

Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine

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Acknowledgements

Over recent years, there has been an increasing interest worldwide in both the health care and economic development aspects of traditional medicine. As traditional knowledge, particularly the knowledge of traditional medicine and medicinal plants, could have an economic and trade value, the need to protect it and to secure fair and equitable sharing of any benefits derived from it, have become of concern to more and more WHO Member States. However, intellectual property rights in the context of traditional medicine is a very complex issue. WHO has been requested to co-operate with the World Intellectual Property Organization (WIPO) and other international organizations to support countries in improving their awareness and capacity to tackle these problems.

The WHO Traditional Medicine team has therefore taken the initiative in proposing this Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. The initial suggestion met with an immediate enthusiastic response from the WHO Regional Office for South-East Asia (SEARO), who were not only willing to organize the meeting but also to provide financial support. Positive responses and active support were also received from the WHO Regional Office for Africa (AFRO), the Regional Office for the Eastern Mediterranean (EMRO), and the Regional Office for the Western Pacific (WPRO).

Our sincere thanks should go, firstly, to the World Intellectual Property Organization (WIPO) and United Nations Conference on Trade and Development (UNCTAD) for their cooperation and support and for providing two speakers: Ms. Maria Perez-Esteve, Economic Affairs Office, Trade, Environment and Development Section, UNCTAD, and Mr. Shakeel Bhatti, of the Global Intellectual Property Issues Division, WIPO, as well to all the other speakers for their valuable contributions to the Workshop.

Secondly, our sincere appreciation should go to the WHO Regional Office for South-East Asia, particularly to the Regional Director, Dr Uton Muchtar Rafei and the Director, Health Technology and Pharmaceuticals, Dr Palitha Abeykoon, as well as to the former Regional Adviser for Traditional Medicine, Dr Kin Shein, for all their assistance in the organization of the Workshop, and in the drafting of this report with Regional Office financial support.

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We must also express our sincere thanks to the Ministry of Public Health, Thailand, for their hospitality and courtesy in ensuring the smooth running of the Workshop. Thanks are especially due to Dr Pennapa Subcharoen, Director, National Institute of Thai Traditional Medicine, Department of Medical Services, and Mrs Iamtip Boonchalermkit, Foreign Relation Officer, Department of Medical Services, without

their, and their colleagues', efforts, the Workshop could not have been arranged, particularly within the very short frame allowed.

Thanks are also due to Professor, Mr Tan Kiok K'ng, WHO Short Term Consultant, for drafting the report and to my colleague, Mr Peter Thorpe, for his editing work.

Limitations of space, unfortunately, preclude the naming of all those who have helped in the Workshop.

This Workshop is only a beginning. Follow-up activities, based on the Workshop recommendations and suggestions from Member States, will continue to be carried out by the Traditional Medicine team in cooperation with WIPO, UNCTAD and the WHO Regional Offices.

Dr Xiaorui Zhang
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1. Introduction

1.1. Opening Session of the Workshop

The Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine was held in Bangkok from 6 to 8 December 2000. This meeting was part of the following-up to the implementation of WHO's revised drug strategy concerned with the monitoring and analysis of the effects of globalization on access to drugs. As the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) is currently revising Article 27.3 (b) of the TRIPS Agreement, which deals with the patentability of traditional knowledge, it is expected that the conclusions and recommendations of the meeting will contribute to this review. Forty-eight participants from 23 countries attended the meeting. In his message to the workshop, read by the WR of Thailand, Dr E.B. Doberstyn, the Regional Director, WHO SEAR, Dr Uton Muchtar Rafei said that traditional medicine is an important part of human health care. The practice of traditional medicine is based on the theory, belief and experiences indigenous to different cultures. Recently, traditional medicine has increasingly gained in importance. At the meeting of ministers of health held in September 1998 in New Delhi, the ministers strongly emphasized that these resources should be used more efficiently in the delivery of primary health care. WHO also encourages and promotes the appropriate use of traditional medicines in member states' national health care systems.

Currently there is an increasing awareness of the value of traditional knowledge and biodiversity resources as economic and tradable commodities. This, coupled with the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) on pharmaceuticals, including traditional medicine, necessitates this meeting of minds to address the complex issue of intellectual property rights so as to achieve better understanding and wider consensus on these issues.

At the Earth Summit for the adaptation of the Convention on Biological Diversity held in Rio de Janeiro in 1992, members accepted the principles that bio-resources are the sole property of sovereign states and that they have the freedom to use them as tradable commodities. However, most developing countries have not so far enacted legislation to implement the resolutions passed at the Convention. The need to protect traditional knowledge and to secure fair and equitable sharing of the benefits derived from the use of biodiversity and associated traditional medicine knowledge has been fully recognized. The Director concluded by expressing the hope that the deliberations of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine would improve the knowledge and capability to tackle problems of intellectual property rights relating to traditional medicine. The full text of the address is at Annex I.

Dr Mongkol Na Songkhla, Permanent Secretary of the Ministry of Public Health, Thailand, in his welcome address read by Dr Winai Sawasdivivoon, Deputy Director General, Department of Medical Services, Thailand, said that it was timely for the workshop to address the important issue of intellectual property rights in the context of traditional medicine. The rich resources of traditional medicine

knowledge and biodiversity in developing countries need to be protected and we need to ensure that there is an equitable sharing of the benefits resulting from their exploitation. He thanked WHO for providing technical and financial supports for the workshop. The text of his address is at Annex II.

Ms Maria Perez-Esteve, Economic Affairs Office, Trade, Environment and Development Section, delivered UNCTAD's opening statement to the workshop. She said that traditional medicine plays an important role in health care in both developed and developing countries in the 21st century. Up to 80% of the world's population depends on traditional medicine for its primary health care needs. Furthermore, traditional medicine is indispensable for those in the poorest segments of societies, including women, indigenous peoples and rural inhabitants in developing countries. In describing work of special relevance to this group, she said that UNCTAD's Member States had decided to address the protection of traditional knowledge as part of their activities in the area of trade and environment. The Plan of Action adopted by UNCTAD's tenth Conference stated that: "UNCTAD should also, in full cooperation with other relevant organizations, in particular and where appropriate the World Intellectual Property Organization and the World Health Organization, promote analysis and consensus building with a view to identifying issues that could yield potential benefits to developing countries". It specifies that this work should *inter alia* focus on: "Taking into account the objectives and provisions of the Convention on Biological Diversity and the TRIPS Agreement, studying ways to protect traditional knowledge, innovation and practices of local and indigenous communities and enhance cooperation on research and development on technologies associated with the sustainable use of biological resources" (paragraph 147 of the Plan of Action, third bullet).

In accordance with its mandate, UNCTAD held an Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, in close cooperation with the secretariats of other intergovernmental organizations, in particular the Convention on Biological Diversity and the World Intellectual Property Organization. The Expert Meeting was held in Geneva from 30 October to 1 November 2000.

The Expert Meeting was the first in UNCTAD's history to involve indigenous groups in the organization's intergovernmental work on such a large scale. Over 250 delegates from nearly 80 countries, representing Governments, non-governmental organizations, UN specialized agencies, academia and the private sector, attended the meeting.

Throughout the Expert Meeting individual experts put forward views and policy options for Governments to consider in protecting traditional knowledge, innovations and practices. A diversity of views was expressed and a summary of the experts' conclusions and recommendations will be submitted to UNCTAD's Commission on Trade in Goods and Services, and Commodities next February.

As an organization mandated to promote trade and development, UNCTAD is very understanding of the role of traditional knowledge, and in particular of traditional medicine, in the development process. This may be the case in particular in the poorest countries and we have to give this serious consideration, for example, in the context of the preparations for the third United Nations Conference for the Least Developed Countries to be held next year in Brussels.

Mr. Shakeel Bhatti, Program Officer, Global Intellectual Property Issues Division, gave an opening statement on behalf of WIPO. He explained that WIPO is a specialized United Nations agency responsible for the protection of intellectual property and its promotion throughout the world. In accordance with the Convention Establishing the World Intellectual Property Organization, (WIPO), (1967), intellectual property may be understood as a comprehensive and dynamic concept, which is open-ended and is constantly evolving (Article 2(viii)). In recent times, this dynamic nature applies also to intellectual property in relation to traditional knowledge. In 1998, Member States requested WIPO to initiate a work programme on intellectual property and traditional knowledge. Over the past four years, the work programme has produced substantial results, including some in the area of traditional medicine.

There are two areas of WIPO's work that are especially relevant to this workshop. Firstly, within WIPO's work on traditional knowledge, traditional medicine is probably the foremost area driving the intellectual property agenda in the field of traditional knowledge. This is especially true for Asian countries where the great systems of traditional Chinese medicine and Ayurvedic medicine are found. Secondly, throughout WIPO's work in the area of traditional medicine, there is a need for bridge-building between national authorities, experts and practitioners in the field of intellectual property on the one hand and traditional medicine on the other. In order to have a truly effective approach to the protection of traditional medicine knowledge and plants, it is necessary to consider the existing situation and practices in both fields.

