

# No. 6

## Intellectual Property and Traditional Medical Knowledge

### Introduction

Traditional medicine is popular throughout the world. In some Asian and African countries, a number of the population depend on traditional medicine, including for primary healthcare. In many developed countries, 70 to 80 percent of the population have used some forms of alternative or complementary medicine such as acupuncture.<sup>1</sup> Many modern drugs and vaccines are based on natural resources and associated traditional knowledge.

Traditional medical knowledge has social, cultural and scientific value and is important for many indigenous peoples and local communities. Growing commercial and scientific interest in traditional medicine systems has led to calls for traditional medical knowledge to be better recognized, respected, preserved and protected.

Traditional medical knowledge, such as the medicinal use of herbs, is often associated with genetic resources. For instance, calanolides, compounds derived from the latex of *Calophyllum* trees found in the Malaysian rainforest, are a potential treatment for HIV and certain types of cancer. Because genetic resources exist in nature and are not creations of the human mind, they cannot be directly protected as intellectual property (IP). They are, however, subject to access and benefit-sharing regulations under international agreements.<sup>2</sup> This brief focuses on IP protection of traditional medical knowledge and does not deal specifically with associated genetic resources.

### What is Traditional Medical Knowledge?

The World Health Organization (WHO) defines traditional medicine as “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 illnesses”.

“Traditional” means that the knowledge is created in a manner that reflects community traditions; it is often inter-generational and created and held collectively. “Traditional”, therefore, does not necessarily mean “old” but is rather related to the way in which the knowledge is created, preserved and transmitted.

Traditional knowledge is generally considered the collective heritage of a particular indigenous people or local community. While individuals, such as a *shaman* in Bolivia or a *sangoma* in South Africa, may themselves innovate, what makes their innovations “traditional” is that they are based on the community’s collective heritage and the innovations are regarded as community-held.

<sup>1</sup> See WHO Fact Sheet N°134 “Traditional Medicine” (December 2008).

<sup>2</sup> In particular, the Convention on Biological Diversity, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and the International Treaty on Plant Genetic Resources for Food and Agriculture.

## Protection of Traditional Medical Knowledge

Different aspects of traditional medical knowledge are under discussion in several international forums, including **WHO**<sup>3</sup> and the **World Trade Organization (WTO)**.<sup>4</sup>

The **World Intellectual Property Organization (WIPO)** is primarily concerned with “protection” of traditional medical knowledge in the IP sense – protection against unauthorized use by third parties. Negotiations currently underway in the **WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)** seek to develop an international legal instrument that would provide effective protection of traditional cultural expressions/folklore and traditional knowledge (including traditional medical knowledge), and address the IP aspects of access to and benefit-sharing of genetic resources.

Calls for the protection of traditional medical knowledge are often based on a number of cases involving misappropriation by unauthorized third parties, who have patented compounds derived from traditional medicines without the prior consent of traditional medical knowledge holders and without fair compensation. Examples of patents based on traditional Indian medicine have included the use of turmeric for healing wounds, the anti-fungal properties of *neem*, and a diabetes medicine made from extract of *jamun*. All three patents were subsequently revoked.

In the case of captopril, a drug used to treat hypertension and heart failure, no benefits have flowed back to the indigenous Brazilian tribe that first used pit viper venom as an arrowhead poison. By contrast, the San people of the Kalahari Desert have a benefit-sharing agreement with South Africa’s Council for Scientific and Industrial Research, which is working with pharmaceutical companies to develop dietary supplements based on *hoodia*, a succulent plant well-known to the San for its appetite-suppressant qualities.

IP protection can take two forms – positive and defensive protection:

- **Positive protection** grants IP rights over the subject matter of traditional medical knowledge. This may help communities to prevent others from gaining illegitimate access to traditional medical knowledge or using it for commercial gain without equitably sharing the benefits. It may also enable active exploitation of traditional medical knowledge by the originating community itself, for example, to build up its own enterprises based on that knowledge.
- **Defensive protection** does not grant IP rights over traditional medical knowledge but aims to stop such rights from being acquired by third parties. Defensive strategies include the use of documented traditional medical knowledge to preclude, oppose or invalidate patents on claimed inventions that are directly based on such knowledge.

