# UNIT 9 PROTECTION OF TRADITIONAL KNOWLEDGE

**Structure**



## 9.1 INTRODUCTION

Traditional Knowledge (TK) is used to refer to the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.

However, WIPO Secretariat besides using the above definition also has the following all-encompassing and working concept of *traditional knowledge*:

Traditional Knowledge *refers to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. "Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge.*

In this Unit we will discuss the importance of protecting Traditional Knowledge, cite some concrete examples of efforts made in protection of TK in India and current international developments in the field of TK protection.

**Objectives**

After studying this unit, you should be able to:

- list reasons for protecting TK;
- describe with example the Indian efforts to protect its TK;
- explain the International Scenario in protection of TK;
- elaborate the role of WIPO in protection of TK;
- describe the tools of TK protection; and
- explain the efforts of India in creating TKDL.

## 9.2 SIGNIFICANCE OF TRADITIONAL KNOWLEDGE (TK)

Traditional Knowledge is a part of the cultural identities of indigenous and local communities. This knowledge system has significance for their future well being and sustainable development and is a key for their cultural vitality. Traditional Knowledge is integrated in their ways of living and has become holistic, thus is an inseparable component of the communities. The protection of this knowledge system hence, is vital for the very existence of the indigenous and local communities. Hence, Traditional Knowledge has been receiving increasing attention in international agenda in recent times.

Traditional Knowledge system has an equally significant role to play in the communities in many countries. In fact, livelihood of many people in these regions is dependent on the use of Traditional Knowledge existing in their countries. It is particularly true with respect to the health care systems. The World Health Organization (WHO) has stated that 80 per cent of the world's population depends on traditional medicine for its primary health care and that Traditional Knowledge is indispensable for its survival. This is due to the fact that most of the people in these regions cannot afford modern medicines and also that these medicines are comparatively safer compared to the modern drugs. Some of the traditional systems of medicine practiced in the developing world include Ayurveda, Unani, Siddha, Chinese, Tibetian, Homoeopathy, Yoga, Meditation, Acupuncture, Acupressure, etc. The following Table provides percentage users of traditional health care practices both in developing and developed world.

Populations using traditional medicine for primary health care include Ethiopia, 90%; India, 70%; Rwanda, 70%; Tanzania, 60% and Uganda, 60%. Populations in developed countries who have used complementary and alternative medicine at least once include Canada, 70%; Australia, 48%; France, 49%; USA, 42% and Belgium, 31%. With this statistics, it is very evident that TK plays a significant role even in modern days and its protection is inevitable.

## 9.3 REASONS FOR PROTECTING TRADITIONAL KNOWLEDGE

Apart from treaties and emerging international norms, which imply both legal and moral imperatives for protecting TK, there are a number of reasons why developing countries want to protect their TK.

### 9.3.1 Improvement of Livelihoods of TK Holders

TK is a valuable asset first and foremost to indigenous and local communities that depend on TK for their livelihoods and well being, as well as for enabling them to

sustainably manage and exploit their local ecosystems (e.g. through sustainable low-input agriculture).

### 9.3.2 Benefits to National Economy

TK is used as an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides. In most cases, firms based in developed countries that can harness advanced scientific, technological and marketing capabilities capture virtually all the value added in the products. This situation needs to be addressed so that developing countries can capture much more of the value added.

Attempts have been made to estimate the contribution of TK, particularly biodiversity-related TK, to modern industry and agriculture. For pharmaceuticals, the estimated market value of plant-based medicines sold in Organisation for Economic Co-operation and Development (OECD) countries in 1985 was US$ 43 billion (Principe 1989). Many of these medicines would have used TK leads in their product development. This fact is supported by the observations of distinguished pharmacognosist Norman Farnsworth that out of 119 plant-based compounds used in medicine worldwide, 74 per cent had the same or related uses as the medicinal plants from which they were derived. It is particularly difficult to estimate the contribution of traditional crop varieties (land races) to the global economy. However, a study on the use and value of land races for rice breeding in India estimated that rice land races acquired from India and overseas contributed 5.6 per cent, or US$75 million. The global value added to rice yields by use of land races can be estimated at US$400 million per year.

