

Commercialisation Of Traditional Medicine Of Indigenous Communities: Interface Of Existing Ip Regime And Human Rights

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Abstract: Exploitation and commodification of indigenous tribal knowledge has raised wide human rights concerns. This is seen more rampant in the field of medicine. The knowledge of the indigenous communities on medicine is popularly known by the nomenclature "Traditional Medicine". The focus of inquiry in this paper is the extent to which the existing legal regime especially the intellectual property paradigm attempts to protect and preserve the interest of the indigenous peoples over their knowledge. The paper analyses whether indigenous medicine fits itself into the existing definition given by WHO on traditional medicine and proceeds to inquire into the threats and challenges faced by the indigenous communities as a result of commercialisation of this knowledge especially bioprospecting, bio piracy etc. It also analyses the various human rights concerns in this area such as protection of cultural identity, protection of collective interest of community, right to self-determination etc when the existing IP regime is applied in this area. Further an attempt is made to study the response of the Indian legislative framework as well as the judiciary to these challenges. The paper evaluates specific instances of negation of indigenous people rights due to patenting of their knowledge on medicine.

The Contradictions between the Forest Act, 2006 and the Biodiversity Act 2002 is being discussed in the paper. The paper proceeds to evaluate the extent to which the recent governmental endeavours in establishing the Traditional Knowledge Digital Library has been successful. Finally the paper suggests a sui generis model for India and lists out the essential elements to be incorporated in such a law.

Keywords: *Traditional Medicine, Indigenous communities, Bioprospecting, Bio piracy, human rights*

I. INTRODUCTION

Capitalisation of knowledge has become the norm of the day. Modern corporate science has lined up against indigenous knowledge and practices in myriad forms leading to exploitation at all levels. This phenomenon had prompted human rights discourses on the need to protect the indigenous communities from the commodification of the knowledge especially in the field of medicine. (Sefi Dei et al ,2000) The knowledge of the indigenous communities on medicine is popularly known by the nomenclature "Traditional Medicine". Several writings on the subject reveal that they are also known by terms like tribal or indigenous medicine, folk medicine, natural medicine, ethno medicine etc. However the very terminology "traditional" prefixed to medicine reveals its

antiquity and that it was a practice of medicine prevalent in every country from the early human civilisation. Thus it is generally understood as a health care approach which is based on cultural practices belonging to the tradition of each country and which has been handed down from generations to generations. It also implies that it is different from modern medicine and its method of diagnosis and healing standards is different from today's medicine. Thus it can be said that traditional medicine is community based collective knowledge on health care practices which might be as a result of innovations carried by predecessors which are transmitted and preserved by communities as a part of their heritage and may have got a distinct cultural and even spiritual identity at times. About 370 million indigenous and tribal people all around the world are the real custodian and holders of traditional

knowledge. Up to 80% of the world's population depends on traditional medicine for its primary health care. An estimated 90 percent of the world's biodiversity lies within the territories of indigenous peoples.

II. BASIC UNDERSTANDING ON TRADITIONAL MEDICINE

Several attempts have been made hitherto, so as to define, demarcate and give a precise definition to it but it is found that it has not been successful yet.

WHO in the Primary Health Care Declaration of Alma Mata of 1978 had recognised the relevance of traditional medicine as a source of primary health care as a part of its endeavour in realising right to health as a basic human right. Following this it attempted to define traditional medicine as the:

"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".

This definition reveals that the traditional medicine may be oral and need not be essentially codified. It might also not be scientifically proved regarding its authenticity. However this definition lacks clarity in several respects. The question as to the inclusion of certain knowledge which may be contemporarily developed has not been brought about. Some old individual practices acquired from predecessors or otherwise is hardly protected. For instance, old individual of different ethnic communities including women treating the patients based on the knowledge acquired from their predecessors. Also there may be folk healers who may not be traditionally trained but experienced in certain health practices (e.g. Dai, bone setters, specialists in treating poisons, jaundice and mental disorders. It does not attempt to distinguish between folk medicines and other systems of medicine which are codified or some partially uncoded such as Unani, Ayurveda, Siddha, Naturo pathy, Yoga medicine etc

The Convention on Biological Diversity (CBD) also does not define the same but under Section 8(j) calls for the protection of it as a part of its mandate to conserve the biodiversity. Thus it is found that the existing legal instruments do not provide clarity as to what types of diagnosis and treatment products, process and practices are to be included under traditional medicine. There also needs to be a clarity between traditional knowledge and indigenous knowledge. It should be understood indigenous knowledge is one type of traditional knowledge. Though the term traditional knowledge is generally used.

