

"Indigenous Medical Knowledge:
the Law and Politics of Protection"

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TRADITIONAL HEALTH SYSTEMS

The World Health Organization estimates that the majority of the population of most non-industrial countries still relies on traditional forms of medicine for everyday health care. In many countries up to 80-90% of the population are in this category. Medicinal plants and, to a lesser but important extent, animal products, form the materia medica of these traditions.

Traditional health systems are based in world views or cosmologies that take into account mental, social, spiritual, physical and ecological dimensions of health and well being.

Central importance on the concept of balance - within the individual and between the individual, society and Nature.

Imbalance arises with the breaking of the interconnectedness of life - and results in discomfort and disease.

Traditional health systems have organized frameworks for classifying plants, animals, landscapes and climatic conditions in relation to their effects on health and disease. These taxonomies have much in common with one another and represent a culturally-relevant empirical framework for assessing medicinal plant biodiversity. Such taxonomies may diverge significantly with Western classificatory frameworks and assumptions. This is of importance when determining prior art as it pertains to intellectual property law.

Food and medicine are often viewed interchangeably. Food is medicine. Diet is the basis of health.

Revitalization movements are drawing on traditional medical knowledge to develop integrated modern and traditional health care projects. These movements and other groups have drawn attention to the shrinking availability of medicinal plants to supply the burgeoning need for herbal medicines in non-Western societies and in the industrial countries. Conservation and horticulture programmes are emerging as vital components of the revitalization of local health traditions.

There is a need for coordinated effort by all engaged in medical plant use to generate new policies, mechanisms and resource flows to preserve the biodiversity used in caring for the health of the majority of the world's population.

The Convention on Biological Diversity (CBD)

The CBD is the only major international convention that assigns ownership of biodiversity to indigenous communities and individuals and asserts their right to protect this knowledge.

Article 8 (j): State Parties 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.”

Article 18.4: Contracting Parties should “encourage and develop models of co-operation for the development and use of technologies, including traditional & indigenous technologies.”

The CBD competes for influence with the far more powerful TRIPS.

TRIPS is now the key international agreement promoting the harmonisation of national IPR regimes. Covers **four types** of intellectual property rights:

1. Patents
2. geographical indications
3. undisclosed information (trade secrets)
4. trademarks

TRIPS makes no reference to the protection of traditional knowledge. Does not acknowledge or distinguish between indigenous, community-based knowledge and that of industry

TRIPS does not require adoption of UPOV standards, but rather provision "for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." (Art. 27(3)(b))

- The debate over ownership of biodiversity and particularly over medicinal plant and the knowledge associated with it is by no means new.
- In Africa, the 1977 Agreement "Copyright and the Cultural Heritage" far predated any discussions through GATT and subsequently TRIPS on such issues.
- In India a 1988 agreement with the US to establish a plant gene bank caused controversy when India did not secure control over the use of national genetic resources.
- Further more, the issue of harmonising international IP legislation has posed challenges for many countries which have prevented patents on what are deemed to be products essential to the national interest.
- It is against the climate of existing national concern about sovereignty over domestic biological and cultural resources that the debate over TRIPS has occurred.

African Intellectual Property Organization (OAPI), Bangui, March 2, 1977.

Annex VII of the Agreement, "Copyright and the Cultural Heritage," Article 8

"Folklore belongs, in the first instance, to the cultural heritage."

"Folklore" is defined for these purposes to mean "literary, artistic or scientific works as a whole created by the national ethnic communities of the member States, which are passed from generation to generation and which constitute one of the basic elements of the African cultural heritage.

Article 46: "Folklore" includes "scientific knowledge and works: practices and products of medicine and the pharmacopoeia, and theoretical and practical attainments in the fields of the natural sciences."

Article 8(5): Proceeds from royalties deriving from exploitation of these works "shall be used for cultural and social purposes. The conditions under which such royalties are shared shall be fixed in a rule to be promulgated by the competent national authority."

Article 45: In addition to folklore "ethnographic material, such as...products of pharmacopoeia, traditional medicine and psychotherapy" shall be considered "as belonging to the cultural heritage of the nation".

Article 50: It shall be forbidden to unlawfully denature, destroy, export, sell, alienate or transfer, in whole or in part, any of the constituent elements of the cultural heritage.

Article 74: Any person who knowingly violates the provisions of Article 50 is liable to imprisonment of from one month to two years, plus a fine, without prejudice to damages.

However, in the absence of strong national IP legislation and vigorous implementation the existence of such agreements does little to protect countries from exploitation of their medicinal resources and knowledge.

Cameroon is a case in point.

