



JUSTIFYING TRADITIONAL KNOWLEDGE UNDER EXISTING MODES OF INTELLECTUAL PROPERTY RIGHTS AND THE SURROUNDING ISSUES

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ABSTRACT

Traditional knowledge is based on the experience of indigenous people and has developed over time. Most often it is transmitted from generation to generation as oral knowledge and this is the weak point which makes traditional knowledge (TK) susceptible to misappropriation. TK provides valuable leads which save time and investment in research and development sector. Therefore transnational corporations exploit biological resources and associated knowledge. Indigenous people nurture these resources and develop traditional knowledge but they did not get any recognition or share of benefit from multinational corporations. This results in many cases of biopiracy in India as well as in other countries. Various strategies have been adopted to protect TK through positive and defensive protection. An efficient effort taken by Council for Scientific and Industrial Research -Government of India to document TK in TKDL (Traditional Knowledge Digital Library) has proved boon in protection of TK. Biopirates use Intellectual Property Rights (IPR) as tool to steal traditional knowledge and exploit biological resources and this happens because of some limitations in IPR system. Therefore it is required to introduce some sui-generis elements in the existing IPR system.

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INTRODUCTION

India is one of the 12-mega biodiversity¹ countries of the world. India is known for its rich heritage of biological diversity and has so far documented over 91,200 species of animals and 45,500 species of plants in its ten bio-geographic regions². India is an acknowledged centre of crop diversity and holds many wild varieties of crop relatives. India is also one of the twelve primary centers of origin of cultivated plants and is rich in agricultural biodiversity. Due to unique bio-diversity and natural bounty, India is rich in traditional knowledge of the properties and uses of these biological resources. Traditional knowledge (TK) is the back bone of cultural heritage. Most indigenous and local communities are situated in most biological rich and diverse areas. For them this natural environment is a way of life and a part of their cultural existence. Indigenous communities³ are repository of traditional knowledge on conservation and sustainable utilization. TK is an essential ingredient in achieving sustainable development. It has always been an easily accessible treasure and thus has been susceptible to misappropriation.

Traditional Knowledge (TK)

TK associated with biological resources is an intangible component of the resource itself. Most often it is transmitted from generation to generation as oral knowledge.

“Traditional knowledge (TK) refers to knowledge that people of an indigenous community, in one or more society, based on experience and adaptation to a local culture and environment, have developed over time, and constantly shaped by innovations and practices of each generation”.

TK is very vast and encompass knowledge related to various categories like knowledge of plants and animals and their properties; minerals and soils and their properties; combinations of organic and inorganic matters; medicinal knowledge; and expressions of folklore in the form of music, dance, song, handicraft, stories and art work. All the intellectual creations, that have been developed by forefathers and gradually improved by subsequent generations of a traditional community, in the field of science, technology, ecology, medicine, agriculture, biodiversity; art and literature also come under the scope of tradition knowledge. TK is used to sustain the community and its culture and to maintain the genetic resources necessary for the continued survival of the community. It is important to preserve the social and physical environment of which the traditional knowledge is an integral

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part. TK is culture specific, context specific, dynamic and adaptive.

Importance of Traditional Knowledge

TK plays an important role in the conservation of biodiversity and its traditional uses. The new technological developments clearly demonstrate the usefulness of TK for the development of new product of commercial importance. It is vital to the food security and health of millions of people in developing and least developed countries.

Healthcare: Many phytochemical based medicines and cosmetics are derived from the knowledge of properties of certain plants. Indian Ayurveda and Unani system of medicines depends on a diversity of biological resources and associated traditional knowledge. In developing countries traditional medicine is the only way for affordable treatment. World Health Organization (WHO) defines traditional medicine (TM) as:

“the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observations handed down from generation to generation, whether verbally or in writing”.

Even in many developed countries 70% to 80% of the population use some form of alternative medicine⁴ (for example acupuncture). Traditional system of medicine is important because it offers therapeutic alternatives for some degenerative and age-related ailments, such as rheumatism, for which other satisfactory therapies are lacking. Health care industry depends on traditional medicinal knowledge as the products derived from medicinal ecological knowledge are eco-friendly and have no or minimum side effects. This knowledge proves boon to the economy of health care industry as herbal products are preferred by the customers.

Agriculture: Continuous development of plant varieties; pest management practices; selection methods; breeding methods by farmers and development of domesticated animals by livestock keepers play important role in agricultural systems of developing countries. Local communities improved and nurtured diversity in flora and fauna through their traditional practices and agricultural techniques.