III. COMMERCIALISATION OF TRADITIONAL MEDICINE OF THE INDIGENOUS COMMUNITIES: THREATS AND CHALLENGES

The tribal health culture and medicine is often found to have an innate relationship with tribal cosmology, environment, beliefs etc and varies from each community to

the other. Thus it is unique yet diverse. The unique aspect of this knowledge is that its ownership is not tied on any legalistic notions on ownership but based on trust, belief and values and hence hardly documented nor protected adequately. The potential of this knowledge in medicine is well documented outside the boundaries of indigenous communities even though to the limited knowledge of the community as such. The sudden surge in the importance of traditional medicine and health practices is due to the fact that it leads to new product development. In the world market today, it is estimated that 74% of the 119 drugs created were discovered from a pool of traditional herbal medicine. (Laird, 1994). Developing countries and their traditional peoples have contributed considerably to the global drugs industry. The Rural Advancement Fund International (RAFI) estimated that at the beginning of the 1990s, worldwide sales of pharmaceuticals amounted to more than US\$130,000 billion annually. However it is found that very minimal benefits only accrue to the indigenous communities. So exploitation tribal medicines and therapy had led to bioprospecting.

Bioprospecting refers to the process of discovery and commercialization of new products based on biological resources. Biological resources and related traditional knowledge are often of great commercial value to business corporations in developing commercial products. Corporations often want to acquire IPRs related to biological resources and traditional knowledge as a way of maximizing their income generation. Thus knowledge of herbs and its medicinal value has led to bio piracy.

Bio piracy is generally understood as a practice in which indigenous knowledge of nature, originating with indigenous peoples, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves. For example, when bio prospectors draw on indigenous knowledge of medicinal plants which is later patented by medical companies without recognizing the fact that the knowledge is not new, or invented by the patentee, and depriving the indigenous community to the rights to commercial exploitation of the technology that they themselves had developed.

However the greatest challenge is the ownership of the knowledge in tribal medicine. The patenting of herbs by pharmaceutical companies totally disregarded on the indigenous communities knowledge on how the herbs worked. Patenting of indigenous knowledge on medicine is being treated as a new form of colonialism. Though the 2010, Nagoya protocol on Access to Genetic Resources and the Fair and Equitable sharing of Fair and Equitable Sharing of Benefits Arising from their Utilisation to the CBD had rules to protect traditional medicine and to compensate for such knowledge that is already patented or being used in an inappropriate manner, it still awaits the ratification by majority nation states.

On the whole, it is found that a significant part of the global economy is based on the appropriation and use of traditional medicine. Indeed, traditional knowledge is increasingly contributing to production in modern economies where property rights are inimical to community intellectual property. Modern economic policies and laws (particularly

modern property laws) undervalue this knowledge: at best they ignore it and at worst they contribute to its destruction.

Thus protection of tribal medicine three important issues need to be addressed:

- ✓ How should the benefits derived from the use of traditional medicine be shared?
- ✓ How can the intellectual property rights (IPR) of the holders of TMK and scientific researchers be protected when the TMK of the former is used by the latter to create modern drugs
- ✓ How can we stop the loss of biodiversity caused by the widespread use of traditional medicine and the rapidly expanding international market for herbal products?