CAMEROON: Regulation of bioprospecting is multisectoral:

1. Foreign collectors must obtain a research permit from the Ministry of Scientific and Technical Research (MINRST), before removing samples of resources.

Removal of small quantities of flora, without charge, is authorised.
Permits are negotiated on an individual basis.

No set formula for amount and type of material to be exported for research purposes.

2. Ministry of Environment and Forestry (MINEF), authorised to issue commercial exploitation permits for large-scale extraction of genetic resources for commercial purposes.

MINEF negotiates an export duty with the buyer, using market prices as a guide to set the duty.

- Neither procedure preserves Cameroon's rights to its genetic resources, or ensures return of a fair percentage of the resources' value.
- No mechanism to enforce mandatory value-added processing in-country, nor to negotiate supply contracts, royalties, or ensure sustainable harvesting.
- Forestry Code - potential impact on bioprospecting. **Gives local communities the right to establish community forest reserves with sovereignty over the use of those resources.** Communities could become directly involved in setting terms for access to and use of genetic resources.
- Cameroon intellectual property laws protect patents (including pharmaceutical patents), trademarks, copyright and "cultural patrimony"- including indigenous medical treatments.
- Protection would be limited only to Cameroon.
- New inventions, based on minor variations on traditional knowledge would be eligible for patent protection in industrialised countries.
- Has made no attempt to develop its own capacity to prepare medicinal plant extracts for sale on the world market, nor to link this trade to conservation and local community development.
- Has obtained only a fraction of benefits from medicinal plant trade.
- Example: *prunus africana*. Bark has important anti-cancer properties. Used in treatment of Benign Prostatic Hypertrophy (BPH).

- Being debarked illegally - causes the tree to die, threatening extinction of the species.
- A French company is the sole holder of a commercial exploitation permit to collect and export the bark to the European market.
- The European market was estimated at \$150 million in 1992.
- None of the profits are repatriated to Cameroon, whose citizens are paid only for the collection of the bark.

INDIA

- ❖ From 1994, Indian Govt did not succeed in repeated attempts to revise 1970 Patent Act to come into line with TRIPS.
- ❖ Efforts to do so resulted in riots on streets. Half a million farmers demonstrating.
- ❖ Late 1999 succeeded in amending it in accord with TRIPS and removing protection for important medicines from patent control.
- ❖ Activist groups are now calling for 2005 deadline for coming into line with TRIPS to allow time for full debate and resolution of all of the issues involved.

TURMERIC

- ❖ The Centre for Scientific and Industrial Research of India filed a re-examination request with the US Patent and Trademark Office, seeking revocation of a 1994 patent issued to the University of Mississippi.
- ❖ Patent, 5,401,504, claimed the use of turmeric for promoting wound healing.
- ❖ India argued that turmeric is a well known traditional medicine used in India, and written about by Indian researchers as early as the 1950s.
- ❖ India secured a revocation of the patent.
- ❖ India is now recording on a set of CD Roms all of the national medicinal plant knowledge. This will be distributed to patent offices world-wide to provide a data base of prior art on Indian traditional medicinal knowledge.
- ❖ India is also pursuing a comprehensive legal strategy to seek revocation on non-Indian patents on Indian life forms.

Social & economic costs of changes in IP legislation

By requiring patents to be applied to pharmaceuticals, it is being argued that TRIPS will have the effect of pricing common drugs out of the reach of most people in poor countries. If herbal medicines are patented - either domestically or internationally - the medicines used as the first and last resort for healthcare by the poor will also become unaffordable. Some examples illustrate the point.

- ❖ 200 % increase in cost of medicines after the 1979 introduction of pharmaceutical product patents in **Italy**.
- ❖ *Welfare loss* to **Argentina, Brazil, India, Mexico, Korea, and Taiwan**) would amount to a minimum of US\$3.5 billion and a maximum of US\$10.8 billion. *Income gains* by foreign patent owners would be between US\$2.1 billion and US\$14.4 billion. (World Bank)
- ❖ 'National health disaster' anticipated by the **Indian** Drug Manufacturers' Association from implementation of TRIPs in India.
- ❖ 30% of Indian population can afford modern medicines.
- ❖ Comparisons of prices of drugs between India and countries where patent protection exists: up to 41 times costlier in countries with patent protection.
- ❖ Drug prices in **Malaysia**, where patent protection exists, 20% to 760% higher than in India. Profit-maximising behaviour based on 'what the market can bear'.