Defensive measures undertaken by WIPO include changes to the **Patent Cooperation Treaty’s Minimum Documentation** and the **International Patent Classification** so as to improve searches for “prior art” and prevent patents from being granted in error. In 2003, it was agreed that certain traditional knowledge documentation, such as the Indian Journal of Traditional Knowledge and the Korean Journal of Traditional Knowledge, should be included in the Patent Cooperation Treaty’s Minimum Documentation. In 2006, the International Patent Classification was amended to include a traditional knowledge category, which covers traditional herbal medicines.

## Legislative and Practical Options for Protecting Traditional Medical Knowledge

### Conventional intellectual property rights

IP rights convey legal ownership over certain intangible assets, such as artistic works, commercial designs and pharmaceutical technologies. Common types of IP include patents, copyright, trademarks, geographical indications and trade secrets.

Generally speaking, **patents** are the most important type of IP protection for medicines. To obtain a patent, an invention must be **novel**, **inventive** and **industrially applicable**. A patent grants a set of exclusive rights for a limited time, usually 20 years, that allows the inventor to prevent others from making, using, selling, offering for sale or importing the patented invention without permission. Patents based on traditional medical knowledge include patents based on *maca*, a traditional Peruvian food and medicine first cultivated by the Incas, and a patent based on *kava*, a medicinal plant first domesticated in Vanuatu. In China, patent law protects new traditional medicine-based products, methods of process and new uses of traditional medicine, including herbal preparations, extracts from herbal medicines, foods containing herbal medicines and methods for preparing herbal formulas.

3 WHO promotes the use of traditional medical knowledge for health care. See WHO Fact sheet No. 134 “Traditional Medicine”, [www.who.int/mediacentre/factsheets/fs134/en/](http://www.who.int/mediacentre/factsheets/fs134/en/).

4 The WTO’s work on access to medicines and IP issues relating to public health is guided by the Doha Declaration on the TRIPS Agreement and Public Health; this clarifies the flexibilities in IP rules available to governments under the WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). See [www.wto.org/english/tratop\\_e/trips\\_e/who\\_wipo\\_wto\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm).

Holders of traditional medical knowledge can nevertheless face significant obstacles in satisfying the conditions required to obtain a patent, especially the requirements of novelty and inventiveness. Because many traditional medicines have been used for generations, disseminated in local communities and documented in publicly available sources, these medicines may fail to qualify for patent protection for lack of novelty.

Moreover, because herbal medicines typically comprise natural products in their raw form, it can be difficult to claim that a remedy involves an inventive step. Identifying how the claimed invention differs from prior art can also be problematic. That said, pharmaceutical drugs derived from natural products usually involve some form of alteration or purification, which may be considered a novel and inventive step making the drugs eligible for patent protection.

A **trade secret** is information not generally known or reasonably discoverable, through which an IP holder can obtain some economic advantage. Once trade secrets become known, they generally cease to provide protection. Traditional medical knowledge holders may choose not to disclose their knowledge and keep it secret. In some communities, traditional medical knowledge is known and transmitted only to individual healers and not to the community at large.

Other forms of IP may also have a role to play. **Trademarks** protect distinctive signs, such as words, phrases, symbols and designs that identify the source of a product. This helps consumers identify products with preferred characteristics, such as a specific brand of herbal medicine. Trademark rights are established through either registration or use in commerce. Trademarks have been used to market products based on traditional medical knowledge, such as *Truong Son Balsam*, a traditional balm of medical plants from Viet Nam. However, while trademarks can help distinguish authentic goods, they do not prohibit third parties from using traditional knowledge without the trademark or under a different mark. Trademarks cannot be used to protect traditional medical knowledge itself.

A **geographical indication** is another sort of IP right that can help to identify the source of goods. Geographical indications identify products as having characteristics associated with their place of origin. However, although geographical indications can be used to distinguish products based on traditional medical knowledge specific to a location, they cannot protect against the same use of traditional medical knowledge that is not associated with a place. The way in which geographical indications are protected varies by country, and may require registration or use in commerce. As with trademarks, geographical indications can be used only for the protection of products based on traditional medical knowledge, not the knowledge itself.