IV. HUMAN RIGHTS CONCERNS AND TRIBAL MEDICINE

Ample concerns have been raised hitherto with regard to the application of IP regime in this area on the ground of human dignity and human rights. Some of them are:

INDIGENOUS TRIBAL IDENTITY AND TRADITIONAL MEDICINE

Generally traditional medicine is looked upon as an alternative medicine by the developed countries to be hooked under the confines of western IPR regime. However this outlook on traditional medicine is misconceived and inaccurate in the sense that it primarily relates to form an integral part of the identity of the community to which it relates. Though formal enumeration of protection of cultural identity of indigenous population as a human right is not recognised yet certain instruments protection of cultural identity certain vulnerable groups as a human rights mandate. The uniqueness and plurality of the identity of different groups and its protection is mandated under not only different human rights instruments which recognises cultural rights but also specifically in Conventions like UN Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities 1992 which recognises cultural identity of minority groups,. UNESCO Universal Declaration on Cultural Diversity, 2001 which stressed on recognition and respect for the cultural identity, diversity and pluralism of different groups, the UN Declaration on Rights of Indigenous Peoples 2007 etc Conservation of traditional medicine as a manifestation of cultural identity is visible under Article 24 of this Convention. It states that apart from the access to other social and health services these communities have the right to their traditional medicines and the right to maintain their health practices which includes conservation of vital herbs, animals and minerals. Article 31 recognises the right of these communities to maintain, control, protect and develop their traditional knowledge on medicine and to maintain, protect and develop their intellectual property regime for the protection of it. However the Declaration is silent on the question as to what extent the existing Intellectual property regime can be made applicable as the Convention mandates a sui generis system of intellectual property

protection rather than the existing regime as a part of maintaining their cultural identity and respecting the diversity.

BIO PIRACY: A BASIC HUMAN RIGHT ISSUE

Bio piracy refers to a situation where indigenous knowledge of nature, originating with indigenous people, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves. The developed countries are exploiting developing countries genetic resources and indigenous communities. Some of the threats posed by bio piracy is that knowledge and /or genetic resources belonging to a region, community or country is stolen or claimed as one's own. Thus, the use of this knowledge or genetic resource in the area of its origin or traditional usage may be hampered and thus the patent holder will unfairly profit from the patent. This in turn means that the patent claimed and awarded illegally and unethically is bound to disturb an established system somewhere in the world.

Once an IPR is acquired by the bio pirate, the original holders of a biological resource or related traditional knowledge are barred from making any commercial use of the IPR-protected knowledge or resource. This could lead to a situation where, for example, a community is not allowed to sell an indigenous product that is covered by an IPR. The IPR-holder dictates the terms of use of the IPR protected resource/knowledge, which could mean that traditional communities who are the original holder could lose access to, or control over, their resource/knowledge.

IMPOSITION OF EXISTING IP REGIME AGAINST RIGHT TO PROTECT COLLECTIVE INTEREST OF THE COMMUNITY

The existing IPR systems are oriented around the concept of private ownership and individual innovation. They are at odds with indigenous cultures, which emphasize collective creation and ownership of knowledge. There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use, and that too without the fair sharing of benefits of the holders of this knowledge. They violate the indigenous cultural precepts by encouraging the commodification of such knowledge. Article 1 and 4 of the Declaration of Rights of Indigenous Communities recognise the need to protect the collective interest of the Indigenous Communities. One of the concerns of the developing world is that the process of globalization is threatening the appropriation of elements of the collective knowledge of societies into proprietary knowledge for the commercial profit of a few. This is very much in the case of application of IP regime in this collective knowledge called traditional medicine.

The norms and principles of existing international IPR regimes have developed in a way that has enhanced the vulnerability of traditional communities to bio piracy. There are several reasons why herbal products and medicines do not get proper IPR or patent protection. Usually, herbal medicines are crude plant materials, such as leaves, flowers, fruits, seeds, stems, wood, bark, roots, rhizomes or other plant parts that

may be used whole or in fragmented or powdered form. It is, therefore, often not possible to seek existing patent law protection for herbal medicines by claiming the discovery of new chemical entities or development of an inventive step.

The next reason is that herbal products are powdered herbal materials, extracts, tinctures, or fatty oils of herbal materials prepared by steeping or heating herbal materials in alcohol and/or honey, or in other liquids. The production process is therefore relatively simple and normally does not involve any sophisticated know-how or invention novel enough to secure protection under existing patent laws.

In most countries, it is very expensive to acquire, exercise, and enforce patent rights, particularly if international protection is required. For traditional practitioners and research institutions, particularly in poorer countries, the cost is prohibitive.

