

# Documenting Traditional Medical Knowledge

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**Prepared by**

**Ryan Abbott, M.D., J.D., M.T.O.M.**

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Readers are invited to consult also the Consultation Draft of the World Intellectual Property Organization Traditional Knowledge Documentation Toolkit, available at:

[http://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),

and the Background Briefs prepared by the WIPO Secretariat, available at:

<http://www.wipo.int/tk/en/resources/publications.html>.

# CONTENTS

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<b>Executive Summary</b> .....	<b>1</b>
<b>List of Abbreviations</b> .....	<b>2</b>
<b>I. Introduction to Traditional Medical Knowledge</b> .....	<b>3</b>
1. Traditional Knowledge.....	3
2. Traditional Medicine .....	3
Traditional Chinese Medicine (TCM).....	4
3. Complementary and Alternative Medicine .....	4
4. Characteristics of Traditional Medicine .....	4
5. Importance of Traditional Medicine for Indigenous Peoples and Local Communities .....	5
<i>Cordyceps Sinesis</i> in Tibet .....	5
Magic and Medicine in Zimbabwe .....	6
<b>II. Traditional Medicine Use</b> .....	<b>7</b>
1. Traditional Medicine Worldwide.....	7
2. Safety Issues .....	7
Good Manufacturing Practices.....	8
Misuse of <i>Ephedra Sinica</i> in the United States of America .....	9
3. Big Business and New Drug Development.....	9
Malaria and Herbal Medicine.....	10
4. Exporting Traditional Medicine .....	11
5. Misappropriation.....	12
Turmeric in the United States of America.....	12
<b>III. National and International Policies on Traditional Medicine</b> .....	<b>13</b>
1. Beijing Declaration.....	13
Excerpts from the Beijing Declaration .....	13
2. National Policies on Traditional Medicine .....	14
3. Cultural Policies and Human Rights .....	14
Excerpts from the United Nations Declaration on the Rights of Indigenous Peoples.....	15
<b>IV. Regulation of Traditional Medicine</b> .....	<b>16</b>
1. Data Exclusivity.....	16
2. Regulation in the United States of America.....	16
Fusing Science and Tradition .....	18
3. Regulation in the European Community .....	18
4. Regulation in China .....	20

5. Regulation in India .....	21
6. Regulation in Brazil.....	21
7. Traditional Systems of Regulation .....	22
<b>V. Intellectual Property and Traditional Medicine .....</b>	<b>23</b>
1. Intellectual Property Rights .....	23
“Hot Yoga” Controversy.....	24
2. Obstacles to Protecting Traditional Medicine .....	25
3. Evolution of Intellectual Property Protection.....	26
4. <i>Sui Generis</i> Regimes .....	27
5. The Public Domain .....	28
Kava .....	29
6. Ownership of Intellectual Property Rights.....	29
Mijikenda Ownership of Traditional Knowledge.....	30
<b>VI. Considerations for Documenting Traditional Medicine .....</b>	<b>32</b>
1. Benefits and Risks of Documentation.....	32
The Traditional Knowledge Digital Library (TKDL).....	33
2. Additional Considerations for Documentation .....	33
3. Traditional Knowledge Databases .....	35
4. External Collaborations.....	36
University of Illinois at Chicago Benefit-Sharing Policy.....	37
Controversial Collaborations .....	38
<b>VII. Practical Strategies for Documentation.....</b>	<b>39</b>
1. Before Documentation .....	39
Lost Opportunities in Brazil.....	40
Pre-Documentation Checklist.....	43
2. During Documentation .....	43
During documentation Checklist .....	44
3. After Documentation.....	45
First Nations Confidentiality Management.....	46
Post-Documentation Checklist .....	47
About the Author.....	48
Acknowledgements.....	48

## EXECUTIVE SUMMARY

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Traditional medical knowledge is experiencing increased attention worldwide in light of global health care demand and the significant role of traditional medicine in meeting the public health needs of developing countries. Traditional medicines already comprise a multi-billion dollar, international industry, and the biomedical sector is increasingly investigating the potential of genetic resources and traditional knowledge. Documenting and protecting these medicines is becoming a greater priority.

Traditional knowledge has historically been at odds with modern intellectual property systems designed to protect innovations such as new pharmaceutical drugs. However, as the financial value of many forms of traditional medicine becomes recognized, traditional knowledge holders and nations rich in genetic resources are arguing for greater protection through non-conventional systems of intellectual property protection. Traditional knowledge holders are increasingly demanding fair and equitable distribution of benefits from the commercialization of traditional medicine, as well as the prior informed consent of indigenous peoples to prevent misappropriation.

Many problems associated with the protection of traditional medical knowledge lack clear solutions. In attempting to protect traditional medicine, traditional knowledge holders are confronted by a confusing and diverse group of national and international policies, regulatory systems designed primarily to accommodate pharmaceutical medicines, safety and efficacy concerns, and challenges to ownership.

This text is designed to assist traditional medical knowledge holders, government representatives and third-party collaborators to think about issues of intellectual property law specifically related to traditional medical knowledge. It is not intended to provide legal advice, but rather to help stimulate thinking about traditional knowledge and to provide illustrative case studies.

There is no generic way to protect traditional medical knowledge. Traditional knowledge holders should carefully consider identified community goals for the use of traditional medicine and the risks and benefits of documentation. Whether traditional medical knowledge is documented can have far reaching consequences on intellectual property protection, commercialization and promotion of traditional medicine, regulatory submissions and interactions with collaborators. It is important that traditional knowledge holders be adequately informed to safeguard their reputations and interests when interacting with third parties.

Hopefully, this text will help traditional knowledge holders better understand the issues related to traditional medicine and intellectual property and make informed decisions about the best use of their knowledge.

## LIST OF ABBREVIATIONS

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ABS	Access and Benefit-Sharing
CAM	Complementary and Alternative Medicine
CBD	Convention on Biological Diversity
CGEN	Council for the Management of Genetic Patrimony (Brazil)
CSIR	Council of Scientific and Industrial Research (India)
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration (United States of America)
GAO	Government Accountability Office (United States of America)
GMPs	Good Manufacturing Practices
GRs	Genetic Resources
INDECOPI	National Institute for the Defense of Competition and Intellectual Property Protection (Peru)
IP	Intellectual Property
IPC	International Patent Classification
IPO	International Patent Office
IPR	Intellectual Property Right
NCCAM	National Center for Complementary and Alternative Medicine (United States of America)
NDA	New Drug Application
SATCM	State Administration of Traditional Chinese Medicine (China)
SFDA	State Food and Drug Administration (China)
SIPO	State Intellectual Property Office (China)
TCM	Traditional Chinese Medicine
TK	Traditional Knowledge
TKDB	Traditional Knowledge Database
TKDL	Traditional Knowledge Digital Library
TKRC	Traditional Knowledge Resource Classification
TM	Traditional Medicine
TMK	Traditional Medical Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNIFESP	Federal University of São Paulo (Brazil)
USD	United States of America Dollar
USPTO	United States of America Patent and Trademark Office
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

# I. INTRODUCTION TO TRADITIONAL MEDICAL KNOWLEDGE

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## 1. TRADITIONAL KNOWLEDGE

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Traditional knowledge (TK) is a difficult concept to define because it encompasses such diversity. TK, or indigenous knowledge, covers wide ranging subject areas from art to agriculture, as well as medicinal uses of plants and traditional systems of medical diagnosis. It may exist in indigenous or local communities as secret oral traditions that have been passed down over generations, but it may also be documented in publicly available written or even electronic media.

There is no generally accepted definition of TK at the international level. As a broad description of subject matter, “traditional knowledge” generally includes the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities. In other words, TK in a general sense embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with TK. “Traditional knowledge” in a narrower sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations. Traditional knowledge can be found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; and biodiversity-related knowledge.<sup>1</sup>

## 2. TRADITIONAL MEDICINE

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Traditional medicine (TM) describes a group of health care practices and products with a long history of use. It frequently refers to medical knowledge developed by indigenous cultures that incorporates plant, animal and mineral-based medicines, spiritual therapies and manual techniques designed to treat illness or maintain wellbeing.<sup>2</sup> TM tends to be practiced outside of allopathic medicine (also known as biomedicine, conventional or Western medicine), which is the dominant system of medicine in the developed world. In many cultures, TM functions as a comprehensive system of health care refined over hundreds or even thousands of years. Some of the best-known TM systems include traditional Indian (Ayurveda) medicine, traditional Chinese medicine (TCM), and traditional Arabic (Unani) medicine.

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.”<sup>3</sup>

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<sup>1</sup> WIPO’s current working definition of traditional knowledge, “refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and any traditional knowledge associated with genetic resources.” World Intellectual Property Organization [WIPO], Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, WIPO/GRTKF/IC/20/INF/7, Annex, page, (January 10, 2011).

<sup>2</sup> World Health Organization [WHO], “Fact Sheet No. 134: Traditional Medicine,” (May 2003), available at <http://www.who.int/mediacentre/factsheets/fs134/en/>.

<sup>3</sup> WHO, “Traditional Medicine: Definitions”, WHO/EDM/TRM/2000.1, 2000, available at <http://www.who.int/medicines/areas/traditional/definitions/en/>.

## TRADITIONAL CHINESE MEDICINE (TCM)

TCM is one of the most widely used and studied systems of traditional medicine.<sup>4</sup> TCM, like many other forms of traditional medicine, differs from allopathic medicine in more than its techniques. It is modeled on a fundamentally different way of looking at health and disease.

Practitioners of TCM utilize a unique system of diagnosis that includes a comprehensive history of symptoms to arrive at an underlying disharmony.<sup>5</sup> Treatments focus on increasing the body's natural defenses through acupuncture, herbal medicine and physical manipulation. TCM considers that mind, body, spirit and the external environment all have a strong role in creating health or disease. Patients are made active participants in their own care through recommendations for lifestyle changes, body-mind exercises such as Tai Chi and Qi Gong, and nutrition and dietary therapy.

### 3. COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and alternative medicine (CAM) describes a group of health care systems, practices and products not presently considered to be part of allopathic medicine.<sup>6</sup> CAM includes traditional medicine, as well as modern practices developed outside of indigenous communities. Sometimes the two terms are used synonymously, or TM may be referred to as CAM when it is adopted outside of its traditional culture.<sup>7</sup> CAM systems and therapies may be grouped into broad categories such as natural products, mind-body medicine, and manipulative and body-based practices.<sup>8</sup>

### 4. CHARACTERISTICS OF TRADITIONAL MEDICINE

TM practices, particularly whole medical systems such as TCM, share many of the same core values.<sup>9</sup> These practices tend to be characterized by a holistic and highly individualized approach to treatment, an emphasis on maximizing the body's inherent healing ability, involving patients as active participants in their own care, addressing physical, mental, and spiritual attributes of a disease, and placing a strong emphasis on prevention and wellness.<sup>10</sup>

At the same time, TM practices display considerable diversity and can vary significantly between regions. TM therapies involve assorted levels of training and have different degrees of evidence-base and efficacy. In addition, TM practices are governed by a heterogeneous group of state and national policies and regulations and have a variety of associated cultural beliefs.

As opposed to relatively modern CAM practices, traditional medicines have the benefit of substantial prior clinical use as well as stronger cultural associations. This can

<sup>4</sup> WHO, WHO Traditional Medicine Strategy 2002-2005, WHO/EDM/TRM/2002.1, 2002 [hereinafter WHO TM Strategy].

<sup>5</sup> See generally Giovanni Maciocca, *The Foundations of Chinese Medicine: A Comprehensive Text for Acupuncturists and Herbalists* (Elsevier 1989).

<sup>6</sup> National Center for Complementary and Alternative Medicine, National Institute of Health, *What is Complementary and Alternative Medicine?* (2010), <http://nccam.nih.gov/health/whatiscam/>.

<sup>7</sup> WHO, Beijing Declaration, [http://www.who.int/medicines/areas/traditional/congress/beijing\\_declaration/en/index.html](http://www.who.int/medicines/areas/traditional/congress/beijing_declaration/en/index.html).

<sup>8</sup> NCCAM, *What is Complementary and Alternative Medicine?* Supra note 6.

<sup>9</sup> Iris R. Bell et al., *Integrative Medicine and Systemic Outcomes Research*, 162 *ARCHIVES INTERNAL MED.* 133-140, 133 (2002).

<sup>10</sup> Ryan B. Abbott et al., *Medical Student Attitudes Toward Complementary, Alternative, and Integrative Medicine, Evidence Based Complementary and Alternative Medicine*, vol. 2011, Article ID 985243, 14 pages, 2011, at 1.

provide evidence of safety and efficacy and result in traditional medicine being more readily accepted by some populations.<sup>11</sup>

WHO has acknowledged that “traditional, complementary, or alternative medicine has many positive features, and that traditional medicine and its practitioners play an important role in treating chronic illnesses, and improving the quality of life of those suffering from minor illness or from certain incurable diseases.”<sup>12</sup>

## 5. IMPORTANCE OF TRADITIONAL MEDICINE FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES

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Traditional medicine is not only a vital source of health care, but also an important source of income for many communities. Traditional medicine may even form an integral part of a community’s identity.

Pre-industrial communities have been responsible for the discovery of most of the medicinal plants in use today, and many communities are still involved in the wild collection, domestication, cultivation and management of medicinal plant resources.<sup>13</sup> This economic activity supports many indigenous peoples and local communities, a benefit that in turn provides incentives for the conservation of TM. While some medicinal plants are cultivated commercially, most continue to be collected from the wild.<sup>14</sup>

### *CORDYCEPS SINESIS* IN TIBET

*Cordyceps sinensis* is an herbal medicine used as a general tonic and aphrodisiac in systems of traditional Asian medicine such as TCM.<sup>15</sup> The herb is a parasitic fungus that feeds primarily on insects such as caterpillars. When spores come into contact with a germinating caterpillar the fungus will invade the caterpillar’s body, killing the insect and replacing the host tissue.

Gathering this herb represents the primary source of income for many Tibetans,<sup>16</sup> and it has become a more significant source of income as growing international demand has caused *Cordyceps* prices to rise substantially over the past twenty years.<sup>17</sup> The Tibetan *Cordyceps* harvesting season begins in April and lasts until the end of June, during which time gatherers comb ground in the wild for *Cordyceps* to extract.<sup>18</sup> The herb is difficult to see and gathering requires concentration and patience.

Demand for *Cordyceps* has recently declined due to the global economic crisis, and this may have a harmful effect on Tibetan communities. Lack of infrastructure for sustainable harvesting may also have a negative long term economic impact.

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<sup>11</sup> Directive 2004/24/EC, 2004 O.J. (L 136) 85, amending, as regards traditional herbal medicinal products, Directive 2001/83/EC. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0085:0090:EN:PDF>.

<sup>12</sup> Fifty Sixth World Health Assembly, Agenda item 14.10, Traditional Medicine, WHA56.3, May 28, 2003 at 1, available at [http://whqlibdoc.who.int/wha/2003/WHA56\\_31.pdf](http://whqlibdoc.who.int/wha/2003/WHA56_31.pdf).

<sup>13</sup> See generally World Health Organization et. al, [WHO/IUCN/WWF], Guidelines on the Conservation of Medicinal Plants, 1993, available at <http://apps.who.int/medicinedocs/documents/s7150e/s7150e.pdf>.

<sup>14</sup> Kjitendra Srivastava et Al., World Bank Technical Paper n° 320, Medicinal Plants: An Expanding Role in Development, (The World Bank, 1996) at 1.

<sup>15</sup> Dan Bensky et Al., Chinese Herbal Medicine Materia Medica, 3rd edition, 772-775 (Eastland Press 2004).

<sup>16</sup> Daniel Winkler, Yartsa Gunbu (*Cordyceps sinensis*) and the fungal commodification of Tibet’s rural economy, 62 Economic Botany 291-305 (2008).

<sup>17</sup> Alessandro Boesi, The dbyar rtswa dgun 'bu (*Cordyceps sinensis* Berk.): an important trade item for the Tibetan population of the Lithang Country, Sichaun Province, China, 27 The Tibet Journal 29-42 (2003).

<sup>18</sup> Alessandro Boesi and Francesca Cardi. *Cordyceps Sinensis* Medicinal Fungus Traditional Use among Tibetan People, Harvesting Techniques and Modern Uses. 83 HerbalGram 53-61, 54 (2009).

Indigenous peoples and local communities may possess knowledge related to harvesting and preparing herbs, as well as knowledge on medicinal use. This information can be invaluable, not only to the indigenous peoples and local communities who have historically used herbal medicines, but also for any attempt to export and use medicine outside of its traditional environment.

TMK may also contribute to a community's way of life and spiritual beliefs. For example, traditional African medicine is characterized by a holistic world-view that embraces people, animals, plants, and inanimate objects in an inseparable whole from which all beings derive their life force.<sup>19</sup> Traditional African medicine may involve spiritual healing, a process thought to be mediated through spiritual or divine powers. The majority of people in Africa living with HIV/AIDS depend on traditional healers and herbal treatments for psychosocial counseling and health care.<sup>20</sup>

### MAGIC AND MEDICINE IN ZIMBABWE

In Zimbabwean traditional medicine, therapeutic herbs are considered supernatural.<sup>21</sup> However, magical properties only become effective when a healer incorporates a system of rituals, divinations and symbols into treatment. In addition to the traditional healer, the entire local society plays a role in the effectiveness of the healing magic.

Access to the traditional medical system begins when a healer selects a family member to assist in practice.<sup>22</sup> The apprenticeship teaches a future practitioner how to identify, prepare and use traditional herbs, a system for diagnosing and treating illness, and lessons in cultural and social practices. Elders grant access to TMK through ceremonies where knowledge is revealed as a gift. While general knowledge of the healing properties of medicinal plants may be widespread, only a select group of trained practitioners knows exactly how herbs are used in the traditional system.

<sup>19</sup> Jaco Homsy et al, Defining minimum standards of practice for incorporating African traditional medicine into HIV/AIDS prevention, care, and support: a regional initiative in eastern and southern Africa, 10 *The Journal of Alternative and Complementary Medicine* 905-910 (2004).

<sup>20</sup> UNAIDS, *Ancient Remedies, New Disease: Increasing Access to AIDS Prevention and Care in collaboration with traditional healers*, (June 2002), at 7.

