which highlights the roles played by women, particularly indigenous women, as custodians of TK and as consumers and producers of traditional medicines. The second section addresses the question: What is being protected by IPRs? The following section summarizes current discussions on intellectual property and traditional medicinal knowledge (TMK) in TRIPS and the Convention on Biological Diversity (CBD). Many countries are taking steps to develop national legislation to protect and promote their TK; however, there are growing concerns about the constraints that may be placed on governments as a result of "TRIPS-plus" conditions within regional and bilateral trade agreements. IPRs in the area of TK are discussed in many international forums, and "forum shopping" appears to be a strategy adopted by some countries to obviate the push for accepting a stringent IP regime. The paper concludes with some suggestions for developed and developing countries to orient the focus of discussions on IP and TK more closely to health concerns. Policy measures should be more consistent with the Doha directive, by adopting a rights-based approach in order to better address gender concerns than do current trade models. This strategy would imply a more bottom-up approach to international rule-making, in which traditional and community governance mechanisms would be better reflected in national and international IP regimes.

## WOMEN AND TRADITIONAL KNOWLEDGE IN MEDICINE

Women's traditional roles as keepers of biodiversity are widely recognized and reflected in several international plans of action and organizations concerned with biodiversity, health and food security, including:

- The *Convention on Biological Diversity* Preamble affirms the central role of women drawing specific attention to "the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation".<sup>12</sup>
- *Agenda 21*, adopted at the Earth Summit, Rio de Janeiro, 1992, stresses the need to strengthen women's involvement in national ecosystem management and control of environmental degradation.
- The *United Nations Food and Agriculture Organization* (FAO) has drawn attention to the different roles that men and women maintain within livelihoods systems that comprise farms and home gardens, common property resources, such as pastures and forested lands, as well as protected areas. In addition to providing vegetables, these home gardens are also experimental plots where women try out and adapt diverse wild plant and indigenous species.<sup>13</sup>

There are gender dimensions to the impacts of processes of globalization on traditional medicine, to the

knowledge itself, and to strategies governments adopt to take advantage of booming markets for traditional medicine. Some of the adverse effects of processes of globalization and trade liberalization on traditional knowledge in medicine include the introduction of imported foods as a result of tariff reductions that impact on and may diminish the use of local varieties of plants; the introduction of alien species for commercial farming that out-compete or contaminate indigenous herbs and medicinal plants; and, shifts to market-oriented agriculture that erode the roles and knowledge systems of indigenous women in agricultural production. Unsustainable levels of harvesting have raised concerns about the long-term viability of natural ecosystems which support medicinal plants and the livelihoods of traditional knowledge-holders. These medicinal herbs are an important source of both income and medicine for poor people, especially women.<sup>14</sup>

In most countries, proportionately more women are engaged in agricultural activities than men (ILO [n.d.]; FAO [n.d.]). In many regions, women and men perform different, complementary roles in cultivating, harvesting and using medicinal plants, however, quantitative and qualitative data describing women's specific roles in collecting, growing or marketing medicinal herbs are difficult to obtain. This level of detail is not included in labour force data, which in

any event tend to under-report the significance of women's economic activities in labour markets and agriculture, since much of this activity takes place outside the realm of the market.

Studies<sup>15</sup> suggest that in most countries, there are well-defined gender roles in agriculture and biodiversity management, although these vary across regions and cultures. In many cultures, women and men have different knowledge of medicinal plants which is linked to the division of labour. In many rural-based and indigenous communities, women play key roles in delivery of informal healthcare alternatives based on medicinal plants.<sup>16</sup> Policies and initiatives that ignore gender dimensions of traditional knowledge in medicine can have serious implications, as one World Bank report concludes: "As a result of this gender differentiation and specialization, the [traditional medicinal] knowledge and skills held by women often differ from those held by men, affecting patterns of access, use and control, while resulting in different perceptions and priorities for the innovation and use of Indigenous Knowledge (IK). It also impacts the way in which IK is disseminated, documented and passed on to future generations" (Pidatala and Rahman Khan 2003). Some studies<sup>17</sup> document women's roles in local knowledge systems, however, despite the recognition of gender in the CBD and other agreements, the literature review conducted for this paper found that case studies setting out women's roles in TMK and gender analyses of TK in the English language were limited, and virtually non-existent in the IP

literature. This "invisibility" persists in technical and scientific research, where women's knowledge and roles, responsibilities and management practices for the conservation and improvement of animal and plant genetic resources tend not to be recognized.<sup>18</sup>

Many governments in South Asia have targeted non-timber forest products (NTFP) and medicinal herbs for development, as sources of livelihoods for rural people and as export commodities. In Bangladesh, for example, the government has encouraged production of medicinal plants. According to one estimate, around 12,000 tonnes of dried medicinal plants are sold from rural collection and production areas, worth around US\$4.5 million. The Bangladeshi MAP sector is worth US\$14 million, with local supply comprising 70 percent by volume and 40 percent by value.<sup>19</sup> Persisting gender-related barriers to women's access to education, training, land, credit and their own labour, however, will limit women's ability benefit equitably from these initiatives. Mobility restrictions, for example, can limit women's ability to participate in market and access extension services (ADB 2004). "Good practice" examples of initiatives that recognize the importance of gender include a Chilean campaign, by ANAMURI<sup>20</sup>, to strengthen a network of community-based organizations of rural and indigenous women farmers to help them protect seeds, medicinal plants, and the TK associated with them. Including gender in programming can lead to the use of more innovative forms of participatory research in the study of medicinal plant biodiversity, the

medicinal plants in general, and marketing potential. A South African study found that the ethnobotanical knowledge of Zulu women enabled them to substitute the bark of plentiful trees which had similar scents and medicinal properties for the bark of a scarce tree (Siles [n.d]). The International Centre for Integrated Mountain Development (ICIMOD), which houses the Medicinal and Aromatic Plants Program in Asia (MAPPA), is engaged in research and pilot projects to promote community-based sustainable development of MAPS and non-timber forest products.<sup>21</sup>

### Box 1: Women and Medicinal Plants in Asia

These examples are a non-exhaustive list of the roles that women carry in the cultivation of medicinal plants in Asia, and they are representative of the multitude of women's and community initiatives throughout the Asia-Pacific region:

- **Bangladesh:** Women account for about 45 percent of total employment in agriculture. The NGO Development of Biotechnology and Environmental Conservation Center (DEBTEC) has encouraged women to cultivate backyard home gardens of medicinal plant, both as a strategy to protect endangered species and to empower women through plant cultivation that will provide a source of earnings.<sup>22</sup> The Government of Bangladesh has advocated farmers to grow more medicinal plants to meet both local

demand and enter export markets: At present, most medicinal plants are gathered from the wild. According to one report (Hossain 2005), the government plans to provide farmers with plants from its nurseries at low cost and give farmers soft loans to cover the cost of cultivating them (Hossain 2005; SciDev.net [n.d.]).<sup>23</sup>

- **Bhutan:** Gender roles are not rigidly assigned, and women and men can take over each other's tasks. According to an FAO Sustainable Development Dimensions report [n.d. (c)]<sup>24</sup> about 45 percent of medicinal plant collectors are women. The government is systematically developing the traditional medicines sector. The South Asia Development Facility (SEDF) also is collaborating with the National Women's Association of Bhutan in a pilot project training women in rural communities to cultivate medicinal herbs to create employment and build SME capacity (IFC SEDF 2005).
- **India** has a rich tradition of indigenous medicine (i.e., Ayurveda, Siddha, Unani, Amchi) and many traditions of "ethno-medicine" (Pidatala and Rahman Khan 2003). Because women are more likely to have family care responsibilities, they tend to be primary practitioners of this indigenous knowledge. A World Bank (2006) study found that a vast majority of community folk healers ("Naitivaidyas") are women.

