



INTELLECTUAL PROPERTY AND TRADITIONAL MEDICAL KNOWLEDGE: INQUIRY INTO THE UNDERSTANDING OF EXISTING STAKE

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Abstract: *Traditional medicine is a popular global practice, with a significant portion of the population relying on it for primary health care. In developing countries, 70-80% of the population uses alternative or complementary medicine, such as acupuncture. Traditional medical knowledge holds social, cultural, and scientific value and is crucial to indigenous peoples and local communities. A growing commercial and scientific interest in traditional medicine systems has led to calls for its recognition, respect, preservation, and protection. Intellectual property (IP) rights over traditional medical knowledge can help communities prevent undue access to this knowledge or use it for commercial gain without fair compensation. Defensive strategies include using documented traditional medical knowledge to prevent, oppose, or invalidate patents for claimed inventions directly based on such knowledge. Common types of IP include patents, copyright, trademarks, geographical indications, and industrial or trade secrets.*

Keywords: *intellectual property rights, Medical Knowledge*

Introduction

Traditional medicine is popular all over the world. In some countries in Asia and Africa, a large part of the population relies on traditional medicine, including for primary health care. In many developing countries, between 70 and 80 per cent of the population has used some form of alternative or complementary medicine, such as acupuncture.¹ Many modern medicines and vaccines are based on natural resources and the traditional knowledge associated with them.²

Traditional medical knowledge has social, cultural and scientific value

and is important to many indigenous peoples and local communities. A growing commercial and scientific interest in traditional medicine systems has resulted in calls for traditional medical knowledge to be better recognised, respected, preserved and protected.

Traditional medical knowledge, such as the use of medicinal herbs, is often related to genetic resources. For example, calanolide, a compound derived from the latex of *Calophyllum*, a tree found in the tropical rainforest of Malaysia, is a potential treatment against HIV and certain types of cancer. As genetic

¹ WHO Fact Sheet No. 134 "Traditional Medicine" (December 2008)

² Bodeker, Gerard. "Traditional Medical Knowledge, Intellectual Property Rights &

(And) Benefit Sharing." *Cardozo J. Int'l & Comp. L.* 11 (2003): 785.



resources exist in nature and are not creations of the human mind, they cannot be protected directly as intellectual property (IP). However, they are subject to rules on access and benefit sharing under international agreements.³

This paper focuses on the IP protection of traditional medical knowledge and does not deal specifically with the genetic resources associated with this knowledge.

What is traditional medical knowledge?

The World Health Organisation (WHO) defines traditional medicine as "the totality of knowledge, skills and practices based on theories, beliefs and experiences specific to different cultures, whether explicable or not, used in the preservation of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses".⁴

"Traditional" means that knowledge is created in a way that reflects community traditions; this knowledge is often inter-generational and created and

held collectively. "Traditional", therefore, does not necessarily mean "old"; it refers more to the way in which knowledge is created, preserved and passed on.⁵

Traditional knowledge is generally considered to be the collective heritage of an indigenous people or a particular local community. Although individuals, such as a shaman in Bolivia or a sangoma in South Africa, can innovate themselves, what makes their innovations "traditional" is the fact that they are based on the community's collective heritage and are considered to be communally owned.

The protection of traditional medical knowledge

Different aspects of traditional medical knowledge have been discussed in various international forums, including the WHO⁶ and the World Trade Organisation (WTO).⁷ The World Intellectual Property Organisation (WIPO) is mainly interested in the "protection" of traditional medical knowledge in the IP sense - protection against unauthorised use by third parties. Ongoing negotiations in the WIPO

³ 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 Utilisation, and the International Treaty on Plant Genetic Resources for Food and Agriculture.

⁴ Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade (WIPO Publication No. 628), www.wipo.int/edocs/pubdocs/eri/global_challenges/628/wipo_pub_628.pdf Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade; A series of notes, www.wipo.int/tk/en/resources/publications.html,

⁵ Consultation draft of the WIPO Traditional Knowledge Documentation Toolkit,

www.wipo.int/export/s/tes/ww/tk/en/resources/pdf/tk_toolkit_draft.pdf.

Project to Consult WIPO Instruments for the Documentation of Traditional Knowledge

⁶ The WHO promotes the use of traditional medical knowledge in health care. See its Fact Sheet No. 134 "Traditional Medicine" (12/2008).

⁷ The WTO's work on access to medicine 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Trade-Related Intellectual Property (TRIPS). See www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.