RIGHT TO SELF DETERMINATION DENIED BY APPLICATION OF PATENT REGIME

The issue of 'protection' of traditional knowledge needs to be looked at from two perspectives, the "protection" may be granted to *exclude* the unauthorized use by third parties of the protected information. On the other hand, the "Protection" is also means to *preserve* traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. Further, the protection also promotes self-respect and self-determination.

Tribal medicines are often found patented by multinational companies due to the lack of awareness among the tribes of its commercial and financial benefits. Knowledge holders are not adequately compensated or, at least, acknowledged. Traditional medicine (TM) and the knowledge thereof often acquired through field research are used in pharmaceutical laboratories as valuable leads in biological and chemical screening for drug discovery projects. The resulted products are patented and commercialised by outsiders, while indigenous people as true knowledge holders are not adequately compensated or, at least, acknowledged. Bio piracy cannot be thwarted by allowing patenting system being extended to indigenous communities. It is found that many as new, inventive step, industrial application makes it impossible to apply patent law to traditional medicine. Moreover, the patent holder will unfairly benefit from the obvious result of nature rather than a product of human efforts or skill

In addition to this the absence of technical character of patentability such as new, inventive step, and industrial application makes it impossible to apply patent law to traditional medicine. Thus patents and traditional medicine do not merge very easily. This is evident from the fact that different facets of these complex issues are being addressed in a number of International forums itself. The Convention on Biological Diversity highlights the important role of traditional knowledge on medicines and local and indigenous communities in the preservation of biological diversity. Moreover the Intellectual property aspects are being also studied in the WIPO Intergovernmental Committee on Intellectual property and Genetic Resources, Traditional knowledge and Folklore. The UN Permanent Forum on Indigenous Issues highlights issues of particular concern to

indigenous peoples. Developing countries are also raising international aspects of TK protection in the World Trade Organization, notably in the TRIPS Council and the 2001 Doha Ministerial Declaration.

V. INDIAN EXPERIENCE ON COMMERCIALISATION OF INDIGENOUS MEDICINE

According to the Government of India 2011 census data, schedule tribe population in India is about 8.6% of the total population. This population is subjected to abject poverty and economic backwardness, often lacking in proper education and healthcare facilities. For healthcare, they mainly rely on traditional medicines that solely depend upon the supply of native medicinal plants. Their knowledge of tribal medicine (also known as 'folk' or 'indigenous' medicine) is mainly verbal, usually passed on from one generation to another without any written script, making documentation and record-keeping almost impossible. Studies suggest that the tribal and ethnic communities in India as part of their healthcare systems use more than 8000 species of plants and approximately 25,000 folk medicine-based formulations. Thus the ethnobotanical knowledge of the Indian tribes and its medicinal properties is extensive and wide. This knowledge needs not only protection but preservation also. Thus the possibilities of translating this knowledge as marketable pharmaceutical drugs and therapy is great.

In India, the Forest Act itself acknowledges this fact and provides a framework for documentation of such knowledge and the nature of evidence required for recognition of the rights of these communities in the intellectual property in respect of such knowledge.

The provisions of the Biological Diversity Act and Forest Rights Act of 2006 both provide a shield for tribal traditional knowledge, by, one the one hand, respecting and protecting the knowledge of the local communities related to biodiversity and on the other, declaring that the intellectual property rights, in such knowledge belongs primarily to members of the community collectively.

The two Acts acknowledge that the traditional knowledge of the tribal/forest dwellers is to be considered as equal to that of documented scientific and technological information otherwise prevalent in the community, thereby redressing the historical injustice done to the forest dwellers who are integral to the very survival and sustainability to the ecosystem.

As a corollary, the amendments made to the Indian Patents Act in 1970, echo this sentiment. For instance, the amendments to Section 25 and Section 64 provide for additional grounds for opposing or revoking a patent on the grounds that what is claimed as an invention is already known within the realms of traditional knowledge. It is envisaged that in the application of these provisions the standards of evidence required to prove these grounds will be considerably less rigorous than those required for establishing the other grounds of opposition or revocation such as lack of novelty and inventive step.