<sup>21</sup> World Bank, *Cultural rights for Zimbabwe's Sui Generis Legislation - Emphasizing symbolic practice related to traditional medicinal knowledge*, IK Notes No. 57, June 2003, at 2. Available at <http://www.worldbank.org/afr/iknt57.pdf>.

<sup>22</sup> *Id.* at 2.

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## II. TRADITIONAL MEDICINE USE

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### 1. TRADITIONAL MEDICINE WORLDWIDE

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The last two decades have witnessed globally renewed interest in the use of traditional and complementary and alternative medicine. A recent study of CAM use in the U.S. population reported that in 2007, almost 4 out of 10 adults had used some form of CAM within the past year.<sup>23</sup> It was estimated that Americans spent 33.9 billion U.S. dollars (USD) out-of-pocket on CAM products and services during the prior year, accounting for 11.2 percent of total out-of-pocket health care expenditures.<sup>24</sup> In other developed nations the use of CAM is equally extensive.<sup>25</sup>

The use of traditional medicine is even more substantial in the developing world. According to data provided to WHO, in India 70 percent of the population and in Ethiopia more than 90 percent of the population depend on TM for primary health care.<sup>26</sup> It is reported that more than 70 percent of the population in Chile and 40 percent of the population in Colombia have used traditional medicine.<sup>27</sup> In China, traditional medicine accounts for approximately 40 percent of all health care delivered.<sup>28</sup>

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### 2. SAFETY ISSUES

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The use of traditional medicine presents unique public health challenges. WHO notes that "inappropriate use of traditional medicines or practices can have negative or dangerous effects" and that "further research is needed to ascertain the efficacy and safety" of many traditional medical practices.<sup>29</sup>

Traditional medicines are not necessarily safe simply because they are "natural" and have a long history of use. The use of traditional medicines may delay the use of effective allopathic treatments, and it can directly cause adverse effects. Health risks may be posed by drug-herb interactions and problems related to quality control.<sup>30</sup> To keep these risks in

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<sup>23</sup> Patricia M. Barnes et al., *Complementary and Alternative Medicine Use Among Children: United States, 2007*, 12 *Nat'l Health Stat. Rep.* 1-24, 1 (2008).

<sup>24</sup> National Center for Complementary and Alternative Medicine, *National Survey Reports on Consumer Spending for CAM Products and Services* (Jan. 2011), <http://nccam.nih.gov/health/whatisacam/>.

<sup>25</sup> WHO TM Strategy, *supra* note 4, at 11–12. According to WHO, the percentage of the population that has used CAM is 31% in Belgium, 48% in Australia, 49% in France, 70% in Canada and 77% of pain clinics provide acupuncture in Germany.

<sup>26</sup> WHO TM Strategy, *supra* note 4, at 9.

<sup>27</sup> WHO TM Strategy, *supra* note 4, at 11.

<sup>28</sup> WHO TM Strategy, *supra* note 4, at 1.

<sup>29</sup> WHO, "Fact Sheet no. 134: Traditional Medicine," (May 2003), available at <http://www.who.int/mediacentre/factsheets/2003/fs134/en/>.

<sup>30</sup> In a study of 59 dietary supplements with Echinacea, 10% were found to contain no Echinacea, and 48% of the samples with Echinacea did not contain the labeled species. CM Gilroy et al., *Echinacea and Truth in Labeling*, 163(6) *ARCH. INTERN. MED.* 699-704, 699 (2003). A different analysis of 25 ginseng herbal supplements found a 15 to 200-fold variation in the concentration of active ginseng ingredients. Martha R Harkey et al., *Variability in Commercial Ginseng Products: An Analysis of 25 Preparations*, 73 *AM. J. CLIN NUTR.* 1101, 1101 (2001). More seriously, a significant number of herbal products have been found to contain pharmaceuticals. Edzard Ernst, *Adulteration of Chinese Herbal Medicines with Synthetic Drugs: A Systematic Review*, 252 *J. Intern Med* 107, 107 (2002). In December 2008, the FDA issued a warning to consumers nationwide advising them to avoid a list of 60 dietary supplements that were found to contain undeclared drugs. An FDA analysis of these supplements uncovered active pharmaceutical ingredients far in excess of FDA-recommended levels, including an anti-seizure medication, a suspected carcinogen, and a drug not approved for marketing in the U.S. Food and Drug Administration [FDA], *FDA Expands Warning to Consumers About Tainted Weight Loss Pills List increases from 28 to 60 products; Agency seeking recalls*, <http://www.fda.gov/newsevents/newsroom/pressannouncements/2008/ucm116998.htm> (last visited Sept 29, 2013). In 2005 researchers purchased 230 traditional Ayurvedic herbal medicines available online for sale in the U.S. and tested these products for the presence of heavy metals. Nearly 21 percent were found to contain lead, mercury or arsenic. Claims by manufacturers that they used Good Manufacturing Practices (GMP) or metal testing were not associated with a lower prevalence of heavy metals. RB Saper et al., *Lead, Mercury, and Arsenic in U.S. and Indian-manufactured Ayurvedic Medicines Sold via the Internet*, 300(8) *JAMA* 915-923, 915 (2008). The issue of adulteration and contamination, particularly from Asian

perspective, it should be noted that despite the widespread use of traditional medicine, reports of serious adverse effects are rare.<sup>31</sup>

## GOOD MANUFACTURING PRACTICES

Good manufacturing practices (GMPs) help to ensure that products are consistently manufactured with appropriate quality standards. In the case of pharmaceuticals, marketing authorities such as the European Medicines Agency (EMA) set standards for drug manufacturing. GMPs aim to diminish risks related to contamination and mislabeling, and to ensure a certain standard of safety and efficacy. GMPs may require rigorous documentation of production methods, and the use of particular manufacturing and testing equipment.

WHO good manufacturing practices are used by pharmaceutical manufacturers and regulators in over one hundred countries worldwide, primarily in the developing world. The EMA and the U.S. Food and Drug Administration (FDA) GMP requirements in certain cases apply more rigorous standards. Other developed regions have GMP requirements similar to the EMA and U.S. FDA.

Many countries do not require manufacturers of traditional medicines to adhere to GMPs. As a result, manufacturers may be only responsible for making a good faith effort to ensure products contain pure substances that are not contaminated, weakened or mislabeled.<sup>32</sup> Enforcing GMPs may help address the issue of contaminated or adulterated supplements. GMPs provide requirements for the manufacturing of herbs that encompass quality control of materials, accurate identification of medicinal plants species, and procedures for harvesting and storing herbs.<sup>33</sup> WHO has long advocated that ensuring GMPs is a critical part of effective national policies on herbal medicine.<sup>34</sup>

The United States of America has only recently begun requiring manufacturers of dietary supplements to adhere to GMPs. The U.S. FDA proposed rules for GMPs in 2003,<sup>35</sup> but nothing was adopted until 2007.<sup>36</sup> These rules set requirements for domestically marketed herbs that include meeting specifications for identity, purity, strength and composition.<sup>37</sup>

The principal drawback to requiring GMPs is that they may have prohibitive costs. In particular, rules based on a pharmaceutical model (such as those originally proposed by the FDA in 2003) may put many small to medium-sized manufacturers out of business.<sup>38</sup>

High-profile cases of adverse effects from herbal supplements have demonstrated the potential dangers of poorly regulated traditional medicine.

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sources, is not limited to herbal medicine. National attention has recently been focused on this matter in the aftermath of incidents related to infant formula, pet food, and toothpaste contamination.

<sup>31</sup> D.H. Phua et al., Dietary supplements and herbal medicine toxicities—when to anticipate them and how to manage them, 2 *Int. J. Emerg. Med.* 69–76, 69 (2009).

<sup>32</sup> Institute of Medicine of the National Academies, [IOM], *Complementary and Alternative Medicine in the United States*, 258-260 (National Academies Press 2005).

<sup>33</sup> WHO, *WHO Guidelines for assessing quality of herbal medicines with reference to contaminants and residues*, (WHO 2007).

<sup>34</sup> *Id.* at 19.

<sup>35</sup> Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements. Proposed rule. 60 *Fed. Reg.* 12157–12263, (March 13, 2003).

<sup>36</sup> Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 *Fed. Reg.* 34752–39958 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

<sup>37</sup> M. McGuffin, Should Herbal Medicines Be Regulated as Drugs? 83 *CLINICAL PHARMACOLOGY AND THERAPEUTICS* 393–395, 393 (2008).

<sup>38</sup> M. Blumenthal, Industry increasingly nervous about drug orientation of FDA's proposed GMPs for dietary supplements: High costs threaten smaller companies, 59 *HerbalGram* 57-58, 57 (2003).

## MISUSE OF *EPHEDRA SINICA* IN THE UNITED STATES OF AMERICA

Herbal products are one of the principal therapeutics of TCM. TCM practitioners use herbs to treat patients under the guidance of TCM theory and traditional Chinese pharmacology. When appropriately prepared and used, traditional Chinese herbs are generally safe and effective. However, if used without proper guidance, significant adverse effects may occur. The use of herbs, including their active ingredients, without appropriate diagnosis and outside of traditional guidelines should not be considered traditional medicine.<sup>39</sup>

*Ephedra Sinica* is one of the oldest and most commonly used medicines in the Chinese herbal pharmacopeia. It was included as one of more than 360 herbs in the first herbal compendium written more than 2,000 years ago. TCM practitioners had recognized that *Ephedra* was capable of causing side-effects or toxic reactions at high concentrations. An important therapeutic agent in TCM, *Ephedra* was only used for certain conditions at recommended dosages, and generally in combination with other herbs believed to mitigate its toxicity.<sup>40</sup> It is usually prescribed by TCM practitioners in combination with other herbs to treat conditions including asthma, nasal congestion and eczema.

In the 1980s and 1990s, some dietary supplement manufacturers began using *Ephedra* as a component of weight-loss and athletic enhancement supplements, without regard for its traditional use, dosage or contraindications.<sup>41</sup> Despite the fact that *Ephedra* was known to raise blood pressure and act as a stimulant to the cardiovascular and central nervous systems,<sup>42</sup> supplements containing *Ephedra* were marketed broadly without health warnings or restrictions. Furthermore, these supplements were of highly variable quality and concentration; an examination of *Ephedra* containing supplements revealed 18-fold variations in the content of ephedrine and ephedrine-like substances.<sup>43</sup> Ultimately, these supplements caused a large number of adverse effects, including heart attacks, strokes and even death.<sup>44</sup> The use of *Ephedra* was eventually banned in the United States of America.<sup>45</sup>

*Ephedra sinica* has been used in TCM for thousands of years. However, as a result of *Ephedra's* misuse, U.S. practitioners of TCM are no longer able to prescribe this herbal medicine.

### 3. BIG BUSINESS AND NEW DRUG DEVELOPMENT

The widespread use of TM has resulted in traditional health care becoming a lucrative, multinational business. Billions of U.S. dollars are spent annually on traditional medicine in many developed countries. For example, in 2012, 32 billion dollars was spent in the United States of America on dietary supplements, an amount projected to increase to 60 billion dollars in 2021.<sup>46</sup> In developing countries, more money may be spent on TM than on

<sup>39</sup> Ka Kit Hui, *Ephedra sinica* in the Practice of Traditional Chinese Medicine (TCM), Report for the U.S. Food and Drug Administration (December 1999), at 1, available at <http://cewm.med.ucla.edu/wp-content/uploads/1999HuiKEphedraSinicaTCM.pdf>.

<sup>40</sup> *Id.* at 3.

<sup>41</sup> *Id.* at 6.

<sup>42</sup> Christina A. Haller and Neal L. Benowitz, Adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids, 343 *New Eng. J. Med.* 1833-8, 1836 (2000).

<sup>43</sup> Graham Dukes, *The Law and Ethics of the Pharmaceutical Industry*, 321 (Elsevier 2005).

<sup>44</sup> Christina A. Haller and Neal L. Benowitz, Adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids, 343 *New Eng. J. Med.* 1833-8, 1833 (2000).

<sup>45</sup> Sales of Supplements Containing Ephedrine Alkaloids (Ephedra) Prohibited. <http://web.archive.org/web/20080126150250/www.fda.gov/oc/initiatives/ephedra/february2004/>. Accessed from FDA website Feb. 28, 2011. Last visited on Sept. 29, 2013

<sup>46</sup> David Lariviere, Nutritional Supplements Flexing Muscles as Growth Industry, *Forbes.com*, <http://www.forbes.com/sites/davidlariviere/2013/04/18/nutritional-supplements-flexing-their-muscles-as-growth-industry/>, (last visited Sept. 29, 2013).

allopathic care.<sup>47</sup> Traditional medicines also contribute to the development of pharmaceutical treatments. As much as one-third to one-half of pharmaceutical drugs was originally derived from plants.<sup>48</sup> Some prominent examples include digitalis, a popular cardiac medication, identified as the active component of the foxglove leaf; morphine and codeine, which alleviate pain, derived from cultivated opium poppy; and atropine, for disorders involving the autonomic nervous system, from the nightshade plant. The anti-cancer drug Taxol was derived from the bark of the Pacific yew tree, and Aspirin was isolated from willow bark.<sup>49</sup>

Traditional medicine does more than provide raw materials for pharmaceuticals—holders of traditional knowledge often have valuable knowledge for new drug development. New drug development is an expensive and risky venture. Pharmaceutical companies invest billions of dollars annually in the hope of developing new chemical entities that are safe and effective, and that can be manufactured in a cost effective way. It is estimated that for every 10,000 pure compounds that are biologically evaluated, only one achieves regulatory approval.<sup>50</sup> A single approval can take upwards of a decade and cost hundreds of millions of dollars.<sup>51</sup>

Traditional knowledge can provide valuable guidance in selecting and obtaining plant material of potential therapeutic interest. Bioactive compounds derived from currently used herbal medicines are more likely to have minimal toxicity, and a long history of clinical use suggests that a herbal medicine may be clinically effective. Plant-derived compounds used as drugs are generally used in ways that correlate directly with their traditional uses as plant medicines.<sup>52</sup>

#### MALARIA AND HERBAL MEDICINE

Malaria is one of the most common infectious diseases and a major public health problem in many developing countries. Half of the world's population is at risk of malaria, and an estimated 247 million cases led to nearly a million deaths in 2006.<sup>53</sup> One hundred and nine countries were endemic for malaria in 2008, 45 within the WHO African region. Malaria also causes significant economic damage in high-rate areas, and disproportionately affects poor people who cannot afford treatment or have limited access to health care.<sup>54</sup>

Traditional medicines are the source of some modern antimalarial drugs (artemisinin and quinine derivatives). Artemisinin was isolated in 1972 as the active ingredient of the plant *Artemisia annua*, and this innovation relied upon the Chinese traditional medical text, "Handbook of Prescriptions for Emergencies", written in the 3<sup>rd</sup> century A.D.<sup>55</sup> *Artemisia annua* had been used to treat malaria in China for thousands of years.

<sup>47</sup> WHO TM Strategy, supra note 4, at 2.

<sup>48</sup> B. Barrett et al., Assessing the risks and benefits of herbal medicine: an overview of scientific evidence, 5 *Altern. Ther Health Med.* 40–9 (1999).

<sup>49</sup> Carmen Avendaño and J. Carlos Menéndez, *Medicinal Chemistry of Anticancer Drugs* (Elsevier 2008).

<sup>50</sup> P.R. Vagelos, Are prescription drug prices high? 252 *Science* 1080–4 (1991).

<sup>51</sup> Joseph A. DiMasi et al., The price of innovation: new estimates of drug development costs, 22 *J. of Health Econ.* 151-185 (2003).

<sup>52</sup> Of the 877 small-molecule new chemical entities introduced between 1981 and 2002, roughly half (49%) were natural products, semi-synthetic natural product analogues or synthetic compounds based on natural products. See Frank E. Koehn & Guy T. Carter, The evolving role of natural products in drug discovery, 4 *Nature Reviews Drug Discovery* 206-220, 206 (March 2005). A study investigating plant-derived pure compounds used as drugs identified 122 compounds obtained from 94 species of plants. These compounds are used globally as drugs and 80% are used in ways that correlate directly with their traditional uses as plant medicines by native cultures. Daniel S. Fabricant and Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 *Environmental Health Perspectives* 69-75, 69 (2001).

<sup>53</sup> WHO, *World Malaria Report 2008*, (2008), at vii, available at [http://whqlibdoc.who.int/publications/2008/9789241563697\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241563697_eng.pdf).

<sup>54</sup> WHO, "Fact Sheet No. 94: Malaria," (April 2010), available at <http://www.who.int/mediacentre/factsheets/fs094/en/index.html>.

<sup>55</sup> WHO, *Public health innovation and intellectual property rights: report of the commission on intellectual property rights, innovation and public health*, (WHO 2006), at 161.

WHO currently recommends using artemisinin based combination therapy (ACT) as first-line treatment for uncomplicated malaria.<sup>56</sup> However, cost remains a major barrier to ACT implementation.

#### 4. EXPORTING TRADITIONAL MEDICINE

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Traditional medicine is commercialized and exported in a variety of settings. Some TM holders have chosen to market their knowledge outside of traditional settings. China, for example, promotes global TCM use to foster domestic economic development. Exports of TCM products from China generate billions of U.S. dollars in revenue annually.<sup>57</sup> China's situation is not unique. In 2004, China accounted for only five percent of the global market for TM.<sup>58</sup>

Biotechnology and pharmaceutical companies also make use of genetic resources (GRs) and TMK in new drug development. GRs are screened for potential medical benefits, and increasingly TMK is used to improve screening. This process is sometimes referred to as "bioprospecting," the development of new therapeutics from products of nature.

On the one hand, bioprospecting can be beneficial to indigenous communities and developing countries. National governments and local communities may receive a portion of revenue from the sale of new medicines developed from traditional resources, and this revenue can support the conservation and sustainable use of biological resources. On the other hand, if unregulated, bioprospecting can result in over-exploitation of limited resources. Habitats that support medicinal plants are being destroyed by over-harvesting and new commercial developments. Many traditional medicines now face extinction with serious consequences for local communities. For example, licorice root, "without a doubt the most commonly used Chinese herb"<sup>59</sup> is now threatened. Licorice root is now grown in less than half its previous area as a result of excessive harvesting and habitat destruction.<sup>60</sup>

GRs and TMK may also be misappropriated when third parties use them without the informed consent of TK holders and without equitable benefit-sharing. Where bioprospecting occurs without benefit-sharing or the consent of source communities it is sometimes referred to as "biopiracy".

