6 | OWNING UP TO OWNING TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS

Josef A. Brinckmann

Introduction

This chapter examines the commodification and globalization of traditional botanical foods and medicines within a context of traditional knowledge (TK). Specifically, the TK that informs local management of eco-climatic regions for the sustainable harvesting, use and trade of medicinal and aromatic plants (MAPs) that possess a quantifiably unique composition, quality and biological activity. Unique nutritional and medicinal characteristics of certain MAPs can be attributed to influences of their natural habitat coupled with traditional agricultural and collection practices including specific methods of post-harvest processing and preparation. Who holds this TK and how is it transmitted? Who else has access to the TK and who benefits from its application? – local, rural and indigenous communities, for-profit corporations, research institutions, the state, or some combination of stakeholders?

There is a growing body of literature suggesting a rapid disappearance of TK (not being transmitted to next generation) and thus an urgent call to preserve and protect such knowledge for important reasons. Reasons include the notion that TK enables local food security and health security, informs global strategies for biodiversity conservation and climate change adaptation, and provides leads for new drug discovery to cure, mitigate or treat diseases, among other uses. In October 2015, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) decided to continue working towards reaching an agreement on an international legal instrument relating to intellectual property (IP) protection of genetic resources (GRs), TK and traditional cultural expressions (TCEs).[1] There are some national legal instruments for IP protection of TK

and GRs. For example both India and Peru have agencies charged with preventing and challenging patents alleged to be based on "their" GRs and associated TK. Peruvian regulations have made illegal the export of viable planting stock of certain medicinal GRs that are considered to be a national heritage. Furthermore, certain native plant species are afforded some protection under "protected designation of origin" (PDO) rules in the IP context. To illustrate, this chapter provides a comparison of the Indian and Peruvian systems along with information on voluntary sustainability standards (VSS) that can be used to demonstrate compliance with international agreements on access and benefit sharing (ABS). It concludes with a brief case study summarizing successes and failures of efforts to "own" the GR and associated TK of the Peruvian medicinal plant known as maca (*Lepidium meyenii* WALPERS; Fam: Brassicaceae).

TEK + TMK = $$??

Throughout history, as a matter of survival, local, rural and indigenous communities developed natural resource management strategies for food security, health security and water security. A comprehensive inventory and knowledge of the whole ecosystem of which a community or tribe is itself a part was essential to long-term survival. For example, knowing what plant parts and animal parts are edible, nutritional, medicinal, poisonous or toxic, specific methods on how, when and where to harvest, post-harvest processing and preparation of traditional foods and medicines. Although, in various literature, traditional management systems are subdivided into specialized types of TK such as indigenous (local or traditional) knowledge (IK), traditional ecological knowledge (TEK) also referred to as indigenous ecological knowledge (IEK), and traditional medical knowledge (TMK), there is considerable overlap in definitions and applications of these types of TK.

TEK has been defined as "a cumulative body of knowledge, practice and belief evolving by adaptive processes and handed down through generations by cultural transmission, about the relationship of living beings (including humans) with one another and with their environment."[2] For its definition of TMK, the World Intellectual Property Organization (WIPO) incorporates the World Health Organization (WHO) definition of 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.

WIPO further elaborates, that in this context, the term "Traditional" means "the knowledge is created in a manner that reflects community traditions; it is often intergenerational and created and held collectively."[3] Dr. Sita Reddy, cultural sociologist at the Center for Folklife and Cultural Heritage, Smithsonian Institution, has suggested that "ownership and control over TMK and biodiversity have become the new realities and tropes of medical globalization."[4] And leave it to the World Bank to provide a working definition for IK:

> Indigenous knowledge is unique to every culture and society. It is the basis for local decision-making in agriculture, health, natural-resource management and other activities. Indigenous knowledge is embedded in community practices, institutions, relationships and rituals. Indigenous knowledge is part of everyday life, such as herbal medicines, acupuncture etc.[5]

These types of TK, essential for survival throughout history, are increasingly viewed as non-essential in the daily life of people today due to the phenomena of commodification and globalization of everything and mass urbanization. At the same time, significant value has been placed upon the preservation of TK which many researchers warn is at risk of not being transmitted to the next generations.[6] The reported decreasing transmission of TK may be due, in part, to an unprecedented global mass migration of young people from rural to urban centers.[7] It may also be due to modernization in rural areas with increasingly easier access to packaged products coupled with disinterest in TK by the younger generations.[8] There is, however, an emerging counter-narrative suggesting an actual increase in cultural plant knowledge associated with migration. For example a recent study found that cultural knowledge about medicinal plants was greater in Dominicans living in New York City compared to those living in the Dominican Republic.[9] Despite a general trend of TK erosion

worldwide, some TK systems may be resilient to modernization, if adaptive to change (not fossilized), and could persist in communities situated in both "developing" and "developed" countries.[10]