## ***Sui generis* systems**

Some countries have adopted special *sui generis* laws and measures, specifically to protect traditional medical knowledge. For example, Thailand's Act on Protection and Promotion of Traditional Thai Medicinal Intelligence protects "formulas" of traditional Thai drugs and "texts on traditional Thai medicine". Only those who have registered their IP rights can research, develop and produce drugs using traditional medical knowledge. At the international level, the international legal instrument on the protection of traditional knowledge negotiated by the WIPO IGC would embody a *sui generis* approach.

## **Documentation**

Documenting traditional knowledge includes recording it, writing it down, taking pictures of it or filming it – anything that preserves it in an accessible form. It is different from the traditional ways of preserving and passing on knowledge within a community, and can promote or damage a community's interests, depending on how the documentation is carried out. Important IP rights may be strengthened or lost when traditional knowledge is documented.

Documenting traditional medical knowledge may be useful for the defensive protection of traditional medicine, for example, by providing information for prior art searches to preclude illegitimate patents (see above under "Defensive Protection"). However, documentation does not ensure legal protection for the underlying traditional knowledge; it does not prevent this knowledge from being used by third parties. In some cases it can destroy rights and options if it is undertaken without an IP strategy in place. The consultation draft of the **WIPO Traditional Knowledge Documentation Toolkit** provides useful practical guidance on how to address critical IP-related issues and questions before, during and after documentation exercises.

### **The Traditional Knowledge Digital Library**

The Traditional Knowledge Digital Library (TKDL), established under the auspices of India's Council of Scientific and Industrial Research (CSIR) and Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), documents existing literature related to four Indian traditional medical knowledge systems – Ayurveda, Unani, Siddha and Yoga. The TKDL provides patent examiners with prior art information, in digitized format, in five international languages (English, German, French, Japanese and Spanish), so as to prevent the erroneous grant of patents.

The TKDL is not open to the public, and patent offices must not reveal the contents of the TKDL to any third party, in order to protect India's interest against possible misuse.

## Other options

Other options can form part of the overall menu to protect traditional medical knowledge.

**Customary laws and practices** may define custodial rights and obligations over traditional medical knowledge, including obligations to guard it against misuse or improper disclosure. They may determine how traditional medical knowledge is to be used, how benefits should be shared and how disputes are to be settled, as well as many other aspects of the preservation, use and exercise of knowledge. For example, in North America, the inheritance and transfer of “medicine bundles” within or between families is accompanied by the transmission of traditional medical knowledge and certain rights to practice, transmit and apply that knowledge.

**Contracts** are another tool that can be used to protect traditional medical knowledge. Contractual agreements, such as the San people’s agreement on *hoodia* mentioned earlier, can ensure that the grant of IP rights and access to traditional medical knowledge is based on prior informed consent and benefit-sharing. In another example, traditional healers of Samoa are acknowledged in a benefit-sharing agreement concerning the development of prostratin, an anti-AIDS compound derived from the Samoan native *mamala* tree.

## Further Information

Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: An Overview (WIPO Publication No. 933), [www.wipo.int/edocs/pubdocs/en/tk/933/wipo\\_pub\\_933.pdf](http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf).

Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade (WIPO Publication No. 628), [www.wipo.int/edocs/pubdocs/en/global\\_challenges/628/wipo\\_pub\\_628.pdf](http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf).

A series of briefs, [www.wipo.int/tk/en/resources/publications.html](http://www.wipo.int/tk/en/resources/publications.html).

Consultation draft of the WIPO Traditional Knowledge Documentation Toolkit, [www.wipo.int/export/sites/www/tk/en/resources/pdf/tk\\_toolkit\\_draft.pdf](http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_toolkit_draft.pdf).

Database of legislative texts on the protection of traditional knowledge and traditional cultural expressions and legislative texts relevant to genetic resources, [www.wipo.int/tk/en/legal\\_texts/](http://www.wipo.int/tk/en/legal_texts/).

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), [www.wipo.int/tk/en/igc/index.html](http://www.wipo.int/tk/en/igc/index.html).

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