Developing countries are increasingly making efforts to protect GRs and TMK through national legislation and international agreements. However, guarding these resources has historically proven challenging due to a lack of national and international regulations and the need for law enforcement.

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<sup>56</sup> WHO, Guidelines for the Treatment of Malaria, Second Edition, (2010), at ix, available at [http://whqlibdoc.who.int/publications/2010/9789241547925\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf).

<sup>57</sup> Overview of Chinese Pharmaceutical Market in 1999 and 2000, Chinese Medical News, issue 107. Beijing, Beijing Consultech, 2001.

<sup>58</sup> WHO, WHO Global Atlas of Traditional, Complementary and Alternative Medicine, 189 (2005).

<sup>59</sup> Dan Bensky et Al., Chinese Herbal Medicine Materia Medica, 3rd edition, 734 (Eastland Press 2004).

<sup>60</sup> Adria Vasil Ecoholic, Your Guide to the Most Environmentally Friendly Information Products and Services in Canada, 54 (2007).

## 5. MISAPPROPRIATION

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TMK holders have historically experienced misappropriation from foreign and even domestic developers. In recent years, unauthorized third parties have patented traditional medicine based products without the consent of TMK holders and without fair compensation. A prominent example includes the patenting of turmeric in the United States of America.

### TURMERIC IN THE UNITED STATES OF AMERICA

Turmeric (*Curcuma longa*) is an herb traditionally used in Ayurvedic medicine. It is applied as an antiseptic for cuts, burns and bruises, taken internally for digestive disorders, and applied topically for skin disorders.

In 1995, the U.S. Patent and Trademark Office (USPTO) granted a patent to the University of Mississippi Medical Center for the medicinal use of turmeric. The patent on "Use of Turmeric in Wound Healing" covered "a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound". The patent application claimed that this was the first use of turmeric for such a purpose.

The issuance of this patent generated international controversy, particularly in India, where it was felt that traditional Indian medicine was being misappropriated. The ensuing public outcry prompted the Indian government to request that the patent be revoked on the basis of lack of novelty due to its known traditional use. The Council of Scientific and Industrial Research of India (CSIR) provided scientific literature documenting prior use of turmeric for wound healing, including an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association.<sup>61</sup>

The patent application for turmeric disseminated TMK. In helping defeat the patent, the Indian government provided evidence that this use of turmeric was not innovative. Because novelty is a necessary requirement for patent protection, it is now difficult for any party to patent the use of turmeric for wound healing or to require compensation for this use. The Indian government is now comprehensively documenting TMK in its Traditional Knowledge Digital Library (TKDL) to help defeat patent applications it views as inappropriate. It is restricting this data from public access in part to protect potential intellectual property rights (IPRs).

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<sup>61</sup> Karen Timmermans, TRIPS, CBD, and Traditional Medicines: Concepts: Concepts and Questions, Report of an Asean Workshop on the TRIPS Agreement and Traditional Medicine (February 13-15, 2001), available at <http://apps.who.int/medicinedocs/en/d/Jh2996e/6.4.html>.

### III. NATIONAL AND INTERNATIONAL POLICIES ON TRADITIONAL MEDICINE

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#### 1. BEIJING DECLARATION

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In Beijing in November 2008, government officials representing Member States of WHO adopted a declaration that provides an endorsement of traditional medicine. The WHO Congress on Traditional Medicine was the first time that WHO Member State representatives came together solely to discuss traditional medicine and to prepare an advocacy document. In the Beijing Declaration, they recognized the role of traditional medicine in the improvement of public health and supported its integration into national health systems where appropriate. The declaration encourages governments to create or improve national policies on traditional medicine. It also promotes improved education, research and clinical inquiry into traditional medicine, as well as improved communication between health care providers.<sup>62</sup>

In May, 2009, the World Health Assembly (WHA), the governing body of WHO, noted the adoption of the Beijing Declaration and urged Member States to implement its policies. The WHA further directed WHO to provide support to Member States in implementing the Beijing Declaration.

#### EXCERPTS FROM THE BEIJING DECLARATION

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I. The knowledge of traditional medicine, treatments and practices should be respected, preserved, promoted and communicated widely and appropriately based on the circumstances in each country.

II. Governments have a responsibility for the health of their people and should formulate national policies, regulations, and standards as part of comprehensive national health systems to ensure appropriate, safe and effective use of traditional medicine.

III. Recognizing the progress of many governments to date in integrating traditional medicine into their national health systems, we call on those who have not yet done so to take action.

IV. Traditional medicine should be further developed based on research and innovation in line with the "Global strategy and plan of action on public health, innovation and intellectual property" adopted at the Sixty-first World Health Assembly in resolution WHA61.21 in 2008. Governments, international organizations and other stakeholders should collaborate in implementing the global strategy and plan of action.

V. Governments should establish systems for the qualification, accreditation or licensing of traditional medicine practitioners. Traditional medicine practitioners should upgrade their knowledge and skills based on national requirements.

VI. The communication between conventional and traditional medicine providers should be strengthened and appropriate training programmes be established for health professionals, medical students and relevant researchers.<sup>63</sup>

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<sup>62</sup> Ryan Abbott, The Beijing Declaration—A Milestone for Traditional Medicine, 13(1) ICTSD-Bridges March 2009.

<sup>63</sup> The Beijing Declaration, Adopted by the WHO Congress on Traditional Medicine, (Nov. 8, 2008), available at [http://www.who.int/medicines/areas/traditional/TRM\\_BeijingDeclarationEN.pdf](http://www.who.int/medicines/areas/traditional/TRM_BeijingDeclarationEN.pdf).

## 2. NATIONAL POLICIES ON TRADITIONAL MEDICINE

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WHO notes that one of the major challenges facing the appropriate use of TM is the lack of comprehensive national policies on TM. WHO stated that national policies on TM "are needed in order to define the role of TM/CAM in national health care delivery systems and how it can contribute to health sector reform. They can also ensure that the necessary regulatory and legal mechanisms are in place for promoting and maintaining good practice, that access to TM/CAM is equitable, and that the authenticity, safety and efficacy of any therapies used are assured. Without such policies, TM/CAM is practiced without government oversight and without patient consumer protection."<sup>64</sup>

The number of countries developing TM policies is rising. According to the first WHO global survey on national policy and regulation of traditional medicine, only five Member States had a national policy on traditional medicine prior to 1990. By 2003, that figure had reached 45, while 51 countries reported national policies pending. The same trend is seen with national laws and regulations regarding herbal medicine.<sup>65</sup>

The United States of America does not have a national policy specifically directed to TM/CAM, and there is no agency specifically responsible for TM. However, a number of governmental and non-governmental organizations affect TM practice. The National Center for Complementary and Alternative medicine (NCCAM) at the National Institutes of Health, Department of Health and Human Services is the agency most responsible for TM. NCCAM was established by an act of U.S. Congress in 1998 to explore CAM practices in the context of rigorous science, train CAM researchers, and disseminate information. For 2013, NCCAM's fiscal budget was 120.7 million dollars.<sup>66</sup> In the past decade it has funded more than 2,500 research projects resulting in more than 3,300 scientific articles in peer-reviewed journals.<sup>67</sup>

In China, the first modern national policy on TM was issued in 1949, the same year as the founding of the People's Republic of China.<sup>68</sup> Traditional medicine has historically played a prominent role in the national health care system and remains well integrated with allopathic care. Both systems of medicine receive government support, and the Chinese Constitution was amended in 1982 to state that "both modern medicine and traditional Chinese medicine must be developed."<sup>69</sup> This was the first time that the promotion and development of traditional medicine had been included in a national constitution.<sup>70</sup>

## 3. CULTURAL POLICES AND HUMAN RIGHTS

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Because traditional medicines may form a vital part of individual or community identity, human rights issues are intimately bound with TMK. Historically, colonialism and cultural imperialism have marginalized traditional practitioners and medicine, and misappropriation of TMK has had disastrous effects on community livelihood and cultural identity. On the other hand, human rights violations have also been committed in the name

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<sup>64</sup> WHO TM Strategy, supra note 4, at 20.

<sup>65</sup> WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO Global Survey, May 2005 at 12.

<sup>66</sup> <http://nccam.nih.gov/about/budget/appropriations.htm>.

<sup>67</sup> <http://nccam.nih.gov/about/offices/od/directortestimony/0410.htm>.

<sup>68</sup> WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO Global Survey, May 2005 at 129.

<sup>69</sup> H. Dong & X. Zhang, An overview of traditional Chinese medicine. In: Traditional Medicine in Asia. New Delhi, World Health Organization Regional Office for South-East Asia, SEARO Regional Publication 39, 2002 at 17–29.

<sup>70</sup> Anthology of policies, laws and regulations of the People's Republic of China on Traditional Chinese Medicine. Beijing, The State Administration of Traditional Chinese Medicine of the People's Republic of China, 1997.

of traditional medicine. Principles of human rights should be applied to all aspects of traditional healing.

In September 2007, the UN General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples. This Declaration was the product of more than twenty years of discussion within the UN system, and indigenous representatives played a key role in the development of this Declaration. Today, there are over 370 million indigenous people in 90 countries worldwide.<sup>71</sup>

**EXCERPTS FROM THE UNITED NATIONS DECLARATION ON THE RIGHTS OF  
INDIGENOUS PEOPLES**

**Article 24**

1. Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services.
2. Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps with a view to achieving progressively the full realization of this right.

**Article 31**

1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.<sup>72</sup>

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<sup>71</sup> United Nations Permanent Forum on Indigenous Issues [UNFPII], About UNFPII and a Brief History of Indigenous Peoples and the International System, <http://www.un.org/esa/socdev/unpfii/en/history.html>.

<sup>72</sup> United Nations Declaration on the Rights of Indigenous Peoples. Adopted by G.A. Res. 61/295 (Sept. 13, 2007), available at [http://www.un.org/esa/socdev/unpfii/documents/DRIPS\\_en.pdf](http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf).

## IV. REGULATION OF TRADITIONAL MEDICINE

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National regulatory systems on traditional medicine vary considerably worldwide. These range from an absence of regulation to highly structured regulation similar to that applied to pharmaceuticals. WHO notes that an appropriate legal and regulatory infrastructure for TM is vital in “promoting and maintaining good practice; assuring authenticity, safety and efficacy of traditional and complementary/alternative therapies; and providing equitable access to health care resources and information about those resources.”<sup>73</sup>

### 1. DATA EXCLUSIVITY

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In many nations, regulatory approval of a new pharmaceutical drug requires the submission of comprehensive information on the medicine’s safety and efficacy.<sup>74</sup> There is ongoing debate whether marketing exclusivity should be granted in return for data submission.<sup>75</sup> Data-based exclusivity prevents generic drug manufacturers from making use of data submitted in an initial application by an originator pharmaceutical manufacturer for a fixed period of time.<sup>76</sup> In effect, this may extend the exclusivity period for an originator drug beyond the patent term or beyond a finding that a patent is invalid.<sup>77</sup> In applying for regulatory approval of a generic equivalent to an approved on-patent medicine, access to or reliance on the original application for regulatory approval is essential. While generics manufacturers can independently generate new clinical data, this is extremely costly and time-consuming. Also, re-generating clinical test data may be regarded as unethical in that it exposes human subjects to a clinical trial that would add no scientific value, and provides a placebo to some patients in place of a medicine with proven efficacy.

If TMK holders are required to submit information to regulatory agencies for marketing approval of traditional medicines, they should be aware of whether that data will be kept confidential. If data submitted to a regulatory agency for marketing approval is made public, this may result in the loss of certain IP protections.

### 2. REGULATION IN THE UNITED STATES OF AMERICA

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In the United States of America, the Food and Drug Administration (FDA) is the government agency primarily responsible for regulating foods and medicines. It is also responsible for regulating dietary supplements, such as herbal medicines, under the Dietary Supplement Health and Education Act (DSHEA) of 1994.<sup>78</sup>

The Act specifies that supplements are to be regulated as foods, rather than drugs or food additives, and this limits the FDA’s premarket regulatory authority.<sup>79</sup> Unlike

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<sup>73</sup> WHO, *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A WHO Worldwide Report*, (WHO 2001) at Page ix.

<sup>74</sup> Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*. 99 *Iowa L. Rev.* 225 (2013). Available at SSRN: <http://ssrn.com/abstract=2246217>.

<sup>75</sup> TRIPS does not discuss “exclusivity” of test data for patent applications; it states that Members should protect such data against “disclosure” and “unfair commercial use”. It is up to national authorities to determine how data protection should occur.

<sup>76</sup> See Ryan Abbott, *Overcoming Barriers to a Global Treaty on Medical Funding and R&D*, 7 *Revista Eletrônica do IBPI [J. Brazilian Inst. for Intell. Prop.]* 70 (2012) (Braz.).

<sup>77</sup> Ryan Abbott et al., *Impact of Strong Intellectual Property Protection on Access to Medicines in Jordan*, *Medicines Transparency Alliance*, 9 *Journal of Generic Medicines* 75 (2012).

<sup>78</sup> The Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417.

<sup>79</sup> DSHEA defines dietary supplements as: a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a

pharmaceuticals, dietary supplements can be produced, sold and marketed without evidence of safety or efficacy. Under DSHEA, it is the FDA's responsibility to prove a dietary supplement is unsafe before it can be removed from the market. To withdraw a product, the FDA must prove that the product places consumers at "significant or unreasonable risk".

Dietary supplement labels may only make health claims, nutrient content claims, and structure/function claims.<sup>80</sup> Health claims describe a relationship between a dietary supplement ingredient and reduced risk of a disease condition, nutrient content claims describe the relative amount of a dietary substance in a product, and structure/function claims describe how supplements may affect the organs or systems of the body without mention of any specific disease. In practice, structure/function claims may promise vaguely worded health benefits that can be similar to claims to treat illness. Examples include "calcium builds strong bones" and "fiber maintains bowel regularity". FDA approval is not required for structure/function claims, but manufacturers must provide the FDA with the text of the claim within 30 days of product marketing.<sup>81</sup> Claims must be followed by the disclosure that "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."<sup>82</sup> In addition, DSHEA requires manufacturers to have substantiation that claims are truthful and not misleading, although they are not required to provide such substantiation to the FDA and DSHEA does not provide a required standard of evidence.<sup>83</sup> Manufacturers that want to legally make a claim to treat illness may only do so if their claims are supported by adequate scientific evidence. Pre-authorization is required by the FDA prior to making claims to treat illness.<sup>84</sup>

DSHEA did not originally require that manufacturers report adverse effects to the FDA. However, since 2006 dietary supplement manufacturers have been required to report any "serious" adverse effects within 15 days of knowledge of the event.<sup>85</sup> DSHEA also did not provide GMPs for dietary supplement production, and as a result manufacturers were only responsible for making a good faith effort to ensure products contain pure substances that were not contaminated, weakened or mislabeled.<sup>86</sup> The FDA proposed rules for GMPs in 2003,<sup>87</sup> however, no rules were adopted until 2007.<sup>88</sup> These rules set requirements for domestically marketed herbs that include meeting specifications for identity, purity, strength, and composition.<sup>89</sup>

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dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325, 4326 (1994) (codified in scattered sections of 21 U.S.C.).

<sup>80</sup> Food and Drug Administration, Claims That Can Be Made for Conventional Foods and Dietary Supplements, <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm> (last visited Sept. 29, 2013).

<sup>81</sup> Food and Drug Administration, Dietary Supplement Labeling Guide, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm> (last visited Sept. 29, 2013).

<sup>82</sup> DSHEA also excludes certain publications about dietary supplements from the definition of labelling. Articles, book chapters, and scientific literature may be used in connection with the sale of dietary supplements to consumers provided such information is: not false or misleading, does not promote a particular manufacturer or brand of dietary supplement, presents a balanced view of the available scientific information, is physically separate from the supplements if displayed in a store, and does not have appended to it any information by sticker or other method. Pub. L. No. 103-417, § 5, 108 Stat. at 4329 (amending 21 U.S.C. § 343-2(a)(1)-(5)).

<sup>83</sup> Pub. L. No. 103-417, § 6, 108 Stat. at 4329 (amending 21 U.S.C. § 343(r)(6)).

<sup>84</sup> Ila Mehra Harris, Regulatory and ethical issues with dietary supplements, 20 *Pharmacotherapy* 1295-1302 (2000).

<sup>85</sup> M. McGuffin, Should Herbal Medicines Be Regulated as Drugs? 83 *Clinical Pharmacology and Therapeutics* 393-395, 394 (2008).

<sup>86</sup> Institute of Medicine of the National Academies [IOM]. *Complementary and Alternative Medicine in the United States*, 258-260 (National Academies Press 2005).

<sup>87</sup> Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements. Proposed rule. 68 Fed. Reg. 12157-12263 (March 13, 2003).

<sup>88</sup> Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34752-39958 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

<sup>89</sup> McGuffin, *supra* note 85.

## FUSING SCIENCE AND TRADITION

In 2006, the U.S. Food and Drug Administration (FDA) approved the first botanical pharmaceutical drug, Veregen (sinecatechins), a purified green tea extract for the topical treatment of warts. This botanical drug was supported by extensive clinical research and was approved in the standard new drug application (NDA) used for pharmaceutical candidates. Although a botanical preparation, this medicine is now approved as a pharmaceutical medicine and prescribed by physicians.

