

# TRADITIONAL KNOWLEDGE HERBAL MEDICINE AND INTELLECTUAL PROPERTY: A DEBATE OVER RIGHTS

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## INTRODUCTION

Indigenous or Traditional medicinal knowledge is generally defined as a subset of TK “*consisting of the medicinal and curative properties of plants in indigenous culture, including genetic resources. Tk is often defined by its general characteristics: creation through a long period of time which has been passed down from generation to generation; new knowledge is integrated to the existing, as knowledge is improved; improvement and creation of knowledge is a group effort; and ownership of indigenous knowledge varies between indigenous peoples.*”<sup>1</sup>

Tk has gained special significance in the past few decades which have seen an explosion in the demand for herbal medicines in the globalized world.<sup>2</sup> This rise in demand is seen as a movement which is alternate to the mainstream pharmaceutical products. This movement towards traditional and alternate source of healthcare was first noticeable in the 60’s. Possibly motivated by the general popularity of holistic healing in the United States and Europe at this time, Traditional medicine gained an international following. Notably in the United States, the United Kingdom, and Australia, acupuncture and herbal remedies became commonplace.<sup>3</sup>

Such a scenario has in the past decade given rise to two major critical issues. Firstly the need for the patenting of traditional knowledge (TK) and its products and the legal and political challenges faces thereto.<sup>4</sup> Secondly the international community continues to debate the benefits of traditional medicine. This paper seeks to delve into the various issues surrounding the state of traditional medicine and the herbal industry in an increasingly globalized world.

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<sup>1</sup> Dr. Gerard Bodeker, *Traditional Medical Knowledge, Intellectual Property Rights & Benefit Sharing*, 11 *Cardozo J. Int'l & Comp. L.* 785.

<sup>2</sup> *Ibid.*

<sup>3</sup> Anil K. Gupta, *Making Indian Agriculture More Knowledge Intensive and Competitive: The Case of Intellectual Property Rights* (1999) at [http:// www.sristi.org/pub.html](http://www.sristi.org/pub.html).

<sup>4</sup> *Supra* note 1.

## PROTECTION FOR INDIGENOUS MEDICINAL KNOWLEDGE

There is currently no patent protection for indigenous medicinal methods and pharmaceutical companies commonly utilize the knowledge in the development of new patentable medicines. Proposals have been made to reform this supposed inequity and “*to place patents for indigenous peoples as a means to empowerment and recognition of their intellectual contributions.*” However, Western patent systems appropriately exclude TK from patent protection. Additionally, intellectual property rights are not reconcilable with the traditional beliefs of indigenous peoples.<sup>5</sup>

In the international scenario the main challenges have taken place against the backdrop of two international legal frameworks these are the Convention on Biological Diversity (CBD), and the World Trade Organization's Trade-Related Aspects of Intellectual Property Systems (TRIPS).

The only major international convention that assigns ownership of biodiversity to indigenous communities and individuals, thereby giving them the right to protect this knowledge is the CBD.

The articles of the CBD clearly outline how member states are to treat their indigenous communities, and to develop relations among each other.

Article 8 (j) declares that State Parties are required to “*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 the 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 utilisation of such knowledge, innovations and practices.*”<sup>6</sup>

Article 18.4 states that Contracting Parties should “*encourage and develop models of co-operation for the development and use of technologies, including traditional & indigenous technologies.*”<sup>7</sup>

However, unfortunately the CBD competes for prominence in the international arena with the more powerful TRIPS.<sup>8</sup> Trips which is now a key international agreement which promotes and regulates the harmonisation of intellectual property around the globe cover only intellectual property which include patents, geographical indications, undisclosed information (trade secrets),

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<sup>5</sup> Paul Kuruk, *Protecting Folklore Under Modern Intellectual Property Regimes: A Reappraisal of the Tensions Between Individual Rights and Communal Rights in Africa*, 48 American L. Rev. 769 (1999).

<sup>6</sup> Article 8 of the United Nations Convention on Biological Diversity (1993).

<sup>7</sup> See, Article 18 of the United Nations Convention on Biological Diversity (1993).

<sup>8</sup> Graham Dutfield, *Trade-Related Aspects Of Traditional Knowledge*, 33 Case Western Reserve J. Int'l L. 239 (2001).

and trademarks. TRIPS make no reference to the protection of traditional knowledge. It does not acknowledge or distinguish between indigenous, community-based knowledge and that of industry.<sup>9</sup> TRIPS does not require adoption of UPOV standards, but rather provision ‘for the protection of plant varieties either by patents, by an effective sui generis system or by any combination thereof’ (Art. 27(3)(b))<sup>10</sup>. Sui generis systems are those that are developed according to the needs of a country or region. They are unique to that country and region.