WIPO strongly believes that representatives of intellectual property offices, ministries of health and traditional medicine research centres need to exchange their experiences and identify common ways forward.

1.2. Objectives of the Workshop

The developmental objectives of the workshop were:

- ◆ To further promote development of traditional medicine taking into consideration intellectual property rights and their implications.

The specific objectives were:

- ◆ To identify those areas of traditional medicine where intellectual property rights protection is of major concern;
- ◆ To identify gaps between those areas of traditional medicine (identified in the above specified objective) and existing modern intellectual property law;
- ◆ To share information on national patent law and policies on intellectual property rights relating to traditional medicine; and
- ◆ To discuss strategies that could be used for protecting traditional medicine knowledge, resources and biodiversity in order to contribute to a fair and equitable sharing of benefits.

Dr S. K. Sharma, Adviser (Ayurveda), Department of ISH&H, Ministry of Health and Family Welfare, Government of India, was nominated as Chairperson and Atty. Elpidio Peria, Philippine Institute of Traditional and Alternative Healthcare,

Philippines, was designated as rapporteur. The agenda for the workshop and the participants' list and secretariat are attached as Annexes III and IV.

2. The role of intellectual property rights in the context of traditional medicine

Dr Xiaorui Zhang, Acting Coordinator, Traditional Medicine, WHO Geneva, made a presentation on this topic.

2.1. Importance of traditional medicine

Dr Zhang highlighted the important role traditional medicine plays in developing countries. She explained that even in developed countries a significant percentage of people have used traditional medicine at least once, for example 50% in the USA, 75% in France and 90% in the United Kingdom. The level of expenditure on traditional medicine is also rising. A 1985 survey in Indonesia found the use of traditional medicine to be twice as great among households in the lowest income group compared to the highest income quartile. In Malaysia, it is estimated that about US\$500 million is spent annually on traditional medicine, compared to about US\$300 million on conventional medicine. In the US, the total out-of-pocket expenditure for complementary and alternative medicine was estimated at US\$27 billion. In Australia, an estimated A\$800 million is spent annually on complementary and alternative medicine and in the United Kingdom, annual expenditure on complementary and alternative medicine has reached £500 million. The world market for herbal medicines, including herbal products and raw materials, has been estimated to reached US\$43 billion with an annual growth rate of between 5 and 15%.

2.2. Intellectual property rights for traditional knowledge

Many activities and products based on traditional knowledge are important sources of income. Traditional technologies and innovations, which are by their very nature adapted to local needs, can provide a viable and environmentally and sustainable path to economic development. Access to genetic resources and the associated traditional knowledge can provide substantial benefits to companies and scientific research centres in both developed and developing countries. However, there is concern that traditional knowledge is sometimes appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent. Developing countries should rally their concern for a fair and equitable sharing of benefits.

At present, there is also no agreement on what would be the most appropriate and effective way to achieve the goal of a fair and equitable sharing of the benefits derived from technologies and innovations based on traditional knowledge by both developing and developed countries.

2.3. Innovations based on traditional medicine knowledge

Depending on the therapies used, traditional medicine can be broadly categorized as medication or non-medication. The former involves the use of herbal medicines, animal parts and minerals, while the latter involves various therapies, primarily

without the use of medication. These include acupuncture and related techniques, chiropractic, osteopathy, manual therapies, qigong, tai ji, yoga, naturopathy, thermal therapy, and other physical, mental, spiritual and mind-body therapies.

She said that there are many possibilities for innovation using traditional medicines and therapies. She cited the examples of *Artemisia annua*, for the management of malaria, and the use of ginkgo leaves in European products instead of the fruits, which are traditionally used in China. Innovations could also involve new dosage forms or new indications for traditionally used medication.

2.4. Individuals and institutions involved in discovery and innovation based on the knowledge of traditional medicine

Dr Zhang identified the following individuals and institutions:

- ◆ Traditional practitioners and local communities;
- ◆ Research institutions and professionals; and
- ◆ Traditional medicines sellers and pharmaceutical companies.

2.5. Challenges to close the gap between existing patent laws and the need to protect traditional knowledge and biodiversity

At present, the requirements for protection provided under international standards for patent law and by most national patent laws are inadequate to protect traditional knowledge and biodiversity. For example, traditional skills in manual and spiritual therapies are different from those in modern practice and there is no record of who was the inventor. Similarly, other traditional non-medication therapies are very difficult to protect using current standards of patent protection.

Existing conventional patent law can and does protect pharmaceutical products. However, herbal medicines and herbal products are different from chemical drugs. The intellectual property standards established by the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994) allows innovation to be protected by the discovery of new chemical components, know-how in producing the product, trademarks and trade secrets. However, for herbal medicines it is difficult to meet all the requirements of patentability due to their intrinsic characteristics.

Firstly, herbal medicines are crude plant materials, such as leaves, flowers, fruits, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered. As such, it is often not possible to obtain existing patent law protection for herbal medicines by claiming the discovery of new chemical entities, which are novel, involve an inventive step and are industrially applicable.

Secondly, herbal products are powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials prepared by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials. The production process is usually simple. There is no know-how or invention in the preparation process that is sophisticated enough to justify protection under existing patent laws.

Thirdly, except for pharmaceutical companies and industries, other holders of traditional knowledge, such as research institutes and practitioners, often do not

have the financial and human resources that are necessary to obtain protection through trademarks.

Fourthly, it is extremely difficult, if not impossible, to keep knowledge a secret, because disclosure of the composition of the product is a prerequisite for registration of herbal medicines before the product can be sold.

Fifthly, it is very expensive to acquire, exercise and enforce patent rights in most countries, particularly if international coverage is required. The cost is prohibitive for traditional practitioners and research institutions, particularly in the poorer countries.

2.6 Briefing for the Workshop

In her briefing, Dr Zhang stated the objectives of the workshop and suggested the procedures for conducting the workshop.

Objectives

The objectives of the workshop are as follows:

- ◆ To determine in which areas of traditional medicine the protection of intellectual property rights is of major concern.
- ◆ To identify gaps between those traditional medicine areas and existing modern patent law.
- ◆ To share information on national patent law, policies and mechanisms for adequate protection of traditional medicine knowledge in order to contribute to a fair and equitable sharing of the benefits.
- ◆ To share and review strategies, systems and approaches that could be used for protecting traditional medicine.

Dr Zhang added that the solutions and methods for the protection of knowledge of traditional medicine would be the focus of the workshop's discussion. She hoped that through these discussions, governments, researchers and traditional knowledge providers can be made aware that their knowledge has great economic potential and that they have sovereign rights to the knowledge, as well as to urge governments to develop and refine regulations and patent law to protect this important commodity.

Procedures

Dr Zhang suggested that after the presentation of papers by the experts in the plenary session, participants should break into two groups, discuss the presentations and make recommendations. The papers and the reports of group discussions as well as the recommendations would form the basis of the workshop report.

3. Globalization, the TRIPS Agreement and access to essential drugs

Dr Germán Velásquez, Coordinator of the Drug Action Programme, WHO Geneva, presented a paper on this topic.

The Uruguay Round led to the creation of the World Trade Organization (WTO), which became operational in January 1995. The WTO is the international organization dealing with rules of trade between nations. WTO administers global trade agreements that were negotiated and approved during the Uruguay Round, and are binding on all Members.

Among these agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) links intellectual property and trade issues for the first time and relates it to a multilateral mechanism for settling disputes between WTO Members on intellectual property. This agreement is the most comprehensive international agreement ever reached on intellectual property. It establishes minimum universal standards for almost all rights in this field (such as copyrights, patents and trademarks), including patent protection for pharmaceutical products, which may have a significant impact on access to drugs in developing countries.

Under the TRIPS Agreement, all WTO Members (139 in November 2000) have to make patent protection available for at least 20 years for any invention of pharmaceutical products or process which fulfils the criteria of novelty, inventiveness and usefulness.

Prior to the TRIPS Agreement, many countries did not make patent protection available for pharmaceuticals, in order to permit the manufacture of copies and generic equivalents of drugs at reduced prices.

Some characteristics of the TRIPS Agreement:

- ◆ Minimum standards for intellectual property.
- ◆ Obligatory for all members of WTO.
- ◆ New: patents for products and processes.
- ◆ Patents for a minimum period of 20 years.
- ◆ A certain amount of freedom for Members.
- ◆ The terms “invention” and “discovery” are not defined in the Agreement.

The TRIPS Agreement obliges Members to treat inventions in the pharmaceutical field like inventions in any other field of technology. But essential drugs are NOT simple commodities and access to essential drugs is a human right. Patent protection has been an incentive for research and development for new drugs although it does not follow that these have been affordable to all people. Patents should be managed in an impartial way protecting the interest of the patent holder as well as safeguarding public health principles. The patent system in the private sector should not be seen as the only source of finance for pharmaceutical research.

WHO also encourages other sources, such as the public sector, to finance research and development in pharmaceuticals.