In 2012, the FDA approved a second botanical prescription drug: Fulyzaq (crofelemer).<sup>90</sup> Fulyzaq is indicated to relieve symptoms of diarrhea in HIV/AIDS patients taking medicines to treat HIV infection. It is the first FDA-approved treatment for HIV-associated diarrhea. Fulyzaq is derived from the red sap of the *Croton lechleri* plant, which is a traditional herbal medicine known as *sangre de grado* ("dragon's blood"). It is used extensively within the indigenous cultures of the Amazon River to treat diarrhea, among other conditions.<sup>91</sup>

### 3. REGULATION IN THE EUROPEAN COMMUNITY

In the European Union (EU), two general pathways exist for authorizing medicinal products: a centralized and a mutual recognition procedure. Under the centralized procedure, companies submit a single marketing authorization application to the European Medicines Agency (EMA), which is the agency that coordinates the evaluation and supervision of medicinal products throughout the EU.<sup>92</sup> The application is then considered by the EMA and, if applicable, a positive opinion is adopted which permits a single market authorization valid for the whole of the EU. Under the mutual recognition procedure, approval by a single national regulatory body is accepted by other countries.<sup>93</sup>

Marketing authorization applications for herbal medicines must fall within one of three categories: 1) full dossier with product-specific safety and efficacy data, 2) well-established use with sufficient safety and efficacy data, or 3) traditional use with sufficient safety data and plausible efficacy (simplified registration procedure).<sup>94</sup> Because product-specific safety and efficacy data is rarely available, most herbal medicines are approved for well-established or traditional use.

To apply for approval under well-established use, the active substances of an herbal medicine must have been in use within the EU for at least 10 years, with recognized efficacy and an acceptable level of safety. A bibliographic application is permitted, which must provide a detailed scientific bibliography addressing non-clinical and clinical characteristics.<sup>95</sup> This can include post marketing studies, epidemiological studies, appropriate monographs,

<sup>90</sup> <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm>.

<sup>91</sup> Miller, MJ et al., Treatment of gastric ulcers and diarrhea with the Amazonian herbal medicine *sangre de grado*, (2000), available at <http://www.reparagen.com/PDF%2014.pdf>.

<sup>92</sup> European Medicines Agency, About us, [http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000235.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp) (last visited Sept. 29, 2013).

<sup>93</sup> Mary Rice, For the European Medicines Agency, a Decade of Challenges, 97(19) *J. Nat'l Cancer Inst.* 1403, 1403 (2005).

<sup>94</sup> European Medicines Agency [EMA], Regulation of Herbal Medicinal Products, [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf&jsenabled=true) (last visited Sept. 29, 2013).

<sup>95</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, art 10(a), 2001 O.J. (L 311) p. 67-128.

etc.<sup>96</sup> The application must include a systematic review of literature, including recent searches of medical and toxicological databases, and all documentation, both favorable and unfavorable, must be discussed.<sup>97</sup> If published literature does not meet minimum requirements, it can be combined with additional non-clinical tests as a mixed application.<sup>98</sup>

The category of traditional use was established in 2004 when the EMA released the Directive on Traditional Herbal Medicinal Products (DTHMP).<sup>99</sup> The EMA designed this separate application procedure for traditional herbal medicines because scientific data on efficacy is often insufficient for standard approval. The requirement for proof of efficacy is replaced by a “plausibility” requirement. “The rationale behind the actual simplified registration procedure is to enable products which have been in long standing traditional medicinal use to be registered according to a simplified procedure because their safety and efficacy can be deduced from their long standing use in the specified conditions of use.”<sup>100</sup> This allows consumers access to medicines that would not otherwise be approved, while at the same time controlling for quality and safety.

For a supplement to qualify for this application there must be documentation that it has been used for a period of at least 30 years, including at least 15 years in the EU.<sup>101</sup> Furthermore, the supplement can only be marketed for minor conditions that do not require physician assistance, and must still fulfill other standard application requirements including evidence of GMPs and the submission of quality measures. Without this simplified procedure, most traditional herbal medicines would be unable to fulfill the well-established use requirement for detailed references to published scientific literature on product safety and efficacy. The EMA states that in the case of traditional herbal medicines, “the long tradition makes it possible to suppress the need for clinical data, in so far as the efficacy of the medicinal product is plausible on the basis of its long-standing use and experience as testified by bibliographic or expert evidence.”<sup>102</sup>

The requirement that a supplement must have been used for at least 15 years in the EU prevents the marketing of a large number of supplements from elsewhere in the world. Traditional medicines from China, India and Brazil, for example, may fail to satisfy this condition. While there has been debate within the EU about eliminating this constraint, it remains part of the regulatory scheme. Other nations, such as China, have similar requirements for a history of domestic use, which may have a protectionist element. In other words, these regulations may promote the sale of local goods while preventing the sale of goods produced in other nations.

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<sup>96</sup> European Medicines Agency [EMA], Post-Authorisation Evaluation of Medicines for Human Use, EMEA/HMPC/104613/2005 (2006), p. 5, available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003644.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003644.pdf).

<sup>97</sup> *Id.* at 5.

<sup>98</sup> European Medicines Agency [EMA], Post-Authorisation Evaluation of Medicines for Human Use, EMEA/HMPC/32116/2005 (2006), p. 3, available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003576.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003576.pdf).

<sup>99</sup> Specific Directive (2004/24/EC) amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use, 2004 O.J. (L 136) p. 85-90.

<sup>100</sup> *Id.*

<sup>101</sup> To qualify for this application a product must fulfill all of the following criteria:

“(a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

(b) they are exclusively for administration in accordance with a specified strength and posology;

(c) they are an oral, external and/or inhalation preparation;

(d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;

(e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience”. See *id.* Article 16a(1).

<sup>102</sup> Specific Directive (2004/24/EC) amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the community code relating to medicinal products for human use, 2004 O.J. (L 136) p. 85-90, Preamble paragraph (5).

## 4. REGULATION IN CHINA

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The most important agencies in China for the regulation of traditional medicine are the State Food and Drug Administration (SFDA) and the State Administration of Traditional Chinese Medicine (SATCM). The SFDA and SATCM both formulate regulations and good practices relevant to TCM and supervise implementation.<sup>103</sup> National legislation specifically for TCM, Regulations on TCM, has been in force since 2003. However, these regulations primarily serve to promote TCM and do not establish criteria for safety or efficacy.<sup>104</sup> The result is that the most important regulations for TCM are issued by state agencies and local governments.

Generally, traditional Chinese medicines are regulated as drugs and must adhere to many of the regulations for pharmaceutical medicines. Manufacturers require a good manufacturing practices (GMP) certificate and sellers require a good supply practices (GSP) certificate. This applies to all Chinese herbal medicines regardless of their dosage form (oral tablet, injection, etc.). Only traditional medicines registered as drugs are permitted to make therapeutic claims.

For a traditional Chinese medicine to be marketed as a drug it must first be approved by the SFDA. A Pharmacopoeia of the People's Republic of China contains a list of the TCM preparations that have already been approved. Without preexisting approval, the new approval process is extensive and similar to the approval process of pharmaceuticals. Approval requires submission of pre-clinical and clinical study data, and approved medicines are then subject to up to five years of additional post-market surveillance. In addition, these traditional Chinese medicines face a number of TCM-specific regulations. For example, traditional medicines are also required to adhere to information in the pharmacopoeia and in relevant monographs.<sup>105</sup> Since 2008, enterprises involved in processing prepared slices of Chinese herbal medicines have been required to comply with GMP requirements.<sup>106</sup>

If herbal products are used as ingredients in food and do not make specific health claims, then there is no registration requirement as a drug.<sup>107</sup> These products are then governed by general food regulations. Traditional medicines in food which claim health effects (these are general health claims, but not specific therapeutic claims) undergo special regulation as health foods.<sup>108</sup> Health foods must have raw materials and final products that comply with food hygiene requirements and that do not cause human harm, animal or human studies to demonstrate a health effect, and a formulation and dosage based on scientific evidence.<sup>109</sup> Traditional medicines that would qualify as health foods, but that are not indigenous to China, have separate regulations as novel health foods.

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<sup>103</sup> State Food and Drug Administration, P.R. China, About SFDA, <http://eng.sfda.gov.cn> (last visited Sept. 29, 2013). State Administration of Traditional Chinese Medicine, available at [http://www.cintcm.ac.cn/gam/e\\_index6.html](http://www.cintcm.ac.cn/gam/e_index6.html) (last visited Sept. 29, 2013).

<sup>104</sup> General Office of the State Council, Decree No. 374 of the State Council of the People's Republic of China-Regulations of the People's Republic of China on traditional Chinese medicine, 7 April 2003. Gazette of the State Council of the People's Republic of China, May 30, 2003, available at <http://www.china.org.cn/e-gongbao/gazette/2003e/gb2003-15e.htm>.

<sup>105</sup> WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey, (May 2005), at 129. Available at <http://apps.who.int/medicinedocs/en/d/Js7916e/9.6.html>.

<sup>106</sup> State Food and Drug Administration, P.R. China, Status Quo of Drug Supervision in China, (July 2008). Available at [http://english.gov.cn/2008-07/18/content\\_1049011.htm](http://english.gov.cn/2008-07/18/content_1049011.htm).

<sup>107</sup> The rules for whether a traditional medicine qualifies as a food or a drug are not clear, and companies may have to consult the SFDA on an individual basis. Annie Tsoi, Pharmaceutical Policies and Regulations in China, June 20, 2007, available at [http://www.deacons.com.hk/eng/knowledge/knowledge\\_290.htm](http://www.deacons.com.hk/eng/knowledge/knowledge_290.htm).

<sup>108</sup> Ministry of Health, Administrative Regulations on Health Food, Order No. 46; Promulgation Date: 1996-03-15; Effective Date: 1996-06-01.

<sup>109</sup> *Id.*

## 5. REGULATION IN INDIA

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Traditional medicines may be regulated as prescription drugs, over-the-counter medicines or dietary supplements and marketed with medical, health or nutrient content claims respectively. Modern regulations on traditional medicine began with the Drugs and Cosmetics Act of 1940, which contained a separate chapter and rules for Ayurveda, Siddha and Unani drugs.<sup>110</sup> The Act, amended in 2000, requires government licensing of manufacturers and sellers of traditional medicines. It contains regulations for misbranded and adulterated drugs, prohibits the manufacture and sale of certain drugs, and stipulates penalties for regulatory violations. The central government is also empowered to inspect and analyze traditional medicines.

Manufacturers of traditional medicines are now required to adhere to good manufacturing practices, as well as requirements related to factory premises and heavy metal contents. Heavy metals are sometimes considered active ingredients of traditional Indian medicines rather than contaminants, but heavy metal testing is now mandatory. In addition, heavy metals may not be present above permissible limits, and labeling must note the presence of heavy metals.<sup>111</sup> Traditional medicine manufacturers are also required to adhere to information contained in national pharmacopoeias and monographs. Safety requirements for traditional medicines are less strict than those applied to pharmaceuticals, and there is generally no submission requirement for clinical trials demonstrating safety and efficacy.<sup>112</sup> The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) is primarily responsible for the regulation of traditional medicines.<sup>113</sup>

## 6. REGULATION IN BRAZIL

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National traditional medicine guidelines have existed in Brazil since 1967, and were most recently updated in 2004.<sup>114</sup> These guidelines establish the core components of traditional medicine regulation such as proper botanical identification of medicines, basic quality standards and the need to ensure safety and efficacy. In addition, several complementary guidelines named *Resoluções Específicas* contain additional regulations and relevant information. The principal authority for regulation of traditional medicine is the Agência Nacional de Vigilância Sanitária (ANVISA).

Under these regulations, traditional medicines can be regulated as prescription and over-the-counter drugs, functional foods, probiotics, bioactive substances and cosmetics. Medical claims are only permitted for traditional medicines registered as herbal drugs. For a traditional medicine to be approved as an herbal drug it must contain only herbal ingredients and it must meet similar quality, safety and efficacy criteria as required for pharmaceuticals. Only manufacturers with ANVISA Good Manufacturing Practices and Control certification may register herbal medicines.<sup>115</sup> More than 600 herbal medicines have been registered from around 150 medicinal plant species, only 16% of which are of South American origin.<sup>116</sup>

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<sup>110</sup> Ministry of Health and Family Welfare, Central Drug Standards Control Organization, Laws Pertaining to Manufacture and Sale of Drugs in India, <http://cdsco.nic.in/html/law.htm>. Also see <http://cdsco.nic.in/html/Copy%20of%201.%20D&CAct121.pdf>.

<sup>111</sup> Pulok K. Mukherjee et al., An Overview on the Development in Regulation and Control of Medicinal and Aromatic Plants in the Indian System of Medicine, 6 *Boletín Latinoamericano y del Caribe de Plantas Medicinales y Aromáticas* 129-137 (2007).

<sup>112</sup> WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey, (May 2005), at 121-122, available at <http://apps.who.int/medicinedocs/en/d/Js7916e/9.5.html#Js7916e.9.5>.

<sup>113</sup> See generally Government of India, Department of AYUSH, <http://indianmedicine.nic.in/>.

<sup>114</sup> RDC 48/2004, Providing for the registration of herbal medicines (March 16, 2004).

<sup>115</sup> National Sanitary Surveillance Agency, Resolution-RDC 210/2003, (August 4, 2003).

<sup>116</sup> Bezerra Carvalho et al., Regulation of plants and herbal medicines in Brazil, 8 *Boletín Latinoamericano y del Caribe de Plantas Medicinales y Aromáticas* (2009), available at [www.blacpma.org](http://www.blacpma.org).

Regulatory requirements for manufacturing also include adherence to pharmacopeias and monographs. For chemical entities based on plant compounds, documentation of efficacy, safety and quality measures are required for registration, which may include clinical trials. Existing scientific documentation may be submitted, instead of newly performed clinical trials or animal tests, if such documentation already exists for the proposed preparation. Pharmaceutical requirements for data on safety and efficacy are waived in the case of herbal medicines with documented safe traditional use. A post marketing surveillance system for traditional medicines was established in 2001.

Producers may prefer to register traditional medicines as foods or cosmetics because quality and safety requirements are simpler. Traditional medicines registered as foods cannot present therapeutic claims, but can be registered in a special food category with the ability to make functional or health claims. Claims should be supported by strong scientific evidence, and references to curing or preventing disease are not permitted.<sup>117</sup> Traditional medicines that have not been traditionally used in Brazil are classified as new foods, and require strong scientific evidence to make functional or health claims. Dried plants with pharmacological effects used to make tea have separate registration procedures.

Like foods, traditional medicines registered as cosmetics are not permitted to make therapeutic claims. These products must be for external personal use, and have no specific regulations beyond those that generally apply to cosmetics. Finally, some traditional medicines can also be registered as “dinamizados” (homeopathic, anthroposophical and antihomotoxic medicines).<sup>118</sup> These are medicines used in homeopathic medicine, and may or may not have exclusively plant based ingredients.

## 7. TRADITIONAL SYSTEMS OF REGULATION

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Customary laws and practices may govern how TMK is developed and transmitted in local communities.<sup>119</sup> For example, TMK may be passed down only among family members or specific individuals within a healing tradition. Exclusive rights and monopoly powers over TMK are not uncommon within traditional communities.<sup>120</sup> Alternately, TMK may be considered communal property of an indigenous group. Traditional systems of regulation may place restrictions on how TMK can be used or disseminated.

In North American societies, traditional Native American healers possess the ability to make “medicine bundles”. These contain a variety of materials such as animal skins and talismans that are important for communal and personal activities.<sup>121</sup> Medicine bundles were used in war and religious ceremonies. The transfer of these bundles is accompanied by TMK and the right to practice as a healer.<sup>122</sup> In Native American communities, transferring ownership of physical bundles is analogous to transfer of modern IPRs.

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<sup>117</sup> Id.

<sup>118</sup> B. Carvalho et al., Regulation of Plants and Herbal Medicines in Brazil, 8 *Boletín latinoamericano y del Caribe de Plantas Medicinales y Aromáticas* 7-11, 9 (2009).

<sup>119</sup> For a more in depth discussion of traditional systems of regulation, see generally WIPO, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) [hereinafter WIPO FFM], available at [http://www.wipo.int/export/sites/www/freepublications/en/tk/768/wipo\\_pub\\_768.pdf](http://www.wipo.int/export/sites/www/freepublications/en/tk/768/wipo_pub_768.pdf).

<sup>120</sup> WHO, The TRIPS Agreement and Pharmaceuticals - Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, (May 2-4, 2000). Available at <http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf>.

<sup>121</sup> Jeffrey E. Anderson, *Conjure in African American Society*, Baton Rouge Louisiana State Univ. Press (2005).

<sup>122</sup> WIPO FFM, supra note 119 at 63.

## V. INTELLECTUAL PROPERTY AND TRADITIONAL MEDICINE

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Modern notions of IP may conflict with traditional systems of knowledge ownership.<sup>123</sup> Indigenous cultures have not historically made the same sorts of property/non-property distinctions supported by current law; however, traditional restrictions on the possession and use of knowledge are common.<sup>124</sup> Social restrictions may govern who, if anyone, can use certain knowledge, and under what conditions. Knowledge may be considered secret or sacred, and making it publicly available would disregard traditional cultural prohibitions. Alternately, some knowledge may be held collectively by a community or considered an integral part of the natural environment. When modern concepts of ownership are applied to traditional medicine, TMK holders may feel their rights are being violated.

### 1. INTELLECTUAL PROPERTY RIGHTS

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IPRs convey legal ownership over certain intangible assets, such as artistic works, commercial designs, and pharmaceutical technologies.<sup>125</sup> Common types of IP include patents, trademarks, copyrights, geographical indications, protection for plant varieties and trade secrets. IPRs generally provide creators of original works economic incentives to develop and share ideas through a form of temporary monopoly.

IPRs are granted nationally, and most countries provide IP protection. Minimum standards for domestic laws are established by a complex framework of international treaties and agreements, including by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>126</sup> TRIPS is a treaty adopted within the framework of the World Trade Organization (WTO).<sup>127</sup>

One of the most important types of IPR for medicines is patent protection. A patent grants a set of exclusive rights to an inventor for a limited time that prevents others from commercially using the patented invention without permission. Patents allow their right holders to prevent third parties from making, using, selling, offering for sale or importing for these purposes a patented invention. In return, an inventor must submit a patent application to the national government which discloses how to replicate the invention by a person skilled in the art. Furthermore, inventions must generally be new, inventive and industrially applicable. Once a patent is expired, third parties may use the claimed invention without the consent of the patent owner. Examples of patents based on TMK include U.S. patents based on *maca*, a traditional Peruvian food and medicine first cultivated by the Incas.<sup>128</sup>

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<sup>123</sup> TRIPS, CBD and Traditional Medicines: Concepts and Questions. 2001.