Wild biodiversity: Through cultural beliefs and traditional practices local communities have conserved wild areas including natural ecosystems. These practices help in maintaining ecological balance.

Why A Sui Generis Traditional Knowledge Protection System?

One of the greatest problems facing bioprospecting contracts has been valuation of the resources covered by the Contract. Genetic resources being public goods exist outside the pale of markets. They are not amenable for pricing. Where both genetic resources and associated traditional knowledge are sought to be accessed through bioprospecting activities matters get complicated. One of the most ticklish issues is to segregate values of genetic resources from its associated traditional knowledge. Since biodiversity legislations largely view traditional knowledge as an associated feature of genetic resources, the former is likely to be devalued in comparison to the latter. A sui generis legislation on traditional knowledge

that recognises its autonomous economic, cultural and development character (independent of its association with other resources) is able to ensure a more objective valuation of traditional knowledge from a benefit sharing perspective. A sui generis law for protecting traditional knowledge is also necessitated by the fact that discussions that narrowly focus on traditional knowledge relating to biological and non-biological resources do not cover the knowledge that is non-functional. A case in point is a traditional knowledge perspective on climate, seasons and related facets of nature. A sui generis regulation that covers all facets of traditional knowledge will be wider in scope and comprehensive in approaching traditional knowledge in its totality. To this extent it will encourage a more objective system of valuation of traditional knowledge that respects its aggregate value, than the value of a small component.

While national sui generis legislations would facilitate a robust system of traditional knowledge protection, international action to frame guidelines and compacts is desirable, given the global character of knowledge and resource flows. International guidelines and compacts not only guarantee reciprocity but also ensure that norms of traditional knowledge protection and benefit sharing are harmonised within the framework of the multilateral regime.

Landmark Judgment Case: Turmeric (*Curcuma longa*) has anti-biotic, ant-inflammatory, antioxidant and coagulant properties. It also has been used externally to heal sores and as a cosmetic. US patent (no.5, 401,504) was granted to two US-based Indians - Suman K. Das and Hari Har P. Cohly of University of Mississippi Medical Center, USA. on the use of turmeric in wound healing in 1995. The Council of Scientific & Industrial Research (CSIR), India challenged the novelty of patent. CSIR requested the US Patent and Trademark Office (USPTO) for re-examination of patent. The council argued that use of turmeric to heal wounds and rashes has been known for centuries so this invention was not novel. CSIR after difficult searching could locate 32 references⁸ to prove their claim. The US Patent Office revoked this patent in 1997 on the basis of evidence provided by CSIR. This case is the just an initiation of the movement of preserving and avoiding misuse of traditional knowledge. The requirement of fixation of prior art⁹ in a tangible, accessible form under the U.S. patent law, make it difficult to challenge patents based on traditional knowledge. Most of the knowledge of the indigenous peoples is undocumented and passed from generation to generation orally. Therefore, a need was felt to create more easily accessible and technical non-patent literature databases on traditional knowledge of India.

Rice Patent

US Patent (no. 5663484) was granted to Rice Tec Inc., USA in 1997 entitled "Basmati Rice Lines and Grains". New rice lines were derived via crossing semi-dwarf varieties with 22 traditional varieties of basmati from India and Pakistan. Patent document contain 20 claims that covers not only novel rice lines developed from rice germ plasm but also covers various varieties which were based on traditional farmer-bred varieties. Moreover Rice Tec also hijacked the term 'Basmati' and by doing so the company claimed exclusive ownership over new varieties based on traditional rice varieties nurtured by generations of farmers. The particular characteristics like fragrant aroma, long and slender grain and distinct taste of

Basmati are due to the geographical region (greater Punjab region divided between India and Pakistan) in which it grows. So this company was misleading the public towards different and inferior product and also adversely affected the export market of India and Pakistan. The Government of India under pressure of Non-Government Organizations (NGOs) filed a request for re-examination in the year 2000 on the ground that rice lines in question lack inventiveness and novelty. In the year 2001, in response to request, USPTO only allowed 5 claims (three independent claims 8, 9, 11 and their dependent claims 12 & 13) out of 20 and title of the invention was also changed from "Basmati Rice Lines and Grains"¹⁰ to "Rice Lines Bas 867, RT1117, RT1121."