SOUTH AFRICA & AIDS DRUGS

- In 1998, President Nelson Mandela signed into a law a measure that would allow South African firms to manufacture low-cost generic versions of the high-price anti-AIDS drugs produced and sold by major Western drug companies.
- Transnational corporations are working to block the law in South African courts. Sought and secured White House support. White House has threatened South Africa with sanctions. V-P Al Gore has pressured South Africa to repeal this law.
- April 30, 1999, the US Trade Representative placed South Africa on its "watch list" for unfair trade practices, citing Pretoria for its attempt to abrogate patent rights.
- Under international trade rules, a country can engage in such "**compulsory licensing**" to combat a national emergency.
- 22.5 million people living with AIDS in sub-Saharan Africa.
- The law also would permit the country to buy drugs when they are found to be cheaper in other nations and import them to South Africa--**parallel importing**.
- Sept. 1999, **UNAIDS** Exec. Dir. Peter Piot: health care gap between rich and poor countries becoming "morally reprehensible". Called for investigation of "mechanisms such as compulsory licensing, transfer of technology, parallel import of drugs and joint procurement by several countries."
- "Very few Africans - who spend an average of 10 dollars a year on health care - can afford life-prolonging and pain-reducing drugs made in the West, and which cost about 12,000 dollars a year per person." (Plenary presentation to ICASA Conference, Lusaka, Sept. 1999.)
- US manufacturers of AIDS suppressants have blocked Brazil from exporting a product to other countries because of patent rights. Brazil has been able to produce an equivalent of AZT (Zidovudine), which limits mother-to-child transmission, for a 100th of the current costs. "**What is more important patent rights or patients' rights?**" Zimbabwean Health Minister, Dr. T. Stamps. (ICASA Conference, Sept. 9, 1999)

Some IPR Models for the protection of traditional knowledge.

1. Changing IPR law: Certificates of origin. (Sociedad Peruana de Derecho Ambiental)

Patent applications based on use of genetic resources and/or traditional knowledge should require:

- (i) a sworn statement as to the genetic resources and associated knowledge, innovations and practices of indigenous peoples and local communities utilised, directly or indirectly, in the research and development of the subject matter of the IPR application;
- (ii) evidence of **prior informed consent** of the country of origin and/or indigenous or local community, as appropriate;
- (iii) international standardisation of these conditions through an international certification system.

Countries providing resources and/or traditional knowledge to issue certificates indicating that all obligations to the country and indigenous people/local community had been fulfilled e.g. prior informed consent, equitable benefit sharing, etc. Patent applications would include these certificates. Without them, they would automatically be rejected.

2. Transforming traditional knowledge into trade secrets. (IAD-supported project, Ecuador).

- Knowledge from communities wishing to participate in the project to be catalogued and deposited in a restricted access database. Each community will have its own file in the database.
- Checks will be made to see whether each entry is not already in the public domain and whether other communities have the same knowledge.
- To avoid the danger of a price war from competition among communities, there would be a cartel developed among those communities sharing a trade secret.
- The trade secret can then be negotiated in a Material Transfer Agreement with the benefits shared between the government and the cartel members.

3. Local innovations databases.

Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), India, has developed databases of traditional knowledge and innovations in close collaboration with local community members.

- ❖ Advocates a global registration system of local innovations. Individual and collective innovators would receive acknowledgement and financial rewards for commercial applications of their knowledge, innovations and practices.
- ❖ Links would be built between small investors, entrepreneurs and innovators for mutual financial benefits.
- ❖ Individuals or communities could seek IPR protection in such forms as inventors certificates and petty patents. (*The intellectual property law of Kenya was amended in 1989 to provide for a petty patent for traditional medicinal knowledge.*)
- ❖ All national patent offices should be able to access local innovation databases when carrying out prior art searches and examinations.

The World Conservation Union (IUCN) recommends:

- Governments should improve public access to patent databases by such means as publishing patent texts on the Internet
- The development of local knowledge registers that patent examiners could access so as to ensure that traditional knowledge is not pirated. These should be bottom-up participatory programmes.
- Ownership of these registers should not be claimed, since this would be an infringement of the rights of the knowledge providers.
- Recognition and protection by States of the traditional knowledge of these communities, and traditional modes of resource use regulation and dispute resolution under customary law.
- Ensuring the consent and involvement of these communities in the wider use of their knowledge and practices.
- Mandating a series of equitable benefit-sharing measures.
- Exclude plants and animals from patentability until the environmental and social impacts of allowing such patents can be assessed;
- Require more exacting standards of novelty or inventive step so that the failure of IPR law to adequately protect traditional knowledge is not compounded by the ability of others to hold patents for inventions closely derived from such knowledge;
- Apply an interpretation of *prior art* that includes public domain knowledge in any part of the world whether published or not.
- Exclude from patentability existing traditional/indigenous knowledge (in current or translated forms), and essentially derived products and processes from such knowledge;
- Develop *sui generis* legislation for protection of folklore based on an understanding of 'folklore' as inclusive of folk knowledge/practices/ expressions of art, craft, music, scientific belief, religious belief, architecture, agriculture, **medicine**, and conservation of natural resources;
- Communities should have the right to define the terms by which they control access and require benefit-sharing – these terms should be transparent.