Intergovernmental Commission on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) seek to create an international legal instrument capable of effectively protecting traditional cultural expressions/folklore and traditional knowledge (including traditional medical knowledge), and of addressing the IP aspects of access to genetic resources and the sharing of benefits arising from their utilisation.⁸

Applications for protection of traditional medical knowledge are often based on a number of cases of illicit appropriation by unauthorised persons, who have patented compounds derived from traditional medicines without the prior consent of the holders of the traditional medical knowledge and without fair compensation. Examples of patents based on traditional Indian medicine include the use of turmeric to heal wounds, the antifungal properties of neem, and a medicine for diabetics made from jamun extract. These three patents were subsequently revoked.⁹

In the case of captopril, a drug used to treat hypertension and heart failure, no benefits accrued to the indigenous Brazilian tribe that first used the venom of the cobra as an arrowhead poison. On the contrary, the San people of the Calaári desert have a benefit-sharing

agreement with the South African Council for Scientific and Industrial Research, which works with pharmaceutical companies to develop dietary supplements based on hoodia, a succulent plant well known to the San people for its hunger-suppressing effect.¹⁰

IP protection - positive protection and defensive protection

Positive protection grants – IP rights over the subject matter of traditional medical knowledge. This can help communities prevent others from gaining undue access to traditional medical knowledge or using it for commercial gain without sharing the benefits equitably. Such protection can also enable the active exploitation of traditional medical knowledge by the community of origin itself, for example by building their own companies based on that knowledge.¹¹

Defensive protection does not grant – IP rights over traditional medical knowledge, but seeks to prevent such rights from being acquired by others. Defensive strategies include using documented traditional medical knowledge to prevent, oppose or invalidate patents for claimed inventions that are directly based on such knowledge.¹²

Defensive measures taken by WIPO include modifications to the

⁸ Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: A Summary (WIPO Publication No. 933),

⁹ Timmermans, Karin. "Intellectual property rights and traditional medicine: policy dilemmas at the interface." *Social Science & Medicine* 57.4 (2003): 745-756.

¹⁰ Munzer, Stephen R., and Kal Raustiala. "The uneasy case for intellectual property rights in traditional knowledge." *Cardozo Arts & Ent. LJ* 27 (2009): 37.

¹¹ Downes, David R. "How intellectual property could be a tool to protect traditional knowledge." *Colum. J. Env'tl. L.* 25 (2000): 253.

¹² Ramcharan, Robin, and Mpazi Sinjela. "Protecting traditional knowledge and traditional medicines of indigenous peoples through intellectual property rights: issues, challenges and strategies." *International Journal on Minority and Group Rights* 12.1 (2005): 1-24.



Minimum Documentation of the Patent Cooperation Treaty and the International Patent Classification, in order to ascertain "prior art" research and prevent patents from being granted unduly. In 2003, it was agreed that certain documentation on traditional knowledge, such as the Indian Journal of Traditional Knowledge and the Korean Journal of Traditional Knowledge, should be included in the Minimum Documentation of the Patent Cooperation Treaty. In 2006, the International Patent Classification was modified to include a category of traditional knowledge, which covers traditional herbal medicines.¹³

Legislative and practical options for protecting traditional medical knowledge

Conventional intellectual property rights

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

Generally speaking, patents are the most important type of IP protection for medicines. To obtain a patent, an invention must be new, involve an inventive step, and be industrially applicable. A patent grants a series of exclusive rights for a limited time, usually 20 years, which allows the inventor to prevent others from making, using, selling, offering for sale, or importing the

patented invention without authorisation. Patents based on traditional medical knowledge include patents based on maca, a 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 legislation protects new products based on traditional medicine, methods, processes and new uses of traditional medicine, including herbal preparations, medicinal plant extracts, foods containing herbal medicines and methods for preparing herbal formulas.¹⁴

Holders of traditional medical knowledge may, however, encounter significant obstacles when trying to fulfil the conditions for obtaining a patent, especially the requirements of novelty and inventive character. Considering that many traditional medicines have been used for successive generations, are widespread in local communities and documented in publicly available sources, it is possible that these medicines will not be able to obtain patent protection due to a lack of novelty.¹⁵

Furthermore, as herbal medicines contain natural products in their raw form, it can be difficult to prove that a medicine involves an inventive step. Determining how the claimed invention differs from the prior art can also be problematic. That said, drugs derived from natural products generally involve some form of alteration or purification, which can be considered new and the

¹³ Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: An Overview (WIPO Publication No. 933), www.wipo.int/tk/en/igfi/index.html.

¹⁴ Kartal, Murat. "Intellectual property protection in the natural product drug discovery, traditional herbal medicine and herbal medicinal products." *Phytotherapy*

Research: An International Journal Devoted to Pharmacological and Toxicological Evaluation of Natural Product Derivatives 21.2 (2007): 113-119.