Neem patent

The patent (No.EP436257) was granted by the European Patent Office to W.R. Grace Company and US Department of Agriculture on a fungicide derived from Neem in 1994. The active ingredient was isolated from the seeds of plant. The company and USD got patent on the method of making a stabilized azadirachtin in solution and the stabilized azadirachtin solution itself. This solution was introduced as a pesticide in the market. The process of isolating and purification of the substance satisfies the grounds of novelty and inventive step as required under laws. The ground on which validity of patent can be challenged is that said use is available in a fixed tangible form and well documented in a printed publication. A group of international NGOs and representatives of Indian farmers filed legal opposition against the patent on the grounds that fungicidal effect of extracts of Neem seeds had been used for centuries in Indian agriculture. After a long battle in 2005 European Patent Office upheld the revocation of Neem Patent.

International Regulatory Framework

Convention on Biological Diversity

Before there were any laws governing the realm of intellectual property, the genetic resources were regarded as "common heritage of mankind" and were mutually shared. As an initiative to start recognizing the contribution of the aboriginals in conservation of Biodiversity, the Convention on Biological Diversity was set up as the first major international convention that assigns the ownership rights to the holders of the traditional knowledge. More than 180 Countries have ratified the convention, agreeing to its main objectives, these being 1) the conservation of bio-diversity, 2) the sustainable use of its components; and 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In its Preamble, CBD has acknowledged the dependence of the aboriginals on biological resources for their livelihood and fulfilment of primary needs and stresses on the desirability of benefit sharing.

Article 8 (j) obligates the State Parties 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 utilization of such knowledge, innovations and practices.*"

Article 18.4 promotes the idea of contractual agreements and states that the contracting parties cooperate and mutually decide the terms and conditions of the contract for the development and use of traditional & indigenous technologies.

Article 10(c) provides that each contracting party takes caution to use biological resources in accordance with traditional cultural practices which do not go against the conservation of biodiversity. However, the said article neither talks about protection of Traditional Knowledge nor makes it legally binding. Ultimately, everything is left at the discretion of the parties.

Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The main intention of TRIPS is to enforce the intellectual property rights while removing any impediment in the way of legitimate international trade. However, there are limited provisions that can be applicable for the protection of traditional knowledge. Protection of Geographical Indications is one stipulation that can be harnessed to keep tabs on the escalating instances of Bio piracy.

Article 27 of the TRIPS agreement lays out the requirements for patentability including any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. However, Article 27.3(b), which was the focus of attention of the 2001 Doha Declaration, does not compel the members to provide for patent protection of plants and animals other than micro-organisms, non-biological and microbiological processes. However, members are required to provide for the protection of plant varieties either by patents or by an effective sui generis system³²⁹ or by any combination thereof.

World Intellectual Property Organisation

The WIPO Intergovernmental Committee (IGC) has been built in an attempt to promote and orchestrate Intellectual Property Rights in relation to Genetic Resources, Traditional Knowledge and Folklore by undertaking text-based negotiations with the objective of reaching an agreement to frame an international legal instrument(s). The three main objectives that WIPO strives for include

1. Protection of the traditional knowledge (the technical know-how, practices, innovation)
2. Expressions of folklore (music, art, symbols, etc. that are the source of traditional knowledge) and
3. Genetic resources and benefit sharing.

It was realized that genetic resources, traditional knowledge and folklore were deeply interrelated and their rising importance to the aboriginals belonging to the countries of the third world made it necessary to entail them in the core objectives of the committee.

The Twenty-Eighth Session of the IGC took place from July 7 to 9, 2014. The Committee confirmed that the texts, as developed during IGC 26 and IGC 27, be transmitted to the 2014 WIPO General Assembly. Delegates also took stock of progress and discussed the future work of the Committee.

The Affairs between Trips and Cbd

In 1999, TRIPS set up a council to reassess its Article 27.3(b) and the relationship of the TRIPs Agreement and the CBD. Proposals were made to necessitate the disclosure of biological source, the country of origin and prior informed consent. In 2001, the TRIPS council was divided on the issue whether there was any conflict between the two confederations. The USA, Japan, 25 Member States of the European Communities and developing countries such as the Republic of Korea and Singapore contended that there is no conflict between the two and both can be implemented in a mutually supportive manner. However, Brazil and India were of the view that there were conflicts which required an amendment to the TRIPS agreement to deal with them.