As well, with large numbers of young men migrating from rural to urban areas, women are becoming responsible for maintaining indigenous knowledge of traditional medicine in rural areas.

A number of case studies have

illustrated the different roles of women and men in collecting NTFP, including medicinal plants. The different roles and responsibilities of men and women vis-à-vis forests and the concomitant social and economic consequences for tribal households at large, and women in particular, are considerable (FAO [n.d.]).<sup>25</sup>

According to studies in Uttar Pradesh, women derive a greater proportion of their income from forests and common lands; poor women derive 45 percent of their income from forests and common lands as opposed to 13 percent for men (FAO & SIDA 1991; Yadama, Pragada, and Pragada 1997).

- **Nepal:** It is mostly women who collect herbs and wild vegetables in Nepal. While sex-disaggregated data is limited, a 2002 Gender Budget Audit in Nepal reported that when unwaged labour is included in the labour force statistics, 56 percent of currently employed women (aged 15 years and older) are engaged in agriculture. Women, however, have fewer rights over land – the lack of equality in inheritance rights in all ethnic communities means that women as a group are disadvantaged in access to productive resources.<sup>26</sup> NGO-sponsored interventions aimed at promoting community-managed enterprises often include initiatives targeting women. The Medicinal and Aromatic Plants Programme in Asia (MAPPA) of the International Centre for Integrated Mountain Development, based in Kathmandu, undertakes research and programmes to develop suitable practices, policies, technologies and locally adaptable practices to sustainably manage MAPs and NTFP resources for South Asia and the Hindu Kush-Himalayas.

Guiding principles include promoting gender equity.<sup>27</sup>

- **Pakistan:** About 80 percent of rural women are engaged in agriculture compared with 61 percent of rural men. Case studies suggest that medicinal plant collectors are usually poor villagers, and that plant collection is a part-time activity in addition to farming and livestock keeping. One survey in the Utror-Gabral Valley in the north western part of the District of Swat found that the “women folk of the area provide the most valuable source of indigenous knowledge of medicinal plants (Hamayun, Khan & Begum [n.d.]). Another study found that tribal women and children collect 90 percent of the medicinal herbs and all drying is done by women. About 71 percent of medicinal herbs are sold by women and children, and 29 percent by men.
- **Sri Lanka:** Over 600 species have been used as medicinal plants, since Ayurveda is widely practiced in Sri Lanka. The demand for medicinal plants for Ayurvedic prescriptions and pharmaceutical companies is largely met from natural plant resources. There are concerns about the impacts of over-harvesting on rural women, who are collectors and vendors, as well as about the availability of local medicinal plants to supply domestic health needs. “Home gardens” play an important conservation role, with women playing a key role by first identifying the economic value of these plants for food, medicine, and other uses, and later domesticating them. Some studies suggest that new farming practices and the emergence of the market economy have played an important role in altering gender roles and reducing the position of women to that of

farm labour, away from their historical roles as planners and managers (FAO [n.d. (b)]).

- **Viet Nam:** Agriculture employs 57 percent of the labour force, but one-half of men and two-thirds of women in rural areas primarily earn their living in agriculture; almost all new employees to the sector are women. In particular, ethnic minorities are engaged in agricultural biodiversity and traditional knowledge (Twarog & Kapoor (eds.) 2004; Jha (ed.) [n.d.]). Viet Nam has integrated traditional medicine into its national

healthcare system, and TMK is viewed as a significant national resource. Despite their heavy participation in agriculture, ethnic women are less likely to have tenure security over the land. For many ethnic groups, inheritance customs that pass down land patrilineally, and women's lack of awareness of their legal rights, exacerbate the situation (World Bank 2006, pp. 4-6).

## WHAT DO INTELLECTUAL PROPERTY REGIMES “PROTECT”?

Discussion of the role that intellectual property regimes play in protecting traditional knowledge raises the question of what is being “protected” and for what purpose. In trade regimes, IPRs mean that the owner of a patent, copyright, trademark or some other type of intellectual property has the legal right to exclude others from using or reproducing it. A different view is “protection” in the sense of safeguarding the continued existence and development of TK. The Philippines’ Traditional and Alternative Medicines Act defines IPRs as “the legal basis by which the indigenous communities exercise their rights to have access to, protect, control over their cultural knowledge and products, including but not limited to, traditional medicines, and includes the right to receive compensation for it.”<sup>28</sup>

Some North American indigenous peoples’ organizations have emphasized that ownership of all traditional knowledge collected from Elders and healers belongs to the communities, and have expressed apprehension about non-indigenous governments regulating traditional medicine (Martin Hill 2003). Some analysts have drawn attention to how colonial influences have marginalized indigenous women’s roles in traditional medicine and ceremonies, a marginalization that may be further perpetuated in appeals to “tradition”. Métis women in Canada testifying to the Royal Commission on Aboriginal Peoples noted that:

“...tradition is invoked by most politicians in defence of certain choices. Women must always ask – Whose tradition? Is ‘tradition’ beyond critique? How often is tradition cited to advance or deny our women’s positions?”<sup>29</sup>

Most national governments have ratified CEDAW and other human rights conventions that set out and protect women’s rights, but these guarantees are not yet mainstreamed in trade forums.