In either case, TK may still provide solutions to big problems facing humans and the planet today. For example there is a growing body of literature suggesting that TK may be important in areas of climate change adaptation,[11] preventing ecosystem collapse and loss of biodiversity,[12] local food and health security,[13] and new drug discovery to cure, mitigate or treat diseases.[14] Gómez-Baggethun et al. assert that TEK, as a component of biocultural heritage, is intrinsic to biodiversity conservation, ecosystem services, and to building community resilience.[15] TEK helps to build resilience in social-ecological systems by promoting biocultural diversity (the interconnected links between biological, cultural and linguistic diversity). Biocultural diversity, developed over many generations of experience of dealing with disturbance, can be viewed as an asset for climate change adaptation strategies. The study carried out by Ahmad et al. showed that rapid urban development in India has been a leading cause of habitat destruction (change of land use for city development, deforestation, highway construction).[16] The result is a significant loss in the diversity of certain medicinal plant species that are widely used in the Indian systems of traditional medicine such as in Ayurveda, Unani and Siddha medicines as well as in folk and tribal medicines. As a solution they suggest a conscious move to sustainable development methods with nature conservation as a component, paying special attention to certain medicinal plant species and their long-term survival thus helping to preserve entire ecosystems. In new drug discovery research, Jantan et al. report that while prioritization of medicinal plant species based on TK serves as an initial biological activity screening step, very little time remains due to the rapid ongoing devastation of tropical rainforest ecosystems.[17] While the number of plant species screened for potential new medical uses thus far is very small (less than 5 percent), Jantan et al. state that the Nagoya Protocol on the Convention on Biological Diversity (on access to GRs and the fair and equitable sharing of benefits) "should encourage more pharmaceutical firms to venture into natural research to discover new drug leads."[18] Screening the other 95 percent of species, however, could take decades while their habitats may be destroyed in the meantime.

Somewhere in all of this there is money to be made. To determine who is allowed to gain financially from commercial use of such TK and who isn't, the concept of ownership comes into question. While TK has become the subject of IP regulations and international agreements such as the Nagoya Protocol on Access and Benefit-sharing,[19] for TK to be protected and to serve as a repository of useful information for survival of species and the planet, does an individual, entity, organization or the state really need to "own" the specified TK?

Precisely to this point, Caruso and Grace provide salient points about the problem of IP law itself being a product of "European ontologies, epistemologies and legal frameworks":

> Indigenous peoples claim that their knowledge, traditions, artistic expressions, and associated practices are indivisible, and that this body of collective biocultural heritage is connected to all aspects – spiritual, intellectual, physical, emotional, cultural, social, economic, political, etc. – of their individual and collective lives. Furthermore, this intangible cultural heritage cannot be understood as "owned" or "invented" by a particular person or group, as indigenous peoples often define themselves as custodians of knowledge and resources that have been bestowed upon them through spiritual means.[20]

In the India context, there are 705 scheduled tribes comprising 8.6 percent of India's total population whilst public and common lands account for nearly one-fifth of India's total geography.[21] Nagendra pointed out that indigenous community institutions have historically served to manage and protect biodiverse forests due to their belief in sacred spirits. These indigenous institutions, however, are insufficiently recognized by the state. Thus their ability to continue protecting forest ecosystems is threatened in the wake of rapid urbanization. Concerning India, political economist Elinor Ostrom (1933–2012) believed that polycentricity would be necessary to effectively manage the commons.[22] The concept of polycentricity has been defined as a "structural feature of social systems of many decision centers having limited and autonomous prerogatives and operating under an overarching set of rules."[23]

Examples of state actors: INDECOPI / NCAB and TKDL

Some nations have established mechanisms for the "protection" of TK such as the Peruvian National Commission against Biopiracy (NCAB), an interagency coordination and technical advisory body chaired by the National Institute for the Defense of Free Competition and Protection of Intellectual Property (INDECOPI). Another example is the Government of India's Traditional Knowledge Digital Library (TKDL), a collaborative project of the Council of Scientific and Industrial Research (CSIR) and the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH).