In contrast to CBD, the TRIPS agreement contains no provisions regarding Prior Informed Consent, Traditional Knowledge and Benefit Sharing. However, the compulsion to safeguard the Geographical Indications can be used as armour to shield the traditional knowledge and genetic resources. Thus we see that makes no direct reference to the protection of traditional knowledge. Essentially, the CBD deems the natives as the true owner of the traditional knowledge, thereby having a rightful claim to control its usage. By contrast, the view under TRIPS is that the owner is the one who obtains a patent over the subject-matter and since there is no individual who owns a patent over genetic resources or its knowledge, it is available for exploitation by all those who wish to.

The Nagoya Protocol

The Nagoya Protocol is an ancillary accord to the Convention on Biological Diversity seeking to establish a transparent legal framework that brings to fruition the objectives of the CBD. Core obligations including Access Obligations, Benefit-Sharing Obligations and Compliance Obligations have been devised to warrant implicit structure for access to genetic resources and equitable share of benefits. Article 5 of the protocol makes certain that parties take legislative and administrative efforts to ensure that the benefits arising out of employment of genetic resources are shared in a fair and equitable manner with the indigenous community for preserving it on the mutually agreed terms. Article 10 of the protocol emphasizes on the need for development of a global multilateral benefit sharing mechanism for communities where it is not possible to take prior consent. A range of tools and mechanism are close at hand to aid the operation at the domestic level but all things considered, it is left upon the national legislations to provide for specific terms and conditions as per their individual needs and policies.

National Regulatory Framework

Traditional Knowledge Digital Library

Since traditional knowledge is the work of the indigenous people of a particular community, it exists in distinctive databases in their native dialect which had erected a vernacular blockade. As a result, the patent officers failed to infiltrate into these databases and acknowledge the existence of such knowledge before approving the patents. The concerted efforts of the Council of Scientific and Industrial Research (CSIR) and the Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy), resulted in the initiation of Traditional Knowledge Digital Library as a contrivance to undertake bio piracy.

Information comprising about 200,000 formulations has been transcribed for realizing the objective of TKDL Project. The converted format of the formulation is available in English, German, French, Japanese and Spanish and is easy to comprehend.

The TKDL has prevailed over the language barriers and is making access to TK a lot easier for major patent offices. Today, as a result of TKDL, India has safeguarded about 0.226 million medicinal formulations and at zero direct cost. Besides the revocation of the patent of Turmeric, Neem and Basmati Rice, TKDL has also helped in foiling the China's bid to patent Pudina, Natreon Inc's attempt to patent the use of Ashwagandha in reducing stress, and the use of 'kumari' plant in case of 'dry eyes'. However, revocation is not the solution every time since the process of revoking a patent can be a costly and time-consuming affair. It takes, on average, five to seven years and costs between 0.2-0.6 million US dollars to oppose a patent granted by a patent office. The cost of protection for India's 0.226 million medicinal formulations without a TKDL, would be prohibitive.

On the face of it, having a digital library appears to be an effective tool to counter bio piracy. In a world where profit and greed have become the new economic mantra, private companies will go to any extent to manipulate what is already known to project it as an invention or novelty. Any tinkering of the original medicinal remedy with a little cosmetic covering can be easily presented as a novel product that was not previously known.³³⁹ The easy access provided to the data of the digital library, though meant for the patent officers, can be easily misused by private companies to scout for therapeutic properties of the data, modify it and present it as a new invention.

Indian Patent ACT

The Patents (Amendment) Act, 2005 was passed as an obligation under TRIPS to bring the Indian Patent Act, 1970 in line with the international laws and to introduce product patents to medicine and agro chemicals, by removing the bar on patentability on these. The amendment act has widened the scope of 'novelty' by defining 'new invention' and further clarifying 'inventive step'. Section 3 of the Patent Act, 1970 was amended whereby an enhancement in the known efficacy of a new form of known substances necessary to get it patented. The amendment now requires that the new use of a known substance should not be allowed. Also, mere use of a known process or method is excluded from protection unless the result is a new product or employs at least one new reactant. While the definitions of food, medicine, etc have been omitted, "pharmaceutical substance" has been defined. The amendment also sets the conditions wherein a person resident in India shall be permitted to make, or caused to be made any application for the grant of the patent outside India. India has made provision for both pregrant and post-grant opposition. This provision will prevent the issuing of trivial patents and provides ample opportunity to the local and generic companies, as well as other interested parties to challenge on specific grounds under section 25(1) of the act. The Amendment Act has inserted section 92-A which provides for export of patented pharmaceutical products in certain exceptional cases such as the importing country having insufficient or no manufacturing capacity, to address public health problems.