There are different views on how legal instruments should be used to protect various kinds of knowledge. Some indigenous peoples’ organizations have pointed out that protecting TK would involve protecting the whole social, economic, cultural and spiritual context of that knowledge, which is not possible to achieve with an IP system designed to protect private property.<sup>30</sup> Conferring IP rights is an instrument of public policy, which should be to the benefit of society as a whole, according to the UK Commission on Intellectual Property Rights.<sup>31</sup> However, the IP right is a private one, so the financial benefits and costs fall on different groups within society.<sup>32</sup> Some TK holders have been able to use conventional IPR instruments to protect their TK, but these instruments were developed for IP protection on industrial innovations, not TK. It is difficult for herbal medicines to meet all the requirements for patentability for the following reasons:



- Herbal medicines are crude plant materials, thus, not eligible for patent law protection as products that involve the discovery of new chemical entities must be novel, involve an inventive step, and be industrially applicable;
- Production processes for herbal products are created using simple methods and do not involve any invention that requires a novel or complicated enough step to justify protection under existing patent laws;
- Holders of TK such as research institutes and practitioners usually do not have the financial and human resources necessary to obtain protection through intellectual property rights;
- It is difficult to keep traditional knowledge a secret because disclosure of the composition of the product is a prerequisite for the registration of herbal medicines before the product can be sold;
- It is prohibitively expensive for traditional practitioners as well as research institutions in developing countries to acquire, exercise and enforce patent rights in most countries, particularly if international coverage is required.<sup>33</sup>

While discussion on the international legal frameworks has intensified, not all observers agree that formal intellectual property rights regimes are the most appropriate way to “protect” this knowledge, particularly medicinal knowledge which is critical for impoverished communities. Some analysts suggest that extension of ownership rights through intellectual products could expedite the very processes that contribute to the appropriation and erosion of

indigenous knowledge resources. IPRs may, under certain circumstances, assist traditional medicine holders to obtain monetary compensation for their knowledge. However, by their very monopolistic nature IPRs may restrict the diffusion of sacred, protected knowledge, thereby potentially reducing access and imposing costs on communities, as follows<sup>34</sup>:

- Formal IPR systems extend to indigenous knowledge mechanisms, which generally are collective in orientation, but IPR systems predominantly reward individual effort. Thus, as TK resources become commercially valuable, individual incentives to cheat could increase, undermining any newly devised collective institutions;
- The incorporation of TK under a system of patents and copyrights strengthens material forces that potentially deplete the resources and strengths of indigenous peoples;
- Commodification of TK situates TK within a world system of mass-production and resource management, rather than valuing indigenous knowledge as important to cultural heritages;
- If herbal medicines are patented, the medicines that are used as the predominant resources for healthcare by people living in poverty may become unaffordable.

## TRADITIONAL KNOWLEDGE IN MEDICINE IN TRADE AGREEMENTS

### **Trade in Medicinal and Aromatic Plants is Big Business**

Adaptations of traditional medicine, known as complementary and alternative medicine,<sup>35</sup> are big businesses. According to the WHO (2003), 70 percent of Canadians have used complementary medicine at least once; the figure for Germany is 90 percent. Medicinal and aromatic plants and traditional medicine are big businesses: Globally, sales of herbal medicines are estimated to have exceeded US\$12.5 billion in 1994 to US\$30 billion in 2000. Annual growth rates of this sector average between 5 percent and 15 percent, depending on the region. In 2000, the Secretariat of the Convention on Biological Diversity reported that the world market for herbal medicines, including herbal products and raw materials, was US\$60 billion (Zhang 2000). World trade in medicinal plants and related products is forecast to reach US\$5 trillion by the year 2050 (Gupta 2005, p. 45).

It is difficult to assess global trade in all medicinal plants, as a substantial part of this trade is not recorded. In addition, official trade statistics either do not identify the plants individually, or they do not separate their medicinal use from other usage. The value imports by the world's top importer of medicinal plants<sup>36</sup>, the United States, from all countries rose from US\$136.9 billion in 2001 to US\$174.7 billion in 2005, with China and India supplying the largest percentage (i.e.,

China in 2001 supplied 26 percent; in 2005 it supplied 28 percent; in 2001, India supplied 27.5 percent and in 2005, 17 percent). Mexico, the third largest supplier, saw its share of the US market increase from approximately 4 percent to 11.4 percent in 2005. The UN Commodity Trade Statistics Database (COMTRADE) shows the United States importing approximately 47 percent of total imports of medicinal and pharmaceutical products<sup>37</sup>, followed by Belgium (14 percent), Germany (12 percent), the EU-25 (10 percent), and France (9.9 percent).<sup>38</sup> According to one estimate<sup>39</sup>, Bangladesh sells approximately 12,000 tonnes of dried medicinal plants from rural collection and production areas worth around US\$4.5 million to the rural economy. In India, a hub in regional trade, up to 40 percent of its national forest-based revenues and 70 percent of forest export revenues come from MAPs and NTFPs, mostly in unprocessed and raw forms. In Nepal it is estimated that every year 20,000 tonnes of MAPs worth US\$18-20 million are traded; about 90 percent is exported mainly to India in raw form.<sup>40</sup> Viet Nam usually exports 100 tonnes of different traditional herbs, both raw and semi-manufactured products, with a turnover of US\$30 million to US\$50 million a year. The turnover of export and import commodities, including NTFPs, has increased by 15 to 30 percent each year.<sup>41</sup>

## **Intellectual Property and Traditional Medicine**

The international legal framework to protect TK includes the TRIPS Agreement, which allows patents to be granted on biological materials and indigenous knowledge, and the Convention on Biological Diversity, which acknowledges the rights of states over their bio-resources and indigenous knowledge. Most biodiversity-rich countries are located in the global South, while technology-rich countries with resources to develop biodiversity are based primarily in the North. Before the CBD codified the sovereignty of nations over their biodiversity, it was considered “the common heritage of men”; that is, in the public domain (Moran 1999). TRIPS and CBD address the overlapping and possibly conflicting interests of different domains: TRIPS addresses private rights, according monopoly rights and benefits to private interests, while the CBD provides for sharing benefits arising from the utilization of genetic resources.

At the WTO Ministerial in Doha, the TRIPS Council was instructed to examine the relationship between IPR provisions within the TRIPS Agreement and the CBD, taking full account of the developmental perspective. At the same time, the World Intellectual Property Organization (WIPO), through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (referred to as the “IGC”) began work on both policy issues at the international level as well as work on some practical linkages between the IP system and concerns of practitioners and custodians of TK.<sup>42</sup> In 2006 the WIPO

Provisional Committee for Proposals Related to a Development Agenda (PCDA) recommended that WIPO take on a key role in technical cooperation, given WIPO’s orientation on the implementation and enforcement of IP obligations.

Other international instruments involved in the IP treatment of traditional knowledge in medicinal plants include the International Treaty on Plant Genetic Resources of the Food and Agriculture Organization (FAO) of the United Nations, the International Union for the Protection of new Varieties of Plants (UPOV), established by the International Convention for the Protection of New Varieties of Plants,<sup>43</sup> the World Health Organization (WHO), and the United Nations Conference on Trade and Development (UNCTAD).<sup>44</sup>

## Box 2: Intellectual Property Rights and Traditional Medicinal Knowledge

A number of unresolved intellectual property issues remain:

- Limited recognition of the importance of TK as a source of food and healthcare for a large proportion of people in developing countries
- Inadequate acknowledgement of the rapid pace at which TK is being lost due to environmental degradation and loss of habitats, which are sometimes linked to the expansion of market-oriented agriculture and over-harvesting of wild plants
- Asymmetry between the benefits obtained by companies, usually from developed countries that commercially exploit products derived from TK, and lack of benefits for the TK holders
- Misappropriation (“bio-piracy” of TK, then using patents and other intellectual property rights without prior, informed consent from originators and traditional knowledge holders).