Each country's strategy towards globalization in the field of the production and distribution of drugs should be incorporated into a national pharmaceutical policy within the national health policy. In this context WHO supports measures which will improve access to all essential drugs, including mechanisms to promote competition, such as: price information, generics policies, reduced duties, taxes, mark ups, equity pricing of newer essential drugs and the application of WTO/TRIPS safeguards, as needed. These safeguards include compulsory licensing, exceptions which can promote generic competition (e.g. Bolar provision) and extension of the transitional period.

WHO recognizes that the TRIPS Agreement does not prohibit parallel imports. "TRIPS-plus" is a non-technical term which refers to efforts to: extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics.

Since the public health impact of the basic TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements. . Finally, WHO also recognizes that over 50 of its Members States are either not WTO members or have an observer status at WTO. These Members States are not constrained by any requirement of TRIPS. Countries acceding to the WTO are encouraged to integrate public health concerns into their national patent legislation.

4. Intellectual property rights

Mr Shakeel Bhatti, Program Officer, Global Intellectual Property Issues Division, WIPO, presented a paper entitled *Intellectual property rights in the context of traditional medicine*.

Mr Bhatti's presentation covered four areas. Firstly, he addressed some terminological issues surrounding traditional medicine, which arise in the intellectual property context. Secondly, he described WIPO's work since 1998 on intellectual property and traditional knowledge, including a WIPO Asian Regional Seminar on Intellectual Property Issues in the Field of Traditional Medicine (New Delhi, October 1998); two WIPO-UNEP case studies on the role of intellectual property rights in the sharing of benefits arising from the use of medicinal plants and associated traditional medicine knowledge; WIPO fact-finding missions on intellectual property and traditional knowledge (1998-99); and two WIPO Roundtables on Intellectual Property and Traditional Knowledge. The third area that Mr. Bhatti covered was a summary of the intellectual property needs of traditional healers, which were identified during these activities by a wide range of stakeholders. These needs included, *inter alia*, the prevention of the acquisition of intellectual property rights over traditional medicine by its documenting and publication as searchable prior art; a reassessment of what constitutes prior art for purposes of patent examinations; the testing of options for the collective management of intellectual property rights by traditional healers' associations; a study of customary laws which protect traditional medicine in local and traditional communities; testing the applicability of the present intellectual property system for the protection of traditional medicine; facilitating access to the intellectual property system for traditional medicine practitioners; legal and technical assistance with the documentation of traditional medicine; and awareness-raising as to the role of intellectual property protection in relation to traditional medicine. Fourthly, Mr. Bhatti elaborated on two WIPO activities which seek to address these existing needs, namely the creation of a WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, as well as a WIPO pilot project to test the feasibility of electronic exchange of traditional knowledge documentation in order to prevent the granting of patents on such traditional knowledge, in cases where the knowledge is already in the public domain. Finally, the presentation included a demonstration of an online prototype of Traditional Knowledge Digital Libraries (TKDL), which included information on about 50 medicinal plants and associated traditional knowledge. The presentation of the WIPO representative concluded by indicating that certain existing intellectual property rights may provide a degree of protection to traditional medicine practitioners and exemplified this possibility through experiments which some grassroots organizations had undertaken to collectively file patent applications and acquire other intellectual property rights on behalf of traditional medicine practitioners.

5. Systems and national experience for protecting traditional knowledge, innovations and practices

Ms Maria Perez-Esteve of UNCTAD, Geneva, presented a paper on this subject.

The importance of protecting the knowledge, innovations and practices of indigenous and local communities (traditional knowledge, TK) is increasingly recognized in international forums. Developing countries seek to ensure that the benefits of cumulative innovation associated with TK accrue to its holders while enhancing their socioeconomic development. They also aim at preventing the improper appropriation of TK, with little or no compensation to the custodians of TK and without their prior informed consent.

UNCTAD's presentation highlighted possible instruments for the protection of traditional medicine knowledge, including traditional/customary law, modern intellectual property rights instruments, *sui generis* systems, documentation of TK and instruments directly linked to benefit-sharing. In addition to national systems, the protection of TK and equitable sharing of the benefits derived from the use of biodiversity resources and associated TK may also require measures by user countries or cooperation at the multilateral level.

Ms Perez-Esteve emphasized the fact that protection of TK is a necessary, but not sufficient, requirement for its preservation and further development. To harness TK for development and trade, developing countries need assistance in building national capacity in terms of raising awareness of the importance and potential of TK for development and trade; developing institutional and consultative mechanisms on TK protection and TK-based innovation; and facilitating the identification and marketing of TK-based products and services. There is also a need to promote an exchange of experience among developing countries on national strategies for TK development, *sui generis* systems for the protection of TK and the commercialization of TK-based products and services.

At the end of the presentation, the UNCTAD representative reported on the outcome of the Expert Meeting including the recommendations at the (i) national level; (ii) multilateral level, and (iii) recommendations to UNCTAD.

6. Problems and gaps in traditional medicine in relation to modern patent laws

6.1. Philippines

Atty. Elpidio V. Peria of the Philippine Institute of Traditional and Alternative Health Care presented a paper on the community protocol as an instrument for protecting the rights of communities in access and benefit-sharing agreements.

The entry into force of the Convention on Biological Diversity in December 1993 ushered in a new era in the utilization of biological and genetic resources all over the world. While before, they were seen as the “common heritage of mankind”, they are now subject to the national sovereignty of the country where they may be found, and these countries can now come up with national legislation to determine how these resources may be conserved and sustainably used.

The same Convention also gave support to the internationally recognized link between indigenous communities and their biological and genetic resources, though it appears that there must be some form of legal mechanism that will promote the use of the knowledge, innovations and practices, aside from ensuring fair and equitable sharing of benefits to the originating communities whenever they are used.

As the dominance of the existing intellectual property rights system looms, due to the accession of most countries of the world to the TRIPS Agreement, there has to be a way to ensure that the knowledge, innovations and practices of communities all over the world will continue to be preserved and protected. The broad problems of the intellectual property rights system and its appropriateness for protecting knowledge systems in traditional medicine are best tackled in a more comprehensive manner than can be dealt with here. However, one particular area where some practical solutions might be derived to these contemporary problems, is to tackle the matter of access and benefit-sharing agreements and see how communities stack up with regard to this contract and to the benefits that they may derive.

The Community Protocol, a series of steps undertaken collectively by a community to achieve a desired result, based on the community’s own rituals, customs, practices and customary laws, is currently undergoing exploratory development in Sabah, Malaysia, and in the Philippines. This is one mechanism that has been proposed that may help address the problems of communities *vis-à-vis* these access and benefit-sharing agreements.

Even if this Protocol need not depend on any specific legislation from the country where the communities are located, it may help, as in the case of the Philippines due to its relatively progressive social legislation, that some legal authority boosts its actual implementation on the ground. The impending ASEAN Framework Agreement on Access to Genetic Resources can help with this aspect and may also serve as a guide to help other ASEAN countries come up with access regulations

that meet certain standards that enhance the grouping's competitiveness *vis-à-vis* other similar regions possessing the same biological and genetic resources. This is also helped by a similar decision by the Conference of the Parties to the Convention on Biological Diversity held in Nairobi in May.

6.2. Thailand

Indigenous knowledge and intellectual property: Thai study

Dr Pennapa Subcharoen, Director of the Institute of Thai Traditional Medicine, Department of Medical Services, Ministry of Health, Thailand, presented this paper.

Problems

Thailand has records of the use of medicinal plants dating back to prehistoric times. Fossils of seeds from 27 genera and 17 families have been found at some sites. Many of these plants are still in use, e.g. *Mormordica charantia*, *Terminalia* spp., beans, etc. Thailand has exported herbs since the Dhavaravadhi period. The famous Royal Pharmacopoeia, the "Tumra Osoth Pra Narai", consisted of the collective traditional medicine from the North, the Northeast, the Central and the Southern parts of Siam. More than 5,000 medicinal plants were recorded in the Palm-leaf Pharmacopoeia, and the figure exceeds 10,000 if food plants are included. Other practices were also recorded, e.g. traditional massage and spiritual healing. Thai traditional medicine (TTM) was the sole health care system for Siam until Western medicine was brought into the country in the Ratanakosin period. Western medicine has gained in popularity because of the availability of antibiotics, vaccines, operations, convenient dosage forms and the influence of international trade. Since the introduction of western medicine, Thai traditional medicine has been discredited, as have traditional healers. Recently, however, Thai traditional medicine has regained its popularity due to some failures in modern treatment and the toxicity of chemicals.