Examples where controversy has arisen over exploitation and patenting of indigenous medical knowledge.

International Cooperative Biodiversity Groups (ICBG) - Maya.

- ❖ **The Contract:** U.S. Government (National Institutes of Health) initiative to identify, patent, and commercialize Mayan knowledge and biological materials - at least in part - through a private biopharmaceutical enterprise.
- ❖ University of Georgia (UGA) has been contracted to develop a project relationship with Mexican officials and Mayan communities that will make the extraction and privatization of some of their knowledge/resources mutually acceptable.
- ❖ UGA offered the experience and acceptance necessary to obtain the cooperation of Mexican and Mayan authorities.
- ❖ **Majority Opposition:** The ICBG in 2nd year - still faces serious local opposition. 24 local organizations in Chiapas have come out in opposition.
- ❖ **Minority local support:** According to ICBG-Maya a few local communities appear to have accepted the project. No consensus among the peoples of Chiapas that the project should proceed. Project organizers, say they need more time to convince people. They seem unclear as to when those who are sought for their Prior Informed Consent (PIC) have the right to declare NIC - No Intention of Consenting.
- ❖ **'Common' Knowledge:** Who constitutes 'no' or 'yes' ? UGA will begin collecting even if only some of the communities agree.
- ❖ **Outside Influences:** Chiapas has sparked the inevitable debate as to whether local communities are being manipulated by outside interests. The ICBG project partners have made this accusation. The Consejo has accused the ICBG project of being dominated by outsiders.
- ❖ **RAFI (Rural Advancement Foundation International):** In the absence of effective protocols and regulatory procedures, neither national governments nor intergovernmental treaties can guarantee the integrity of any bioprospecting contract.
- ❖ RAFI considers that unless, and until functioning mechanisms are in place, all bioprospecting agreements jeopardize the right and interests of local communities.
- ❖ RAFI does not believe that there exists any adequate mechanism including the CBD capable of safeguarding the rights and interests of local communities. RAFI regards all bioprospecting agreements to be biopiracy.

THE KANI & A HERBAL PATENT

Tropical Gardens Botanical Research Institute (TGBRI), Trivandrum, India holds patent on *Trichopus zeylanicus*. 'Jeevani' is the local term.

Jeevani's proerties:

- ❖ Immunomodulator
- ❖ Hepato-protective
- ❖ Aphrodisiac

Indigenous knowledge of the plant resides with the Kani tribe in the Western Ghat forests.

TGBRI has commitment to share royalties with the Kani. TGBRI is sole patent holder.

7 year license to Arya Vaidya Pharmacy which produces herbal extracts from Jeevani.

Difficulties:

1. Kani Trust has to negotiate with State Govt for transfer of funds
2. Kerala Forest Dept seeking share of royalites & licence fee.
3. Kani don't hold title to their customary land - Forest Dept. preventing them from harvesting Jeevani.
4. High return on Jeevani plants resulting in over-harvesting by immigrant workers drawn to this source of income.

OTHER HERBAL EXAMPLES

1. Phyllanthus amarus - Ayurvedic treatment for jaundice. U.S. patent for use with Hepatitis B.
2. Piper nigrum. Ayurvedic treatment for vitiligo (a skin pigmentation disorder). UK patent for application of a molecule from piper nigrum for use in treatment of vitiligo.
3. Shaman Pharmaceuticals: AIDS diarrhea herbal drug. Contract for benefit sharing with source of origin of the information.

FUTURE

1. Debate over patenting will hinge much on what constitutes prior informed consent. How to determine who represents a community, what represents full consent.
2. State vs. Community ownership of indigenous knowledge. Should states get royalties from knowledge that originates from communities within those states. Or should royalties go direct to the traditional knowledge holders?
3. Disputes over patents on herbal products - impact on local herbal use and developing country exports of herbals. (World Bank: \$3 trillion herbal market by mid 21st century)
4. More examples of the S. African AIDS drugs type - & with herbals. "Patent rights v. Patients' rights".
5. Restrictions on collaborative research (e.g. India's Biodiversity research approval committee now requires Central Govt approval for all collaborative research pertaining to indigenous knowledge)
6. Southern (Eastern? e.g. ASEAN) alliance to combat prejudicial aspects of TRIPs.