Protecting India's Traditional Knowledge

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In just under two years, in Europe alone, India has succeeded in bringing about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations. The key to this success has been its Traditional Knowledge Digital Library (TKDL), a database containing 34 million pages of formatted information on some 2,260,000 medicinal formulations in multiple languages. Designed as a tool to assist patent examiners of major intellectual property (IP) offices in carrying out prior art1 searches, the TKDL is a unique repository of India's traditional medical wisdom. It bridges the linguistic gap between traditional knowledge expressed in languages such as Sanskrit, Arabic, Persian, Urdu and Tamil, and those used by patent examiners of major IP offices. India's TKDL is proving a powerful weapon in the country's fight against erroneous patents, sometimes referred to as "biopiracy". In this article, **Dr. V.K. Gupta**2, the author and architect of India's TKDL, explains the critical role that this unique tool plays in protecting India's traditional knowledge.

The significance of traditional knowledge

Traditional knowledge (TK) is integral to the identity of most local communities. It is a key constituent of a community's social and physical environment and, as such, its preservation is of paramount importance. Attempts to exploit TK for industrial or commercial benefit can lead to its misappropriation and can prejudice the interests of its rightful custodians. In the face of such risks, there is a need to develop ways and means to protect and nurture TK for sustainable development in line with the interests of TK holders. The preservation, protection and promotion of the TK-based innovations and practices of local communities are particularly important for developing countries. Their rich endowment of TK and biodiversity plays a critical role in their health care, food security, culture, religion, identity, environment, trade and development. Yet, this valuable asset is under threat in many parts of the world.

There are concerns that this knowledge is being used and patented by third parties without the prior informed consent of TK holders and that few, if any, of the derived benefits are shared with the communities in which this knowledge originated and exists. Such concerns have pushed TK to the forefront of the international agenda, triggering lively debate about ways to preserve, protect, further develop and sustainably use TK. Documenting and digitizing TK-related information in the form of a TKDL is proving to be an effective means of preserving TK and of preventing its misappropriation by third parties. India is a pioneer in this field.

How it all began

India's TKDL, a collaborative project between the Council of Scientific and Industrial Research (CSIR), and the Department of AYUSH3, is a home-grown effort to ensure patent offices around the world do not grant patents for applications founded on India's wealth of age-old TK. The idea to establish a TKDL came to the fore amid India's efforts to revoke the patent granted by the United States Patent and Trademark Office (USPTO) on the wound healing properties of turmeric, and the patent granted by the European Patent Office (EPO) on the antifungal properties of neem. These endeavors, while successful, proved extremely costly and time-consuming.

Around the time the TKDL was established in 2001, the TKDL expert group estimated that, annually, some 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world.

For a patent to be granted, an applicant must satisfy certain criteria as defined by national patent law, in particular, an applicant must prove that a claimed invention is novel and not previously known. Why then had patents been granted for so many applications relating to Indian medicinal systems? When patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India's traditional medicinal knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil.

These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted.

The fact that so many patents had been wrongfully granted in the U.S. and Europe caused a great deal of national distress. The people of India felt that knowledge belonging to India was wrongfully being taken away from them. On top of this, these "wrong" patents conferred exclusive rights to exploit the technology in the country in which patent protection was granted. This posed a very real economic threat to Indian producers and to their freedom to operate in foreign markets.

Bridging the divide

The TKDL has overcome language barriers and is bridging the gaps in TK information in major patent offices. Using information technology tools and a novel Traditional Knowledge Resource Classification System (TKRC), the TKDL has converted and structured ancient texts into 34 million A4-sized pages along the lines of a patent application. These have been translated into English, French, German, Japanese and Spanish.

Today, thanks to its TKDL, India is capable of protecting some 0.226 million medicinal formulations and at zero direct cost. Access to the database helps patent examiners root out those applications that clearly do not satisfy the novelty requirement at an early stage. Without a TKDL database, 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. Multiply this by India's 0.226 million medicinal formulations and it is clear that the cost of protection, without a TKDL, would be prohibitive.

An innovative classification system

India's innovative TKRC is modeled on WIPO's International Patent Classification (IPC). It consists of some 27,000 subgroups for Ayurveda, Unani, Siddha and Yoga and, like the IPC, is indispensable for the retrieval of relevant information.

The TKRC has prompted the reform of the IPC – an essential tool in enabling effective search and examination of patent applications – as it relates to TK. The IPC divides technology into eight sections with approximately 70,000 subdivisions each of which is assigned a symbol consisting of Arabic numerals and letters of the Latin alphabet. Until 2005, only one subgroup – A61K35/78 – existed for medicinal plants, meaning that patent examiners were ill equipped to examine traditional medicine-based patent applications.

India took up the lack of recognition for traditional medicines in the IPC's Committee of Experts. Following the establishment of a five-nation 'Traditional Knowledge Classification Task Force' – comprising China, the European Union, India, Japan and the United States – the number of IPC subgroups relating to medicinal plants rose to 207 bringing about a fundamental and far-reaching reform of the international patent system. In 2004, it was agreed to link the TKRC's 27,000 subgroups to the IPC.

