

TRIPS, WTO and IPR: Protection of Bioresources and Traditional Knowledge

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The World Trade Organization (WTO) was set up in 1995 and has been the custodian of all matters related to the implementation of the TRIPS Agreement endorsed by 153 member countries. WTO is therefore the most important body which monitors and influences working of global intellectual property rights protection in all its member countries. This opinion discusses about the protection of bioresources and traditional knowledge.

TRIPS Agreement

One of the most important components of the General Agreement on Tariffs and Trade is the one related to TRIPS dealing with a globally harmonized protection system for intellectual property rights (IPR) which has become mandatory for implementation by all member countries within specified time frames, the last one being 2016 by which time even the countries with the least developed status have to have in place an appropriate legislative system of protection available to all inventors in all fields of technology. According to TRIPS, the minimum criteria for enabling filing of a patent application is to ensure that the invention is novel, has inventive (non-obvious) merits and has commercial application. While the entire system of patent protection is based on these basic tenets, it has left wide void in the matter of protection of natural assets which are owned by nation states, communities or individuals. Such assets include biological resources of plant, animal and microbial origin as well as intangible assets of traditional knowledge (TK), practices, cultural expressions, art forms and even folklore belonging to rural communities in many countries of the world. They are present in documented as well as non-documented forms in which case they need to be collected and documented in order to evaluate their real worth. Besides, it is necessary to develop them where required, protect them from unauthorized use by third parties and develop methods to exploit them for the benefit of the owners of such assets.

Several international agencies, such as UNEP, UNCTAD, FAO, WHO, WIPO, CBD, WTO and the World Bank have been engaged in the development of strategies to address the above issues. Among the many countries which have initiated action in this area are India, Philippines, Thailand, Costa Rica, Ecuador, Brazil, Venezuela, Egypt and African countries.

The Indian Scene

In India, the Biological Diversity, Plant Varieties Protection, and Geographical Indications Acts have been legislated; however in the present form, they do not cover protection of TK. Problems also exist in the implementation phase of these legislations, with several grey areas related to ownership issues, prior informed consent (PIC), material transfer, access and benefit sharing (ABS), yet to be clarified and put into operation. In addition, protection of life forms due to Article 27.3 (b) of TRIPS is also being addressed by several countries. The ambiguities resulting from this Article relate to patenting rights on life forms present in nature or created by man, patenting of genes, DNA sequences, gene therapy etc.; and protection of TK including traditional systems of medicines. The Geographical Indications (GI) Act permits registration of names and source of origin, however, how these can be converted into economic gains to the community which 'owns' them and to what extent they are legitimized and accepted as IP in other member countries are not clear. Also, the restriction of GIs to wines and spirits as per Articles 23 of TRIPS is another area of concern. The India's Plant Variety Protection and Farmers' Rights Act, 2001 has extended rights to new varieties and seeds not only to

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breeders, but also to farmers, though, not for commercial use. India has been actively participating and is a party to many proposals on all these issues at the WTO, WIPO, CBD and others.

Protection Issues

Any discussion on the subject of protection of TK, genetic resources (GRs), traditional cultural expressions (TCEs) and folklore has to answer four major questions, namely: (i) Why is protection important? (ii) What needs to be protected? (iii) What are the protection modalities? and (iv) In what way can the owners of TK benefit from the protection system? While there has been no agreement on the definition of TK, it would include all traditional scientific and medical knowledge or practices, unique verbal expressions (folktales), musical expressions (folk music) and tangible expressions (textile, pottery, sculpture, jewelry, medicines etc). Protection is important to the owners, since TK can be treated as a valuable tradable commodity bringing economic benefits to the owners, while simultaneously ensuring that such knowledge is not eroded or destroyed. For example, indiscriminate use of medicinal plants without ensuring sustainability through conservation, has led to massive endangering of valuable plant bioresources. Similarly, due to lack of documentation and poor dissemination of knowledge by chance or by design (as a protective mechanism), much of indigenous knowledge is getting irretrievably lost. Moreover, multinational companies routinely exploit such knowledge to gain commercial benefits through the patenting system. In the absence of searchable databases disclosing existence of such knowledge as prior art, patent offices grant patents on the use of this knowledge to produce useful products. The patents on turmeric for wound healing (revoked by the USPTO on the basis of CSIR's evidence of prior art), karela, brinjal and jamun for diabetes, neem formulations as insecticides and fungicides, *Phyllanthus amarus* for its anti-viral activity etc., highlight the compulsions faced by traditional societies to ensure protection of their knowledge base from unauthorized exploitation. India's pioneering efforts to develop a unique Traditional Knowledge Digital Library (TKDL) has been accepted as a model for prior art search by many patent offices around the world. The use of such an authentic database will hopefully eliminate patenting activities in the area of TK, traditional medicines etc. The need for recognition of sovereign rights of member countries over their bioresources resulted in

signing of the Convention on Biodiversity (CBD) at the Earth Summit in Rio de Janeiro in 1992 by several countries which are now part of the WTO with few notable exceptions like the USA. The CBD has three basic tenets namely, establishment of the sovereign rights to bioresources by the countries of origin, modalities for exploitation exclusively by the owners and equitable benefit sharing in cases where third parties exploit these resources.