Along with the right, the responsibility and authority is also bestowed on the holders of traditional knowledge, for the sustainable use of these diverse forest resources, conservation

of biodiversity, maintenance of the delicate ecological balance and strengthening the conservation regime of the forests.

The recognition of Forest Rights Act of 2006 provides for the fact that the intellectual property rights (IPRs) in all forest produce belong to forest dwellers themselves whereas the Biological Diversities Act of 2002 has provisions by which the forest dwellers and other individuals and communities conserving biological resources and holders of knowledge and information relating to the use of biological resources will secure and share benefits from these IPRs.

Since rural and tribal/ethnic people are major stakeholders of the traditional medicinal knowledge, attempts should be made to protect their rights (e.g. Intellectual Property Rights (IPR)). The relationship between traditional medicinal knowledge and IPR is intricate, and is related to the equitable sharing of benefits arising out of the commercial exploitation of such knowledge.

The local ethnic communities in India is exploited by market forces as they pay very less for the medicinal plants collected by them from forest. Apart from this bio piracy is rampant in India. Some of the popular instances are patent being granted by United States Patent Office to a fungicidal product derived from the seeds of the neem tree, India opposed the claim, arguing that the fungicidal properties of the Neem tree had been public knowledge in India for many centuries. The oil from neem has been used traditionally by farmers to prevent fungus. It was neither a novel idea nor was it inventive in any way. Thus the patent was finally revoked by the European Patent Office.

Another issue was on the patenting of haldi or turmeric. In December 1993, a patent was filed by the University of Mississippi Medical Centre, Mississippi. The applicants received US patent for the use of turmeric powder as a wound-healing agent. Meanwhile the Indian Government objected to the patent. However the turmeric patent failed to satisfy the criteria of novelty in view of the cited turmeric's qualities documented in ancient medical textbooks.

Recently India had opposed granting patent for yoga postures to a US based NRI Bikram Chaudhary by the USPTO. The Indian Scientist are also against the Coalgate tooth paste company for applying patent for its herbal tooth powder comprising rust-like red iron oxide, clove oil, camphor, black pepper and spearmint etc

In order to avoid wrongly granting patents, India has amended its Patent Act (Indian Patent Act 1970). The amendments to Section 25 and Section 64 provide additional grounds for opposing or revoking a patent on the grounds that what is claimed as an invention is already known within the realm of traditional knowledge. As a part of it the Traditional Knowledge Digital library (TKDL) was established.

The Traditional Knowledge Digital Library (TKDL) serves as a tool for prevention of misappropriation of traditional knowledge. TKDL records our age old traditional knowledge.

TKDL contains more than 2.60 lakh formulations from the texts of traditional medicine systems of India which are Ayurveda, Unani and Siddha. The library gives access to non-patent literature databases on traditional knowledge of India.

This library covers most of the Indian Systems of Medicine, viz., Ayurveda, Unani, Siddha and Yoga which are

available in public domain. (Shaver, 2011) The abstraction is done by the subject experts. The database provides information on modern as well as local names in a language and format understandable to Patent Examiners. It acts as a bridge between formulations existing in local languages and a Patent Examiner at a global level thus it enables fusion of country's traditional knowledge with modern science.

The library collects the information on traditional knowledge from the literature existing in local languages such as Sanskrit, Urdu, Arabic, Persian and Tamil in digitized format. Information on traditional knowledge is available in five international languages: English, German, Spanish, French and Japanese. It is mandatory for patent examiners to refer to this database before granting a patent now.

Reportedly, prior art ascertained on the basis of the TKDL already prevented the patenting of a melon extract formulation, which is a traditional Indian method of treatment, for the treatment of leukoderma. The Indian authorities also challenged the patents on neem and turmeric. Similarly other notable challenges includes the Brazilian and Italian patenting on grapes used for obesity, diabetes etc. It has also been reported that other developing countries wish to build similar databases and seek assistance from India. (Antons, 2010)

However, the TKDL remains a defensive protection of traditional knowledge that does not fully ensure that the benefits of the information reach its original holders as far as possible. For this legal recognition of rights of the holders of the knowledge is required. Positive rights need to be legally recognised which would empower the communities to preserve and protect the knowledge on medicines. Moreover, it is to be understood that everything cannot possibly be recorded.