In essence the objective view of CBD is that if a product or process has been present in a culture for a long period of time that it should be considered to be owned by that community and hence provided protection under intellectual property laws. However, TRIPS takes a different view, it advocates if something is not patented that it is not owned.<sup>11</sup> If something is not owned than that knowledge is part of the public domain and thus represent such knowledge which is part of the global commons and is available for exploitation by all whom so wishes.

## TRADITIONAL KNOWLEDGE AND BENEFIT SHARING

Despite the trend for the herbal sector to develop products based on traditional knowledge and to rely on market edge and competitive forces as a means of gaining market share and profit, there has been a growing trend of herbal or natural products companies specializing in the medicinal applications of plant extracts to seek patents for application of TMK.<sup>12</sup>

One such example to highlight the issue is a recent court action by the San people (formerly referred to as the Bushmen) of the Kalahari region of Southern Africa against the South African government has raised the profile of patenting of indigenous medical knowledge.<sup>13</sup> The South African Government had undertaken a research on the Hoodia cactus, traditionally, the stems of which have been used by the San as an appetite suppressant when staying in the desert for extended periods.<sup>14</sup>

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<sup>9</sup> *Ibid.*

<sup>10</sup> See, World Trade Organization, Trade Related Aspects of Intellectual Property Systems (TRIPS) (2002).

<sup>11</sup> *Supra* note 1.

<sup>12</sup> *Supra* note 3.

<sup>13</sup> Tamar Kahn, *Prickly Dispute Finally Laid to Rest*, AllAfrica.Com, at

<http://allafrica.com/stories/200203220129.html>.

<sup>14</sup> OAU - Organisation of African Unity, African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, PMB 2359 (OAU Scientific, Technical and Research Commission, Lagos, Nigeria) 2000.

The Government's Council for Scientific and Industrial Research had patented the active molecule from Hoodia and had then gone on to sell the licence to a British herbal medicine manufacturer, Phyto Pharma.<sup>15</sup> The company, after some further research and development, sold the rights for development to Pfizer for \$21 million as a potential anti-obesity drug. Pfizer plans to market a new drug based on Hoodia within three years and consider that this will generate for the company a significant share of the \$6 billion market for slimming products.<sup>16</sup>

This cause a great hue and cry in South Africa, especially from the traditional communities and therefore as a result in March 2002, a legal settlement took place between CSIR and the San, resulting in a memorandum of understanding which recognized the San people as the customary custodians of Hoodia. At the same time it also recognized CSIR's right to protect the work it had done in isolating the active ingredient from Hoodia. The final result was an agreement to have a benefit sharing agreement in place by September 2002.<sup>17</sup>

However such a agreement had come in for criticism form various quarters. Critics argue that the agreement between CSIR and the drug companies are confidential and thus there is no means by which an effective monitoring of the benefit sharing process can take place.<sup>18</sup> However this incident forced the Government to develop a new legislation namely the Indigenous Knowledge Systems Bill which was tabled in the Parliament in late 2002.<sup>19</sup>

## **BENEFIT SHARING IN INDIA**

The concept of benefit sharing in the development of herbal medicines has only recently begun to find its place in the intellectual property sphere. In India one such example of benefit sharing programme is that of a partnership between the Kani tribe and the Tropical Gardens Botanical Research Institute (TGBRI), Trivandrum, India. The TGBRI holds the patent on *Trichopus*

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<sup>15</sup> *Ibid.*

<sup>16</sup> See, Paul Kuruk, *Protecting Folklore Under Modern Intellectual Property Regimes: A Reappraisal of the Tensions Between Individual Rights and Communal Rights in Africa*, 48 American L. Rev. 769 (1999).