The tropical forests of Thailand have been exploited for their wood and also for their herbs. Hundreds of herbs have been collected and exported by collectors at low prices, e.g. 7 bahts/kg, or traditional healers were hired at the rate of 200–500 bahts/day. Generosity is a part of the Thai culture and wisdom is often given away for free, not knowing that there is a system designed to internalize the externalities. An example is the book *Traditional herbal medicine in northern Thailand* written following an interview with a traditional healer, which declares on the front page that there is nothing to be given back in return for his knowledge. "Our relationship with the herbalists was a personal one based on mutual interest. We did not enter into any formal teacher–pupil relationship with any of them, nor did we make any promises or formal arrangements regarding economic compensation for the information they provided." It is obvious that the authors intentionally quoted this statement to avoid sharing any benefits arising from this work. The latest biopiracy centres on a marine fungus taken by Portsmouth University in England, while working under a gentleman's agreement with the Thai government. In this case, Thailand has no chance of sharing the ownership of the biological material taken from her. These events demonstrate that Thailand lacks several instruments for the protection of the country's assets. The first instrument is the biological specialist, which explains Thailand's dependency on the developed countries. The second instrument is a national policy for the minimal standards of equitable sharing of benefits and codes of conduct. The third instrument is the responsible institution to manage these transactions and compensation for the local people. Thailand has foreseen that several international laws and agreements concerning intellectual

property rights might hinder the development of local business or the health care system based on TTM. Moreover, Thailand has not prepared the system to cope with biological prospecting and the minimal standards of agreement have not been set. This is the reason why Thailand has not yet ratified the CBD.

Dr Pennapa also reported on Thailand's efforts to protect traditional knowledge, the Protection and Promotion of Thai Traditional Medicines Intelligence Act 1999 and the Plant Protection Act 1999.

Thailand's efforts to protect traditional knowledge

At present, Thailand has more than 30,000 licensed traditional healers and about 100,000 unlicensed practitioners. These people are the first group in the inventors' chain of drug discovery. Before the Dhavaravadhi Period, it was recorded that Queen Jama Dhevi gathered together 500 local traditional healers to join her on her journey to Haripunchai City (now Lumpoon Province) where she ruled. The Traditional Pharmacopoeia was originally engraved on stone (pre-Sukhothai Period), then on palm leaf (Sukhothai Period) and then on the tooth brush tree (Ayuthya Period).

The conventional patent system was designed to protect the interests of the inventor in promoting new inventions and to provide an incentive for the owner to bring inventions to the public and business. This concept could be applied justly to the first group of the inventors' chain instead of taking for granted that traditional knowledge is a common heritage, and that industry can simply make use of it without providing any compensation. It is increasingly admitted that equity in the sharing of benefits will not happen unless traditional knowledge is accepted nationally and internationally as another form of intellectual property. However, the present system cannot be applied to traditional knowledge. An example of how this has been attempted is the Thai patent on Kwao Kruae.

Invention: All traditional preparations containing Kwao Kruae, or plants and animal product mixtures.

Comment: Kwao Kruae has been used in Thai traditional medicine for many years. Traditional healers have been preparing products for household use and for sale in the community for more than 100 years. Today, there are more than 35 companies producing more than 50 formulae containing Kwao Kruae. The granting of a patent for Kwao Kruae, has, therefore, closed down companies that have been trading for years by turning their activities into an illegal business.

Questions: Are these patents possible? Is it fair to traditional healers and local business? How could traditional healers share the benefits when there was no information on the source of the traditional knowledge? Will patent of use claims in terms of crude drugs and traditional drugs provide free access by multinational companies? What benefits would any developing country gain from this type of patent?

The Protection and Promotion of Thai Traditional Medicine Intelligence Act 1999

From these events, it is clear that the present system of intellectual protection is not suitable for traditional knowledge, and we should not encourage traditional knowledge to be patented under this system. The 1999 Act was designed to protect and promote local wisdom in the following areas:

Traditional formulations

- ◆ National Formulae are formulations given to the nation which are crucial for human health; anyone wanting to use and develop these formulae must obtain a license.
- ◆ Individual Formulae are private formulations, the owner can use freely and develop these formulae, anyone else must obtain permission from the owner and a license.
- ◆ General Formulae are free to use by anyone.

The advantage of this law is that all three types are free, if used domestically by traditional healers or by the Thai community in limited quantities. This is impossible under the western patent system.

Medicinal herbs

For the sake of conservation and the sustainable utilization of medicinal plants, plants rated as being at high risk of extinction will be announced in the Near Extinction List: permission would then need to be obtained for any management activities involving these plants. Plants would be withdrawn from the list when appropriate measures have been taken to correct the risk. The areas where these plants are growing, if not covered by other laws or if not in private hands, can be licensed so as to receive technical assistance and development from the Institute.

Thai Traditional Knowledge Development Fund

The funds received for these transactions will be allocated to various activities, e.g. conservation, research and development, intellectual property rights, NGOs, land development, etc. The definition of Thai herbs in this Act also covers microorganisms, parts of plants and animals, and minerals. The methodologies used in the preparation of traditional medicines for human and animal use are also protected by this Act. The organization responsible, the Institute of Thai Traditional Medicine, was also established by this Act after functioning informally for 7 years. A committee composed of equal numbers of NGOs and governmental officials governs the institute. Authority for registration and other activities are distributed to 75 provincial offices throughout Thailand. This is a good example of bureaucratic reform.

The Plant Protection Act 1999

As a member of the WTO, Thailand has to promulgate the Plant Protection Act to comply with the WTO and TRIPS Agreements. The Act was based on the UPOV Convention 1978, FAO and CBD. It protects both new breeds of plants and local plants. Local plants may also be categorized as Specific, General or Wild Plants. Compensation to a legal person was also provided for in the Act.

7. Group discussion on existing problems and gaps for the protection of traditional medicine knowledge

The Participants were divided into two groups to discuss the existing problems and gaps in traditional medicine *vis-à-vis* modern patent law. The problem areas and gaps identified by the two groups were further deliberated in plenary session. The problem areas and gaps identified are summarized below:

- ◆ Lack of a national policy to develop traditional medicine and lack of organizational infrastructure to utilize traditional medicine in the national health care system
- ◆ Lack of any system for traditional medicine protection and equitable sharing of benefits
- ◆ The importance and prioritization of traditional medicine has not been fully recognized and explicitly mentioned by various international health organizations
- ◆ Absence of formal or informal mechanisms for the participation of traditional healers in policy making and intellectual property development
- ◆ Lack of mechanism or strategy for equitable benefit sharing among all stakeholders
- ◆ Lack of policy and regulations for the protection of biodiversity and traditional medicine knowledge
- ◆ Lack of understanding of intellectual property rights system among stakeholders
- ◆ Lack of mechanism for developing linkages between traditional medicine of different countries
- ◆ Lack of appreciation of the potential of traditional medicine to solve the health problems of developing countries
- ◆ Lack of understanding, awareness, communication and respect between traditional medicine and intellectual property rights offices
- ◆ Differences between the concepts and fundamentals of traditional medicine and modern medicine
- ◆ Limited applicability of existing intellectual property rights laws to protect traditional medicine knowledge from biopiracy
- ◆ Inability to meet the cost of requiring, exercising and enforcing intellectual property rights for the holders of traditional medicine knowledge

The two groups also made suggestions and recommendations to address the problems and gaps in relation to patent protection in the context of traditional medicine and traditional medicine knowledge. The recommendations were further

discussed in plenary session and the final outcome is reported under the Workshop recommendations in Section 9.

8. Presentations on national patent law: means, experiences and proposals

Seven countries, China, Colombia, India, Indonesia, Kenya, Pakistan and the Republic of Korea, presented papers on their national patent laws, the existing national situation concerning problems, needs, gaps and means in relation to the protection of intellectual property rights in the context of traditional medicine and traditional knowledge. One WHO Collaborating Centre presented a paper on its policy of benefits sharing in research on drugs derived from natural products.

8.1. China

China's national patent law: means and experiences

Dr Zheng Yongfeng of the Patent Office of China presented this paper.

China promulgated its patent law in 1985. Since then, it has been amended twice, most recently in August 2000. The latest amendments will come into effect from 1 July 2001. There have been more than 10,000 patent applications in the past, the majority from within the country. However from 1992 onwards, about 1400 applications were received each year. With a view to joining WTO, China is providing more effective means to protect inventors in traditional medicine, consistent with the provisions of the TRIPS Agreement.

The objects of protection in traditional medicine

Chinese patent law usually protects products, methods and usage. However, for traditional medicine, products and usage were not protected, except that the method of preparation could be patented before 1 January 1993. After the first amendment, products, methods and usage can now be patented.

Pharmaceutical products

The pharmaceutical products which can be patented in the field of traditional medicine include traditional medical compositions, herbal preparations, extracts from herbal medicines or compositions, treated herbal materials and health foods with herbal medicines, etc.

Methods

The methods that can be patented in the field of traditional medicine include methods for the preparing the pharmaceutical preparations, methods for extracting special substances from natural medical materials and methods for treating natural medicine materials.

Usage

If a known drug is found to have any new indication, Chinese patent law protects the new indication.

The method used in drafting claims and descriptions for patent applications is critical to the success of the application. For example, if an application is described as a method of treating diseases, it will be rejected. On the other hand, if it is claimed as a method used in the preparation of drugs for the treatment of specific diseases (which is the new indication of a known drug), the application can be granted a patent.

Requirements for the granting of a patent in traditional medicine

Under Chinese patent law, invention-creation can be patented as three types i.e. inventions, utility models and designs. Inventions and utility models should possess novelty, inventiveness and practical application. In the context of traditional medicine, novelty means that before the date of filing no identical invention or utility model had been publicly disclosed in China or abroad, or had been publicly used or made known to the public by any other means in China, nor had any other person filed previously with the Patent Office an application which described the identical invention or utility model and was published after the said date of filing. Three types of inventiveness are recognized, namely inventiveness of pharmaceutical products, inventiveness of method and inventiveness of new use.