## Box 3: International Forums

Intellectual property rights involve many international forums which can help to resolve the outstanding issues for equitably and sustainably protecting traditional knowledge:

- **Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources for Food and Agriculture (IPGRA)** (FAO International Treaty) relates to issues on conservation and the sustainable use of biodiversity.
- **International Covenant on Economic, Social and Cultural Rights of the United Nations:** The General Comment No.14 (GC 14) of the Covenant defines the right to health as the “right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.”<sup>45</sup>
- **The International Convention for the Protection of New Varieties of Plants<sup>46</sup>** (UPOV Convention) is silent on the subject of TK, but its provisions are relevant to protection of the interests of small farmers and local communities. While UPOV is an independent intergovernmental organization, WIPO provides administrative and financial services to the organization.
- **International Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries** states that governments have the responsibility to develop measures for the full realization of indigenous and tribal peoples’ social, economic and cultural rights.

- **The UN Commission on Human Right and UN Permanent Forum on Indigenous Issues** focus on issues related to the rights of indigenous peoples.
- **UN Educational, Scientific and Cultural Organization** focuses on cultures with the potential of protecting cultural resources using various methods.
- **UNCTAD** addresses traditional knowledge in the context of its work on trade, environment and development. UNCTAD's "BioTrade Initiative" promotes the trade of natural ingredients from developing countries' domestic biodiversity, and incorporating CBD objectives into trade for the conservation and sustainable use of biodiversity and benefit-sharing.<sup>47</sup>
- **The World Health Organization (WHO)** encourages the use of traditional medicines in national healthcare systems in its Traditional Medicine Strategy (WHO 2002). By making this connection, the WHO has examined the relationships between intellectual property rights, innovation and public health (WHO 2006).
- **World Intellectual Property Organization (WIPO)**<sup>48</sup>: Prior to TRIPS, WIPO had exclusive oversight and competence in IP matters. Its mandate is to harmonize the international patent system. WIPO engages in IP discussions with several organizations, including UNEP (which houses the CBD Secretariat) particularly on the role of IPRs in benefit-sharing (Gupta 2005).
- **WTO TRIPS** outlines the global rules on intellectual property rights.

## THE WTO AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The TRIPS Agreement covers seven types of intellectual property rights: patents, Geographical Indications, copyright, trademarks, trade secrets (undisclosed information), industrial designs, and layout-designs of integrated circuits. TRIPS does not acknowledge or distinguish between indigenous, community-based knowledge and that of industry; according to Kibet A. Ng'etich (2005) it does not make reference to the protection of traditional knowledge. One contentious issue is Article 27.3(b) on patent protection on "life forms", which requires WTO members to provide patent protection on micro-organisms as well as non-biological and micro-biological processes. Members are required to provide for protection on plant varieties either by granting patents or by using "an effective *sui generis* system".

The TRIPS Article calls for a review of Article 27.3(b), by the TRIPS Council, a review broadened by the Doha Declaration to include strengthening the relationship between TRIPS and CBD on the protection of traditional knowledge and folklore. The debate has centred on the extent to which TRIPS is supportive of or runs counter to the principles in the CBD. According to some analysts, TRIPS "paves the way for the privatization of biological resources" by allowing patents to be granted on biological materials and associated indigenous knowledge, and it pressures developing countries to increase levels of protection based on standards developed by and for developed

countries.<sup>49</sup> There also are ethical, social and environmental concerns about patenting life forms. In the lead-up to the Doha Ministerial, developing countries had lobbied for incorporating CBD principles within TRIPS that recognize the authority of governments to grant access to genetic resources, subject to prior informed consent (PIC), on mutually agreed terms, with fair and equitable benefit-sharing, including with respect to TK. Most developed countries opposed this proposal. Since Doha there has been considerable discussion within the TRIPS Council; however, the North-South divide between the technology-rich developed countries, and bio-diversity rich developing countries persists.<sup>50</sup>

Some areas of flexibility within TRIPS have been identified that could afford protection for traditional medicine, including:

- **Special and Differential Treatment (SDT)**

TRIPS contains almost no significant differences in rules for developing countries, LDCs and developed countries, maintaining a "one size fits all" with respect to minimum rules for IPR protection in patents, trademarks and copyright, except that the timing of implementation of the rules differs. One measure that has been advocated is that WTO members should have the right to adopt any effective *sui generis* system which is compatible with their TRIPS

obligations (Michalopoulos 2003). There are also two non-legally binding provisions involving commitments by developed countries to promote technology transfers and technical and financial assistance to developing countries.

- ***Sui Generis* Systems**

Article 27.3(b) requires the protection of plant varieties through patent laws or through effective *sui generis* systems. *Sui generis* refers to methods of protection other than the use of a patent: At the national level, it could be a form of “plant breeders’ rights.” National plant variety laws could require the disclosure of origin of the plant materials that are used as well as evidence of PIC from the country, farmer or TK holder that provided the materials and associated knowledge (Connolly-Stone 2004; Drahos 2004). UPOV represents one standard of protection that is mainly used by developed countries and some developing countries. Yet as the UPOV system has evolved, it has resulted in more and more restrictive interpretations of farmers’ rights which many critics say are more appropriate to corporate farms in developed countries than to the traditional knowledge and practices prevalent in most developing countries. In addition, some preferential, free trade arrangements between developed and developing countries have reduced the flexibility in Article 27.3(b) by requiring participating developing countries to adopt a particular system of plant protection, typically UPOV 1991. This later version of UPOV sets higher standards for patent protection than TRIPS (i.e., includes TRIPS-plus measures). Cambodia, China, and Viet

Nam are several countries that have been required to adopt UPOV 1991 standards as part of the terms of their WTO accession.

- **Disclosure of Source of Origin**

IP protection in the international trading system could require mandatory disclosure of the source of genetic resources and associated TK in applications for patents and plant variety rights, through an amendment to TRIPS Article 29. This Article could incorporate mandatory disclosure, assess whether the collection of information used prior informed consent, and ensure equitable benefit-sharing (Connolly-Stone & Correa 2003). This approach has been proposed by Brazil, China, Cuba, India, Pakistan, Peru, Tanzania, and Thailand at the WTO TRIPS Council.

- **TK and Geographical Indications**

Some IP analysts advocate expanding the scope of Article 23 of TRIPS to strengthen the protection of Geographical Indications. The TRIPS Council has been considering whether protection afforded under TRIPS to Geographical Indications<sup>51</sup> should be increased through either the establishment of an international register of protected indications or through the extension of additional protection currently available for wines and spirits to other products. Movement forward in the Doha Development Round, however, has been limited to discussion on wines and spirits.