In fact TKDL only transcribes traditional knowledge that has been written before in India's traditional medicine systems, which are Ayurveda, Unani and Siddha etc. but it does not record traditional knowledge that passed through word of mouth. Considering the purpose of forming TKDL seems that it was for prior art reference in the patent system where novelty is a mandatory requirement for invention in order to get patent protection. Thus, the date of publication of the traditional knowledge is very important in order to destroy the novelty of an invention.

The National Biodiversity Authority under the Biodiversity Act 2002 lays down the procedure to govern the activities such as access and benefit sharing and Intellectual Property Rights regarding tribal medicine. The overall implementation of the Act is governed by three functional bodies viz. National Biodiversity Authority, State Biodiversity Board, and at local levels, Biodiversity Management Committees.

NBA is the national competent authority to discharge all decisions pertaining to ABS, including prior informed consent process, approval for access and transfer of biological resources and scientific research results and technologies to foreign citizens, companies and non-resident Indians (NRIs), prior approval for applying for IPRs based on biological resources or traditional knowledge obtained from India, fixing criteria for benefit sharing, approval of third – party transfer of accessed biological resources and traditional knowledge, and several other matters related to ABS.

The Act stipulates norms for access to biological resources and traditional knowledge based on three ways: (i) Access to biological resources and traditional knowledge to foreign citizens, companies and NRIs based on 'prior approval of NBA (Section 3, 4, 6 of the Act and Rule 14-20). (ii) Access permits to Indian citizens, companies, associations and other organizations registered in India on the basis of 'prior intimation to the State Biodiversity Board' concerned (Section 7 of the Act). (iii) Exemption of prior approval or intimation for local people and communities, including growers and cultivators of biodiversity, and vaidas and hakims, practicing indigenous medicines (Section 7 of the Act).

The access procedures are only regulatory in nature, not prohibitive in any manner to any applicant irrespective of their nationality, affiliations, origin, etc (Venkataraman, 2008)

The Indian Biodiversity Act has also attracted criticism in the academic literature. Firstly, the very lenient treatment of Indian citizens and especially companies and the limitations to knowledge holders vis-à-vis these local interests. Secondly it can be found that, lack of extraterritorial authority of the NBA as it cannot effectively monitor applications outside India and it would neither have the time nor the resources to challenge patents in many foreign jurisdictions.

Another drawback is the relationship between the discretionary decisions of the NBA on benefit-sharing and the agreements reached between applicants and knowledge holders remains unclear as does the relationship between the NBA and SBBs and the BMCs.

Again the local communities have no automatic right to the benefits, but depend on the direction of the funds by the authorities. Moreover the legislation promotes a strong property rights framework under central control with little regard to common property arrangements.

The lenient provisions for Indian nationals and especially for Indian industry "even seem to encourage commercial exploitation of resources rather than giving impetus to the conservation of biodiversity or to benefit-sharing with the local communities."

However we find that the Act contains benefit sharing clauses which includes:

- ✓ Grant of joint ownership of IPRs to the benefit claimers which attempts to include all the conservers of the biological resources, creators and holders of knowledge and information and individuals or communities practicing such benefits.
- ✓ Transfer of technology for adequate consideration from the benefit sharers to bodies wanting to use the technology.
- ✓ Locating of production, research and development facilities which will provide employment to and otherwise facilitate the betterment of living standards of the benefit claimers.
- ✓ Asking upon the bodies who are applying for a patent to associate Indian scientists, benefit claimers and the local people with the research and development in the biological resources, bio-surveys and bio-utilization and finally;
- ✓ Direct payment of monetary compensation and other non-monetary benefits to the benefit claimers.

In India, there is an example of benefit-sharing in the case of Arogyapacha. During an ethno-botanical expedition in the tribal region of the Western Ghats in the state of Kerala, a team of scientists encountered the Kani practice of eating seeds of the wild plant *Trichopus zeylanicus* which gave them energy. The Kani tribe has used the plant, locally called 'Arogyapacha', for several years to help them through periods of physical exertion.