But accurately estimating the full value of TK in monetary terms is impossible, first because TK is often an essential component in the development of other products, and second because most TK-derived products never enter modern markets. In any case, a great deal of TK is likely to have cultural or spiritual value that cannot be quantified in any monetary sense.

In short, it seems that protecting TK has the potential to improve the performance of many developing-country economies by enabling greater commercial use of their biological wealth and increasing exports of TK-related products. At the same time, it is important not to overestimate the economic potential of TK.

### 9.3.3 Conservation of Environment

A large number of field studies have proved that the conservation ethic is a prevalent feature of the subsistence and resource management practices of many present-day indigenous or native people and traditional communities. Several academic studies on traditional communities provide ample evidence that the protection of TK can provide significant environmental benefits. For example, in may forest areas, members of traditional societies plant forest gardens and manage the regeneration of bush fallows in ways that take advantage of natural processes and mimic the biodiversity of natural forests. Researchers are increasingly aware of the extent to which traditional natural resource management can enhance biodiversity, and in this way have realized the extent of anthropogenic landscapes even within “pristine” tropical forests. Much of the world’s crop diversity is in the custody of farmers who follow age-old farming and land use practices in ecologically complex agricultural systems, which enable the conservation of biodiversity. These traditional communities maintain the centres of crop genetic diversity, which include the traditional cultivars, or land races, that constitute an essential part of the world’s crop genetic heritage and non-domesticated plant and animal species.

### 9.3.4 Prevention of Biopiracy

The term **biopiracy** was coined by the North American advocacy group Rural Advancement Foundation International as part of a counter-attack strategy on behalf of developing countries that had been accused by developed countries, particularly the United States, of *Intellectual piracy*. It normally refers either to the unauthorized extraction of biological resources and / or associated TK from developing countries, or to the patenting, without compensation, of spurious *inventions* based on such knowledge or resources.

Problems have been experienced by indigenous people trying to protect their traditional knowledge under intellectual property laws. Even the prohibitive costs of registering and defending a patent or other intellectual property right may curtail effective protection. Within the context of scientific progress, modern intellectual property laws have allowed the industries particularly the pharmaceutical industries to monopolize the benefits derived from the use of indigenous knowledge with disregard for their moral rights and material (financial) interests of indigenous people themselves.

Many incompatibilities between TK and IPRs have begun to surface with the rapid global acceptance of western concepts and standards for intellectual property. These incompatibilities appear when ownership of TK is inappropriately claimed or TK is used by individuals or corporations that belongs to local communities, primarily in developing countries.

The codified traditional knowledge has also become an open treasure for misappropriation. Since this knowledge exists in local languages and in format not understandable to patent examiners, patents have been obtained on this knowledge. Several examples are known where patents have been granted on applications, which are based on codified traditional knowledge.

Now discuss some well-known examples of biopiracy of traditional knowledge.

**a) Turmeric *(Haldi*)**

The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and as a colour dye. As a medicine, it has been traditionally used for centuries to heal wounds and rashes.

In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5,401,504) on use of turmeric in wound healing. The Indian Council of Scientific & Industrial Research (CSIR) filed a re-examination case with the US PTO challenging the patent on the grounds of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the USPTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

**b) Neem**

Neem extracts can be used against hundreds of pests and fungal diseases that attack crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis.

In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted neem oil. In 1995 a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of neem seeds had been known and used for centuries in Indian agriculture to protect crops, and thus was a prior art and unpatentable. In 1999 the EPO determined that according to the evidence, all features of the present claim have been disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on neem was revoked by the EPO in March 2005.

**c) Basmati Rice**

Rice Tec. Inc. had applied for registration of a mark *TEXMATI* before the UK Trade Mark Registry. It was successfully opposed by Agricultural and Processed Food Exports Authority (APEDA). One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec. This US utility patent had claimed a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The patent was granted to Rice Tec by the US PTO on September 2, 1997. It covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains; seed deposit claims; method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. These claims would have come in the way of Indian exports to US, if legally enforced.