- **Exclusions to Patentability**

This discussion aims to incorporate into domestic patent laws all the

exclusions to patentability that are allowed under TRIPS Article 27. This move could involve excluding plants and animals from patentability (but not micro-organisms). It also encourages countries to adopt an expansive interpretation of the exclusions in Article 27.2, which allow Members to exclude patentability of inventions when it is necessary to protect public order and morality, including the protection of human, animal or plant life, and to avoid serious damages to the environment (Connolly-Stone 2004).

Currently, WTO members are divided on whether to include a mandatory requirement to disclose the source of origin of genetic resources and associated traditional knowledge while applying for a patent. If such a requirement is included, the TRIPS Council would continue discussions on the modalities for prior informed consent and benefit-sharing.



## BILATERAL TRADE AND INVESTMENT AGREEMENTS

Although one of the main reasons developing countries accepted the TRIPS Agreement during the Uruguay Round was the expectation that they would not be subject to bilateral pressures on IPRs by developed countries, bilateral and regional trade and investment agreements between developed and developing countries often include mutual commitments to implement intellectual property regimes that go beyond TRIPS' minimum standards (Vivas-Eugui 2003). These are referred to as "TRIPS-plus standards",<sup>52</sup> which often remove or deter countries from using the flexibilities available under TRIPS. Obligations for the protection of IPR in bilateral investment agreements may also limit the ability of developing countries to apply "performance requirements," a constraint that would be inconsistent with the spirit of the CBD on access to resources and transfer of technologies which makes use of those resources.<sup>53</sup>

There are four regional agreements related to access and benefit-sharing: The Andean Pact Decision 391 on the Common Regime on Access to Genetic Resources, which is a legally binding instrument; the draft Central American Agreement on Access to Genetic Resources and Bio-chemicals and Related Traditional Knowledge, the draft Association of Southeast Asian Nations (ASEAN) Framework Agreement on Access to Biological and Genetic Resources; and the African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to.<sup>54</sup>

Many stakeholders believe that traditional knowledge can best be protected and promoted through national systems of law that recognize and respect customary and community systems of governance. A policy coherence approach would seek to build regional multilateral governance systems that recognize and are coherent with such national systems. This approach is in contrast to the paradigm followed in many trade regimes, in which multilateral, regional or bilateral agreements set standards for national legislation.

Considerable work has been conducted in the CBD Working Group on Article 8(j) to support *sui generis* systems that recognize customary law. Many countries have introduced such legislation to protect traditional knowledge and promote traditional medicine.<sup>55</sup> Examples include the Philippines' Traditional and Alternative Medicine Act, passed in 1997, which established the Philippine Institute of Traditional and Alternative Health Care and a Traditional and Alternative Health Care Development Fund.<sup>56</sup> India recognizes customary law as well. The Government of India has decided to protect its TK and folklore by creating a public database that catalogues traditional herbal medicines, plants and yoga practices. The database constitutes a state of *prior art* and is intended to be a deterrent to potential bio-pirates. It is a legally valid form of *sui generis* protection for TK. Information is available in English, French, German, Japanese, and Spanish. However, there are limits to the database approach: In addition to the cost and

accessibility factors for marginalized groups, some communities refuse to provide their TK, or they provide incomplete information because they believe that storing TK in a database separates their TK from traditional systems, which govern access to that knowledge.<sup>57</sup> In addition, there are concerns about how inclusive such databases can be for women's TK, where their knowledge is not well documented or may not well represent women's voices.

In Thailand, traditional knowledge is protected in two laws: The Plant Variety Protection Act (1999) and the Act on the Protection and Promotion of Thai Traditional Medicinal Intelligence.<sup>58</sup> The Acts include access and benefit-sharing arrangements and measures for prior informed consent, and they are being implemented in stages. The Constitution of the Kingdom of Thailand provides for the rights of communities to continue their traditional practices, inclusive of resource management. Extensive negotiations involving communities, non-governmental organizations (NGOs) and other stakeholders have been underway on a Community Forests Act which attempts to balance traditional utilization and custodianship of local environment with broader conservation objectives. This process is seen as an important step towards securing broader community rights. Thailand may be the first country to have conducted a human rights impact assessment of a proposed bilateral trade agreement (the Thai-United States Free Trade Agreement [FTA]).

A study by the Thai Human Rights Commission found that demands made by the United States in bilateral negotiations on IP protection exceed those required by the TRIPS Agreement. The study found

that US pressure on Thailand to remove patent exemptions on life forms under the FTA would be viewed by many Thais as an action that could accelerate biopiracy and further make existing Thai legislation partially or completely redundant.<sup>59</sup>

Under their bilateral trade agreements with the United States, Jordan, Singapore and Viet Nam have been required to become UPOV signatories. One analysis of bilateral free trade agreements identifies a persisting North-South pattern in agreements: When negotiating with the United States, trade negotiators concerned about biopiracy try to put limits on when and how researchers and corporations can get patents on biodiversity or TK in the US. When the US is not involved, they carve out spaces to define their own legal systems of rights to traditional knowledge.

The Bay of Bengal grouping of countries (BIMSTEC) adopted an FTA in 2004 and members are working together to develop systems of legal rights over biodiversity and traditional knowledge. Governments are looking into expanding their IP regimes to cover traditional knowledge. The draft ASEAN Framework Agreement on Access to Biological and Genetic Resources and Fair and Equitable Sharing of Benefits addresses potential problems that may emerge when biological resources are shared across borders (as many countries in Southeast Asia share ecosystems). One of its objectives is "to accord recognition and protection to traditional knowledge of indigenous peoples and local communities, and to facilitate fair and equitable sharing of benefits with the said communities where traditional knowledge is utilized."<sup>60</sup> The members of the South Asian Association for Regional Cooperation

(SAARC) also are working to develop systems of documenting local and indigenous knowledge in order to safeguard intellectual property.<sup>61</sup>

## THE CONVENTION ON BIODIVERSITY

The CBD and TRIPS have overlapping views on private rights versus public rights, on the rights of indigenous communities versus the rights of pharmaceutical corporations, and on the rights of commercial breeders versus the rights of private or small-scale farmers. Biopiracy, and the effectiveness of the international IP regime to effectively address developing countries concerns on biopiracy, are continually discussed at CBD forums, following several high profile challenges to illegal patents. Several medical properties of plants used by traditional healers in South Asia had been patented by companies in developed countries: five properties of neem, two properties of bitter gourd, six of turmeric, and three of jackfruit. The US patent on the use of turmeric was revoked in a high profile challenge led by India's Centre for Scientific and Industrial Research.<sup>62</sup>

Signed at the 1992 Earth Summit, the CBD has three main goals:

- The conservation of biological diversity,
- The sustainable use of all components of biodiversity, and
- The fair and equitable sharing of the benefits from the use of genetic resources.