Inventiveness of pharmaceutical products means that the product composition is newly created and a new active ingredient (herbal medicine) is added, or a medicine is prepared by varying its existing composition resulting in it having new indications, or being more effective, or having fewer side effects than existing products. Such a preparation is considered to possess inventiveness and can be patented.

Inventiveness of method means a method of production that shows advantages, such as increased output or lower cost or increased purity of the extract separated from the raw material or decreased side effects of the product.

Inventiveness of new uses means any new indication for the known medicine for which data are provided to validate the claim.

In addition to the above requirements, applicants must provide a detailed description of the technology relating to the invention and disclose them clearly and completely so that a person skilled in traditional medicine can carry out the production.

Experience in the protection of traditional medicine

Over the past 15 years, China has promulgated the National Patent Law and amended it twice so as to be more consistent with the TRIPS Agreement. She has joined the Patent Cooperation Treaty (PCT) and her patent office has become an International Reception Bureau as well as an International Search and Primary Examining Bureau of the World Intellectual Property Office for PCT applications. In March 1999, China became a member state of the Union for the Protection of New Varieties of Plants (UPOV). A month later, China promulgated the *Regulations of the People's Republic of China on the Protection of New Varieties of Plants* by which a new herbal medicine could be protected if it was first found to have curative effects.

The existing problems associated with the protection of intellectual property rights in traditional medicines in China can be summarized as follows:

- ◆ Patent rights are granted for a period of 20 years, but the time taken for research and development of the invention takes 2-5 years. This period of time is not deducted from the validity period of the patent, resulting in time lost for which no compensation is given.
- ◆ Inventors are reluctant to disclose their technology before patents are granted, but such disclosures are required for publication 18 months after the date of filing of the application.

- ◆ It is usually difficult for patent applicants to describe the constitution of a traditional medicine clearly, because most of the time traditional medicine is a mixture of many unknown substances, so it is also difficult for the judge to determine whether an infringement has taken place between the patented drugs and the products suspected.

8.2 Colombia

Proposal for the protection of intellectual property rights on Amazonian vernacular knowledge

Dr Alvaro Zerda of the National University of Colombia presented this paper.

- ◆ To develop a *sui generis* institution that recognizes the intellectual property rights of the indigenous communities over their vernacular knowledge related to the use of medicinal plants, or some kind of medicinal practices, which had been proved as useful, effective, and secure.
- ◆ To establish a fund for the distribution of royalties, common for the different ethnic communities that share the same habitat. This would recognize the potential development of new existing medicines in the indigenous communities and it would also serve as an incentive for different communities to co-operate in collective projects, so avoiding competition for priority in achieving recognition.
- ◆ The royalty payments may be made part in money to help with the community's needs, and part by capacity building in the community, enabling individuals who possess vernacular knowledge (shamans, bush doctors, and so on) to also master western knowledge and become "cultural amphibians", so giving the scientific dimension to their knowledge.
- ◆ In this sense, communities should have direct participation in bioprospection and development of new products that make use of their knowledge, from the moment of project design and in the subsequent stages. In this way, it is possible to contribute to the construction of a bridge between the western scientific structures and the indigenous communities.
- ◆ Finally, an international regulation mechanism must be established, so that transactions may be conducted between a particular community in one country and entrepreneurial or scientific organizations in another country. The existence of an international authority to represent the interests of the different participating actors is also justified by the fact that many times the State may have interests that do not necessarily match the national public interest, nor that of indigenous communities.

8.3. India

National measures and experience for protection of traditional Indian medical knowledge of Ayurveda in the regime of intellectual property rights

Dr K. Sharma, Adviser Ayurveda, Govt. of India, presented this paper.

Introduction: Ayurveda – the Indian system of medicine

India is an ancient, vast country, having a wide variety of vegetation zones from the high alpine Himalayas, to extensive seashores, arid western zones and humid eastern regions. India's flora is very rich in having all types of plants ranging from the lowest to the most highly developed flowering plants.

The rational utilization of herbs for treating illness and other purposes began with Vedas (6000 BC). This knowledge was developed and documented in the Samhita Period (1000 BC) and was further enriched up to the Nighantu Period (19th Century). More and more plants were added to the Ayurvedic Materia Medicas with the passage of time.

Lord Buddha (600 BC) was also a great scholar of Ayurveda. Ayurveda travelled with Buddhism from India to China, Myanmar, Sri Lanka, Thailand, Japan, Korea, etc.

Texts of Ayurveda like Charak Samhita (1000 BC) and Sushrut Samhita (600 BC) are still being taught in India in the Ayurvedic Medical Colleges.

Ayurveda – the science of life is said to have evolved with the evolution of the human race in the universe. Ayurveda is a continuous living tradition and an official health care system in India having the following infrastructure.

- ◆ Independent Department of Indian Systems of Medicine (Ayurveda) under the Ministry of Health & Family Welfare, Government of India.
- ◆ Twenty States of the Republic of India have separate Directorates of Ayurveda and Indian Systems of Medicine.
- ◆ There are over 400,000 registered practitioners of Ayurveda in India, most of them institutionally qualified.
- ◆ There are 190 graduate degree colleges of Ayurveda and 50 post-graduate (MD – Ph.D. Ayurveda) degree awarding institutions under the university education system.
- ◆ Education and practice is regulated by the Indian Medicine Central Council Act, 1970 (IMCC Act 1970).
- ◆ Ayurvedic medicines are regulated under the Drugs & Cosmetics Act, 1940 and Rules thereunder.
- ◆ Ayurvedic Pharmacopoeia of India (3 Volumes) is readily available.
- ◆ Ayurvedic Formularies of India (2 volumes) have been published.
- ◆ There are over 22,000 Government dispensaries, 3000 hospitals and 9000 drug manufacturing units.
- ◆ Research Councils of Ayurveda, Siddha and Unani are functioning.
- ◆ Knowledge of systems and medicament of Ayurveda is documented in Sanskrit, Hindi and ten regional languages of India.
- ◆ Much Ayurvedic and related knowledge is also in oral tradition, which is yet to be documented.
- ◆ Folk medicines, tribal medicine and home remedies in India have roots in Ayurveda, and need documentation, protection and propagation.

The Traditional Knowledge Digital Library

Recently, an increasing number of plants, routinely and commonly used in India for medicinal purposes, are being patented, with the claim that they are efficacious for a variety of diseases. Such uses are being treated as new discoveries based on a novel use of such plants, although these have been utilized for their medicinal properties for centuries and continue to be in active use even today. Patents have been granted in large numbers covering the use of such plants, treating the claim as a discovery or an invention. It is, therefore, necessary to see that the knowledge that is available in the texts which relates to the concepts, skills, procedures, processes, formulations and the medicinal properties of the plants, minerals and metals, is made available in a manner that can be easily accessed to show that prior art already exists, which alone can forestall the future grant of patents for similar or derived uses.

The World Intellectual Property Organization (WIPO)'s Forum on Intellectual Property Policy and Strategy in the 21st Century, held in New Delhi in July 2000, resolved to extend protection of areas of traditional knowledge utilizing the established advantages of information technology through the setting up of a Traditional Knowledge Digital Library. It also resolved to consider the possibility of creating a *sui generis* system for the protection of traditional knowledge, including expressions of folklore and genetic resources, where the existing intellectual property regime does not adequately address concerns relating to these areas. It further resolved to protect and preserve traditional knowledge, encourage innovation and creativity and promote the sharing of benefits through the effective use of appropriate systems, including intellectual property systems.

Setting up of task force

A task force was set up consisting of representatives of the Department of Indian Systems of Medicine, Ayurveda experts, patent examiners, information technology experts, scientists from the Council of Scientific and Industrial Research (CSIR), the Department of Industrial Policy and Promotion, the National Informatics Centre, and Ayurvedic experts from Banaras Hindu University. The Task Force, after detailed deliberation, submitted a report on establishing a Traditional Knowledge Digital Library (TKDL) so as to make all documented information easily and comprehensively accessible to patent examiners with the objective of preventing the granting of patents for non-original inventions by making available what is already available in our traditional system in published form. Once we have prepared such a database, WIPO would be able to make it available to others through their Intellectual Property Network.

Outputs

TKDL will help to integrate widely scattered references on our traditional Ayurvedic systems in a retrievable form. It will act as a bridge between traditional and modern systems of medicine and will also provide a major impetus to modern research. TKDL will thus prevent misinterpretation of knowledge existing in the public domain and therefore obviate the need for contesting patents, which is a costly and time-consuming exercise. It will thus save time, energy and exorbitant expenditure on contesting patents that are granted and help protect our intellectual property. In addition, TKDL will directly benefit and facilitate practitioners of Ayurveda, manufacturers and the public, as the information which is presently in Sanskrit, Persian, Urdu, Tamil and other regional languages contained in the classical texts, will be available in a comprehensive, intelligible and easily accessible manner in other languages such as English, German, French, etc.

