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The Realities Of Traditional Knowledge And Patents

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In India, laws acknowledge the fact that traditional knowledge cannot be protected by intellectual property rights and that if documented the knowledge would be lost by the communities to which it belongs through expropriation. Putting the laws into reality reveals some interesting- and sometimes painful – lessons.

A little publicised fact about India is that there are around 100 million forest dwellers in India, most of whom belong to tribal communities. The forests provide them with sustenance, providing both timber and non- timber forest produce. In turn, the forest dwellers have over the centuries gathered knowledge from the natural environment around their community. This community has in one sense been thankfully insulated from the ways of modern man and have carried on the traditions of their ancestors. As a whole, the forests and its dwellers gives to India an abundant knowledge about the traditional value of various forest products.

The way intellectual property rights have been designed in modern commerce, traditional knowledge cannot be protected. For instance, traditional knowledge cannot be patented because such knowledge lacks inventive character, because of the inherent lack of novelty. Traditional knowledge is also often held collectively by communities, rather than by individual owners. This traditional knowledge is information that is transmitted from generation to generation generally within the community or within families within the community in an oral form without any adequate documentation. This has caused traditional knowledge to be undervalued and marginalised. In fact, one of the fears in these communities is that if the knowledge were to be documented it would have been lost to the community by expropriation.

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 in 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 2002 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. The Biological Diversities Act also provides for conservation and development of areas which are declared as biological diversity heritage sites.

The biological resources envisaged under the Act include plants, animals, micro organisms and parts of the above, genetic material and by-products. Human genetic material is specifically excluded.

The Act specifically provides (Section 6 of the Act) that if any person applies for a patent within or outside India for an invention based on any research or information on a biological resource obtained from India, such a person will have to obtain approval from the National Biodiversity Authority for making such an application. This approval may be delayed up to the time of sealing of the patent. At the time of granting of the approval the National Biodiversity Authority may impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

It is envisaged that these benefits of royalty will be transferred to the communities who grow or rear the biological resources and who have the traditional knowledge relating to its properties which are utilised by the applicant for a patent. The Patent Office in India acts in conjunction with the National Biodiversity Authority. In case of any patent application which suggests the use of biological resources from India, the examiner at the Patent Office asks the applicant to obtain the approval from the National Biodiversity Authority and a patent is not granted until such approval is obtained.

The scheme of the Act provides for two methods for royalty collection. When a patent application relates to a biological resource per se and the invention is for instance for the extraction, treatment, modification or purification or use of the biological resource as such, approval has to be obtained from the National Biodiversity Authority. On the other hand, for the commercial use of the biological resource in a value-added product, such as for example in a formulation with other ingredients, royalties will be payable to state authorities. The use of traditional biological resources by practitioners of traditional medicine, the medicine men is exempt.

The Act also has provisions for the equitable distribution of any benefits arising out of inventions and innovations and practices associated with the use and applications of knowledge. The benefit-sharing includes the following:

1. Grant of joint ownership of Intellectual Property Rights to the benefit claimers which include all the conservers of the biological resources, creators and holders of knowledge and information and individuals or communities practicing such benefits.
2. Transfer of technology for adequate consideration from the benefit sharers to bodies wanting to use the technology.
3. Locating of production, research and development facilities which will provide employment to and otherwise facilitate the betterment of living standards of the benefit claimers.
4. 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;

5. Direct payment of monetary compensation and other non-monetary benefits to the benefit claimers.

I propose to illustrate a bittersweet episode of the practical implementations of the combined effects of both these legislations, which actually occurred before the coming into force of these legislations.

There are a group of around 20,000 tribals in the southern state of Kerala in India known as the 'Kani'. Although these tribals were traditionally nomads travelling from forest to forest, for the past 150 years they settled down in tribal hamlets of between 10 and 20 families in the forest of the Agast-Hymalai hills of the Western Ghats. The Kanis are subsistence dwellers of the forest and are collectors of non-timber forest produce. Their society includes medicine men and women who have expert knowledge of the medicinal and nutritive value of the plants, herbs and tree products of the vegetation that grows around them. They consider this knowledge secret and sacred and the knowledge is passed on from generation to generation by the oral tradition.