The CBD affirms that the state has sovereign rights over its biological resources (Article 15), and explicitly calls for equitable sharing of any benefits arising from the use of these resources (Article 8(j)). The Convention does not

address ownership of resources, which is to be determined at the national level in accordance with national legislation or practice. This area of potential conflict arises between indigenous peoples and some non-indigenous governments that have declared that all resources, including TK, belong to the state.

The three key elements of the CBD framework are:<sup>63</sup>

- The need to obtain the prior informed consent (PIC) of the country of origin before obtaining access to resources;
- The need for mutually agreed terms of access with the country of origin (and potentially with the direct providers of genetic resources such as individual holders or local communities); and
- The importance of benefit-sharing; the obligation to share, in a fair and equitable way, benefits arising from the use of genetic resources with the party that provides those resources.<sup>64</sup>

The 2002 Bonn Guidelines on Access and Benefit-Sharing set out voluntary guidelines on how this framework is to be implemented. They include specific supports for indigenous and local interests, including calling on governments to provide support measures to enhance indigenous and local communities' capacity to represent their interests at negotiations on access to genetic resources.<sup>65</sup>

Implementation of CBD commitments occurs through decisions from the Conference of the Parties (COP), the Convention's governing body. The COP has set up ad hoc working groups to carry out work and advise the COP on biosafety, on Article 8(j) and Related Provisions of the CBD, and on Access and Benefit-Sharing. While the CBD is an international treaty, national governments are responsible for its implementation, and COP decisions only constitute guidance to governments on how to implement their CBD commitments. In contrast, WTO commitments are legally binding and disputes may be taken before a WTO dispute settlement mechanism.

The CBD was the first international legal instrument to recognize the importance of traditional knowledge, recognize the usefulness of TK, innovations and practices to their conservation (in contrast, an underlying notion in TRIPS is that TK involves a private right in areas such as micro-organisms and microbiological processes). CBD Article 16.5 states that contracting parties shall cooperate to ensure that IPRs are "supportive of and do not run counter to" the CBD's provisions. Article 22, however, states that the CBD's provisions do not affect the rights and obligations of countries to other "existing international agreements, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity" (Adhikari 2005, pp. 261-264).

Unlike the WTO process, the CBD process provides space for indigenous peoples and other traditional knowledge holders to participate in and influence the CBD process. The 2005 Asian Regional Meeting on the Composite Report on

Traditional Knowledge, for example, involved both governments and indigenous organizations. The report noted the erosion of complementary gender roles and loss of important roles and knowledge systems of indigenous women in agricultural production, labour and seed diversity that participants linked to globalization processes.<sup>66</sup>

## CONCLUSIONS

The study of the TRIPS and CBD approaches to intellectual property and traditional knowledge highlights very different visions of “protecting” TK: a “business” vision and a “sustainability” vision. The “business case” is concerned with promoting innovation and commercialization of TK and emphasizes the need to protect traditional knowledge and secure fair and equitable sharing of benefits to be derived from the use of biodiversity and associated traditional medicine. Many governments interested in helping small-scale producers participate in potentially lucrative regional and international markets for traditional medicines and MAPs recognize the IPR issues for TK.

The gender dimensions of TK are much less well understood. Women’s TK is not well documented, thus strategies and frameworks that rely on formal systems of knowledge may exclude their TK. As women play key roles in TMK, trade development and promotion policies and strategies need to address persisting gender-based barriers that constrain women from gaining income from their TK (for example, barriers to inheritance and ownership of property), and recognize as legitimate stakeholders in policy dialogues. Where decision-making is based on institutional patterns on property rights that discriminate against women, women may not be defined as actors (Padmanabhan 2005).

Inequalities between women and men and their different gender roles with respect to TK have generated different levels of access to medical plants and their

genetic resources in many countries. These differences in turn affect legal and financial possibilities for women to negotiate benefit-sharing agreements. “Recognition of gender roles and responsibilities contributes to a better understanding of women’s roles in knowledge generation, care, harvesting, production and marketing of medicinal plants. This will promote a more equitable distribution of benefits derived from biodiversity and its genetic resources” (Siles *op cit.*). The ILO/Commonwealth Secretariat’s “Gender and TRIPS” checklist offers some questions for policymakers (and donors) to consider that help ensure that gender dimensions are addressed in policy processes:

- What are the mechanisms for recognizing, protecting and rewarding men’s and women’s knowledge, innovation and practices? Are systematic processes established that identify women’s contribution to this body of knowledge?
- Are there accessible mechanisms in place for capacity-building and training for women to understand the IPR system.<sup>67</sup>

Most developing countries have not fully utilized flexibilities available under TRIPS. As the UK Commission noted, underutilization may be because of an informed decision not to do so, or because countries may be constrained by other commitments, such as within bilateral agreements, “... or those in

charge may not have been aware of other options available.” The Commission recommended that developed countries could take a positive step by “review[ing] their policies in regional/bilateral commercial diplomacy with developing countries so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS”.<sup>68</sup>

The “sustainability case” is concerned more with ensuring traditional users’ continued access to traditional medicines. This view is concerned with over-harvesting due to intensified local use or exploitation to meet export demand. A gender perspective highlights women’s and men’s different and often complementary roles and responsibilities in TMK, different access to resources and the knowledge associated with those resources. Some governments recognize customary or tribal laws and systems of governance. A concern here is ensuring that equality obligations are respected in situations where customary law is gender-blind. ILO Convention 169, that clarifies that indigenous rights are superceded by fundamental human rights, provides guidance.<sup>69</sup>

While many governments have begun addressing IP protection for TK in national legislation, international protection is important since national policies have limited effect beyond national borders. With so many international and national agencies involved in IP and TK, there is growing consensus that the most appropriate protection for traditional knowledge will have to be based on a combination of approaches. The analysis of ways forward at WTO and WIPO deliberations on IP and TK suggests that governments are engaging in “forum shopping” to get the

best deal: Many developing countries consider the CBD most sympathetic to their perspective, but the WTO, with its broad membership and dispute settlement mechanism that has “teeth” is recommended in a recent UNCTAD study.<sup>70</sup> Developed countries including the EU and US have argued that WIPO, which has technical expertise on IPRs, should be the main forum for establishing a consensus on a new global IP protection framework for TK. Some observers have questioned WIPO’s ability to reflect the development concerns of developing countries given its tendency to emphasize the benefits of IP protection.<sup>71</sup>

One way forward might be to put a much higher priority on the public health dimensions of TK. The Doha Declaration on WTO members’ rights to promote “public health and ... access to medicines for all” argues for a rights-based approach to IP and TK. The International Covenant on Economic, Social and Cultural Rights of the United Nations offers guidance. General Comment No. 14 (GC 14) of the Covenant defines the right to health as the “right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.” It further states that “the vital medicinal plants, animals and minerals necessary to the full enjoyment of health of indigenous peoples should also be protected.” It also calls for more coordinated efforts to enhance involvement and interaction “among all the actors concerned, including various components of civil society”, along with the various members of the UN system and the WTO.<sup>72</sup>

A rights-based approach would also create more space to mainstream gender concerns in IP policy. This

approach would include space for women, in particular, indigenous women, to participate in and shape decisions at international forums. The CBD process, for example, is noticeably more inclusive of indigenous and tribal peoples than the WTO; however, in most countries, indigenous peoples' and women's organizations need resources, training and capacity-building to participate effectively in international policy forums. Groups participating in international meetings also need the capacity and resources to consult with their own communities. Trade-related capacity-building initiatives could target indigenous groups and women's organizations for "train the trainer" programs that offer culturally relevant information and strategies.