The TKDL model developed by India to protect its traditional Ayurvedic knowledge could be followed by other nations to set up TKDLs of their knowledge. This is the only way to protect one's national heritage, knowledge that has already existed in the public domain for centuries.

8.4. Indonesia

Indonesian perspectives on intellectual property rights in the context of traditional medicine

Ms Mawarwati Diamaluddin, Secretary of Food and Drug Control Directorate General, Ministry of Health, Republic of Indonesia, presented this paper.

Conceptual context of intellectual property rights and traditional medicine

The role of traditional medicine in the health care system

- ◆ traditional medicine is not just a tradable commodity
- ◆ traditional medicine comprises social, economic and technological aspects
- ◆ traditional medicine is an integral part of the public health service. For example, more than 40% of the population who seek health care go to traditional healers who use traditional medicine. In addition, traditional medicine is also being used as complementary medicine
- ◆ traditional medicine is culturally, economically and geographically accessible. Therefore, the role of traditional medicine in the health care system is indispensable

The role of intellectual property rights in traditional medicine cannot be separated from the national health care system

The application of intellectual property rights in traditional medicine should provide benefits and additional value to the health care system, leading to equitable health services, in a manner conducive to social and economic welfare.

Analysis situation on the role of traditional medicine in the health care system in Indonesia

Opportunities

- ◆ Global trend of "back to nature", increased use of herbal medicine as complementary medicines
- ◆ At the national level, traditional medicine is popular, accepted and used by most of the population
- ◆ It is the most accessible and affordable treatment option for the poor and people in remote areas
- ◆ Indonesia is a mega-centre of biodiversity, second richest country after Brazil, for example, 30,000 plant families, 940 species having therapeutic properties, 100 species in use by national industries

Limiting factors

- ◆ Quality assurance of traditional medicine is limited
- ◆ Efficacy of most traditional medicine therapies is not based on established clinical trials
- ◆ Limited advanced research activities and fragmented data
- ◆ Lack of qualified or properly trained practitioners

- ◆ Acceptance of traditional medicine by the modern health care system is limited
- ◆ Ignorance of stakeholders about intellectual property rights

Challenges

- ◆ How to optimize the use of intellectual property rights by the rights holders
- ◆ How to prevent abuse and misuse of intellectual property rights by non-rights holders

Laws and regulations

At present, the main laws on intellectual property rights in Indonesia are as follows:

- ◆ Copyrights Law (Law No.6 of 1982, amended by Law No.7 of 1987 and Law No.12 of 1997);
- ◆ Patents Law (Law No.6/1989, amended by Law No.13/1997);
- ◆ Marks (Trade marks) Law (Law No.19/1992, amended by Law No.14/1997)

Recommendations

- ◆ Realizing the importance of traditional medicine in the health care system for the population, particularly those in rural areas, as well as its role as a complementary medication, the use of intellectual property rights should be seriously and systematically promoted among stakeholders
- ◆ Efforts should be made for a generic model for patent or other related intellectual property rights law as well as for an international agreement, to support the health sector at the national level, and to develop national law

8.5. Kenya

Indigenous knowledge and intellectual property rights: Kenyan experience

Dr John E. K. Muchae, Deputy Director, Legal Department, Kenyan Industrial Property Office, Ministry of Tourism, Trade and Industry, presented this paper.

Intellectual property system in Kenya.

Kenya has the requisite legislation providing for protection of intellectual property rights. The relevant Acts of Parliament are:

- ◆ The Industrial Property Act, cap. 509.
- ◆ The Trade Marks Act, cap. 506
- ◆ The Copyright Act, cap. 130, and
- ◆ The Seeds and Plant Varieties Act, cap. 326.

Intellectual property legislation is being revised in order to make it TRIPS compliant. New bills such as the Geographical Indications and Layout Designs of Integrated Circuits Bills have been drafted.

The Industrial Property Act contains provision for protection of pharmaceutical products and processes and in addition, it has provision for protection of herbal medicine under the utility models provisions.

Kenya strongly supports the WIPO initiative on traditional and indigenous knowledge

As a member of the African Regional Industrial Property Organization (ARIPO), Kenya supports the unanimous decision of the ARIPO Council of Ministers and the decision of the Administrative Council of ARIPO to link ARIPO's initiatives with those undertaken by WIPO on matters relating to indigenous knowledge, and to pursue vigorously issues relating to the same.

Study on herbalists

A study, carried out by Paul M. Chege, a patent examiner attached to the Kenya Industrial Property Office, found that local and regional herbalists hold a substantial amount of knowledge on medicinal properties of biological resources in their environment. The study also found out that although herbalists are required to submit samples of their herbal medicines to the Kenya Medical Research Institute before they are registered and issued with recognition certificates by the Ministry of Culture, there is no effective communication between them, the Ministry of Culture and Social Services and the Kenya Medical Research Institute. As a result, the herbalists feel that they have, so far, been given a raw deal.

Recommendations

- ◆ Owing to the fact that indigenous knowledge and innovations in herbal medicine play a very important role in health care delivery, there is an urgent need to formulate legislation that would provide for protection of indigenous knowledge.
- ◆ Public awareness campaign should be intensified in order to make Kenyans aware of the importance of legislation, and exploitation of indigenous knowledge in Kenya. Holders of protected indigenous knowledge should be encouraged to register their trademarks and use such marks to aggressively market their products.

8.6. Pakistan

Intellectual property rights and traditional medicine from a developing country's perspective

Dr. F.R.Y. Fazli of Pakistan presented this paper.

Developing countries are faced with the challenges of poverty and disease in their efforts to provide health care to the majority of their population. Traditional medicines help to fill the gaps in modern health care and therefore are of great importance to them. While considering the protection of intellectual property rights of traditional medicine, the obligations and implications of TRIPS/WTO must be taken into account. Past experience of intellectual property rights protection of pharmaceuticals indicates that it has made access by people difficult, while TRIPS lays down conditions which are likely to make access even more difficult. Although complying with the TRIPS obligations, national laws may exclude traditional medicine and natural materials from patent protection as allowed for within the framework of TRIPS. However, separate legislative measures or a system including a *sui generis* system may be considered for intellectual property rights protection of traditional medicine and traditional knowledge as well as to stop biopiracy. WHO can provide invaluable help in this direction.

8.7. Republic of Korea

Endeavours with traditional herbal drugs in Korea

Prof. Il-Moo Chang of the Natural Products Research Institute, Seoul National University, Republic of Korea, presented this paper.

In Korea, three governmental organizations are engaged in dealing with intellectual property. The Korea Intellectual Property Office (KIPO), is concerned with evaluating industrial property (patents), trade marks and designs. It has its own international intellectual property training centre where courses in intellectual property for national and foreign participants are regularly offered. The Ministry of Culture and Tourism (MCT) is concerned with the evaluation and registration of copyright.

With regard to the intellectual property of traditional medicine, specifically traditional herbal drugs, usually three different registrations are feasible: new formulations using traditional herbal materials, preparations or dosage forms, and computerized data of classical medical information. New formulations may be granted a composition patent with new use claim. When active ingredients in a pure form are isolated, a new substance patent may be granted. When new activity is found, a new use-bound patent may be claimed. New dosage forms can also be a good target for obtaining a new patent. For example, a pill formulation of a certain traditional Chinese formula was successfully switched into a liquid form. Consumers prefer the liquid form, because they believe the active ingredients are absorbed more quickly and prefer the easy administration.

In the case of copyright, the TradiMed DB (Traditional Oriental-Chinese Medicine Database) is a successful example of obtaining the copyright of classical medical information by using computer technology. To obtain copyright, simple conversion of information, e.g. digital characterization recognition technology can not be eligible. That information should be interpreted in terms of present knowledge and processed by computer technology for database construction.

8.8. WHO Collaborating Centre (Chicago)

University of Illinois at Chicago's (UIC) policy of benefit sharing in research on drugs derived from natural products

Prof. Djaja Djendoel Soejarto of UIC presented this paper.