Connecting TK holders and patent examiners

The TKDL is a unique, proprietary database that integrates diverse knowledge systems and languages. It is based on 148 books of prior art relating to Indian systems of medicine, available at a cost of around US$1,000. The TKDL connects patent examiners around the world with these books of knowledge.

The TKDL is available to all patent offices that have signed a TKDL Access Agreement which has built-in, non-disclosure mechanisms to safeguard India's interests and counter any possible misuse. Under such an agreement, patent examiners may use the TKDL for search and examination purposes only and its contents may only be revealed to third parties for the purposes of citation.

So far, India has signed TKDL Access Agreements with the EPO and the patent offices of Australia, Canada, Germany, the United Kingdom and the United States. Negotiations are also ongoing with the patent offices of New Zealand and Japan where agreement in principle has already been reached.

Global IP-watch systems

The national patent laws of most countries allow for third parties – any member of the public – to file a submission questioning the novelty and non-obviousness of a patent application before a patent is granted. There is a need, therefore, to ensure that patent applications that wrongly claim rights in prior art are readily identifiable so that such "third party observations (TPOs)" can be filed and made easily searchable. Global IP-watch monitoring systems have an important role to play in enabling the identification of published TK-related applications on which third parties – in accordance with the patent law of the country concerned – may file observations.

To date, the submission of TPOs has proven the only cost-effective way of preventing misappropriation of TK at the pre-grant stage. The TKDL database has enabled the submission of TPOs that have resulted in the successful opposition of hundreds of patent applications filed around the world. Without documenting and digitizing TK and making these databases easily accessible to patent examiners operating in the major languages of commerce, this would not have been possible.

The TKDL has an integrated global biopiracy watch system that allows monitoring of patent applications related to Indian medicinal systems. It enables effective detection of attempts to misappropriate this knowledge by third parties filing applications with patent offices around the world. It means that immediate corrective action can be taken, and at zero direct cost, to prevent biopiracy. India is the only country to date to have put such a system in place.

Comparison of time and costs associated with post-grant opposition and pre-grant opposition based on the submission of prior art evidence supported by TK documentation

No.	Methodology & Process	Post-grant Opposition	Pre-grant Objections supported by a database such as TKDL
1.	Nature	Opposing party is part of re-examination process, can submit counter documents and	Objecting party can only file evidence as a third party and cannot participate in the

		participate in re-examination and hearing process.	examination process.
2.	Cost	Highly expensive and requires legal assistance.	Inexpensive and does not require legal support because prior art evidence is available from the TKDL.
3.	Time period	4 – 13 years	3 – 20 weeks
4.	Documentation	Does not require extensive documentation.	Requires extensive digital documentation.
5.	Patent	Applicant can appeal invalidation of the patent.	Patent applicant cannot appeal as the application is rejected at the pre-grant stage.

Impact of TKDL on biopiracy

TKDL outcomes against bio-piracy. Clockwise from top left: green tea; pomegranates; pink lotus; turmeric root. (Photos: iStockphoto Kevin Jean - Narcisa - Fotografia Basica - Gomez David)

The TKDL's impact is already being felt at the EPO. Since July 2009, 215 patent applications relating to Indian medicinal systems for which third party TKDL evidence has been filed have been identified. In two such cases the EPO has already reversed – on the strength of TKDL evidence – its earlier intention to grant the patents. In one case the applicant modified the claims submitted and, in

33 other cases, the applicants themselves withdrew their four to five-year-old applications upon presentation of TKDL evidence.

It is expected that in the coming months some 179 cases that are currently in the balance will either be rejected by the EPO or withdrawn by the applicants. A recent study by a TKDL expert team at the EPO shows a sharp decline (44 percent) in the number of patent applications filed concerning Indian medicinal systems, particularly in relation to medicinal plants. The TKDL is clearly proving to be an effective deterrent against biopiracy.

Misappropriation of TK and biopiracy of genetic resources are of great concern to many countries and indigenous and local communities. While these issues have been taken up within various multilateral forums such as the Convention on Biological Diversity (CBD), the TRIPs4 Council of the World Trade Organization (WTO) and at the World Intellectual Property Organization (WIPO), a global framework to protect TK has not yet been established. WIPO's IGC5 is, however, making progress and it is hoped that in the near future consensus will emerge on an internationally legally binding instrument to effectively protect TK.

A success story

India is the only country in the world to have set up an institutional mechanism - the TKDL - to protect its TK. The TKDL enables prompt and almost cost-free cancellation or withdrawal of patent applications relating to India's TK.

To date the TKDL has enabled the cancellation or withdrawal of a large number of patent applications attempting to claim rights over the use of various medicinal plants. India's TKDL is a unique tool that plays a critical role in protecting the country's traditional knowledge.