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## Endnotes

<sup>1</sup> See Michalopoulos (2003), p. 9.

<sup>2</sup> The Secretariat of the WIPO defines “traditional knowledge” as “knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or indigenous culture or community which preserves and transmits it between generations;
- linked to a local or indigenous community or other groups of persons identifying with a traditional culture through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive, a relationship that may be expressed formally or informally by customary law;
- knowledge in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and
- identified by the community or other group as being traditional knowledge.” (WIPO-IGC 2003, para. 45).

In addition, the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources and Fair and Equitable Sharing of Benefits defines traditional knowledge more simply as: “knowledge, innovations and practices of indigenous and local communities relating to the use, properties, values and processes of any biological and genetic resource or any part thereof,” (ASEAN Framework Agreement on Access to Biological and Genetic Resources and Fair and Equitable Sharing of Benefits, GRAIN 2000).

<sup>3</sup> According to the WHO (2001), “traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.” The term “traditional medicine” includes several components: a *system of treatment* that normally take a holistic approach; a *source of knowledge* about natural remedies that are effective and based on natural products; *natural products that are an important source for discovering and isolating new modern medicines*, and *traditional medical practitioners* who are an important part of the healthcare system in many developing countries.

<sup>4</sup> “Western medicine” refers to what is also called “conventional medicine”, “clinical medicine”, or allopathic systems of medicine, as distinguished from other medicinal paradigms. The Compact Oxford English Dictionary defines Western medicine as “the treatment of disease by conventional means, i.e. with drugs having effects opposite to the symptoms” See “allopathic medicine” at [http://en.wikipedia.org/wiki/Allopathic\\_medicine](http://en.wikipedia.org/wiki/Allopathic_medicine), accessed December 2006.

<sup>5</sup> See DEBTEC [n.d.].

<sup>6</sup> See discussion in Adhikari (2005), p. 265.

<sup>7</sup> See Dutfield, Graham (2004). “Biopirates,” according to Dutfield, are “(i) those individuals and companies accused of one or both of the following acts: the theft, misappropriation of, or unfair free-riding on, genetic resources and/or traditional knowledge through the patent system; and (ii) the unauthorized and uncompensated collection for commercial ends of genetic resources and/or traditional knowledge.” Biopiracy goes beyond law and includes issues of morality and fairness, and it

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is difficult to draw the line between acts of biopiracy and legitimate practices. He suggests the main challenges are to enhance economic and social welfare through the more effective use of biodiversity at local and national levels, and ensure that TK holders and the societies responsible for generating and maintaining TK get better protection from corporations and governments.

<sup>8</sup> “Bioprospecting” is the collecting and testing of new chemicals in living species that will have some medical or commercial use. It also includes collecting indigenous knowledge to help in discovering and exploiting genetic or biochemical resources. While it is a high risk area for investors, it can have massive returns. Of the world’s 25 top-selling pharmaceuticals, 10 were originally sourced from animals, plants or micro-organisms.

See Australian Museum Online, <http://www.amonline.net.au/factsheets/bioprospecting.htm>; Wikipedia, <http://en.wikipedia.org/wiki/Bioprospecting>

<sup>9</sup> The Convention on International Trade in Endangered Species of Wild Fauna and Flora provides detailed reports on the impacts of trade in medicinal species. See, for example, a 2005 review of trade in seven Asian medicinal species, CITES PC15 Doc. 10.2.2, <http://www.cites.org/eng/com/PC/15/E-PC15-10-02-02.pdf>

<sup>10</sup> For example, Williams (2003); UNCTAD (2004); Randriamaro (2006).

<sup>11</sup> CEDAW is based on the principle of substantive equality between men and women, guaranteeing not just equality of opportunity, but real equality – equality of outcomes.

- CEDAW provides a complete definition of discrimination as any distinction, exclusion, or restriction on the basis of sex, which intentionally or unintentionally nullifies or impairs the recognition, enjoyment and exercise of women’s social, cultural, political and economic rights.
- CEDAW binds all States Parties to fulfill, protect, and respect women’s rights. States Parties must not discriminate against women in any way.
- CEDAW requires that State Parties must ensure that private organizations, enterprises and individuals promote and protect women’s rights.
- CEDAW addresses gender inequalities at all levels and in all spheres- the family, community, market and state. (UNIFEM South and Southeast Asia Regional Office [n.d.]).

<sup>12</sup> See UNEP Secretariat of CBD (1992). Preamble.

<sup>13</sup> FAO (1998).

<sup>14</sup> See UNEP Secretariat of CBD (2005).

<sup>15</sup> See FAO [n.d. (a)].

<sup>16</sup> See Siles [n.d.].

<sup>17</sup> See case studies cited in “Women and Medicinal Plants in South Asia” section of this E-Discussion Paper.

<sup>18</sup> See FAO (1998).

<sup>19</sup> See Global NTFP Partnership [n.d.], [http://ntfp.inbar.int/wiki/index.php/Medicinal\\_plants](http://ntfp.inbar.int/wiki/index.php/Medicinal_plants), citing SEDF 2003.

<sup>20</sup> Visit ANAMURI the National Association of Rural and Indigenous Women, <http://www.anamuri.cl/> (website in Spanish).

<sup>21</sup> See ICIMOD [n.d.].

<sup>22</sup> See DEBTEC [n.d.].

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<sup>23</sup> See Hossain (2005).

<sup>24</sup> Visit <http://www.fao.org/sd/WPdirect/WPre0105.htm>

<sup>25</sup> As referenced in “Tribal Household Economy, Forests, and the Role of Women, in Yadama et al. (1997).

<sup>26</sup> Institute for Integrated Development Studies (2002); Bennett (2004). See also Karki (2003) for analysis on certification and marketing of MAPS in South Asia.

<sup>27</sup> See ICIMOD website, <http://www.icimod.org/home/projects/projects.content.php?prid=8>

<sup>28</sup> Traditional and Alternative Medicines Act, Philippines 1997. Article II, Definition of Terms (i) Intellectual Property Rights, <http://www.grain.org/brl/?docid=573&lawid=1495>, accessed February 2007.