Evidence from the Indian Agricultural Research Institute (IARI) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. The various grain characteristics were evaluated by CFTRI scientists and accordingly the claims 15-17 were contested on the basis of their reports.

Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filing the re-examination request, Rice Tec chose to withdraw the contested claims.

Briefly, we can summarise the reasons for protecting TK as:

- **Moral**
  - to fulfil moral obligations towards indigenous/ local communities.
- **Legal**
  - to comply with international treaties and emerging norms (e.g. the CBD, the Universal Declaration of Human Rights, the International Undertaking on Plant Genetic Resources).
- **Utilitarian**
  - for *local* economic, welfare (health and food security) and subsistence benefits;
  - for *national* economic and welfare benefits;
  - for *global* economic and welfare benefits; and
  - for improved sustainable management of biodiversity and conservation.

There are ample reasons for governments to take steps to legally protect TK. For example Brazil and the Philippines have introduced access legislation. However, it is

important to remember that the protection of TK cannot be dealt with satisfactorily in isolation from the more fundamental needs, interests and rights of the holders of TK.

*Spend 3 min.*

**SAQ 1**

What do you think are the reasons that the TK has lately become one of the hot topics of study and research?

## 9.4 CURRENT INTERNATIONAL DEVELOPMENTS IN THE PROTECTION OF TK

### 9.4.1 Doha Ministerial Conference

A key issue raised at the fourth WTO Ministerial Meeting in Doha, in November 2001, was that the TRIPS Agreement needs to be amended in order to provide that the Members shall require an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:

i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;

ii) evidence of prior informed consent (PIC) through approval of authorities under the relevant national regime; and

iii) evidence of fair and equitable benefit sharing under the relevant national regime.

Amendments to the TRIPS Agreement to include an obligation to disclose the origin of genetic resources and associated traditional knowledge and to provide evidence of PIC and fair and equitable benefit sharing are imperative to implement the TRIPS Agreement and the CBD in a mutually supportive and complementary way. This obligation would ensure transparency as regards the origin of biological materials that are used in the patent claim, as well as make the CBD provisions on the PIC and fair and equitable benefit sharing more effective.

### 9.4.2 Conference of CBD Members

The sixth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP6) held in The Hague, in April 2002 considered the progress made in the integration of the relevant tasks of the programme of work on Article 8(j) in the thematic programmes of the Convention, and identified actions to be taken with respect to forest biological diversity, marine and coastal biological diversity, inland water ecosystems and agricultural biological diversity. We have elaborately discussed about the Article 8(j) of CBD in Unit 6 on Protection of Genetic Resources. But for ready reference it is reproduced below:

*Subject to its national legislation, 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 their 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*

The requests made by COP were to address the issues of *sui generis* systems for the protection of traditional knowledge based on Article 8(j) and related provisions of the CBD. The focus was in particular on identifying the main elements to be taken into consideration in the development of *sui generis* systems and the equitable sharing of benefits arising from the utilization of traditional knowledge, innovations and practices of indigenous and local communities. It needs to take into account the work carried out by WIPO's Intergovernmental Committee Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGCGRTKF) with a view to

promote mutual supportiveness, and existing regional, sub-regional, national and local initiatives.

### 9.4.3 Global Biodiversity Forum

At the 18th session of the Global Biodiversity Forum (GBF 18), held in September 2003 in Cancun, Mexico, biodiversity and sustainable livelihood issues related to international trade were discussed. The GBF emphasised that economic growth must take place within the natural limits of ecosystems while respecting the environment at all times.