¹⁵ Willcox, Merlin, et al. "Intellectual property rights, benefit-sharing and development of "improved traditional medicines": A new approach." *Journal of ethnopharmacology* 176 (2015): 281-285.



result of an inventive step, which makes the drugs eligible for patent protection.¹⁶

An industrial or commercial secret consists of information that is neither generally known nor relatively easy to discover, through which an IP holder can obtain some economic advantage. Once they become known, industrial or commercial secrets are generally no longer protected. Holders of traditional medical knowledge may prefer not to disclose their knowledge and keep it secret. In some communities, traditional medical knowledge is known only to a few and passed on only to individual healers and not to the community at large.

Other forms of IP may also have a role to play. Trade marks protect distinctive signs such as words, phrases, symbols and designs that identify the origin of a product. This helps consumers identify products with preferred characteristics, such as a specific brand of herbal medicine. Trade mark rights are established through registration or use in commerce. Trademarks have been used to commercialise products based on traditional medical knowledge, such as Truong Son Balsam, a traditional herbal ointment from Vietnam. However, although they can help distinguish authentic products, trademarks do not prevent other people from using traditional knowledge without the trademark or under a different one. Trademarks cannot be used to protect traditional medical knowledge itself.¹⁷

A geographical indication is another type of IP right that can help identify the origin of products. Geographical indications identify products as having characteristics associated with their place of origin. However, while geographical indications can be used to distinguish products based on traditional medical knowledge particular to a locality, geographical indications cannot protect against the same use of traditional medical knowledge not associated with a place. The way in which geographical indications are protected varies from one country to another, and may require registration or use in commerce. As with trademarks or geographical indications can only be used to protect products based on traditional medical knowledge and not the knowledge itself.¹⁸

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 the Protection and Promotion of Traditional Thai Medicinal Intelligence protects "formulae" of traditional Thai medicines and "texts on traditional Thai medicine". Only people who have registered their IP rights can research, develop and produce medicines using traditional medical knowledge. At international level, the international legal instrument on the protection of traditional knowledge negotiated by the

¹⁶ Gehl Sampath, Padmashree. "Intellectual Property Rights on Traditional Medicinal Knowledge: A Process-Oriented Perspective." *J. World Intell. Prop.* 7 (2004): 711.

¹⁷ Alamgir, A. N. M., and A. N. M. Alamgir. "Intellectual Property Right (IPR), Traditional Knowledge (TK) and Protection of Traditional Medical

Knowledge (TMK)." *Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy* (2017): 515-528.

¹⁸ The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), www.wipo.int/ik/en/igc/index.html.



WIPO IGC would have a sui generis orientation.¹⁹

Documentation

Documenting traditional knowledge includes recording it, describing it, photographing and filming its applications - everything that preserves it in an accessible form. It is different from the traditional ways of preserving and transmitting knowledge in a community, and can promote or harm a community's interests, depending on how the documentation is done. Important IP rights can be strengthened or lost when traditional knowledge is documented. The Digital Library of Traditional Knowledge (BDCT), set up under the auspices of the Council of Scientific and Industrial Research (CSIR) of India and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) (Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy), catalogues existing literature related to four systems of traditional Indian medical knowledge - Ayurveda, Unani, Siddha and Homeopathy. Yoga. The BDCT provides patent examiners with information on prior art in a digitised format in five international languages (German, Spanish, French, English and Japanese) to prevent patents from being granted improperly. The BDCT is not open to the public and patent administrations should not reveal the contents of the BDCT to

third parties in order to protect India's interests against possible misuse.²⁰

Documenting traditional medical knowledge can be useful for the defensive protection of traditional medicine, for example through the disclosure of usable information in prior art research aimed at preventing the granting of 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 undertaken without the availability of an IP strategy. The draft WIPO Instruments for the Documentation of Traditional Knowledge offers practical guidance on how to address IP-related difficulties and issues before, during and after documentation work.²¹ Other options could form part of the global list of instruments designed to protect traditional medical knowledge.²²

Conclusion

Customary laws and practices can define custodial rights and obligations for traditional medical knowledge, including obligations to protect it from misuse and abusive disclosure. These laws and practices can determine how traditional medical knowledge should be used, how benefits should be shared and how conflicts should be resolved, as well as many other aspects of preserving, using and exercising knowledge. Contracts are another instrument that can be used to

¹⁹ Arihan, Okan. "Traditional medicine and intellectual property rights." *Journal of Faculty of Pharmacy of Ankara University* 36.2 (2007): 135-152.

²⁰ Database of legislative texts on the protection of traditional knowledge and traditional cultural expressions and legislative texts related to genetic resources, www.wipo.int/tVen/legal/texts

²¹ WIPO Intergovernmental Commission on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), www.wipo.int/tk/en/igc/index.html.

²² O'Connor, Bernard. "Protecting traditional knowledge: an overview of a developing area of intellectual property law." *J. World Intell. Prop.* 6 (2003): 677.



protect traditional medical knowledge.
The granting of IP rights and access to
traditional medical knowledge are based
on prior informed consent and benefit
sharing are pivotal.