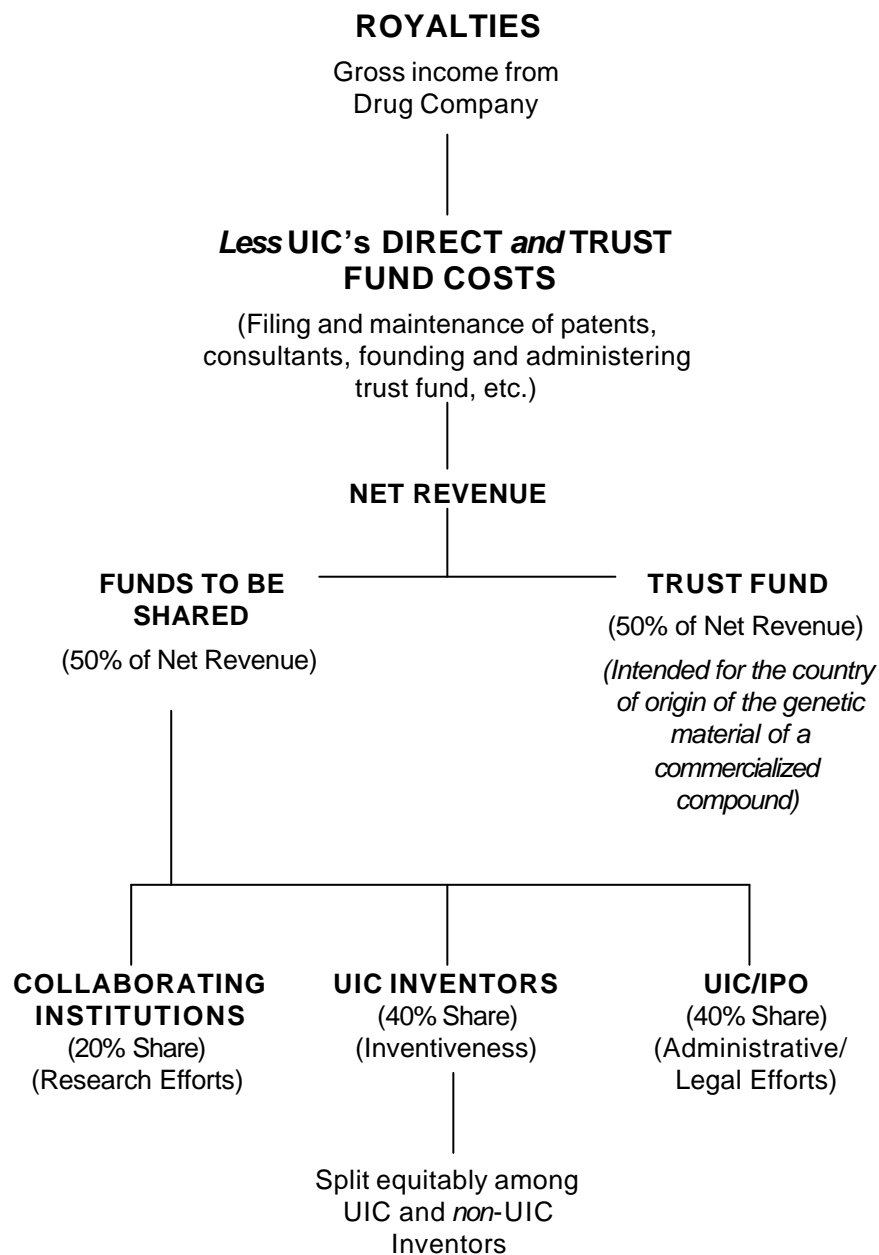
Modern research in the discovery of biologically active compounds from natural sources, with particular reference to plants, as potential candidates for drug development, has been ongoing at UIC for the past twenty-five years. Presently there are two possible schemes for sharing the benefits.

The first scheme is exemplified by a project, in which a group of UIC faculty collaborates with a group of counterpart scientists or an institution in a biodiversity-rich country, which also supplies the plant genetic material. If a compound is discovered and patent protection is sought, the co-authorship of the patent will take into account and may include a scientist from that country, as inventors, if this scientist played an inventive role in the invention. Following the filing of the patent by the UIC, licensing of the invention will be offered to a pharmaceutical firm. If eventually a drug goes onto the market as a result of the licensing process, the UIC

will receive a stream of royalties. Costs for the original patenting process and for the establishment of a Trust Fund are to be paid by UIC. The net royalty income is then split 50-50 between a common fund and a Trust Fund. Income to go to the Trust Fund is intended solely to be returned to the country of origin of the genetic material, while the common fund is to be distributed as follows: (a) to the collaborating institutions (20%), who will divide the share based on agreed proportions among themselves, namely, between the PCRPS in the US, and the foreign institution or institutions; (b) to the inventors (40%), who will divide this

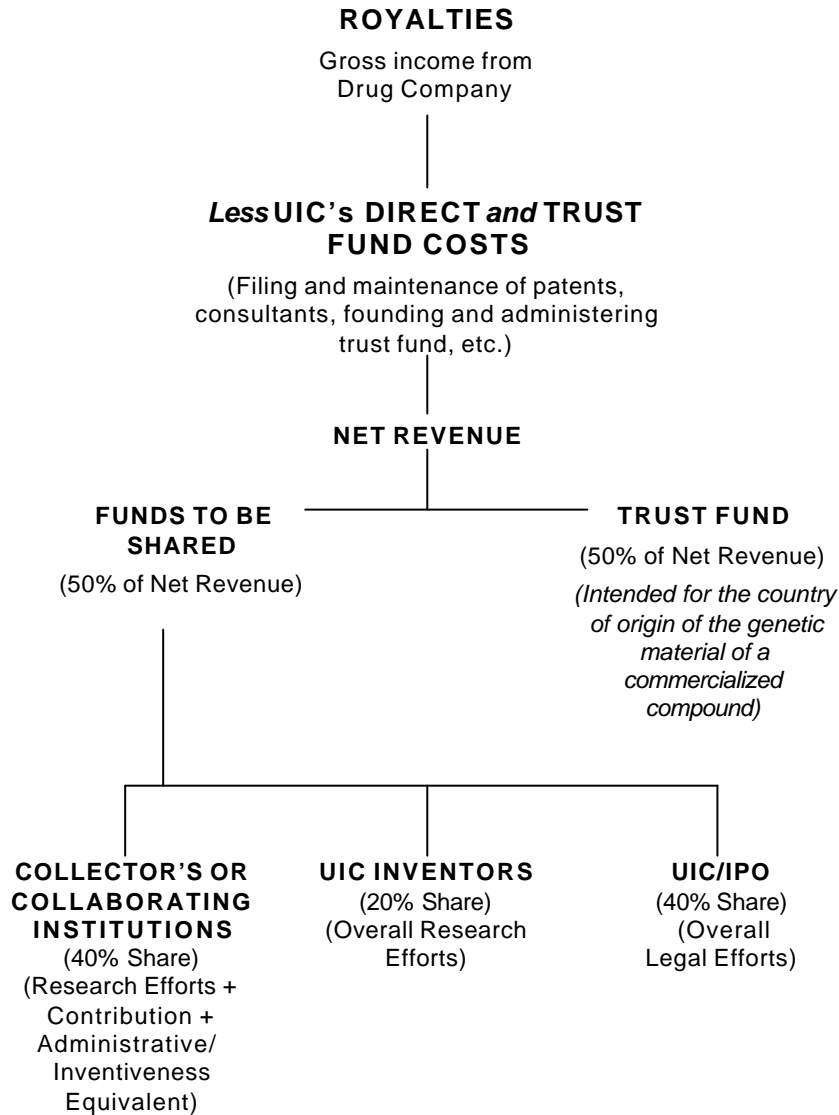
SCHEME 1

ROYALTIES SHARING IN THE EVENT THAT UIC DISCOVERS AND CHARACTERIZES A COMPOUND AND A PHARMACEUTICAL COMPANY DEVELOPS THE DRUG



SCHEME 2

ROYALTIES SHARING IN THE EVENT THAT A PHARMACEUTICAL COMPANY DISCOVERS A COMPOUND, CHARACTERIZES IT AND DEVELOPS THE DRUG



The second scheme is exemplified by a project, in which a group of UIC faculty collaborates with a counterpart institution, which supplies the genetic material for the drug discovery process, and an industrial partner, in which the industrial partner undertakes both the discovery and the development of the drug. In this scenario, if a drug is discovered and developed by the company, and a product goes onto the market, the UIC will receive royalties from the pharmaceutical company. Again, initial UIC costs are deducted. The net royalty income is then split 50-50 between a common fund and a Trust Fund. Income to go to the Trust Fund is intended solely to be returned to the country of origin of the genetic material, while the common fund is to be distributed as follows: (a) to the collaborating foreign

institution (40%); (b) to the PCRPS (20%); and to the University of Illinois at Chicago (40%). A bigger percentage is destined for the collaborating foreign institution to justify research effort, inventiveness equivalent and contribution of the genetic material. *In this scenario, the total amount of funds that will go back to the source country will be: funds from the Trust Fund plus the share of the source country institution, for a total of 68% or higher, depending on the total amount of royalty payment.*

9. Recommendations

The workshop participants stressed the important role of traditional medicine in developing countries and reiterated that countries should develop a national traditional medicine policy. This national traditional medicine policy should include the issue of R&D in the area of traditional medicine, the formal recognition of traditional medicine systems and the integration of traditional medicine in the national health care system.

The meeting noted that many activities and products based on traditional knowledge are important sources of income and health care, as well as environmentally sustainable routes to economic development for large parts of the population in many developing countries. The use of traditional medicine and the vast majority of plant genetic resources and other forms of biodiversity are found in, or originate from, developing countries. Access to these resources and the associated traditional knowledge can provide substantial benefits to companies and scientific research centres in both developed and developing countries. There is concern that traditional knowledge is at times appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent. This is a trade issue, as traditional knowledge and products derived from traditional knowledge often cross international borders. Developing countries should rally their concern for fair and equitable sharing of benefits.