The overall objective of this session of the GBF was to provide a platform for the trade and biodiversity communities to consider how the pursuit of their respective goals and objectives might complement or hinder each other. Specifically, GBF18-Cancun aimed to:

i) Build greater understanding of the positive and negative impacts of the international trade agenda on biodiversity from a range of perspectives.

ii) Explore key issues that could lead to mutual supportiveness between international processes related to trade, biodiversity and sustainable development.

iii) Provide informed recommendations on biodiversity-related policies to key actors in the Doha Round of the World Trade Organization; and

iv) Build new networks and strengthen existing ones among the trade and biodiversity communities.

The inter-linkages between trade and biodiversity was felt to lie in three areas, viz.

- trade and sustainable livelihoods;
- risk, precaution and biosecurity; and
- the relationship between the Convention of Biological Diversity (CBD) and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs).

Significant concerns have been felt over the impacts of trade liberalisation on biodiversity conservation and use. The inter-linkages between trade and biodiversity have remained scattered with little interaction between the communities involved. However, there has been recent broadening of the agenda in the WTO to cover more and more aspects that directly impact on people's livelihoods.

## 9.5 GLOBAL ISSUES IN IMPLEMENTATION OF TK PROTECTION

### 9.5.1 Risk, Precaution and Bio-security

There is no global consensus on where the delicate balance lies among risk, precaution and bio-security. At the same time, finding an agreed solution to the current tensions surrounding these issues is fundamental to the future of biodiversity conservation, and therefore sustainable development. In designing and implementing national systems for risk assessment, in formulating national regulations, and in trade negotiations with respect of these issues, the principles of transparency and inclusiveness are fundamental -especially in dealing with invasive species. While the impact of invaders on agriculture is well known, the impact on ecosystems needs further analysis. This is true with respect of the risk of genetically modified (GM) products and biosafety requirements. The trade regime must safeguard the ability of states to set their own rules in respect of biotechnology, including the right not to admit products that they do not wish to have in their markets.

### 9.5.2 Prior Informed Consent (PIC)

*Prior informed consent* means the consent of the government and other Stakeholders which must be obtained prior to access to genetic resources and based on full disclosure of information, such as the intended use of the resources.

Several international instruments (in particular the CBD) that support recognition of the rights of indigenous peoples and other local communities to prior informed consent (PIC) for access to genetic resources and TK are in focus. While it was clear that uncertainties regarding the implementation of PIC remain, the successful utilisation of PIC in some cases, together with best practices guidelines, are providing valuable lessons and guidance for future application of PIC.

Given the different property regimes applicable to biological resources and genetic resources there is uncertainty in the legal system regarding who owns genetic resources in indigenous territories. If we are dealing with biological organisms, they are considered collective property of the indigenous communities who hold title to the territory. But when dealing with access to genetic resources, it is the state who grants permission through the national authority. It is not understood by the communities that they can own the biological organisms but not the genetic information that makes up the animals, plants and other living beings. The property regime of biological resources is even more confusing when indigenous territories overlap with national parks. The uncertainties regarding property regimes are numerous when dealing with traditional knowledge. Additionally, even if knowledge or innovations were recognized as belonging to indigenous and local communities, there are still issues to resolve. The law does not have rules to apply when there are different rights holders for example, neighbouring communities. Uncertainties on the legal rights on the subjects of access (genetic resources and traditional knowledge) make transaction costs too high or impossible to cover.

### 9.5.3 Access and Benefit Sharing (ABS)

International legally binding system on access and sharing of benefits from the use of genetic resources has been debated, since national instruments alone is not seen as sufficient to guarantee the rights of states nor the rights of local communities. However, it is also felt that an international regime negotiated by national governments is an adequate and trustful framework to protect local community rights, and call for a system based on needs expressed by communities themselves.

Megadiverse countries feel that there is a need for positive (i.e. recognition of community rights over traditional knowledge and biodiversity) as well as defensive (to defend from 'misappropriation') strategies as well as certificates of origin, for these countries to promote an appropriate distribution of benefits and technology transfer.