The focus of these governmental projects has been primarily to challenge patents misappropriated to "inventors" based on documented prior art of TEK and/or TMK. But there are also cases of patents being challenged based on the inventors' use of illegally obtained GRs. For example, there are Chinese patents involving Peruvian maca being cultivated in China without agreements on access and/or material transfer from Peru.[24] Here below, similarities and differences between the Peruvian and Indian systems are summarized. One apparent point of difference is that the Peruvian system includes a clear mechanism for the state to facilitate collective ownership of GRs and associated TK by indigenous peoples or rural communities. The Indian system assumes that TK attributed to the codified Indian systems of medicine (Ayurveda, Siddha, Unani, and Yoga) is owned by the state.

INDECOPI and NACB The mission of NCAB is to "develop actions to identify, prevent, and avoid potential cases of 'biopiracy' with the objective of protecting the interest of the Peruvian State."[25] NCAB membership includes governmental organizations, NGOs, research institutions and business associations, and is chaired by INDECOPI. For context, it is useful to review a timeline of significant actions taken by the Peruvian government since 1992 as they pertain to the maca root case study discussed later in this chapter:

- 1992: Through an executive order, INDECOPI was founded with one of its main functions to protect Peruvian IP from trademarks, copyrights, patents and biotechnology.

- 1997: Peruvian Law No. 26839 provided for conservation and sustainable use of biodiversity with measures for enforcement of IP laws concerning GRs and TK.[26]
- 2002: Peruvian Law No. 27811 made provisions for INDECOPI to manage a national registry for the preservation of collective knowledge of indigenous peoples related to biodiversity. Under this law, Peruvian indigenous peoples are to be protected against unfair access to their TK without informed consent. Indigenous groups can negotiate license agreements for access to and use of their TK and not less than 10 percent of sales of products based on their TK is to be earmarked for deposit into a trust fund called the Indigenous Peoples Development Fund.[27]
- 2003: Two presidential decrees were enacted, firstly Decreto Supremo No. 039-2003-AG prohibited the export of seeds or vegetative plant material of maca (*Lepidium meyenii*) as well as unprocessed maca raw materials.[28] The related Decreto Supremo No. 041-2003 provided definition to the processed, value-added forms of maca that may be exported legally.[29]
- 2004: Peruvian Law No. 28216 created a National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of Indigenous Peoples, also known as the National Commission against Biopiracy (NCAB), which is chaired by INDECOPI.[30]
- 2011: INDECOPI issued a "Designation of Origin" specification for Maca Junín-Pasco, i.e. maca that is cultivated and produced in specified geographic zones and altitudes within the provinces of Junín and Pasco.
- 2012: INDECOPI registered its Maca Junín-Pasco as an "Appellation of Origin" through the World Intellectual Property Organization.[31]

Peruvian Law No. 27811 is a *sui generis* law. *Sui generis*, meaning "a special kind," refers to an IP protection regime outside of the Western concept of individual property ownership. Because TEK and TMK are premised on a concept of community ownership, this special form of protection can be applied for TK associated with certain GRs.[32] As per Peruvian Law No. 27811, indigenous peoples or rural communities may submit an application to INDECOPI in order to register certain collective knowledge related to a GR (such as the TK of maca

root) in the National Register of Collective Knowledge of Indigenous Peoples. Within the national register there are three traditional knowledge registers: confidential, local and public. The public register serves as an instrument to prevent biopiracy. Indigenous peoples granted TK registrations through this system include the Aguaruna, Ashaninka, Bora, Ocaina and Shipibo Conibo, among others.[33] As of 2014 there were 2,226 entries or registries of TK in Peru's national register; 844 public and 1,422 confidential.[34] Concurrently, the NCAB has examined thousands of patent documents for possible cases of biopiracy including, as of 2013, 2,800 concerning yacón (*Smallanthus sonchifolius* (Poepp.) H.Rob.; Fam.: Asteraceae), 2,229 for tara (*Caesalpinia spinosa* (Molina) Kuntze; Fam.: Fabaceae), 555 for uña de gato (*Uncaria tomentosa* (Willd. ex Schult.) DC.; Fam.: Rubiaceae), and 550 patent documents concerning maca (*Lepidium meyenii* Walpers; Fam.: Brassicaceae), among several other prioritized Peruvian GRs.[35] The NCAB has prioritized 35 economically important Peruvian GRs for biopiracy research and actions. Dossiers are being prepared on these which are provided to IP offices in third countries as well as studies outlining potential cases of biopiracy and prior art. NCAB has also provided contributions to the IGC. As of 2014 NCAB data has contributed to the rejection, abandonment or withdrawal of nine patents involving Peruvian GRs and associated TK.[36] At the time of this writing (January 2016), NCAB had made ten completed dossiers publicly available at their website, including one prepared for maca, which also includes quantifications of maca-based patents filed globally, sorted by patent office, by year of filing, by applicant, by country and by class and subclass.[37]