<sup>17</sup> *Ibid.*

<sup>18</sup> *Ibid.*

<sup>19</sup> *Supra* note 14.

zeylanicus, or 'Jeevani' as it is known locally.<sup>20</sup> However TK of the plant resides with the local community which in this case is the Kani tribe in the Western Ghats. Through their customary use and, more recently, with advanced research in laboratory studies, Jeevani has been found to be contain various medicinal properties. It is used as an immunomodulator, hepato-protective, and an aphrodisiac.<sup>21</sup>

As per the benefit sharing agreement TGBRI, the sole patent holder on Jeevani as an immunomodulator, has reached an agreement by which it has agreed to share royalties with the Kani. TGBRI has subsequently issued a seven year license to Arya Vaidya Pharmacy which produces herbal extracts from Jeevani.<sup>22</sup>

Although undoubtedly this is an important turn of events with respect to rights of community to their knowledge and through benefit sharing agreements yet this present model is not without its flaws.<sup>23</sup> First, the Kani Trust has to negotiate with state government for transfer of funds. Second, the Kerala Forest Department is seeking a share of royalties & licence fees. Third, the Kani does not hold title to their customary land and the Forest Department has been reported to be preventing them from harvesting Jeevani. Fourth, a high return on Jeevani plants has resulted in over-harvesting by immigrant workers drawn to this source of income.<sup>24</sup>

However what this model does highlight is the unlimited potential for benefit sharing in the context of herbal medicine development. In spite of their being a patent involved in the process the Jeevani case shows the road ahead in terms for partnership between TK and herbal and pharmaceutical industries. Clearly what is needed in knowledge exchanges involving the herbal sector is a focus on benefit sharing. The focus in establishing an equitable IP agreement then needs to shift from patenting alone to benefit sharing with or without patents.<sup>25</sup>

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<sup>20</sup> Makonnen Bishaw, *Promoting Traditional Medicine in Ethiopia: A Brief Historical Review of Government Policy*, 33 *Social Science & Medicine* 193 (1991).

<sup>21</sup> P.J. Bouic, S. Etsebeth, R.W. Liebenberg, C.F. Albrecht, K. Pegel & P.P. Van Jaarsveld, *Beta-Sitosterol and Beta-sitosterol Glucoside Stimulate Human Peripheral Blood Lymphocyte Proliferation: Implications for Their Use as an Immunomodulatory Vitamin Combination*, 18 *Int'l J. Immunopharmacol* 693 (1996).

<sup>22</sup> WHO Geneva & Zhang X, *Integration of Traditional and Complementary Medicine into National Health Care Systems*, 23 *J. Manipulative & Physiological Therapeutics* 139 (2000).

<sup>23</sup> Gerard Bodeker & Fredi Kronenberg, *A Public Health Agenda for Complementary, Alternative and Traditional (indigenous) Medicine*, 92 *Am. J. Pub. Health* 1582 (2002).

<sup>24</sup> *Supra* note 23.

<sup>25</sup> Jocelyn Kaiser, *NIH To Limit Scope of Foreign Patents Science*, 296 *Science* 2316 (2002).

The need for regulations in industrialized countries would require full disclosure by corporations or individuals seeking patent protection on a plant-based drug or other natural product. Furthermore disclosure should provide that the source material has been rightfully and lawfully acquired, where "rightful" acquisition would involve moral as well as ethical issues in access to biodiversity.

In addition to the above community-based initiatives to protect local TK with respect to indigenous medicine, there are two new and important database initiatives, designed to establish prior art as a pre-emptive measure against patenting of indigenous medical products and applications of plants. One of these, in India, operates internationally for the defence of national TK, and the other, established by the Science and Human Rights Program of the American Association for the Advancement of Science (AAAS), operates internationally for the defence of TK globally.<sup>26</sup>

## **PROTECTION OF TRADITIONAL MEDICINE**

The Indian subcontinent has a rich heritage in traditional medicinal knowledge which is derived from multiple medicinal traditions, including Ayurveda, homeopathy, naturopathy, Siddha, Unanani, and Yoga. Although the majority of this knowledge has been passed down through the oral tradition, considerable parts of it are described in diverse but usually inaccessible classical literature in different traditional or local languages such as Hindi, Sanskrit, Urdu, Tamil, and others. However in spite of their inaccessibility, their age-long codification warrants that they receive public domain status. In extant times, transnational pharmaceutical corporations and research institutions have sought to exploit India's medicinal heritage through the patent system.<sup>27</sup> Notable examples include the turmeric, basmati, and neem patents, the applications for which were the subject of controversy at the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), and elsewhere. The experience served as a wake-up call for India to address the issue of the exploitation of its TK and the scourge of bio-piracy. India's experience is

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<sup>26</sup> Makonnen Bishaw, *Promoting Traditional Medicine in Ethiopia: A Brief Historical Review of Government Policy*, 33 *Social Science & Medicine* 193 (1991).