<http://apps.who.int/medicinedocs/en/d/Jh2996e/1.html>.

<sup>124</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Seventeenth Session, Note on the Meanings of the term "Public Domain" in the Intellectual Property System with special reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore, WIPO/GRTKF/IC/17/INF/8 (Nov. 24, 2010).

<sup>125</sup> This text is only intended to provide an overview of intellectual property rights. For a more complete discussion of these issues, see Frederick Abbott et Al., *International Intellectual Property in an Integrated World Economy* (Aspen Publishers 2007).

<sup>126</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

<sup>127</sup> As of October, 2013, 159 nations are members of the World Trade Organization (WTO), the global international organization that deals with the rules of trade between nations. WTO provides a forum for Member States to negotiate and sign trade agreements in order to help producers of goods and services, exporters, and importers conduct their business. See generally [www.wto.int](http://www.wto.int).

<sup>128</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fifth Session, WIPO/GRTKF/IC/5/13 (May 12, 2003), available at [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_5/wipo\\_grtkf\\_ic\\_5\\_13.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_13.pdf).

Other forms of IPRs also have a role in the protection of TMK. Trademarks protect words, phrases, symbols and designs that identify a source of goods. This helps consumers identify products with preferred characteristics, such as a specific brand of herbal medicine. Trademarks have been used to market products that are based on TMK, such as *Truong Son Balsam*, a traditional balm of medicinal plants from Vietnam.<sup>129</sup> However, while trademarks can help distinguish authentic goods, they do not prohibit third parties from using traditional knowledge. Trademark rights are established either through registration or use in commerce. A collective trademark is a trademark owned by an organization whose members use the mark to identify themselves with a certain characteristic. Whereas trademarks are intended to indicate an individual source of goods or services, collective marks are intended for group use.

Copyright is granted to creators of original works against unauthorized use by third parties. Protectable subject matter is broad and includes books, films, music recordings and computer software, but not functional works or ideas. Protection generally lasts for the creator's lifetime plus at least 50 years.

#### "HOT YOGA" CONTROVERSY

*Bikram Yoga* is a 90-minute sequence of 26 traditional yoga postures and two breathing exercises performed in 105-degree heat.<sup>130</sup> It was developed by Bikram Choudhury, who received copyright protection for his yoga sequence in 1978 and trademark protection in 2002. It has since become popular worldwide, with about 900 franchise studios marketing Bikram Yoga classes. IP protection for Bikram Yoga has resulted in very significant financial benefits for its founder.<sup>131</sup>

Bikram Yoga has also become a focus of criticism from the Indian media, government officials and yoga experts.<sup>132</sup> The Indian government is now filming hundreds of yoga poses to help challenge current, and prevent future, IP protection for Bikram Yoga, as well as hundreds of other yoga-related copyrights, trademarks and patents.<sup>133</sup>

A geographical indication (GI) is another sort of IPR that helps identify a source of goods. Geographical indications associate a product with a place based on a characteristic associated with the product's place of origin. The classic example of a GI is "Champagne," which refers to sparkling wine produced in a specific region of France. GIs could be used to distinguish TMK based products by location, but cannot protect against the same use of TMK not associated with a place. GIs have been used in the Russian Federation to protect traditional craft making industries.<sup>134</sup> The way in which GIs are protected varies by nation, and may require registration or use in commerce.

New plant varieties may be protected by more than one form of IPR, such as by patent or under a *sui generis*<sup>135</sup> registration system. Protection applies to new varieties of plants that have been invented with human involvement. Patent protection for plant varieties requires novelty, which may fail to protect plant varieties that have been cultivated over

<sup>129</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fourth Session, WIPO/GRTKF/IC/4/7 (Nov. 5, 2002) at Annex II, page 8.

<sup>130</sup> See generally <http://www.bikramyoga.com/>.

<sup>131</sup> Maureen Farrell, Bikram Yoga's New Twists, *Forbes Magazine*, Sept. 21, 2009, available at <http://www.forbes.com/forbes/2009/0921/entrepreneurs-franchising-bikram-yoga-new-twists.html>.

<sup>132</sup> Jeremy Page, American Attempt to Patent Yoga puts Indians in a Twist, *The Sunday Times*, May 31, 2007, available at <http://www.independent.ie/world-news/us-attempt-to-patent-yoga-puts-indian-government-in-a-twist-26294268.html>.

<sup>133</sup> India Moves to Patent Hundreds of Yoga Postures, *The Telegraph*, June 8, 2010, available at <http://www.telegraph.co.uk/news/worldnews/asia/india/7809883/India-moves-to-patent-hundreds-of-yoga-postures.html>.

<sup>134</sup> WIPO/GRTKF/IC/4/7, supra note 129, Annex II, page 8.

<sup>135</sup> *Sui generis* regimes are described later in this section.

many generations. However, slight modifications to existing traditionally used plants may qualify.

IP holders may also elect not to disclose information about an invention, and to protect their invention through secrecy. A trade secret is information not generally known or reasonably discoverable, through which an IP holder can obtain some economic advantage. Trade secrets must be the subject of efforts that are reasonable under the circumstances to maintain secrecy; once trade secrets become known they generally cease to enjoy protection.

## 2. OBSTACLES TO PROTECTING TRADITIONAL MEDICINE

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Current IP regimes were not designed to accommodate traditional knowledge, and many experts have claimed that conventional patent laws are inadequate to protect TK and biodiversity.<sup>136</sup> Patent protection is limited in duration, and that may be problematic for TMK that TMK holders believe should be protected retroactively and/or indefinitely.<sup>137</sup> TMK holders are also presented with significant obstacles in attempting to obtain patents for TMK. The most significant challenge may be the requirement for novelty in any new invention. In the EU, if an invention becomes publicly available in any way before a patent application is filed, the application will be rejected.<sup>138</sup> The U.S. has a similar requirement with a one-year grace period.<sup>139</sup> Making the invention publicly available may include selling the invention, disseminating information about the invention, or documenting the invention in a way that documentation can be accessed by a third party. 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. The U.S. patent for turmeric was invalidated when evidence was provided that a traditional use had previously been documented in an ancient Sanskrit text as well as other sources.

The requirement for inventiveness is also a significant barrier to patenting traditional medicines. Pharmaceutical drugs derived from natural products involve some form of alteration or purification, and such compounds may be considered a novel and inventive step over naturally occurring substances. Because herbal medicines typically comprise natural products in their raw form, it may be difficult to claim that these remedies are novel and involve an inventive step (or, in U.S. terminology, are non-obvious). It can also be problematic with TM to differentiate between prior art<sup>140</sup> and a claimed invention, and ascertaining that difference is a prerequisite for assessing inventive step.<sup>141</sup> In addition, patent applications require the identification of inventors, and determining inventorship of TMK may be difficult.<sup>142</sup>

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<sup>136</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Session, WIPO/GRTKF/IC/3/7 (May 6, 2002) at 39.

<sup>137</sup> See Ryan Abbott, *Treating the Health Care Crisis: Complementary and Alternative Medicine for PPACA*, 14 DePaul J. Health Care L. 35 (2011).

<sup>138</sup> European Patent Convention, Oct. 5, 1973, Article 54.

<sup>139</sup> The one year grace period afforded by U.S. patent law allows an inventor to file a patent application within one year after public disclosure of an invention or first sale of a patented product. 35 U.S. Code Section 102 (2011). The recently enacted Leahy-Smith "America Invents Act" (AIA), which represents the most significant change to the U.S. patent system since the U.S. Patent Act of 1952, retains the uniquely American grace period but redefines what "disclosures" an inventor can make. Section 102(b)(1). Leahy-Smith America Invents Act of 2011, H.R. 1249, 112th Cong, § 1–37 (2011).

<sup>140</sup> Prior art is, in general, all the knowledge that existed prior to the relevant filing or priority date of a patent application, whether it existed by way of written and oral disclosure. In some legal instruments there is a differentiation between printed publications, oral disclosures and prior use and where the publications or disclosure occurred. See Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions (WIPO/GRTKF/IC/20/INF/7), at 16 of Annex.

<sup>141</sup> Xuan Li and Weiwei Li, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, 10(2) J. World Intell. Prop. 125-148 (2007).

<sup>142</sup> Silke Von Lewinski, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 97–100, (Second Edition 2008).

Finally, financial and human resource constraints can impair the ability of TMK holders to obtain patent protection. Applying for a patent is a complicated process, requiring technical expertise and the services of trained legal professionals. The cost of applying for a patent can be prohibitive for TK holders.

### 3. EVOLUTION OF INTELLECTUAL PROPERTY PROTECTION

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The issue of TM and IPRs has become a more prominent topic of debate in recent years. Developing countries, concerned about misappropriation of natural resources and preservation of biodiversity, are pushing for greater protection of TMK. IP protection for TM remains controversial, and discussions as well as negotiations are still ongoing at WIPO, within the framework of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC)<sup>143</sup>, and WTO.

The Convention on Biological Diversity (CBD) is an international treaty adopted in 1992 to promote conservation of biological diversity, sustainable use of natural resources, and fair and equitable benefit-sharing arising from use of GRs.<sup>144</sup> It recognizes that States have the sovereign right to exploit their own resources and to control access to GRs.<sup>145</sup> Article 8(j) is directly relevant to TM. It states that a contracting party to the Convention shall, as far as possible and as appropriate, "subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."<sup>146</sup> Currently, 193 nations are parties to the CBD.<sup>147</sup>

A supplementary agreement to the CBD was adopted in October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol).<sup>148</sup> It provides a legal framework for access and benefit-sharing (ABS) arising from the utilization of GRs and associated traditional knowledge.<sup>149</sup> The Protocol establishes more detailed rules regarding the mechanisms for providing information to national patent offices and other stakeholders, and for sharing benefits on mutually agreed terms. The Protocol has not yet entered into force.

However, the CBD and Nagoya Protocol still require strong national policies and legislation to truly support the rights of TMK holders. In the absence of a strong international framework for TMK protection, regional and domestic efforts have been made to protect TM. National laws are currently the prime mechanism for achieving protection and practical benefits for TMK holders.

China, which has substantial interests in the protection of its TM and biodiversity resources for commercial exploitation, has enacted pro-TM patent laws. China is one of the largest TMK-holding countries of the world, and its patent law, enacted in 1993, is the oldest

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<sup>143</sup> See <http://www.wipo.int/tk/en/igc/>.

<sup>144</sup> Convention on Biological Diversity [CBD], Text of the Convention on Biological Diversity, <http://www.cbd.int/convention/convention.shtml>.

<sup>145</sup> *Id.* at Art. 3 and 15.

<sup>146</sup> Convention on Biological Diversity, *supra* note 144, at Art. 8(j).

<sup>147</sup> CBD, List of Parties, <http://www.cbd.int/convention/parties/list/>.

<sup>148</sup> CBD, Secretariat of the Convention on Biological Diversity, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, (Montreal 2011), <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

<sup>149</sup> CBD, About the Protocol, <http://www.cbd.int/abs/about/>.

patent regime for TMK protection.<sup>150</sup> Chinese patent law protects new TM products, methods of process, and uses of TM. This includes herbal preparations, extracts from herbal medicines, foods containing herbal medicines, methods for preparing herbal formulas and new medical indications for traditional formulas.<sup>151</sup> By 2002, the Chinese State Intellectual Property Office (SIPO) had received 20,864 patent applications related to TCM.<sup>152</sup> These applications are managed by a group of more than 30 TCM-specialist patent examiners.

China has also required the disclosure of the source of GRs in domestic patent applications. This is an attempt to both shield its large domestic market and to promote exports of biological resource based inventions to foreign markets. China has joined a group of developing countries with diverse biological resources including Brazil and India in negotiating at WIPO and WTO to require mandatory disclosure of the source and origin of GRs and/or associated TK, and to provide evidence of compliance with applicable national prior informed consent and equitable benefit-sharing requirements.<sup>153</sup>

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#### 4. *SUI GENERIS* REGIMES

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In the context of IP, *sui generis* laws refer to a unique set of protections for a particular subject matter.<sup>154</sup> For example, TRIPS requires that nations provide IP protection for plant varieties, but permits nations to either provide patent protection or *sui generis* protection. The African Union, a regional organization, has developed a model law that protects both plant varieties and TK.<sup>155</sup> The objectives of this legislation include ensuring the sustainable use of biological resources, benefit-sharing and the protection of traditional knowledge. Indigenous peoples and local communities have the right to refuse third parties access to TK when they determine that sharing access may threaten the integrity of their cultural heritage.<sup>156</sup>

Several nations have taken the initiative in providing specialized protection for TM in IP systems. Peru, for example, established a *sui generis* regime to promote respect for, and protection of, the collective knowledge of indigenous people.<sup>157</sup> The objectives of the law include promoting the fair and equitable distribution of benefits, ensuring the use of TK takes place with the prior informed consent of indigenous peoples, and preventing misappropriation.

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<sup>150</sup> Xuan Li and Weiwei Li, Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China, 10(2) J. World Intell. Prop. 125-148 (2007).

<sup>151</sup> WHO, Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, WHO/EDM/TRM/2001.1, Dec. 6-8, 2000, at 22.

<sup>152</sup> Von Lewinski, *supra* note 142, at 104.

<sup>153</sup> Study Prepared by Frederick M. Abbott for The World Bank. China and the Protection of Biological Diversity: Options in WTO Negotiations. Final text of June 14, 2007.

<sup>154</sup> For analysis of these laws in more detail, see generally WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, Fifth Session, Consolidated Analysis of the Legal Protection of Traditional Cultural Expressions, WIPO/GRTKF/IC/5/3 (May 2, 2003).

<sup>155</sup> African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000, (OAU), available at [http://www.grain.org/brl\\_files/oau-model-law-en.pdf](http://www.grain.org/brl_files/oau-model-law-en.pdf).

<sup>156</sup> *Id.* at Art. 19.

<sup>157</sup> Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources, 2002, Law No. 27,811 (Peru), available at <http://www.wipo.int/wipolex/en/details.jsp?id=3420>.

## 5. THE PUBLIC DOMAIN

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The public domain is generally thought to consist of knowledge, ideas and innovations over which no one has any proprietary rights, and which are, therefore, freely available to be used or exploited.<sup>158</sup> Information in the public domain is often considered in negative terms, as whatever is left over after various tests of legal protection have been applied.<sup>159</sup> Inventions, for example, may enter the public domain if the subject matter is ineligible for protection,<sup>160</sup> or if prior IPRs have expired.<sup>161</sup>

This common understanding of the public domain ignores some critical distinctions. Being publicly available is not the same as being in the public domain. For example, use of publicly available traditional medicine may still require prior informed consent from TMK holders as well as benefit-sharing. Also, information in the public domain may not be publicly available. For instance, access to unpublished texts may be physically restricted, and this may convey more control over use than IP laws provide.<sup>162</sup> Certain uses of materials covered by IPRs may also be permitted under exceptions authorized by international IP rules, such as fair uses of copyrighted material. In addition, IPR protected material may be made available under licenses that permit wide use (e.g., Creative Commons [CC]).

In regards to TMK, the role of the “public domain” is controversial. It has been criticized by TMK holders as operating to exclude traditional medicine from protection and to justify misappropriation.<sup>163</sup> On the other hand, the public domain can be thought of in positive terms as a valuable resource.<sup>164</sup> Information in the public domain serves as the foundation for the creation of new knowledge, and as a rich source of content for education.<sup>165</sup>

A substantial amount of TMK is already publicly available. TCM, for example, is taught extensively outside of China in both Europe and the United States of America, and both traditional and modern sources of information on Chinese herbal therapeutics are freely available in a variety of languages.

TMK holders have the option of voluntarily disseminating knowledge without IP protection. The Government of China has made the strategic decision to disseminate some knowledge and promote codified<sup>166</sup> TCM worldwide. China may hope that increased use of TCM will still produce economic benefit in the absence of formal IPRs.<sup>167</sup> The Government of India, on the other hand, has chosen to restrict information it is documenting on Ayurveda.

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<sup>158</sup> See WIPO, Standing Committee on the Law of Patents, Dissemination of Patent Information, Thirteenth Session, SCP/13/5, Feb. 18, 2009, at para. 110.

<sup>159</sup> E. Samuels, The Public Domain in Copyright Law, 41 J. Copyright Soc’y U.S.A. 137 (1993), quoted in Pamela Samuelson, Enriching Discourse on Public Domain, 55 DUKE L.J. 101, 105 (2006).

<sup>160</sup> See Dissemination of Patent Information (SCP/13/5), supra note 158, para. 11.

<sup>161</sup> See Dissemination of Patent Information (SCP/13/5), supra note 158, para. 116.

<sup>162</sup> Id. at 24–25.

<sup>163</sup> William van Caenegem, The Public Domain: Scientia Nullius, European Intellectual Property Review 2002, at 324.

<sup>164</sup> See Boettiger, S. and C. Chi-Ham, “Defensive Publishing and the Public Domain”, in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, (Krattiger A., R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satyanarayana, G.D. Graff, C. Fernandez, and S.P. Kowalski (eds.), 2007, MIHR (Oxford, U.K.), PIPRA (Davis, U.S.A.), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil) and bioDevelopments-International Institute (Ithaca, U.S.A.).

<sup>165</sup> Committee on Copyright and Other Legal Matters [CLM], Joint Statement by IFLA, EIFL and EBLIDA to the Provisional Committee on Proposals Related to a WIPO Development Agenda, Second Session, Geneva, June 26-30, 2006, available at <http://www.ifla.org/III/clm/p1/A2K-7.htm>.

<sup>166</sup> Codified traditional medicine knowledge refers to knowledge that is documented and arranged systematically. For example, the different traditions of Indian medicine such as Ayurveda, Siddha, and Unani Tibb are documented in at least 54, 29, and 13 authoritative books respectively. See: WIPO FFM, supra note 119, at 59.

<sup>167</sup> A significant portion of TCM may remain non-codified (not-recorded). This is particularly true of practical applications of TCM theory and TMK developed by ethnic minorities outside of mainstream TCM. Xuan Li and Weiwei Li, supra note 141.

India may later decide to release TMK under IP protection, or may use TMK to develop new technologies and therapeutics.