Arogyapacha was investigated and finally a standardized drug based on the Kani knowledge of Arogyapacha was developed. The drug called "Jeevani" was released for commercial production in 1995. Patent applications were filed by TBGRI for the process of making the novel formulations. No product patent was applied for at that time since India did not have a product patent regime in place but only a 7 year process patent was available. It appears that no patents were applied for outside India. The TBGRI licensed the process for manufacturing and marketing the drug to Arya Vaidya Pharmacy, a private company, for a period of 7 years [the term of the patent] for a consideration of an upfront licence fee of Rs 1 million (USD \$25,000) and a right to receive royalties from the sale of the drug at a rate of 2 percent ex-factory price on the sales of the product. 'Jeevani' was successfully sold in India as well as in other countries like the USA and Japan.

TBGRI voluntarily agreed to share 50 percent of the licence fee and 50 percent of the royalty from the licensing agreement with the Kani tribal, although at that time neither the Biological Diversities Act nor the Rights to Forests Act had come into existence. With the help of officials Kerala State Government, the Kanis set up a trust which kept the money in a fixed deposit, and used the interest for activities benefiting the Kani community. The trust started with 9 members in 1997, and by 1999 had 1000 members. Subsequently, a majority of the Kani families became members of the trust.

Many of the Kani elders believe that the knowledge relating to the use of the plant and other plants indigenous to the area was sacred and should have remained exclusive within the tribe. Secondly, Kanis from other areas expressed unhappiness about the fact that only a few Kanis had been consulted by the TBGRI and had given 'permission' to use the knowledge, though the knowledge belonged to the Kani tribe as a whole. Thirdly, traditional healers were upset because of the fact that they had not been consulted about the use of this traditional medical knowledge.

TBGRI trained 25 tribal families to cultivate the plant around their dwellings in the forest. In the first year itself, each family started to earn from the sale of leaves from cultivation of *T. zeylanicus*. But unfortunately as often happens, the left hand obstructed what the right hand bestowed. The forest department which controlled the use of the forest land objected to the cultivation on the pretext that cultivation of the plant in the forest was a non-forest activity that the tribal were indulging in and that the tribal might remove the plants from the natural population of the species in the forests and thereby make it endangered.

Before Jeevani, the Forest Department had turned a blind eye to the Kani's activities in collecting the plant but after the properties of the plant became well known, traders directly started entering the forest in search of the plants and removed

the plant in large quantities. The Forest Department had to halt all collection activities, thus curtailing and punishing even the traditional collection by the Kanis. Attempts were made to grow the plant in nurseries outside the forest, but it was found that these nursery grown plants did not have the same properties as the forest variety. By 1999 the drug could not be produced in sufficient quantities. Financially, therefore, everyone lost out – not only Arya Vaidya Pharmacy and TBGRI, but also the Kanis, who were probably the biggest losers, firstly because they had sold their sacred knowledge but now had little prospect of receiving royalties from the sale of the drug; and secondly because even their traditional collection of the plant had been curtailed.

Probably, this would not have happened under the new regime of the Biological Diversities Act and the Forest Act, where the Kani tribe would have been directly involved in the making of Jeevani and the Biological Diversity Authority would have been able to control the exploitation of the plant to the exclusions of the traders.

Unfortunately, lack of foresight prevented the holders of the patent applications or the licensees to protect the trademarks or the patents outside India. A US-based company Nutri science Innovations, the US distributor for the licensees, registered Jeevani as a trade mark in the US. The product was sold in the US market without the knowledge of TBGRI. Nutri science was sourcing Jeevani in bulk quantities from Arya Vaidya Pharmacy. This was also discontinued. The American company and another company Good Earth is now using Jeevani in its product 'Jeevani Jolt 1000' without technically infringing the intellectual property rights of the original Jeevani. The ingredients mentioned in the American products are the same as those in the original Jeevani, including Arogyapacha. This shows that existing IPR regime is unsuitable for protection of traditional medicine.