In view of the above, the workshop made the following recommendations:

1. Countries should have a national policy on traditional medicine as part of the national health policy and countries should develop and utilize traditional medicine in a meaningful manner in the national health care system.
2. Organizational infrastructure of traditional medicine should be developed and/or strengthened and official recognition accorded to it.
3. National and regional strategies should be developed for the protection of traditional medicine with the support of WHO and other international agencies.
4. Ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge of the community from biopiracy.
5. Simultaneously, efforts through technical cooperation among countries need to be made to add value through innovation for public health. Indigenous and local communities should be involved in devising these models.
6. Traditional knowledge which is in the public domain needs to be documented in the form of traditional knowledge digital libraries in the respective countries with the help of WHO to WIPO's work in this area. Such information needs to be exchanged and disseminated through systems or mechanisms relating to intellectual property rights.

7. WHO, in cooperation with other agencies including UNCTAD, needs to support the initiatives taken by governments of Member States for capacity building, implementation and enforcing the legislation to protect and promote traditional medicine knowledge through training, seminars and workshops. International cooperation should be increased in this area.
8. Governments should develop and use all possible systems including the *sui generis* model for traditional medicine protection and equitable benefit sharing.
9. Countries should develop guidelines or laws and enforce them to ensure benefit sharing with the community for commercial use of traditional knowledge.
10. Traditional knowledge should be recognized in the form and concepts of the traditional medicine system of a particular country, and not necessarily on a western model.
11. Efforts should be made to utilize the flexibility provided under the TRIPS Agreement with a view to promoting easy access to traditional medicine for the health care needs of developing countries.

Annex I

Message to the Workshop from Dr Uton Muchtar Rafei, Regional Director WHO South-East Asia Region

(Read by Dr E.B. Doberstyn, WHO Representative, Thailand)

Distinguished participants, dear colleagues, ladies and gentlemen,

I have the honour to present greetings from Dr Uton Muchtar Rafei, Regional Director of the WHO South-East Asia Region, to the organizers of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine and to the distinguished participants. As the Regional Director could not be present here today, I have the honour to read his message. And I quote:

“Traditional medicine is an important part of human health care. It is the sum total of the knowledge, skills and practices based on the theory, beliefs and experiences indigenous to different cultures used in maintaining good health as well as in curing diseases.

The use of medicinal plants in therapy has been known for centuries in all parts of the world. The traditional systems of many developing countries use medicinal plants in formulations or their extracts. Such use among various communities has even led to the discovery and development of a large number of drugs that are now used as therapeutic agents. Digitalis for heart failure, morphine for pain, colchicine for acute attacks of gout, artemisinin for the treatment of drug-resistant malaria are just a few examples of medicines derived from plant sources.

With the tremendous expansion in the use of traditional medicines worldwide, safety and efficacy, as well as quality, of herbal medicines and traditional non-medication therapies have become important concerns for both health authorities and the public. In addition to the safety and efficacy issues, another important issue relating to the protection of knowledge, innovations and practices of traditional and indigenous medicine has been receiving increasing international attention in recent years. The Council on TRIPS of the World Trade Organization has just started the revision of Article 27 – 3(b) which deals with patentability of traditional knowledge. The conclusions and recommendations of this meeting could contribute to the revision of the article.

The global herbal market and industry have been growing rapidly in recent years. Today, medicinal plants enjoy great potential for export. It must be noted that the vast majority of plant resources originate from developing countries. It is recognized that traditional knowledge plays a key role in the protection and sustainable use of biodiversity.

Developing countries are repositories of large resources of medicinal plants. In the past, multinational corporations have exploited these resources by converting them into products of commercial value without paying compensation for the knowledge that was transferred along with the material. At the Convention on Biodiversity held in Rio de Janeiro in 1992, members accepted the principle that bio-resources are the sole property of sovereign states and that they have the freedom to use them as tradable commodities. However, most countries in the developing world have not so far enacted legislation to implement the resolutions passed at the Convention. It is necessary to invoke bilateral and multilateral agreements on the basis of accepted norms for the transfer of indigenous germplasms used for research and development or for commercial production.

Access to plant resources and the associated traditional knowledge can provide substantial benefits to companies and research institutes in both developing and developed countries. There is growing concern that knowledge of traditional medicine is at times appropriated, adopted and patented by scientists and industry, with little or no compensation to its custodians, and without their prior informed consent. This is a trade issue, as such products often cross international borders.

The need to protect traditional medicine knowledge and to secure fair and equitable sharing of benefits derived from the use of biodiversity and associated traditional medicine knowledge have been fully recognized. At present, existing conventional patent law protection requirements are not applicable to 'traditional' knowledge. There is no agreement as to how and what would be the most appropriate and effective way to achieve protection of traditional medicine in developing countries.

This meeting is the fruit of contributions from the African, American, South-East Asian and the Western Pacific Regions of WHO. These regions also have the most important systems of traditional medicine in the world. Exchange of information and interactions would improve knowledge and capability to tackle problems facing these Member countries. The outcome of this meeting will provide Member countries with the basis for tackling issues of Intellectual Property Rights relating to their national traditional medicine programmes.

I wish you all success in your deliberations and a very productive meeting. I also wish you a pleasant stay in Bangkok." Unquote

I shall, of course, apprise the Regional Director of your deliberations and its outcome. I would like to thank the organizers of this Inter-Regional Workshop for giving me this opportunity to bring the Regional Director's message to this august gathering.

Thank you.

Annex II

Welcome address from Dr Mongkol Na Songkhla Permanent Secretary, Ministry of Public Health, Thailand

Dr. Doberstyn,

Distinguished Delegates,

Ladies and Gentlemen.

It is a great pleasure and honour for me to welcome all distinguished participants attending the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine today.

Nowadays, many countries around the world are competing hard to develop their own society and economy, especially commerce. Thus, it is the right time and very essential for patents to be addressed. Though the developed countries are in a more advantageous position—they have high technology offering more potential—they, too, are facing problems. They do not want anyone to copy their intellectual property. As a result, they have developed patent legislation. Anyone who would like to copy, he or she must get approval and pay the fee first, as well as having to agree the contract and conditions, on which the developed countries have the monopoly.

By contrast, the developing countries are facing problems, learning the high technology from the developed countries. So, the developing countries are always in trouble with the patent law, because some kinds of medicines are very expensive. They cannot produce them by themselves, so they have to depend on developed countries.

Developing countries have their own intellectual property of culture and indigenous knowledge that should be organized. This includes the concept of promoting the use of herbal medicine at low cost. It is only fair to do so.

I believe that with the interest of the World Health Organization in intellectual property rights protection for traditional medicine, and its financial support to mobilize so many countries like these to work together to develop strategies for protecting traditional medicine knowledge, resources and biodiversity, there will be fair and equitable sharing of the benefits of using medicinal plants in the future.

In closing, on behalf of the Ministry of Public Health, I would like to express my appreciation to the World Health Organization for its kind support and cooperation as well as to all the other participating countries for their contributions – all of which have made this useful workshop possible.

May I once again extend a warm welcome to all of you as well as wish you a successful and productive Workshop and a pleasant stay in Thailand.

Thank you.

Annex III

Workshop Agenda

Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Bangkok, 6–8 December, 2000

06 December 2000, Wednesday

0800-0900	Registration
0900-1000	Welcome address from the Ministry of Public Health, Thailand Message from the Regional Director, WHO South-East Asia Regional Office and Opening of Workshop by WR Thailand Message from UNCTAD Message from WIPO Group photograph
1000-1030	Coffee Break
1030-1230	Nomination of Chairpersons and designation of Rapporteurs Adoption of agenda The important role of intellectual property rights in the context of traditional medicine by <i>Dr Xiaorui Zhang</i> Globalization, the TRIPS Agreement and access to essential drugs by <i>Dr G. Velásquez</i>
1230-1400	Lunch
1400-1530	Intellectual property rights by <i>Mr. Shakeel Bhatti, WIPO</i> Systems and national experiences for protecting traditional knowledge, innovations and practices-by <i>Maria Perez-Esteve, UNCTAD</i>
1530-1545	Coffee Break
1545-1800	Existing problems and gaps in traditional medicine relation to modern patent laws– <i>Speakers - Philippines and Thailand</i> Group discussion on the existing problems and gaps for protection of traditional medicine knowledge

07 December 2000, Thursday

- 0830-1000 Country presentations on national patent law, means, experiences and proposals
Speakers - China, Colombia, India, Indonesia, Kenya, Pakistan, Republic of Korea, Thailand & WHO Collaborating Centre (Chicago)
- 1000-1015 Coffee Break
- 1015-1230 Country presentations on national patent law, means, experiences and proposals (contd)
- 1230-1400 Lunch
- 1400-1530 Country presentations national patent law, means, experiences and proposals (contd)
- 1530-1545 Coffee break
- 1545-1700 Group reports on existing problems and gaps in Tradition Medicine in relation to modern patent laws

08 December 2000, Friday

- 0830-1000 Plenary review of recommendations and outline of workshop report
- 1000-1015 Coffee Break
- 1015-1200 Finalization of recommendations
Closing session

Annex IV

List of Participants

Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Bangkok, 6–8 December, 2000

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