TMK holders may have non-economic motivations for disseminating information as well. Social and environmental pressures currently threaten the preservation of some forms of TMK, and concerns that knowledge may be lost may prompt holders to disseminate information. Some holders may choose to release information for altruistic purposes, as TMK may improve health care outside of indigenous communities.

If TMK has already been made publicly available, TK holders may no longer have the option of applying for certain IP protections.<sup>168</sup>

## KAVA

Kava is a medical plant first domesticated in the Republic of Vanuatu, an island nation located in the South Pacific Ocean, and it is used as a traditional medicine in several Asian countries. Today, many large pharmaceutical companies make kava based products, and genetic elements of the kava plant have been patented in Europe.<sup>169</sup> The U.S. Patent office has granted a U.S. based company a patent for “kavatrol,” a dietary supplement that serves as a general relaxant, composed of Kava, chamomile, hops, and schizandra.<sup>170</sup> Two German companies have obtained a patent for Kava as a prescription drug for treating strokes, insomnia and Alzheimer’s disease. A cosmetics company has patented the use of Kava against hair loss in France.<sup>171</sup>

## 6. OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

The IP system has been criticized for not adequately taking into account collective ownership of traditional knowledge.<sup>172</sup> The modern concept of property rights belonging to one or more identifiable individuals may be poorly suited to capture the shared development of ideas within an indigenous community.

Some national *sui generis* regimes provide special rules for collective ownership of traditional knowledge. For example, Brazil permits traditional knowledge associated with GRs to be owned by an indigenous community, even if only one member of that community holds the knowledge.<sup>173</sup> On the other hand, a number of countries stipulate that IPRs associated with TK are the sole property of a government agency.<sup>174</sup> Although indigenous communities possess the knowledge, in these countries they are not directly entitled to IP protection.

Within conventional frameworks there are still ways in which TMK holders can attempt to control IPRs collectively. This can be accomplished through individual ownership

<sup>168</sup> Some *sui generis* regimes may still provide some method for compensation. For example, Peruvian legislation requires that an unspecified percentage of the income derived from products related to TK that has passed into the public domain within the past 20 years be contributed to the National Fund for Indigenous Peoples. Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources, *supra* note 157, Art. 13.

<sup>169</sup> WIPO FFM, *supra* note 119, at 77.

<sup>170</sup> David R. Downes & Sarah A. Laird, Innovative Mechanisms for Sharing Benefits of Biodiversity and Related Knowledge: Case Studies on Geographical Indications and Trademarks, in UNCTAD Biotrade Initiative (1999), at 5.

<sup>171</sup> Marion Panizzon, Traditional Knowledge and Geographical Indications: Foundations, Interests and Negotiating Positions, Working Paper No. 2005/01, Oct. 2006, available at <http://www.nccr-trade.org/images/stories/publications/IP8/Traditional%20Knowledge.pdf>.

<sup>172</sup> World Bank, Cultural Heritage and Collective Intellectual Property Rights IK Notes n° 95, Aug. 2006, available at <http://siteresources.worldbank.org/INTINDKNOWLEDGE/Resources/iknt95.pdf>.

<sup>173</sup> *Id.*

<sup>174</sup> Alexander Peukert, Individual, Multiple and Collective Ownership of Intellectual Property Rights: - Which Impact on Exclusivity? Page 18, Forthcoming 2010 in Annette Kur & Vytautas Mizaras (eds), “Can one size fit all?” (ATRIP Series).

of IPRs, which involves only one entity holding one or more IPRs. In the legal sense, an “entity” or “person” does not need to be an individual; it can be a business organization, for example, a corporation, limited liability company, or partnership. Even a national government can be treated as a “person” for purposes of ownership. Indigenous group members can jointly control IP through ownership or control of a business entity.

Community members may also collectively control IPRs through licensing. Licensing permits an IPR owner to authorize one or more licensees to use protected subject matter. Contracts can be structured to permit a variable degree of use by licensees, and non-licensed third-parties must still observe the IPR. Licensing could permit members of an indigenous community to use the subject matter, or could allow the TMK to be marketed outside of the community without sharing direct ownership of an IPR.

Finally, multiple individuals can directly share joint ownership of IPRs. The rights and requirements of joint ownership vary by form of IP and also by country. Collective trademarks and geographical indications are intended for group use. Collective marks are owned by one entity, but they may be used and enforced by multiple individuals. Geographical indications allow a group to identify a good as originating in a territory, region or locality, where a given characteristic of the good is essentially attributable to its geographical origin. For patents and copyrights, multiple individuals usually share joint undivided interests in the subject matter. It is more difficult, though sometimes possible, to have joint ownership of trade secrets and trademarks. Because trademarks, for example, are designed to designate origin from an enterprise, joint ownership is only possible where joint owners are structured to assure joint control over the goods or services sold under the mark. TMK holders may wish to modify default rules of joint ownership by contractual agreements, although national laws may limit what contracts can stipulate.

#### MIJIKENDA OWNERSHIP OF TRADITIONAL KNOWLEDGE

The Mijikenda tribe consists of nine closely related sub-tribes located along the coast of Kenya.<sup>175</sup> Clans consist of several family groups with a common patriarchal ancestor. Each clan has its own sacred place known as a *kaya*, a shrine for prayer, sacrifices and other religious rituals, located deep in the surrounding forests. TMK is restricted to clan or family members, and access brings a responsibility to ensure proper use for the benefit of community healthcare. A rating process is traditionally used to assess the personal conduct and motive of an applicant for TMK.

The Mijikenda have not generally transmitted traditional knowledge to foreigners or non-villagers, although a council of elders may grant consent in special circumstances.<sup>176</sup> TMK is protected through the belief that it will only be effective if used with proper rituals and initiations, and that non-compliance will be severely punished by spiritual powers. However, such beliefs may not be shared by third parties, leaving communities vulnerable to misappropriation.

Recently, there has been criticism that customary Mijikenda laws have been modified or completely lost.<sup>177</sup> Loss of traditional territories due to commercial use and conservation efforts, growing integration with western society, and the extension of the government have been criticized for undermining time-honored authorities and values. As clans become westernized, a number of traditional healers have begun practicing commercially.<sup>178</sup>

<sup>175</sup> See generally The Mijikenda Tribe, The Nine Sub-tribes of Kenya's Mijikendas, <http://www.kenya-information-guide.com/mijikenda-tribe.html>.

<sup>176</sup> K. Swiderska, Information and Views for the CBD Expert Group on Traditional Knowledge Associated with Genetic Resources, Hyderabad 16-19 June 2009, <http://pubs.iied.org/pdfs/G02495.pdf>, at 8.

<sup>177</sup> Id. at 4.

<sup>178</sup> Id.

Whereas Mijikenda healers traditionally charged small token fees, ensuring benefits for the whole community, some now charge high fees for herbal treatment which local patients may be unable to afford.

Traditional community authorities have also been circumvented for access to TMK, either through direct contact with individual TMK holders or the government. In one case, permission to access a Mijikenda kaya for research purposes was granted by the local government authority without the tribal community's prior informed consent. Mass extraction of plants and biodiversity degradation allegedly ensued.<sup>179</sup>

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<sup>179</sup> Swiderska, *supra* note 176, at 17.

## VI. CONSIDERATIONS FOR DOCUMENTING TRADITIONAL MEDICINE

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TK holders are increasingly documenting TMK to preserve, protect, and commercialize traditional medicine.<sup>180</sup> However, the issues related to documenting TMK are complex, with potentially far reaching consequences. TMK holders should ensure they understand both the risks and benefits of documentation prior to taking action. If TMK is documented, it is important that it be documented in the most appropriate manner.

### 1. BENEFITS AND RISKS OF DOCUMENTATION

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Documenting TMK may help preserve knowledge. Today, the cultural survival of many indigenous communities is threatened, and some traditional systems of disseminating knowledge may already be lost. Modern lifestyles and the disruption of traditional ways of life may cause younger generations to lose interest in learning about traditional medicine. Traditional languages used to pass down information may no longer be as widely understood. Documenting TMK may help preserve this knowledge for future generations.

Documenting traditional medicinal knowledge may also improve the use of TM. Documentation can be a vital step in facilitating research on TM safety and efficacy. In addition, documentation may assist with clinical practice and teaching. Given the important role traditional medicine plays in providing health care, documenting TMK may help improve public health.

Documentation may also promote commercialization of TMK. Documentation is necessary to obtain certain types of IP protection, which may help TMK holders to market traditional medical based products and services. Documentation may also facilitate investment and innovations related to traditional medicine. TMK can be useful for bioprospecting, and may facilitate basic research on the healing properties of medicinal plants. For example, in South Africa, the Research Group for Traditional Medicines has established a database to improve research on TM.<sup>181</sup> The Group aims to provide a scientific infrastructure for the use of TMK, improve communication between conventional and traditional practitioners, promote the use of TM and build human resources.

Documenting TMK may also be useful for *defensive* protection of traditional medicine. Defensive protection prevents third parties from improperly obtaining IP rights over TMK. For example, the Indian government provided information to the European Patent Office to invalidate a patent granted on the anti-fungal properties of Neem, a traditional Indian medicine. The Indian government presented documentation of the traditional use of Neem, and the patent was revoked in 2008. However, defensive protection does not prevent third parties from using TMK. In fact, providing information that TMK constitutes prior art can prevent TMK holders from obtaining some types of IP protection.

The most prominent example of defensive protection has been the Traditional Knowledge Digital Library (TKDL) established by the Indian government<sup>182</sup>; however, other

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<sup>180</sup> For additional information on documenting traditional knowledge more generally, see WIPO, The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit, (Nov. 1, 2013), available at [http://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). The WIPO Traditional Knowledge Documentation Toolkit provides useful practical guidance on how to undertake a TK documentation exercise as a process and how to address critical IP related issues and questions, as they surface during this effort.

<sup>181</sup> WIPO FFM, *supra* note 119.

<sup>182</sup> European Patent Office [EPO], India's Traditional Knowledge Digital Library (TKDL): A powerful tool for patent examiners, (Jan. 25, 2010), [http://www.tkdل.res.in/tkdل/TKDL\\_CSIR/pressrelease/press%20images/www.epo.org\\_topics\\_issues\\_traditional.html.pdf](http://www.tkdل.res.in/tkdل/TKDL_CSIR/pressrelease/press%20images/www.epo.org_topics_issues_traditional.html.pdf).

large-scale defensive projects exist. In 2008, the Chinese State Intellectual Property Office (SIPO) granted the European Patent Office access to its database on TCM.

### THE TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)

This project is an initiative of several Indian government agencies designed to document traditional Indian Ayurvedic medicine.<sup>183</sup> Information on Ayurveda may be publicly available in India, however it is difficult for patent examiners in other countries to search *prior art* and determine if a claimed invention is novel. Traditional knowledge may be documented in languages such as Sanskrit that are not accessible to international patent examiners. The founding objective of the TKDL was to make documented information easily and comprehensively accessible to patent examiners with the objective of preventing the granting of patents for traditional Indian medicines.<sup>184</sup> The TKDL expert group estimated that internationally, about two thousand unjustifiable patents on Ayurveda were being granted annually.<sup>185</sup> The TKDL makes digital information on Ayurveda available in multiple languages.

Although the initial objective of the TKDL was to compile and widely disseminate information on Ayurveda, the Indian government more recently elected to restrict access to the database. In February, 2009, the TKDL became accessible to patent examiners at the European Patent Office (EPO) under an access agreement.<sup>186</sup> This contract helps prevent the grant of patents where evidence of prior art exists in the TKDL, but information in the database is otherwise kept confidential. Access to the TKDL database was granted to the India Patent Office (CGPDTM) in July 2009, to the German Patent Office (DPMA) in October 2009, to the USPTO in November 2009, to the United Kingdom Patent and Trademark Office in February 2010, to the Canadian Intellectual Property Office in September 2010 and to IP Australia in January 2011.<sup>187</sup> It is unclear at this point to what extent the Indian government may try to exploit information in the TKDL commercially.

Documenting TMK also has drawbacks. It may expose knowledge to third parties, and if TMK is freely available it may become part of the public domain. At this point, TMK holders generally cannot obtain trade secret or patent protection for TMK. In addition, public disclosure may facilitate the unauthorized use of TK which TK holders wish to protect.

TMK holders have limited control over TMK which is publicly available. While this information may have initially been released for altruistic purposes, third parties are able to commercialize TM in ways TMK holders may find objectionable. For example, a foreign manufacturer might choose to market a traditional herbal medicine for traditionally contraindicated symptoms. In addition to safety concerns, such marketing efforts may negatively affect the reputation of the traditional medicines or groups involved.

## 2. ADDITIONAL CONSIDERATIONS FOR DOCUMENTATION

Documenting traditional knowledge is complex, and potential challenges should be resolved prior to any documentation. Failure to address these issues in advance may result in loss of IP protection, misappropriation of resources, legal challenges to ownership and failure to adequately utilize TMK.

<sup>183</sup> The TKDL also contains information on other forms of traditional medicine used in India, including Yoga, Naturopathy, Unani, Siddha, and Homeopathy. See generally <http://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdl.asp?GL=Eng>.

<sup>184</sup> K. Sharma, National measures and experience for protection of traditional Indian medical knowledge of Ayurveda in the regime of intellectual property rights, WHO/EDM/TRM/2001.1, *supra* note 151.

<sup>185</sup> Government of India Press Information Bureau, India Partners with EU to prevent India's traditional medicinal knowledge from Biopiracy, Feb. 9. 2009, <http://pib.nic.in/release/release.asp?relid=47343>.

<sup>186</sup> EPO, India's Traditional Knowledge Digital Library, *supra* note 182.

<sup>187</sup> <http://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdl.asp?GL=Eng>.

Complex questions of ownership surround many forms of TMK. In Zimbabwe, for example, TMK may be passed down along hereditary lines within a particular tribe or indigenous group. Who then “owns” this knowledge? Ownership claims may be brought by members of the healing community, members of the larger indigenous community or even the national government. It can be further challenging to identify who qualifies as a community member or “practitioner trained in the art”. Likewise, who should be authorized to represent a community? Should groups maintain traditional organization, or should modern notions of fair representation take precedence?

There are no simple answers to questions of ownership, and ownership issues are likely to receive more attention as the financial value of TMK is increasingly recognized. The WIPO Secretariat suggests that community consultations should be held in order to assess the views of community members.<sup>188</sup> Community members may have differing opinions on whether TMK should be shared or commercialized, as well as how this should be accomplished. Ideally, consensus should be reached within a community.

TMK holders should also have a clear idea of the goals and likely effects of documentation prior to taking any action. Is knowledge being documented defensively to prevent third parties from obtaining IP rights? Is knowledge being documented to assist researchers in finding new uses for traditional medicines or to develop new drugs from medicinal plants? Is knowledge being developed for widespread dissemination in order to promote and improve traditional medicine use? Understanding the goals of documentation is critical to ensuring a successful outcome. This will determine how knowledge should be documented, including whether knowledge should be kept confidential.

Community consensus is vital in setting the goals of documentation. Undertakings to document TMK should first focus on raising awareness within a community on why documenting may be necessary and why it is being done. TMK holders should have, to the greatest extent possible, a common direction for the use of documentation.

TMK holders or community representatives should establish, preferably in writing, that community members were informed in advance of any efforts to document or use TMK outside of its traditional context. This may require communicating the following information: the purpose of the proposed documentation, collaboration or research, including any commercial plans; options for participation by stakeholders; disclosure of the potential value of transferred knowledge or GRs; potential outcomes, including the likelihood of commercial success; rights available to stakeholders under the law; and options for benefit-sharing.<sup>189</sup> TMK holders should also agree upon equitable benefit-sharing before any potential commercial activities are undertaken.

After identifying community goals and interests, TMK holders need to determine the most appropriate form of documentation. Different sources of TMK such as oral traditions, written texts, medical practices, biological materials and GRs may have different documentation requirements. For example, GRs may require laboratory investigation to compile genetic code suitable for basic research. Medical practices involving ritual music may not be adequately described in writing. Where TMK is part of a whole medical system, such as traditional Arabic medicine, the suitability of documentation for practitioner use should be considered. Documentation may need input from a variety of sources, including TMK holders, experts and community members.

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<sup>188</sup> See, e.g., WIPO, The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit, (Nov. 1, 2013), available at [http://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).

<sup>189</sup> Daniel Putterman, Incorporating Genetic Resource Utilization into ICZM – Policies and Institutions in Jamaica, at 189, in Kent Gustavson et Al., eds., Integrated Coastal zone Management of Coral Reefs: Decision Support Modeling (World Bank 2000), available at <http://www.oas.org/dsd/IABIN/Component1/ReefFix/Mobay%20Book/Chap%2012-13%20Anexos.pdf>.

The question of the most appropriate form for documentation to take is also dependent on the type of IP protection being sought. Patents, for example, generally require a written description of any new invention that sufficiently describes the invention and how to use it. If TMK is to be protected under a trade secret regime, documentation of how to replicate TMK must be undertaken with caution. Access to the documentation must be strictly limited to maintain its secret character.

There is no widely accepted template for documenting TMK, and given the variation within traditional medicine, there is no single “best” way to document. If TMK is being documented to develop innovations or improve the use of traditional medicine, extensive data may be necessary. In the case of herbal medicines, information related to herb gathering, cultivation, preparation, storage and the differences between various species of a particular herb can all be important to TM use. Clinical information on herbal medicine use, including indications and contraindications, dosages, toxicity and side-effects, methods of administration and combinations of herbs is likewise important.

TMK holders should carefully consider how and under what conditions access to documentation will be permitted. It is important that TMK holders be adequately informed to safeguard their reputations and interests when interacting with third parties. TMK holders may wish to consider providing access only under licensing agreements.

### 3. TRADITIONAL KNOWLEDGE DATABASES

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A database is a collection of related information, and traditional knowledge databases (TKDB) refer to compilations of traditional knowledge. Databases exist in many different forms. They may be compilations of printed material, or information may be stored electronically. Electronic databases, in turn, may be simple and publicly accessible, or complex with varying levels of restrictions on information access. For example, access may be reserved for the exclusive use of indigenous and local communities and protected under customary law. Three principal types of TKDBs exist: community TKDBs managed by indigenous communities, external TKDBs managed by non-community collaborators, and TK registers which are usually managed by governments or organizations.