A group of scientists working on the All India Co-ordinated Research Project on Ethnobiology (AICRPE) was assigned to survey the Kani tribal settlements, for which purpose, in the absence of any road network through the region, was in 1987 trekking through the tropical forest hills. The group was accompanied by some Kani tribesmen who acted as pointsmen. Members of the group grew tired and had to halt periodically. However, their Kani guides continued to be fresh and energetic throughout the trek by occasionally munching small wild-growing blackish fruit. One of the guides offered the fruit to some of the tired scientists who were astonished to find their fatigue disappearing and that they were able to continue the trek at a faster pace. After considerable cajoling, the guides who were initially reluctant to give up the secret of this sacred tradition were finally persuaded to disclose the plant from which they sourced the fruit. The members of the group reported this episode to the Tropical Botanical Gardens Research Institute (TBGRI) in Kerala who was assigned the task of scientifically testing the plant. This plant was identified as *Trichopus zeylanicus* ssp. *Travancoricus*, colloquially referred to as Aarogyappacha. Chemical and pharmacognosical investigations showed that the leaf of the plant contained various glycolipids and some other non-steroidal compounds with profound adaptogenic and immuno-enhancing properties and the fruit of the plant has stress and fatigue combating properties.

Using this plant, and extracting substances from the plant, and after standardisation the TBGRI formulated a drug named 'Jeevani'. The Kani tribe members were using only the fruit of the plant whereas jeevani was developed from its leaves (never used by the Kani tribe members). Only 13 to 15 percent of the plant was used for the final product, while the remaining ingredients were based on other ingredients developed from ayurvedic knowledge and wisdom.

The commercial formulation contained:

1. Arogyappacha (15%) (*Trichopus zeylanicus*) a powerful adaptogenic tonic herb from the Southern Himalayan rain forests of the Western Ghats (Kerala).
2. Ashwagandha (*Withania somnifera*) powerful adaptogenic, immuno-enhancing and aphrodisiac herb.
3. Shankhpushpi (*Evolvus alsinoides*) considered to be the most powerful memory enhancing herb and nerve tonic used in Ayurveda. In Jeevani Shankhpushpi is used to enhance mental calmness.
4. Pippali (*Piper longum*) a type of black pepper used in Ayurveda for improving metabolic heat, sperm count and ejaculation, without causing any toxic side effects. Pippali is also quite suitable for women, as it is believed to improve female sexual response.
5. Other Ingredients: Permitted preservatives and binding materials.

Twelve active compounds were isolated from arogyapacha. Five patent applications emanated from the research work. Five process patent applications were filed since 1994.

Out of them, there were three patent applications in which the plant *Arogyappacha* was included. One was for diabetes, the second a sport medicine, and third for cancer. Following is an overview of the drugs based on these patent applications filed:

- 'Jeevani', a novel immunoenhancing, anti-fatigue, anti-stress and hepatoprotective herbal drug.
- 'SISAIROSP', a herbal formulation for control of psoriasis and dandruff.
- A new anti-diabetic herbal drug from the plants *Trichopus zeylanicus*, *Withania somnifera* and *Piper longum*.
- A new sports medicine from *Trichopus zeylanicus* named 'Vaji'.
- A new anti-inflammatory and analgesic oil / ointment.
- A new anti-pyretic herbal formulation
- An anti-cancer formulation from *Trichopus zeylanicus* and *Janakia arayalpathra*

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 tribals, 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 tribals were indulging in and that the tribals 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 Nutriscience Innovations, the US distributor for the licensees, registered Jeevani as a trademark in the US. The product was sold in the US market without the knowledge of TBGRI. Nutriscience 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.



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Note: This article is an extract that is copyright from the forthcoming book (Routledge, September 2010) entitled "Intellectual Property, Innovation, Management in Emerging Economies" edited by Ruth Taplin and Alojzy Z. Nowak. The extract is by Dr. Mohan Dewan, owner of R.K. Dewan & Co Trademark and Patent Attorneys. The title of the chapter is, "Socioeconomic Changes effected by Intellectual Property Rights – the Indian Perspective." For further information concerning the book please contact Dr. Ruth Taplin: ruth.taplin@btinternet.com [2].

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[3] WIPO Traditional Knowledge Committee Opens With Hope For Text-Based Talks:

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[4] Perpetual Protection Of Traditional Knowledge "Not On Table" At WIPO: **<http://www.ip-watch.org/weblog/2009/10/22/perpetual-protection-of-traditional-knowledge-%e2%80%9cnot-on-table%e2%80%9d-at-wipo/>**

[5] WIPO Traditional Knowledge Negotiators Dodging Roadblocks: **<http://www.ip-watch.org/weblog/2009/12/10/wipo-traditional-knowledge-negotiators-dodging-roadblocks/>**