<sup>27</sup> *Supra* note 8.

unfortunately only representative of a general trend in many developing countries with rich genetic resources and a traditional knowledge base.<sup>28</sup>

India has established a defensive anti-appropriation strategy in response to the rampant biopiracy in the form of the TKDL. This approach is an aggressive attempt to make previously inaccessible but codified Indian traditional medicinal knowledge available in digital form, so that patent examiners will have them handy as evidence of prior art (i.e., pre-existing knowledge), with a view to scuttling subsequent frivolous or biopiracy patents.<sup>29</sup> The TKDL for India's systems of medicine is a massive state-sponsored interdisciplinary and interdepartmental project. It deploys the nation's wealth of human resources in medicinal knowledge systems, information technology, science, research, and bureaucracy. According to its manifesto, "[t]he project ... involves the documentation of the knowledge available in [the] public domain on traditional knowledge from the existing literature related to Ayurveda, Unani and Siddha, in digitalized format in five international languages which are English, German, French, Japanese and Spanish." Throwing further light on the process, the Director of India's National Institute of Science Communication and Information Resources (NISCAIR) where the project is being implemented, V.K. Gupta, avers that the TKDL database acts as a bridge between ancient traditional knowledge in the original languages (which may be in Hindi, Sanskrit, Urdu, Persian, Arabic, Tamil, etc.) and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners. The gap in prior art knowledge is minimized. The prior art has sufficient details on definitions, principles, and concepts to minimize the possibility of getting accepted minor insignificant modifications as novelty.<sup>30</sup>

Conceptually, therefore, the TKDL is not necessarily limited to a patent-related prior art search. Conscious effort is directed at guarding against its subversion for potential counter-productive outcomes, such as when information in the TKDL is mismanaged in a way that facilitates biopiracy. In this regard, the access and use of the TKDL database is subject to an agreement that imposes a restrictive obligation on those who legitimately possess the database and are in a position to make it accessible to third parties. Those in this privileged position include national and regional patent offices that need the TKDL databases to assist them in conducting prior art searches.

One of the most significant contributions of the TKDL project within its short period of existence is its success in the proactive integration of its database "with the international intellectual

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<sup>28</sup> *Supra* note 1.

<sup>29</sup> *Supra* note 5.

<sup>30</sup> *Supra* note 5.

property office activity of search and examination of the prior art search systems." For instance, the TKDL has improved on the problem associated with the classification system regarding the documentation of traditional knowledge.<sup>31</sup> It has done this by creating a modern classification system fashioned after the framework of the International Patent Classification (IPC). The resulting classification, which so far covers only Unani and Ayurveda medicinal systems, is ambitiously called the Traditional Knowledge Resource Classification (TKRC). The IPC was created pursuant to the World Intellectual Property Organization (WIPO) administered multilateral treaty, the Strasbourg Agreement Concerning the International Patent Classification. It provides a hierarchical system in which technological or innovation categories are divided into a range of sections, classes, and subclasses for easy identification in prior art examination. Patent offices of more than one hundred countries, other intellectual property regional offices, as well as the International Bureau of the WIPO and the Patent Corporation Treaty (PCT) rely on the IPC for prior art searches.<sup>32</sup>

The Indian initiative on the classification of traditional knowledge within the IPC has resulted in a detailed and improved IPC structure relating to traditional medicine. This includes the 2003 decision by the IPC Union to expand the classification of medicinal plants by about two hundred subgroups via the creation of a brand new group (A61K36) and, perhaps most importantly, the linkage of IPC with the TKRC through a concordance table prepared by India. Currently, the TKRC includes about 500 subgroups for medicinal plants, whereas IPC contained only one subgroup (i.e., A61K35/78).<sup>33</sup> In its operational modern system, the TKDL software incorporates the novel classification system, TKRC, and converts documented knowledge into target languages. In essence, medicinal formulations codified in ancient texts on Indian systems of medicine are transcribed or decoded into patent application formats in five so-called international languages under the meticulous supervision of scientists, technical officers, and distinguished experts in the particular systems of medicine. As opposed to transliteration, the software does knowledge based conversion where data abstracted once is converted into several languages by using state of the art technology such as Unicode, XML and metadata methodology. Software also converts traditional terminology into [Western scientific] modern terminology, for example, Kumari (local name) to Aloe barbadensis, Masurika (Sanskrit name for a disease) to small pox, etc. In general, the TKDL software is designed to translate local and previously inaccessible information buried in India's

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<sup>31</sup> Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties* (2000).