<sup>29</sup> See Castellano, Brant (2003). *Women of the Métis Nation*, 1993. Cited by Dawn Martin Hill, “Traditional Medicine in Contemporary Contexts: Protecting and Respecting Indigenous Knowledge and Medicine.” National Aboriginal Health Organization, 19 March.

<sup>30</sup> As referenced GRAIN (2004).

<sup>31</sup> See Commission on Intellectual Property Rights (CIPR) (2002). “Executive Summary: Integrating Intellectual Property Rights and Development Policy.”

<sup>32</sup> *ibid.* (2002).

<sup>33</sup> Adapted from Zhang, Xiaorui (2000). “The Role of Intellectual Property Rights in the Context of Traditional Medicine,” Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. Bangkok, Thailand, 6-8 December, WHO/EDM/TRM/2001.1

<sup>34</sup> This section draws on Ng’etich, Kibet A. (2005). “Indigenous Knowledge, Alternative Medicine and Intellectual Property Rights Concerns in Kenya,” Council of Social Science Research in Africa (CODESRIA) 11<sup>th</sup> General Assembly, Maputo, Mozambique, 6-10 December.

<sup>35</sup> The terms “complementary” and “alternative” medicine may be used inter-changeably with “traditional medicine” in some countries, and “refer to a broad set of healthcare practices that are not part of that country’s own tradition and are not integrated into the dominant healthcare system.” (WHO 2003).

<sup>36</sup> HS Code 1211: Plants and parts used primarily in pharmacy, perfumery, insecticides, fungicides or similar purpose.

<sup>37</sup> HS Code 54: Man-made filaments.

<sup>38</sup> From United Nations Commodity Trade Statistics Database Statistics Division (COMTRADE)[n.d.]. SITC Rev. 3, Medicinal, Pharmaceutical Products (HS Code 54) <http://comtrade.un.org/>, accessed 13 July, 2006.

<sup>39</sup> See Global NTFP Partnership [n.d.], [http://ntfp.inbar.int/wiki/index.php/Medicinal\\_plants](http://ntfp.inbar.int/wiki/index.php/Medicinal_plants), citing SEDF 2003.

<sup>40</sup> *ibid.* [n.d.].

<sup>41</sup> See Vietnam Investment Review (2006).

<sup>42</sup> Nineteen (19) Ministers instructed the Council for TRIPS to examine the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore and instructed the TRIPS Council to take fully into account the development dimension. See WIPO website, [www.wipo.int/tk/en](http://www.wipo.int/tk/en), for a list of TK-related materials by WIPO.

<sup>43</sup> The objective of the Convention is the protection of new varieties of plants by an intellectual property right, according to the UPOV. See UPOV website, <http://www.upov.int/>, accessed December 2006.

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<sup>44</sup> UNCTAD (2006) has conducted several studies on IP and TK, including a recently released study “Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications,” (See [www.unctad.org/en/docs/ditcted200514\\_en.pdf](http://www.unctad.org/en/docs/ditcted200514_en.pdf)), which were requested by the CBD for input on issues such as model provisions for disclosure requirements, options for incentive measures for applicants, and IP related issues raised by proposed international certificates of origin/source and legal provenance.

<sup>45</sup> See UNHCR (2000), [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument)

<sup>46</sup> Union International pour la Protection des Obtentions Vegetales, French acronym. See also a detailed discussion on UPOV in Drahos (2004) and Twarog (2004).

<sup>47</sup> See UNCTAD. BioTrade Facilitation Programme, [www.biotrade.org](http://www.biotrade.org).

<sup>48</sup> See also Åhrén (2002) for a useful discussion on WIPO’s Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Expressions of Folklore.

<sup>49</sup> The discussion on TRIPS draws from the “Executive Summary” in CIPR (2002).

<sup>50</sup> See South Asia Watch on Trade, Economics and Environment (SAWTEE) (2006). “South Asian Common Position of TRIPS Review: Situation, Options and Positions.” *Trade Insight*, Vol. 2, No. 2, <http://www.sawtee.org/pdf/TI%20Vol2.%20No%202.%202006.pdf>, accessed 2006.

<sup>51</sup> Indications that identify the origins of a product as a mark of quality and provenance (CIPR 2002).

<sup>52</sup> For a discussion of the scope of “TRIPS plus”, see El-Said (2005).

<sup>53</sup> See Correa (2004). The report found that the provision to expand the scope of patent protection to cover all categories of living organisms would be an important US demand. Implementing this would require amendments to the Thai Patent Act and its *sui generis* Plant Varieties Protection Act which was designed to suit Thailand’s socioeconomic conditions.

<sup>54</sup> See Convention on Biological Diversity Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (2004).

<sup>55</sup> For a discussion and examples of legislation, see CBD (2005b).

<sup>56</sup> See Philippines Traditional and Alternative Medicine Act 1997, <http://www.grain.org/brl/?docid=573&lawid=1495>

<sup>57</sup> See Bodeker (2003); United Nations University Institute of Advanced Studies (UNU-IAS) (2003).

<sup>58</sup> Refer to Thailand IPR Service Centre, Department of Intellectual Property website, <http://61.19.225.226/Static/GeneralTK.aspx>

<sup>59</sup> See Robinson (2006); Smith (2007).

<sup>60</sup> See the ASEAN Framework Agreement on Access to Biological and Genetic Resources Draft Text, 24 February 2000, <http://www.grain.org/brl/?docid=785&lawid=1261>, accessed December 2006.

<sup>61</sup> See Cervantes and GRAIN (2006).

<sup>62</sup> There are many accounts of these high profile cases. For a summary, see Adhikari (*op cit*), p. 269.

<sup>63</sup> See Gross, Johnston & Barber (2006).

<sup>64</sup> *ibid.*, p. 18.

<sup>65</sup> *ibid.*, p. 19.

<sup>66</sup> See Convention on Biological Diversity (2005a).

<sup>67</sup> See ILO/Commonwealth Secretariat [n.d.].

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<sup>68</sup> See CIPR (2002), *op cit*, p. 29.

<sup>69</sup> The International Labour Organization Convention 169, Concerning Indigenous and Tribal Peoples in Independent Countries, Article 8(2), provides that “These peoples shall have the right to retain their own customs and institutions, where these are not incompatible with fundamental rights defined by the national legal system and with internationally recognized human rights.” I am grateful to Russell Barsh for pointing this out to me.

<sup>70</sup> See Sarnoff and Correa (2006), commissioned at the request of the CBD.

<sup>71</sup> See Musungu and Dutfield (2003).

<sup>72</sup> From UNHCR (2000). “The Right to the Highest Attainable Standard of Health, (Article 12 of the International Covenant on Economic, Social and Cultural Rights.” Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultral Rights. General Comment No. 14, [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument)

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