TKDL The government of India's establishment of the Traditional Knowledge Digital Library (TKDL) in 2001 facilitated a registry for TMK of India's codified and scholarly systems of medicine and health care, namely Ayurveda, Siddha, Unani and Yoga as prior art.[38] The TKDL database of medicinal formulations used in the Indian systems of medicine is made freely available to patent examiners; as scanned books along with translations from the original Sanskrit, Urdu, Arabic, Persian or Tamil, etc., into English, French, Spanish, German and Japanese.

At the time of this writing (January 2016), the TKDL website showed that, through the European Patent Office alone, 89 patent

applications had been withdrawn, 4 refused, and 36 applicants had amended or modified claims due to TKDL prior art evidence. Thirty-seven patent applications had been declared "dead" by the Canadian Intellectual Property Office (CIPO) due to TKDL evidence. Eleven claims had been rejected by the US Patent and Trademark Office (USPTO) and another 14 claims amended or modified due to TKDL prior art evidence. Even in India, some patent applications submitted by governmental research organizations, for example by the Central Council for Research of Ayurveda and Siddha, had been refused.[39]

Then there is TMK that stems from India's non-codified folk and tribal medicines, which is largely undocumented (oral tradition) and thus falls outside the scope of the TKDL database mechanism. Such TMK therefore remains unprotected from biopiracy.[40] Furthermore, the question has been raised about TMK that is now claimed to be part of the Indian systems of medicine that may have existed prior to the advent of Ayurveda, and therefore may be the "community property" of certain tribal groups from whom the TMK was appropriated long ago into the eventually codified system of Ayurveda.

According to Deekshitha Ganesan, LLB, "TKDL remains a defensive protection of traditional knowledge that does not fully ensure that the benefits of the information reach its original holders as far as possible." Ganesan suggests that "*sui generis*" protection for TK is needed and that India should adopt a framework similar to that of Peru so that local communities can benefit from the use of their TK by third parties.[41]

With that said, India does have a framework for access to GRs for commercial utilization and sharing benefits arising out of such access. As per India's Biological Diversity Act 2002, companies may submit an application to the National Biodiversity Authority (NBA) for approval to use an Indian GR and its associated TK. The NBA may grant such approval if there is agreement from the relevant State Biodiversity Board (SBB) and only if mutually agreed terms and an equitable benefit sharing agreement has been reached between the applicant and the "resource owners."[42]

VSS that require ABS

The implementation of voluntary sustainability standards (VSS) that include economic, environmental and social criteria and

indicators is an emerging market-based approach to biodiversity conservation, sustainable harvesting and commercial use of MAPs, and to demonstrate compliance with international agreements. While such standards are voluntary, in that compliance is not required by governmental regulations, independent third-party inspection and certification organizations determine if companies are operating in compliance with the standard.[43]

Some VSS contain access and benefit sharing (ABS) requirements. ABS refers to benefit sharing as per the Convention on Biological Diversity (CBD) for the use of GRs and associated TK. The objective of the Nagoya Protocol on Access and Benefit-sharing, an international instrument for the implementation of ABS provisions of the CBD, is the fair and equitable sharing of benefits arising from the sustainable use of GRs, which theoretically should contribute to biodiversity conservation.[44] ABS has become a significant point to consider for businesses in the growing international market for traditional herbal medicinal products (THMPs) and other natural health products (NHPs). That is because TMK is central to product development and for documentation of the safety and efficacy evidence requirements for companies to obtain marketing authorization from national authorities.[45] This is also a market that attorneys are paying attention to. In 2016, capacity building courses on Nagoya Protocol implementation and enforcement, aimed at lawyers and policy officials, were launched jointly by the International Development Law Organization (IDLO) and the Secretariat of the Convention on Biological Diversity (SCBD). The course emphasizes that "Genetic resources are the raw ingredients for innovation in medicine, biotechnology, cosmetics, food and beverages, and more."[46]