In early 2010, the NBA released a number of draft amendments and requested public comments, including on the Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity Rules (subsequently Traditional Knowledge Rules). Apart from other provisions these rules suggest TK register for India

Criticism exists that this sui generis legislation for traditional knowledge protection is not introduced as a Bill and as such subjected to parliamentary scrutiny, but as delegated legislation in the form of rules under the Biological Diversity Act of 2002. Given the broad scope of some of the provisions, the question has been raised whether this is constitutional.

The Traditional Knowledge provisions go significantly beyond and frequently contradict those of the Biological Diversity Act. The NBA has just collected public reactions to the Traditional Knowledge Rules. These reactions were collected jointly with those related to the further debates on an international regime on access and benefit sharing and on amendments to the Biological Diversity Act, 2002, and the Biological Diversity Rules, 2004. Since the parent legislation for the Traditional Knowledge Rules could also be amended, it is unclear at this stage how these various laws and rules will ultimately relate to each other and which form the Traditional Knowledge Rules will finally take.

Nevertheless, a few preliminary comments can be offered. First, it is interesting to note that the Rules apply a very wide definition of 'traditional knowledge', which includes traditional cultural expressions. Thus, 'traditional knowledge' relates not only to "properties, uses and characteristics of plant and animal genetic resources; agriculture and healthcare practices, food preservation and processing techniques and devices developed from traditional materials", but also to "cultural expressions, products and practices such as weaving patterns, colours, dyes, pottery, painting, poetry, folklore, dance and music."

Equally wide is the definition of beneficiaries belonging to a 'traditional community', which includes "families, people belonging to Scheduled Tribes as per Article 342 of the Constitution of India, and other notified tribal groups including nomadic tribes..." The inclusion of families shows that tradition is, quite rightly, not supposed to remain confined to tribal groups. However, in view of the definition of 'misuse of traditional knowledge' as "access to and/or use of traditional knowledge by persons not belonging to the traditional community" without license or in breach of licensing terms, it brings back the question how group/community membership is defined and who decides about membership. This is all the more important, because the Traditional Knowledge Rules differ from the regulations in the Biodiversity Act in that they provide for direct negotiations between a user (or 'accessor' in the terminology of the Rules) and a traditional community and for direct payment of the benefits to the traditional community.

While the Rules in so far strengthen the role of the communities, the national and state authorities still have the final say in many instances, for example, if traditional knowledge is already in the public domain, not specifically owned by any particular community or is owned by communities spread out over more than three states. It gives the NBA decision-making powers over access by one traditional community to the knowledge of another community, if this is for earning their livelihood and not for commercial gain. It requires from communities to comply with the registration requirements of the Traditional Knowledge Register, if they want to receive benefits.

Users, on the other hand, have to await the outcome of fairly complicated and potentially lengthy procedures, involving national and state authorities as well as local communities, to finally get access. These procedures include a potential waiting period of up to one year to allow states to set up State Biodiversity Boards and/or Biodiversity Management Committees, where they do not yet exist. Assessment further involves a report by such committees on such complicated matters as sustainability of resources, social and environmental implications and potential value of the knowledge as well as a resource management plan.

VI. CONCLUSION AND SUGGESTIONS

TOWARDS A SUI GENERIS MODEL

It is found that the thrusting of existing IPR regime into traditional medicine of indigenous communities is violated of

their basic rights. Primarily this is because IPRs protect individual property rights, whereas traditional knowledge is collective or communal resources. Moreover, traditional knowledge evolves over a long period of time stretching over generations and may not meet the criteria of novelty or inventive step required for IPRs like patents. However the main problem of traditional knowledge protection is misappropriation from pharmaceutical and agricultural companies. Amendment of existing IPR regime might sound an easier way but this will only prevent cross border misappropriation. It would not empower the local indigenous communities to preserve and protect their interest. A sui generis regime for the protection of traditional knowledge will set out legal rules and procedures applicable to traditional knowledge and will define what purpose or role a registry will play. A sui generis model should necessarily incorporate laws which expressly recognises exclusive rights for indigenous people over their traditional knowledge. It should also contemplate registries that promote documentation, maintenance and preservation of traditional knowledge. Institutional mechanisms establishing a duty to negotiate in good faith should be articulated as well as measures for resolving conflicts arising from access to and use of traditional knowledge need to be laid down.

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