Biological Diversity Act

The Biological Diversity Act, 2002 was passed in compliance with the provision of CBD to provide for upkeep, sustainable deployment of the genetic resources and equitable sharing of benefits arising out of it. The preamble of the act clearly establishes the autonomy of the state over its biological resources. The act has instituted authorities to ensure its proper execution at different levels including the National Biodiversity Authority, various State Biodiversity Boards and at the local level, Biodiversity Management Committees which comprise of the panchayats and the municipalities. It provides a framework for access to biological resources for the purpose of bio-survey and bio-utilization and sharing the benefits arising out of such access and use. The Act also includes in its ambit the transfer of research results and application for intellectual property rights (IPRs) relating to Indian biological resources³⁴². The Biological Diversity Rules, issued in 2004 are an appendage to the Act, which confine the important decision making powers regarding the access, knowledge transfer and intellectual property rights with the Authority. In 2007, *panchayats* and community representatives submitted over 3000 resolutions to the Prime Minister expressing their concerns over the reduced role of the Biodiversity Management Committees. The act provides that if the compensation or benefit sharing is paid in money, these funds may, upon the discretion of the NBA, be accrued to the source of the resource or knowledge, if identified. Otherwise, they shall be deposited in the National Biodiversity Fund. Another important provision of the act is regarding the consequences of non-compliance with the act, making any offence under the act cognizable and non-bailable. The punishment may include a fine, or imprisonment, or both.

SUGGESTION AND CONCLUSION

The grants of patents on non-original inventions which are developed by using the traditional knowledge of the developing world have been causing a great concern to the developing countries. Unfair exploitation of biological resources and associated traditional knowledge are the issues of great concern for the developing world. TRIPS is the most influential agreement because it is the part of WTO which has the power to enforce commitments made by member countries. In order to check bio-piracy, it is imperative to bring about a comprehensive change in the intellectual property system the world over, through appropriate amendments in the TRIPS Agreement, which codifies the rules for the protection of intellectual property internationally. Three principles, that are required to prevent bio-piracy, should be included in TRIPS. These principles are;

- Disclosure of the geographical origin of biological resources or related traditional knowledge used in invention.
- Obtaining prior informed consent of the relevant local community.
- Ensuring equitable benefit sharing arrangements.

Definition of prior art is different in different countries, the Patent Act of India has provision that if an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' is not patentable. This provision

can prevent bio-piracy within the territory of India but cannot protect traditional knowledge outside India, for example in USA such subject matter is considered patentable and only scientifically authenticated printed publications are considered as prior art. There is need to harmonize the definition of prior art on international basis.

There are certain inadequacies in the conventional IPR system which makes it difficult to provide complete protection to TK and its holders. If someone improves a part of traditional knowledge and establishes novelty within a narrow range, novelty would be satisfied and the owner of the patented property would be under no legal obligation to share any part of the profit gained with the original holders of that traditional knowledge. Because of these limitations, it is difficult to provide an overall protection through existing intellectual property rights to traditional knowledge – including traditional medicine. An urgent need is felt for the insertion of *sui generis* elements into conventional IPRs for the protection of traditional knowledge. Such a system would act as a bridge between indigenous community and national as well as international legal system in order to secure the effective recognition and protection of rights. It can offer flexibility in developing frameworks that deal with knowledge control; use of biological resources and sharing of benefits derived from the exploitation of resources.

IPR regime should have 'protection of indigenous interests' as an underlying policy goal. Only then IPRs could be used as tools for the protection of cultural heritage and TK of the country. Indigenous communities are not aware of their rights over the biological resources and related knowledge. The level of literacy, time and money required for the registration of IPRs, It is highly unlikely that these indigenous people would go through this process, thus leaving the field open for third party to acquire rights over their resources and associated knowledge. Therefore the registration procedure of intellectual property rights and cost and litigation procedure should be simplified in order to make IPR system affordable and accessible for traditional communities. There should be some organizations appointed by the law that particularly take care of the registration, prosecution processes of IPRs, development of trademarks and marketing of the registered goods like GI goods for the indigenous communities.

Till now there is no universal agreement on the best way to protect biodiversity and associated knowledge from the threats it faces from conventional IPRs regime. In order to protect misappropriation of biological resources and the rights of indigenous people, efforts should be carried out both at national as well as international level.

"When we protect the places where the processes of life can flourish, we strengthen not only the future of medicine, agriculture and industry, but also the essential conditions for peace and prosperity."

(Harrison Ford, Environmentalist, 2002 World Ecology Award)

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