One way for an enterprise to demonstrate compliance with the ABS requirements of the Nagoya Protocol is to implement a relevant VSS, one that is subject to annual inspections by an accredited third-party control body. For example, VSS that include ABS requirements include the "FairWild Standard" (FWS), developed by the FairWild Foundation (FWF), and the "Ethical BioTrade Standard," developed by the Union for Ethical BioTrade (UEBT). Criterion 4.2 of the FWS, titled "Respecting Customary Rights and Benefit-Sharing," requires that agreements made with local communities and/or indigenous peoples are executed in compliance

with relevant international and national laws and ABS regulations including protection of TK.[47] Written and mutually accepted fair and equitable agreements on use of GRs and associated TK must be in place to maintain FairWild certification.[48] Section 3 of the "Ethical BioTrade Standard," titled "Fair and Equitable Sharing of Benefits Derived from the Use of Biodiversity," includes comparable requirements.[49] Some of the largest processors and traders of medicinal plant ingredients in Europe and a growing number of finished herbal product brand-holders in Europe and the Americas are participating in the FairWild and Ethical BioTrade initiatives, respectively.

The case of Peruvian maca

Maca root (actually the "hypocotyl" of *Lepidium meyenii* WALPERS of the Brassicaceae family), an herbaceous perennial, was, up until recently, grown only on the Andean central sierra of Peru, in the puna agroecologic zone above 4,000 meters above sea level, for example in the regions of Junín and Pasco.[50] In presentations made (by this author) at conferences in Lima, Peru in the early 2000s, it was emphasized that if the emblematic Peruvian plant maca should become internationally famous it would only be a matter of time before agronomists would find a way to illegally obtain planting material in order to begin cultivation trials in suitable high-altitude areas of eastern Asia. Recent history has shown that if global market demand for a MAP increases significantly, regardless of its geographical origin, enterprises in China in particular will be interested to control some part of that market. This was forewarned even with the knowledge that Peru has strict regulations in place that disallow the export of viable GRs that could be planted outside of Peru. Having been contacted directly by Chinese researchers requesting assistance towards (illegally) obtaining maca planting material, which I declined, the following rhetorical question was raised in a 2007 article: "Is it just a matter of time before viable maca germplasm (seeds, cell-cultured plantlets, or tubers) is smuggled from the Andes and cultivation experiments begin in the mountains of Asia?"[51]

Despite the regulations for protection of Peruvian GRs and associated TK, experimental cultivation of maca somehow began in the mountains of Yunnan province, China about ten years ago.

In 2015, this author also observed experimental maca cultivation in neighboring Sichuan province as well as in the Garzê Tibetan Autonomous Prefecture. China has increasingly become one of the main export destinations for Peruvian grown maca. In 2014, large numbers of Chinese buyers arrived in the Peruvian Andes just prior to the start of the maca harvest. They began making advance cash payments directly with farmers in order to take ownership of the entire harvest and control the market. In violation of Peruvian law, which requires value-adding of maca prior to export, an estimated 80 percent of the 2014 harvest was smuggled out (unprocessed) to China. Viable planting stock was also allegedly smuggled out of Peru. Some buyers/smugglers seen in Peru during the 2014 harvest season were reportedly armed members of crime syndicates from Hong Kong.[52] Where there is lots of money to be made from a medicinal GR that has become a high-demand and high-value economic crop, do the traders – and does the market – care about the many protections that have been put in place to protect GRs and the associated TK?

So far, NACB has been able to facilitate the rejection of five maca-based patents, three from Japan, one from the Republic of Korea and another through the WIPO Patent Cooperation Treaty (PCT) system,[53] and NACB is challenging Chinese patents on the basis that the starting materials for Chinese-grown maca was obtained illegally, i.e. smuggled, without informed consent or written agreements on access and use.[54] Furthermore, besides making illegal the export of viable unprocessed maca genetic materials, INDECOPI established a Maca Junín-Pasco geographical indication (GI).[55] According to WIPO, GI products "have a specific geographical origin and possess qualities or a reputation that are due to that origin," and a GI right "enables those who have the right to use the indication to prevent its use by a third party whose product does not conform to the applicable standards." In practice, how can these national and international protections work if there are actors in third countries who will apparently disregard the entire notion of GRs and associated TK being IP subject to the terms of international agreements?

Concluding remarks

Depending on who you ask, there are 195 to 206 independent states in the world, of which 193 are member states of the United

Notes

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