<sup>32</sup> *Ibid.*

<sup>33</sup> Gerard Bodeker, *Traditional (i.e. Indigenous) and Complementary Medicine in the Commonwealth: New Partnerships Planned with the Formal Health Sector*, 5 *Journal of Alternative & Complementary Medicine* 97 (1999).

traditional medicinal knowledge heritage into their modern scientific correlation, which patent examiners can readily use for prior art searches.<sup>34</sup>

The digital capture of traditional medicinal knowledge has given new momentum to traditional knowledge in many respects. Interestingly, the popular and longer standing policy responses to intellectual property's problematic relationship with traditional knowledge remain inchoate and do not seem to have translated into any concrete results, let alone one with as much practical impact as the TKDL initiative.<sup>35</sup> Specifically, the TKDL has fueled an epistemological encounter and dialogue between traditional medicine as a local knowledge form and its more cosmopolitan Western counterpart through the direct attempt to increase traditional medicine's stake within the patent system. Even though digitization of traditional medicine through the TKDL primarily aims at establishing aspects of its standing as prior art, it must be noted that pre-existing patents, like those associated with Western medicine, are *prima facie* prior art. To that extent, the TKDL calibrates, or levels up, traditional medicine with its Western counterpart. This creates a semblance of psychological parity in favour of traditional medicinal knowledge vis-à-vis the extant recognition of Western scientific medicine under the patent regime. The difference is that while traditional medicine-related knowledge may be, at least in theory, freely accessible because it is part of the public domain, its Western biomedical or scientific counterpart is protected for the term of any applicable patent. Like the conventional patent system, the TKDL does not directly address the exclusive and proprietary aspects of traditional medicine. However, by creating a new classification system based on traditional medicine (i.e., the TKRC), and by informing the IPC and global patent literature, the TKDL “*provides a bridge between modern science, modern medicines and traditional knowledge.*”<sup>36</sup>

Beyond bridging, the TKDL's adoption of the concordance methodology to entrench traditional medicine in the IPC system exposes the interaction, interrelationship, and realization between Western medicine and traditional medicine in a way that blunts the sharp and uncritical loyalty to the prevalent rigid classification of the two knowledge forms. Even though the TKDL deals with codified information on traditional medicine in the public domain, as a permanent and

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<sup>34</sup> *Ibid.*

<sup>35</sup> News Release, 13th Commonwealth Health Ministers' Meeting, Health Ministers Meeting (Nov. 29, 2001) at <http://www.13chmm.org.nz/meeting/communique.htm>.

<sup>36</sup> *Supra* note 1.

growing feature of the global patent process, the TKDL promises to be of significant importance for the patentability of non-codified and independent traditional medicinal innovations.<sup>37</sup>

## CONCLUSION

The IP/TK debate has reached new levels of serious review and new prospects for TK protection since the Doha meeting of November 2001 and the resulting process for the harmonization of TRIPS and CBD with respect to TK.

The growth of the herbal sector and the constant demand for new and saleable traditional medical products is new in the field of IP and traditional medical knowledge. This trend will clearly grow and should become a primary focus of IPR development. Of fundamental importance in this is the need for the herbal industry to become more proactive and responsive to this dimension. The herbal and traditional medicine industry should, of its own accord, develop industry standards that are based on ethical practice and are overseen jointly by industry-government-NGO-indigenous monitoring groups.<sup>38</sup>

To provide new models for development, information needs to be gathered on current practice. This in turn needs to be analyzed according to principles of best practice in benefit sharing and IPR. Sui generis systems alone may or may not be the way forward: they offer unique local means of protecting traditional knowledge that work for the local context. At the same time, they are at risk of being un-enforceable outside of the country or region of origin and hence creating vulnerability to the bio-piracy that they are designed to prevent. For sui generis systems to work there will need to be reciprocity among countries to respect one another's local sui generis regimes - a prospect that would seem somewhat distant in the prevailing international IP political environment.<sup>39</sup>

Such developments as those outlined above require backing and enforcement within the context of national and international IPR regimes.<sup>40</sup> This would require WIPO, the CBD and the WTO to coordinate their policies and legal instruments in partnership with traditional knowledge holders as well as with conventional stakeholders such as governments and industry. If this can be achieved, the health benefits offered to the world through the globalization of traditional medical

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<sup>37</sup> Christine Padoch & Brian M. Boom, *Professional Ethics in Economic Botany: A Preliminary Draft of Guidelines* (Society for Economic Botany) 1996.

<sup>38</sup> *Supra* note 23.

<sup>39</sup> *Supra* note 37.

<sup>40</sup> *Supra* note 1.

knowledge also stand to benefit communities and countries in terms of economic development and the growth of national pride in the preservation of culture and it's harnessing for human well being in the context of principles of fair trade.<sup>41</sup>

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