TMK holders may create, develop and maintain databases directly, with or without external assistance. If TMK holders are documenting TMK independently, the process of collecting information essentially creates a database. Community TKDBs have the advantage of permitting TMK holders a high degree of control over documented TMK. Sophisticated electronic databases, however, can be expensive and technically challenging to develop. An example of a community TKDB is the Kaska Traditional Knowledge Network (KTKN) in British Columbia, Canada.<sup>190</sup>

Databases created by external collaborators are the most common form of TKDB.<sup>191</sup> These may be maintained by organizations including universities, museums, corporations, and NGOs. External collaborators have a variety of motivations for maintaining databases, such as to provide legal protection for traditional knowledge or to make knowledge easily accessible to facilitate academic research. Some of these databases have been created with the participation of TMK holders, but others simply consist of information claimed to be

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<sup>190</sup> United Nations Environment Programme (UNEP), Composite Report on the Status and Trends Regarding the Knowledge, Innovations and Practices of Indigenous and Local Communities, UNEP/CBD/WG8J/4/INF/9 (Dec. 21, 2005), p. 11.

<sup>191</sup> *Id.* at 12.

in the public domain. Examples include the World Bank Database of Indigenous Knowledge and Practices and the Honeybee Network.<sup>192</sup>

Registers usually function to help establish legal rights. Publication of information in a registry puts the public on notice that the registrant asserts a claim. For example, submission of documented TMK to a register may establish positive rights of ownership or may be used to prevent patents based on misappropriation. Panama established a special registry through legislation designed to help indigenous peoples gain property rights over traditional knowledge.<sup>193</sup> Rights over TK under this law are not recognized until knowledge is registered in the national Collective Register for Intellectual Property administered by the Dirección Nacional de Derechos de Autor.<sup>194</sup>

Peru has a *sui generis* regime for traditional knowledge that establishes registers to preserve and safeguard TK, and to provide the National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) information necessary to defend the interests of indigenous peoples.<sup>195</sup> TK is stored in three types of registers.<sup>196</sup> It may be stored in a public register, in a confidential register administered by the government and inaccessible by third parties, or in local registers organized by indigenous peoples directly, with government technical assistance available upon request. INDECOPI should provide information in the Public National Register to national patent offices in order to prevent patents it views as misappropriation.<sup>197</sup> Applications for registration must include a clear and full description of the TK being registered, known use of related biological resources, and a designation of biological resources relevant to the TK.<sup>198</sup>

External databases and public registries may be particularly useful for defensive protection of TMK. These may be placed online for open-access in formats useful to patent examiners. Information simply stored in databases or posted on the internet, even if publicly accessible, may not be searchable or useable to patent examiners.<sup>199</sup> If TMK holders are considering partnership with an externally controlled database, they should understand how information in the database is stored, who owns the information, and whether there are limitations on access and use.

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#### 4. EXTERNAL COLLABORATIONS

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TMK holders may elect to collaborate with outside individuals or organizations in order to protect IPRs or to commercialize traditional medicines. There are many ways to structure such partnerships, and forming and maintaining collaborations can be challenging for TMK holders who may lack experience in this area. TMK holders should exercise caution prior to entering into agreements with academic institutions or pharmaceutical companies interested in researching or commercializing TMK. TMK holders may wish to consult experts on any proposed collaboration and seek legal counsel. Guidance for TMK holders may be available from government agencies such as INDECOPI, and non-governmental

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<sup>192</sup> World Bank Database of Indigenous Knowledge and Practices, <http://www.worldbank.org/afr/ik/datab.htm>; The Honey Bee Network (<http://www.sristi.org/honeybee.html>).

<sup>193</sup> Law on the Special Intellectual Property Regime with Respect to the Collective Rights of Indigenous Peoples to the Protection and Defense of their Cultural Identity and Traditional Knowledge, 26 June 2000, Law No. 20 (Panama).

<sup>194</sup> UNEP/CBD/WG8J/4/INF/9, *supra* note 190, at 20.

<sup>195</sup> Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources, 2002, Law No. 27,811 (Peru), Art. 16, available at <http://www.wipo.int/wipolex/en/details.jsp?id=3420>.

<sup>196</sup> *Id.* at Art. 15.

<sup>197</sup> *Id.* at Art. 23.

<sup>198</sup> *Id.* at Art. 20.

<sup>199</sup> WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Inventory of existing online databases containing traditional knowledge documentation data, WIPO/GRTKF/IC/3/6 (May 10, 2002), available at [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_3/wipo\\_grtkf\\_ic\\_3\\_6-main1.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/wipo_grtkf_ic_3_6-main1.pdf).

organizations (NGOs) such as the Bioresources Development and Conservation Program (BDCP).

Outside parties may have different motivations for collaborating with TMK holders. Pharmaceutical companies may wish to utilize TMK purely for commercial purposes such as bioprospecting, new drug development or dietary supplement manufacturing. Academic institutions may wish to study TMK to understand how and why traditional medicine works. Increasingly, many academic institutions are functioning as for-profit research centers.

#### UNIVERSITY OF ILLINOIS AT CHICAGO BENEFIT-SHARING POLICY

The University of Illinois at Chicago (UIC) has a policy on benefit-sharing from research on drugs derived from natural products.<sup>200</sup> Researchers from UIC collaborate with counterparts in other countries who supply plant genetic material. In the event that UIC researchers discover a new compound for which patent protection is sought, co-inventorship is awarded to scientists from the host country that played an inventive role in the discovery. In addition, net royalty income paid to the University from licensing to pharmaceutical firms is shared, with one-half paid to a Trust Fund for the benefit of the country of origin of the genetic material.

TMK holders should consider establishing the rights and responsibilities of all parties in writing prior to any proposed collaboration. Contracts, which are legally binding agreements between parties, may be used to enforce access and benefit-sharing agreements, maintain confidentiality of trade secrets, license the use of knowledge, or govern the transfer of GRs. If a proposed collaboration is likely to result in IPRs, a contract should establish who will own or control those rights, and how they may be used.<sup>201</sup>

Confidentiality, or non-disclosure, agreements keep transferred information private. They may prevent collaborators from sharing knowledge publicly or with other parties. Confidentiality agreements may be necessary to maintain trade secret protection. Trade secret protection only applies to information for which reasonable steps have been taken to protect against disclosure.

Licensing agreements grant rights to a licensee to use protected subject matter. These agreements may permit TMK holders to determine who will control knowledge and how it will be used. TMK holders can transfer the entire right to control knowledge to a third party, or only the right to use knowledge for a limited time, specific purpose, or in a particular geographical area. Licenses can be granted to a single party, or to an unlimited number of parties.

Material transfer agreements (MTAs) govern the transfer of research materials between two parties. They define the rights and responsibility of both parties with respect to the materials. This type of contract is frequently used with the transfer of GRs, and may specify conditions for access and permitted uses of the resources. MTAs are common between academic or research institutions and private industry.

External collaborators may offer benefits in return for the ability to use TMK. This may include monetary compensation in the form of advance payments for access to TMK or royalty payments made after commercialization of a final product. Indigenous communities may also benefit from capacity building in human resources (training) and infrastructure

<sup>200</sup> WHO/EDM/TRM/2001.1, supra note 151 at 30.

<sup>201</sup> WIPO, Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization: Consultation Draft, (Feb. 4, 2013), available at [http://www.wipo.int/export/sites/www/tk/en/resources/pdf/draft\\_guidelines\\_feb\\_2013.pdf](http://www.wipo.int/export/sites/www/tk/en/resources/pdf/draft_guidelines_feb_2013.pdf). These draft guidelines provide practical information for providers and recipients of GRs and relevant policy and legal information.

(e.g., computer equipment, roads), and from establishing long-term collaborative relationships. The distribution of financial benefits may be governed by national laws, and may, for example, require payments for benefit-sharing to go to a community trust fund or government agency rather than to specific individuals.

TMK holders should ensure that the details of any proposed collaboration are clearly agreed upon prior to the initiation of any substantive discussion. At the least, it is important that TMK holders understand what the collaboration will entail and that an informed decision is made. Outside collaborations have historically met with varying degrees of success.

## CONTROVERSIAL COLLABORATIONS

In 1995, the University of Zimbabwe and the Swiss University of Lausanne signed an agreement to collaborate on traditional medicine research. The agreement stipulated that joint patent applications would be made for any collaborative innovations, and that future royalty payments from any licensing agreements would be jointly negotiated. The University of Zimbabwe then provided TMK and GRs to the University of Lausanne.

The University of Zimbabwe in turn had been assisted by the Zimbabwe National Healers' Association (ZINATHA). ZINATHA provided the University of Zimbabwe with TMK and medicinal herbs from the African tree, "Swartzia madagascariensis". The University of Zimbabwe did not inform the national government or the traditional healers of its agreement with the University of Lausanne.<sup>202</sup>

In 1997, the University of Lausanne filed a U.S. patent for anti-microbial compounds termed "diterpenes".<sup>203</sup> The patent application acknowledged these new compounds relied on TMK and GRs from Zimbabwe. The University of Lausanne then entered into a licensing agreement with Phytera, an American pharmaceutical company, to market diterpenes. The University of Lausanne also decided the percentage of royalty payments it would contribute to the National Herbarium and the Botanical Garden of Zimbabwe and to the Department of Pharmacy at the University of Zimbabwe.<sup>204</sup>

When details of the patent application and these agreements were made public, the University of Lausanne was denounced by the Berne Declaration, an international non-governmental organization (NGO), and two NGOs from Zimbabwe, the Community Technology and Development Association (CTDA) and ZINATHA. The NGOs claimed that neither Zimbabwe nor the traditional healers affected by the bioprospecting gave prior informed consent for the use of local GRs, and also that the University of Lausanne violated its contract with the University of Zimbabwe by excluding it from licensing negotiations with Phytera, and by unilaterally establishing a relatively low percentage of benefit-sharing for Zimbabwe.<sup>205</sup>

In 2003, the University of Lausanne agreed to renegotiate the controversial agreement. Phytera later discontinued its research on diterpenes after negative results emerged from clinical trials.

<sup>202</sup> Carlos M. Correa, Protection and Promotion of Traditional Medicine – Implications for Public Health in Developing Countries, (University of Buenos Aires 2002), available at <http://apps.who.int/medicinedocs/en/d/Js4917e/5.3.html>.

<sup>203</sup> U.S. Patent No. 5,929,124 (filed Aug. 22, 1997).

<sup>204</sup> Chakravarthi Raghavan, Bio-piracy in Zimbabwe, patenting by Swiss university denounced, South-North Monitor (2001), reproduced in Third World Network (Apr. 26, 2001), available at <http://www.twinside.org.sg/title/denounced.htm>.

<sup>205</sup> Id.

## VII. PRACTICAL STRATEGIES FOR DOCUMENTATION

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General recommendations for documentation cannot replace individualized legal counsel. However, there are strategies that TMK holders may find useful to consider. As indicated in *The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit* (Nov. 1, 2013),<sup>206</sup> though there is no mandatory sequence of steps to take in documenting TMK, the process can be roughly divided into three phases: before, during and after documentation.

By far the most important phase of the documentation process occurs prior to documentation. It is during this time that TMK and stakeholders will be identified, a framework for documentation established, and goals and strategy agreed upon.

### 1. BEFORE DOCUMENTATION

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The first step to documenting traditional knowledge is to broadly identify the TMK in question. This may be anything from a whole medical system, such as that practiced by traditional healers in Africa and South America, to an individual herb or natural product. Identification of the relevant TMK is necessary to identify stakeholders in the documentation process and to establish a strategy.

After deciding on the TMK to be documented, the second step is to determine who should be included in documentation efforts. This should include individuals traditionally entitled to possess or use the knowledge. This may also include persons who have non-traditionally acquired the knowledge, community members with a specific interest in the knowledge, the entire community or even other communities. There is no universal rule regarding who needs to be included in documentation efforts, but neglecting TMK holders with claim to the knowledge may generate challenges to IP later on (or claims of misappropriation). Third-party collaborators may also be hesitant to partner with groups that do not have clear and uncontested rights to TMK. On the other hand, if knowledge is restricted to an individual or a particular group within a community, the rights to that knowledge may rest with those persons rather than the entire community. Some countries, such as Brazil, have laws that determine who must be included in documentation efforts.<sup>207</sup> National laws may also determine who can own the IPRs to TMK, and who can benefit from commercialization.

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<sup>206</sup> WIPO, *supra* note 180.

<sup>207</sup> The first ABS law in Brazil, MP 2186-16, created a legal regime for authorizing access to GRs and associated TK, and the BS contract. The Act grants indigenous peoples and traditional communities certain legal rights over GRs within their territories. Third-party access to GRs and associated TK requires PIC and BS agreements from indigenous peoples and traditional communities. After PIC and BS agreements are concluded, government permits must be obtained before access may be granted. Implementation of the Act began in April 2002 with the creation of the Department of Genetic Heritage (DPG), a division of the Ministry of Environment, and the first meeting of the Genetic Heritage Management Council (CGEN). CGEN is an organizational body composed of eight ministries and ten federal organizations responsible for development of standards for access and benefit-sharing in Brazil's national territory. As of March 2009, CGEN had approved and registered 22 contracts for ABS. Eduardo Vélez, *Brazil's Practical Experience with Access and Benefit-sharing and the Protection of Traditional Knowledge*, June 2010 at 1–2. Available at: <http://ictsd.org/downloads/2011/12/brazils-practical-experience-with-access-and-benefit-sharing-and-the-protection-of-traditional-knowledge.pdf>. For more information on the legal regime for ABS to GRs and TMK in Brazil, see generally *Traditional Knowledge and the Law Solutions for Access and Benefit Sharing* (Evanson C. Kamau and Gerd Winter eds., Routledge 2009).

## LOST OPPORTUNITIES IN BRAZIL

The Krahô Indians, one of the indigenous peoples living in Brazil, have a tradition of using plant based medicines in spiritual rituals and health care. In 2001, researchers at the Brazilian Federal University of São Paulo (UNIFESP), interested in developing modern medicines from GRs and TMK, negotiated an access agreement with the Krahô.<sup>208</sup> The agreement established the prior informed consent of the Krahô people from an organization, Vyty-Cati, which represented the three Krahô villages involved in the research. In the agreement, UNIFESP committed itself to invest in the Krahô community and to share ownership of, and royalty payments from, any potential patents. After the conclusion of the agreement, UNIFESP researchers began removing indigenous GRs for laboratory research and interviewing shamans regarding their traditional knowledge.<sup>209</sup>

After learning of the agreement, the fourteen Krahô villages that had not been consulted by UNIFESP, represented by the Kapéy organization, opposed continuation of the research and conditioned future negotiations on payment of moral damages and an upfront prospecting fee. A local Brazilian newspaper published an article denouncing “bio-piracy” practices, which had a negative impact on the research activities of UNIFESP.<sup>210</sup> Later attempts to negotiate a new access agreement failed, and pharmaceutical laboratories stated they were unwilling to finance the project due to concerns that new accusations of bio-piracy might be raised.<sup>211</sup> The result was that a project that could have brought tangible benefits to both indigenous communities and Brazilian society did not materialize because of dispute over who should represent TMK holders.

Partially in response to this incident, Brazil's Council for the Management of Genetic Patrimony (CGEN) now requires an independent anthropological study before obtaining prior informed consent in order to ensure fair representation of TMK holders.<sup>212</sup> At a minimum, an independent anthropological study must determine the community's forms of social organization and political representation, the extent to which the community has been informed about the content of a proposal and its consequences, the social and cultural impacts arising from a project, the procedure used to obtain consent, and the degree of respect for the process in which prior informed consent is to be obtained.<sup>213</sup>

TMK holders should decide how they will be organized. Will everyone be completely engaged in every step of documentation, or will only some group members have responsibility (an IP committee)? If documentation is expected to result in financial benefits, how will money be distributed or shared? If possible, major decisions should be by consensus, but different stakeholders may have different goals for documentation (or even oppose documentation). There is no simple answer to how differences should be resolved. If acquisition of IPRs and collective ownership are desired, there may be advantages to forming an official business entity recognized in the country of origin. Business entities may be able to hold IPRs collectively in place of a group of individuals.

<sup>208</sup> Tania Bubela et al., *Respecting, Promoting, and Protecting Traditional Knowledge: A Comparative Case Study of Brazil, Kenya and Northern Canada*, Working Document prepared for the International Expert Group on Biotechnology, Innovation and Intellectual Property, at 45 n.188, available at [http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP\\_TK\\_Case\\_Study.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_TK_Case_Study.pdf).

<sup>209</sup> Eliana Rodrigues & E.A. Carlini, *Plants with Possible Psychoactive Effects Used by the Krahô Indians, Brazil*, 28 *Rev Bras. Psiquiatr.* 277 (2006), available at <http://www.scielo.br/pdf/rbp/v28n4/2282.pdf>.

<sup>210</sup> Bubela, *supra* note 208, at 51.

<sup>211</sup> Bubela, *supra* note 208, at 51.

<sup>212</sup> Article 4/II of the Genetic Patrimony Management Council (CGEN) Resolution 6/2003 and Article 6 para 2 of the CGEN Resolution 12/2004.

<sup>213</sup> Evanson C. Kamau and Gerd Winter, EDS., *Genetic Resources, Traditional Knowledge and the Law Solutions for Access and Benefit Sharing*, (Earthscan 2009) at 314.

It is important that clear goals be established for documentation. If commercialization is a goal, TMK holders should maintain reasonable expectations regarding financial benefits from documentation. Although *some* TMK has proven lucrative, other TMK has not. It can be very challenging to capitalize directly from TMK. Determining the *why* of documentation will help determine strategy.

Existing forms of documentation should be identified. TMK may be recorded in, for example, written and electronic databases, modern and traditional texts (in a variety of languages), oral traditions, films, photographs, songs, poetry, theatrical performances, community ceremonies, and other daily activities. TMK may be available outside the community (from scientists, academics or community members living elsewhere), within the community or only within certain portions of the community (for example particular families or health care providers). Ideally, all sources of documentation should be accounted for as awareness of existing sources of documentation will help inform collection and IP strategies. Knowledge not already in written form should not be written down until a complete documentation strategy is in place.