Status of Global Developments on CBD

The Nagoya Protocol

There have been several discussions and debates as to whether the TRIPS Agreement which forbids monopolistic protection of natural resources is in conflict with CBD. The current consensus is however, that they indeed are separate agreements designed for different purposes and that there is no conflict between the two. In the past, the CBD itself hardly had any presence (even as an observer) in the WTO. It was only in 2001, at the Doha Conference, that it was agreed under Para 19 of the Doha Declaration that pursuant on Article 71.1 of TRIPS, the TRIPS Council should examine the relationship between TRIPS and CBD. After several years of debate at various fora, the parties to the CBD met at Nagoya, Japan in October 2010 and finalized the draft protocol (Nagoya Protocol) which defines the terms for access to GRs, their utilization and fair and equitable sharing of benefits from such utilization. The Protocol is open for signature till February 2011 and it is hoped that majority of the signatories to CBD will approve, endorse and sign the protocol.

In order to make the terms of the Protocol effective, member states need to enact appropriate national legislations to ensure the rights of indigenous and local communities, design and administer policy measures, set up norms for enabling access to and utilization of GRs and TK, monitor related activities at the national and international levels, finalize benefit sharing standards and norms and establish dispute settlement systems acceptable to all the stake holders.

Protection of Traditional Knowledge

The present instruments for protection of intellectual property (IP) under TRIPS or bioresources under CBD are inappropriate for the protection of TK. IP protection under the patent system requires the subject matter to be novel, inventive and useful. Since much of TK comes from the public domain, in the conventional sense they would be deemed to lack

novelty. It is therefore necessary that the protection modalities have to be through a novel ‘*sui generis*’ system, which should: (1) Protect nascent TK and derive benefits there from and, (2) Reap benefits and rewards from property derived from TK, even if such property is novel, inventive and commercially useful and therefore patentable.

According to what can be termed the ‘derivation principle’, innovations which are based on GRs and TK also would qualify for benefit sharing. The Indian Patents Act (2nd Amendment) stipulated that all patents should disclose the origin of the materials used (e.g., medicinal plants) and the knowledge based on which the innovation was made possible. Perhaps this is the first step for invoking the derivation principle, which at the moment does not find a place in the Indian Patent Act.

Negotiations at the WIPO

The ongoing negotiations under the auspices of the World Intellectual Property Organization (WIPO) address various issues associated with the protection of GRs, TK, TCEs and folklore. Several proposals have been submitted by groups of countries with their common interests. The primary objectives are:

- 1 Defining TK, and GRs useful for the Indian systems of medicine
- 2 Ensuring that valuable indigenous resources are not expropriated without authorization by third parties
- 3 Developing a universally acceptable (*sui generis*) protection system based on current IP protection systems or any other viable system
- 4 Establishing norms for ensuring systems of PIC before utilization of these assets for commercial or other uses, and
- 5 Ensuring that owners of these assets have legal rights for sharing benefits accruing from the utilization of these assets for development and commercialization of products and processes based on them.

Sui Generis Law for Protection of TK

Nothing prevents WTO members from developing a *sui generis* system at the national level for the protection of TK. A model law should cover:

- (i) a definition of subject matter for protection,
- (ii) extent of rights to exclude others from unauthorized use,
- (iii) methods of deriving benefits when TK leads to commercial products,
- (iv) conservation strategies to ensure sustainability,
- (v) registration of title holders of TK,
- (vi) material transfer agreements, and
- (vii) duration of protection.

PIC has often been mooted as a pre-requisite for the use of TK. While this is desirable, there are a number of implementation problems associated with such a requirement, which need to be sorted out before it is made mandatory. It is also to be decided whether all forms of TK can be incorporated under a single *sui generis* legislation. For example, is it possible to include artistic creations, folklore and heritage systems and products on the one hand; and plant genetic sources for food, agriculture and medicines on the other hand under one *sui generis* legislation?

Need for International Recognition of National *Sui Generis* Legislation

While member countries can bring in national legislations (as long as Articles 3 & 4 of TRIPS are satisfied), for protection of TK, under a *sui generis* system or a combination of other legislations on patents, trademarks, GIs, trade secrets, plant variety protection or biological diversity; unless it is recognized and accepted by other members of WTO and CBD, it has no global legitimacy. This is where the proposal to have a ‘Development Coalition’ of representative countries agreeing on a common framework for protection of TK becomes important. The outcome cannot be taken for granted, since there are members who agree with the US stand that ‘a regime to protect TK cannot by definition adhere to the principle of IPR, namely, as an incentive mechanism for innovation’. WIPO’s efforts are primarily directed to evolving a consensus on the absolute minimum acceptable to all. Overall, it is obvious that while a large amount of efforts are being deployed to arrive at a consensual approach for the utilization and protection of these major assets of sovereign states, progress today has been extremely slow and tardy. Hopefully some compromise formula to resolve some of the contentious issues will be arrived at during the coming years.