TMK holders should identify financial and human resources available for documentation. Depending on the knowledge in question, documentation can be costly and time-consuming. It may also require subject matter expertise. For example, traditional healers may need to be involved in documenting oral traditions or persons with language skills may be necessary to translate written texts. If documentation in electronic registries is desired, this requires computer equipment and technical expertise.

External collaborators may be able to assist with documentation. However, TMK holders should exercise caution prior to sharing knowledge with third parties. For example, anthropologists from developed country universities may have valuable expertise in documenting traditional practices, but there may be concerns about transmitting knowledge outside of the community. The details of any proposed collaboration should be clearly agreed upon prior to the initiation of any substantive discussion, and should be governed by written contract rather than relying on informal agreements. TMK holders may also obtain assistance from multinational organizations, governments or non-governmental organizations.

Once the goals of documentation and existing sources of documentation are established, an IP strategy should be developed. In creating this strategy, TMK holders should consider the entire range of options available to meet their objectives as well as the implications of those options. TMK holders should also consider which protections are still possible. For example, if the TMK is widely known outside of the community of origin it may no longer be eligible for trade secret or patent protection. However, just because information is publicly available does not mean it should not be documented. Some forms of IP protection may still be possible, and there may be other benefits from documentation.

The IP strategy will help determine the format for documentation. Because it is hard to know in advance what knowledge will prove useful in the future, it may be advisable to document as comprehensively as possible. In addition to recording TMK in writing, documentation may include videos, maps, photographs, drawings and physical specimens (for example of plants). A documentation plan should be created to detail exactly how data will be acquired and a timeline.

If documentation is intended to help disseminate knowledge outside of the community of origin then it should be documented in a manner that is easily comprehended by third parties that lack specific background in TMK. If a product is being described, documentation should include all known names, variations, and both traditional and modern uses. For example, if a traditional Chinese herbal formula is being documented, relevant

information may include the name of the herbal medicine in Chinese, English and Latin, when it was developed and by whom, the names of all the ingredients, modifications of ingredients and associated effects, different methods of preparation, indications, contraindications, dosages, side-effects, modern uses and claims supported by scientific evidence.

If a process is being described, documentation should detail every step in the process, including all of the required materials and any information necessary to allow someone else to recreate the process. It should also describe the results of the process and any possible variations. Documentation should also contain the name, location and contact information of stakeholders claiming ownership.

If stakeholders want patent offices to consider documentation in evaluating IP applications, information should be recorded in a format easily accessible to examiners and in the appropriate national language. For example, the United States of America Patent and Trademark Office (USPTO) requires documentation to be provided in English. The Indian Traditional Knowledge Digital Library (TKDL) provides information in English, French, German, Japanese and Spanish.

The TKDL organizes entries based on International Patent Classification (IPC), a language independent classification system for the organization of patents (and utility models).<sup>214</sup> IPC is used internationally by patent offices for organizing conventional, non-traditional knowledge based patents. The TKDL also utilizes a specially developed classification system, the Traditional Knowledge Resource Classification (TKRC), which provides greater definition of traditional knowledge information by expanding IPC groups into sections, classes, subclasses, groups and subgroups. For example, the TKRC system expands one IPC group (i.e., AK61K35/78 related to medicinal plants) into about 5000 subgroups.<sup>215</sup> A WIPO-TK Task Force consisting of representatives from patent offices in the United States of America, European Union, Japan, China and India provided input into this system and linking it with existing IPC.<sup>216</sup> Data is also significantly more accessible to researchers and patent examiners if provided in an electronic, searchable database. The TKDL is searchable by multiple methods, including keyword, botanical name, disease and IPC code.

Finally, while full stakeholder involvement should be obtained as early as possible, it should be obtained no later than the beginning of the documentation. If possible, everyone with a claim to TMK should be in agreement regarding goals and strategy. Written evidence of prior informed consent to documentation and future uses of traditional knowledge should be obtained. Any agreement regarding benefit-sharing should also be obtained in writing.

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<sup>214</sup> Utility models are similar to patents, but usually with shorter terms and less stringent patentability requirements. See generally <http://www.wipo.int/classifications/ipc/en/>.

<sup>215</sup> WIPO, World Trade Organization, TRIPS on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (Sept. 2002), at 81, available at [http://www.cipr.org.uk/papers/pdfs/final\\_report/CIPRcoverintrofinal.pdf](http://www.cipr.org.uk/papers/pdfs/final_report/CIPRcoverintrofinal.pdf).

<sup>216</sup> WIPO, Special Union for the International Patent Classification (IPC Union), IPC/CE/31/6 (Feb. 18, 2002), available at [http://www.wipo.int/edocs/mdocs/classifications/en/ipc\\_ce\\_31/ipc\\_ce\\_31\\_6.pdf](http://www.wipo.int/edocs/mdocs/classifications/en/ipc_ce_31/ipc_ce_31_6.pdf).

## PRE-DOCUMENTATION CHECKLIST

- Identify the relevant TMK.
- Gather stakeholders, decide on organization.
- Establish clear objectives for documentation.
- Identify existing sources of knowledge.
- Assess available financial and human resources.
- Consult with experts.
- Develop an IP strategy based on goals and objectives.
- Determine documentation format, create a documentation plan.
- Achieve stakeholder consensus prior to beginning documentation.
- Obtain prior informed consent in writing, and benefit-sharing arrangements if applicable.

### DO:

Engage the entire stakeholder community.  
Obtain expert advice from recognized authorities.  
Consult legal experts throughout this phase.  
Make deliberate and informed decisions.  
Base strategies on clear goals.  
Understand relevant national laws and regulations.

### DO NOT:

Document TMK in this phase.  
Disclose TMK outside the stakeholder community.  
Share information with third parties except as part of an informed strategy.

## 2. DURING DOCUMENTATION

As documentation proceeds it should follow the pre-documentation strategy and format. However, adjustments may be necessary if, for example, unexpected TMK is encountered or if unforeseen parties claim interest in the subject matter. Events that occur outside the community may also impact the documentation process, for instance, if a third-party independently patents TMK that is the subject of documentation efforts. Any significant changes to the documentation plan or IP strategy should be approved by all stakeholders. If TMK holders are not conducting documentation efforts directly, they should remain connected to the process. Regular meetings should occur to evaluate progress, and TMK holders should have a plan to monitor and verify that documented TMK is being used as agreed.

Once the documentation phase is ready to begin, the first step should be to comprehensively gather all existing sources of documentation. Based on existing documentation, stakeholders should evaluate where gaps in knowledge exist.

If the documentation plan calls for comprehensive information collection then all modern and traditional information related to TMK should be recorded. This includes traditional terms and concepts as well as local names. For example, in addition to its modern role in treating peptic ulcer disease, the Chinese herbal formula *Yi Wei Tang* treats

“yin deficiency” from a traditional perspective.<sup>217</sup> Terminology of this nature is useful to include in documentation, however it may not be easily comprehensible to outside parties. A dictionary or glossary of special terms or phrases used to describe TMK should be developed. Any customary laws or practices should also be recorded.

Consider an entry in the TKDL as an example.<sup>218</sup> For each traditional knowledge-based product, documentation is provided for title, IPC and TKRC code, details of process/formulation, therapeutic composition, preparation, dosage, mode of administration, indications and a list of publications containing the knowledge.

Documentation should also include basic bibliographic information associated with TK, for instance the names, addresses and contact data of information providers and custodians of TK and GRs.<sup>219</sup> This should include the date and time information is collected and the site where TMK is recorded. If relevant, documentation should include conditions for access and use, including socio/cultural taboos and restrictions, as well as information on arrangements with TMK holders.<sup>220</sup>

Depending on the goals of documentation, TMK holders may wish to prioritize the documentation of specific traditional knowledge. For example, if preservation of TMK is a goal, knowledge at risk of disappearance (through loss of traditional healers, language, or natural habitat) should be documented first. If preventing third parties from applying for IP based on TMK is a goal, knowledge with commercial applications should be prioritized. This includes efforts by the Indian government to document yoga practices in video.

If external collaborators are involved in documentation efforts, these relationships should be carefully managed and the confidentiality of documentation maintained. Contracts directly between TMK holders and collaborators are generally advisable, which should have been concluded prior to beginning documentation.

#### DURING DOCUMENTATION CHECKLIST

- Compile all existing documentation.
- Determine knowledge gaps.
- While documenting, include all relevant modern and traditional knowledge.
- Conduct regular meetings to evaluate progress and adherence to pre-documentation strategy.

#### DO:

Document in a consistent and thorough manner.  
Ensure documentation follows the agreed approach.  
Consult with all stakeholders regarding any changes to pre-documentation plans.  
Maintain knowledge holder involvement.  
Identify sources of knowledge and stakeholders who claim ownership.  
Create a dictionary of traditional terms and phrases.  
Ensure confidentiality from external collaborators if applicable.

<sup>217</sup>Anshen Shi, Etal, *Essentials of Chinese Medicine: Internal Medicine*, 379, (Bridge Pub. Group 2003).

<sup>218</sup> See generally <http://www.tkdil.res.in/tkdil/langdefault/common/Home.asp?GL=Eng>.

<sup>219</sup> Technical Proposals to the WIPO Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore, WIPO/GRTKF/IC/4/14, Proposal by the Asian Group, 6 December 2002, annex, p. 8; adopted by the 5<sup>th</sup> Session of the IGC (WIPO/GRTKF/IC/5/15).

<sup>220</sup> Id.

#### DO NOT:

Disclose any TMK outside of the community unless an informed decision has been made to this extent.

Share information with third parties except as part of an informed strategy.

### 3. AFTER DOCUMENTATION

After documentation has been completed, TMK holders will have to manage documented TMK. This may involve applying for IP protections based on documentation or disseminating the collected knowledge. A clear understanding of how documentation will be used should be in place prior to initiating documentation. Nevertheless, stakeholders should review the different forms of IP discussed earlier and reconsider all available options.

For example, if patent protection for TMK is desired, TMK holders should consult with a patent attorney/agent, as applying for a patent is a complex task requiring legal expertise. TMK holders should also be familiar with national *sui generis* systems of protection, which may impact obtaining IPRs. For example, the protection of TCM inventions in China is effectively integrated with the regular patent system. It is reported that about 4,000 applications a year are submitted in this field domestically.<sup>221</sup> An increasing number of these patents are also entering the international patent system.<sup>222</sup> Although patents are granted nationally, WIPO maintains an “international” patent application system in which a single application is transmitted to multiple countries.<sup>223</sup>

As part of the IP strategy created prior to documentation, TMK holders may wish to form a business entity to collectively own and administer IPRs if they have not already done so. Here, legal advice is important to select the proper form of organization. Different ownership structures have different advantages and disadvantages, such as possible tax benefits or reduced personal liability. It is important to choose the most appropriate structure initially, for instance a corporation rather than a partnership, as changing forms of ownership later may be very difficult and costly. The specific structure of a business entity, for example how decisions will be made or how benefits will be distributed, may be shaped by contract, within the requirements of national law.

Controlling IPRs collectively can be challenging due to the potential for internal disputes. One collaborator may block the whole team on the basis of an individual right. Internal disputes should be anticipated at the outset of an IP strategy, and rules to resolve internal disputes should be established by contract prior to applying for IP ownership. Otherwise, and possibly even with a contract to the contrary, internal disputes may be governed by national law. This may not be in the best interest of TMK holders. For example, in the U.S. and France, patent law authorizes each of the joint owners of a patent to exploit the invention without the consent of the other owners.<sup>224</sup> In Germany, copyright law permits alterations to a jointly created work only with the consent of all authors.<sup>225</sup> However, a joint author may not unreasonably refuse consent to publish, exploit or alter a joint work.

<sup>221</sup> Von Lewinski, *supra* note 142, at 124.

<sup>222</sup> *Id.* See, e.g., PCT application WO/2004/052382 (publishing 24 June 2004), for “A Kind of Traditional Chinese Medicine Having Efficacy of Reducing Blood-Fat”.

<sup>223</sup> WIPO, Patent Cooperation Treaty (PCT) (1970), <http://www.wipo.int/pct/en/treaty/about.html>.

<sup>224</sup> 35 U.S.C. § 262 and Art. L613-29 CPI.

<sup>225</sup> Sec. 8(2) German Copyright Act (German CA, Gesetz über Urheberrecht und verwandte Schutzrechte) (“Das Urheberrecht ist nicht übertragbar...”), available at <http://www.gesetze-im-internet.de/urhg/> (accessed Feb. 28, 2011- Last Visited Sept. 29, 2013).

If the decision has been made to keep documentation confidential, for example as part of a strategy to maintain trade secrets related to TMK, then TMK holders should carefully restrict access to documentation. Its commercial value will be significantly lessened once knowledge becomes public. If TMK is being transmitted to external collaborators, this should be done under contract with confidentiality restrictions so that reasonable steps are taken to protect the knowledge. For example, a confidentiality clause could be written into research agreements to stipulate the recipient of such knowledge would be granted the right to use it in research and development but could not divulge the knowledge publicly. If considering partnerships with third parties, stakeholders may have a stronger bargaining position with external collaborators once they have taken the initiative to document TMK.

If documented knowledge is required for regulatory submissions, stakeholders should determine in advance whether that information will be kept confidential, and if so for how long. For example, to approve a foreign traditional medicine for marketing approval in Brazil, the Brazilian regulatory authority requires data to be submitted on clinical safety and efficacy. However, as a general matter, regulatory submissions may release data into the public domain. This may also apply to documentation submitted to IPOs to invalidate patents based on misappropriated TMK. For information submitted to patent offices to be kept confidential, special licensing agreements may be necessary. Submitting documentation to IPOs may affect available IP protections. TMK holders should be completely informed prior to any uses of documentation.

#### FIRST NATIONS CONFIDENTIALITY MANAGEMENT

The First Nation of Na-Cho Nyak Dun is an indigenous community in the Yukon Territory in Canada.<sup>226</sup> The First Nation of Na-Cho Nyak Dun Government maintains holdings of documented traditional knowledge, and it serves as the primary contact for requests to access community traditional knowledge. The Government has established safeguards and information management systems that enable it to gather knowledge and ensure appropriate and respectful use.<sup>227</sup>

The Government determines the sensitivity of traditional knowledge and accordingly restricts access. Knowledge is categorized as low sensitivity (information commonly known outside the community), medium sensitivity (information known only to those within the traditional community), and high sensitivity (spiritual information known only according to customary laws or information which might harm the community if it was released). Based on sensitivity, access to knowledge is permitted for full disclosure, partial disclosure, in-house access only, or no disclosure.

Methods for restricting access include preventing reproductions of documentation or electronic exchange of information. The Government protects against unauthorized disclosure by limiting information access to authorized employees, specifying which additional persons may access information, and allowing users only to view information (prohibiting copying and distribution). Confidential data in electronic databases is further protected by allowing sign-on only by authorized staff, and by using passwords and read-only formatting.

<sup>226</sup> See generally First Nation of Na-Cho Nyak Nyak Dun, History, <http://nndfn.com/history/>.

<sup>227</sup> See generally First Nation of Na-Cho Nyak Nyak Dun, [http://nndfn.com/images/uploads/pdfs/NNDFN\\_Traditional\\_Knowledge\\_Framework.pdf](http://nndfn.com/images/uploads/pdfs/NNDFN_Traditional_Knowledge_Framework.pdf), pg 8-11.

Prior to disclosure of traditional knowledge outside the community, the Government requires an agreement with knowledge recipients identifying the level of disclosure, the terms and conditions for sharing the information, the steps the third party will take to ensure confidentiality (when required) is maintained, the purpose for which the traditional knowledge can be used and ultimate ownership of traditional knowledge that has been gathered.

If documentation is intended strictly to *defensively* protect against misappropriation and to disseminate TMK, then disclosed knowledge should be easily locatable by patent examiners during a search for prior art. TMK holders should consider submitting information to an established traditional knowledge database or registry for this purpose. In U.S. patent law, evidence of prior art outside the United States of America requires a printed publication describing the invention. Publication may occur in scientific journals, newspapers, magazines, websites, etc. The European patent system does not limit evidence of prior art to printed publications, and includes everything made available to the public in writing or orally before the date of filing the patent application. If evidence of prior art is not found during the patent filing process and a patent is granted, the costs to have an existing patent invalidated may be significant. Disclosure and publication of TMK may be anonymous.

If TMK holders are uncertain regarding disclosure of documentation, it may be better not to disclose. A decision to disseminate TMK can always be made at a later time, whereas disseminated knowledge cannot be recalled. On the other hand, it may be burdensome and expensive to challenge IPRs once they are granted.

#### POST-DOCUMENTATION CHECKLIST

- Carefully monitor/restrict access to, and use of, documentation.
- Verify planning objectives have been met.
- Consult with all stakeholders to address remaining concerns.
- Reconsider applications for IP protection.
- Review collaborations with third parties.
- Update documentation as new knowledge develops.

#### DO:

Evaluate all possibilities for IP protection.  
Continue consultations with experts.  
Consider how documentation can be used to the greatest benefit of the community and to those outside the community.

#### DO NOT:

Disclose any TMK outside of the community unless an informed decision has been made to this extent.  
Share information with third parties except as part of an informed strategy.

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## ABOUT THE AUTHOR

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Ryan Abbott, M.D., J.D., M.T.O.M., is Associate Professor of Law at Southwestern Law School and Visiting Assistant Professor of Medicine at the David Geffen School of Medicine at UCLA. He has served as a consultant on health care financing and regulation, intellectual property and public health for international organizations, academic institutions and private enterprises including the World Health Organization and World Intellectual Property Organization. Professor Abbott has published widely on issues associated with health care law and intellectual property protection in legal, medical, and scientific peer-reviewed journals.

Professor Abbott is a licensed physician, attorney, and acupuncturist. He is a graduate of the University of California, San Diego School of Medicine and the Yale Law School, as well as a Summa Cum Laude graduate from Emperor's College (MTOM) and a Summa Cum Laude graduate from University of California, Los Angeles (BS). Professor Abbott has been the recipient of numerous research fellowships, scholarships and awards, and has served as Principal Investigator of biomedical research studies at University of California. He is a registered patent attorney with the U.S. Patent and Trademark Office and a member of the California and New York State Bars.

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