At the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit Sharing of the Convention on Biological Diversity held in February 2005 in Bangkok, Thailand, the working group addressed the following issues:

i) the use of terms not defined in the CBD;

ii) additional approaches to complement the Bonn Guidelines on ABS, such as an international certificate of origin/ source/ legal provenance;

iii) measures to ensure compliance with prior informed consent of Parties providing genetic resources and of indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms (MAT) for granting access; and

iv) options for indicators for ABS, to be used for evaluating progress in the implementation of the CBD's Strategic Plan.

The meeting's discussions focused on the international ABS regime. The complexity of the matters, such as the inter-linkages with intellectual property rights, the difficulty to develop a common vision regarding the nature of the regime or even its necessity, and the unclear international framework indicate the long road ahead.

**SAQ 2**

*Spend 3 min.*

What do you understand by Megadiverse countries? Give names of five countries, which could be called Megadiverse countries.

## 9.6 ROLE OF WIPO IN PROTECTION OF TK

WIPO began its work on TK-related subject matter in 1978, when it initiated discussions on the *sui generis* protection of expressions of folklore in collaboration with the United Nations Educational, Scientific and Cultural Organization (UNESCO). This work resulted in 1982 in the adoption of "Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions". Following the adoption of the Model Provisions in 1998, WIPO began a new set of activities designed to explore the IP aspects of the protection of TK. The main objective of these activities was to identify and explore the IP needs and expectations of the holders of TK in order to promote the contribution of the IP system to their social, cultural and economic development.

After discussions among WIPO Member States beginning in September 1999 about intellectual property and genetic resources, the WIPO General Assembly decided that a distinct body should be established within WIPO to facilitate discussions among Member States on issues related to genetic resources, TK and expressions of folklore. The Member States decided to establish this body in the form of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (The Intergovernmental Committee, IGC).

The IGC constitutes a forum for discussions among Member States on intellectual property issues arising in the context of i) access to genetic resources and benefit sharing; ii) protection of TK, whether or not associated with those resources; and iii) protection of expressions of folklore.

In considering the relationship between IP and genetic resources, TK and folklore, the Committee has undertaken information gathering, policy discussion, and practical capacity building in these three policy areas. This work has highlighted the overlapping nature of this subject matter and pointed to the benefits of an integrated approach to continuing international cooperation on these IP concerns.

The Committee developed a series of studies on legal protection of TK, which included surveys of national experiences with IP protection of TK, analysis of the elements of a *sui generis* TK system and analysis of the definition of TK. These documents included details of national *sui generis* laws for protection of TK, and the range of experiences reported using IP laws (*sui generis* and otherwise) to protect TK. These materials can form the basis for continuing international policy discussions on specific TK protection, and can be used to support national policymaking and the assessment of practical options both for the use of existing IP tools and the development of new forms of IP protection.

*Customary law* is generally derived from custom, meaning long-established practices that have acquired the force of law by common adoption or acquiescence.

The Committee gave extensive consideration to the use of databases, registries and other collections and inventories for the protection of TK, and this discussion clarified that databases could be used for the preservation, positive protection and defensive protection of TK. The role of databases for the positive protection of TK was shown in the use of databases with security or access controls, which give effect to customary laws and protocols governing the authorised access and distribution of knowledge.

A detailed analysis was also given to the use of databases and other collections of information in the context of general defensive protection strategies. This focused on approaches to ensure that existing disclosed TK was taken into account in the patent examination process. Based on responses to widely distributed questionnaires, inventories of relevant on-line databases and periodicals were developed to assist in

the creation of tools for more ready access to publicly disclosed TK in searches for relevant prior art. This in turn led to the creation of a TK portal as a pilot version of a potential searching tool for patent examiners. **The purpose of this was not to induce the disclosure of TK, but to ensure that any TK already disclosed would be taken into account when potentially relevant patent claims were being assessed**.

A further defensive mechanism that was considered by the Committee concerned the use of disclosure requirements in the patent system to ensure disclosure of TK (and potentially also its origin and the legal circumstances surrounding its access) that is used in the development of a claimed invention.

The work of the Committee on IP aspects of genetic resources associated with TK took two general directions. First, it considered licensing practices concerning IP aspects of access to genetic resources; and second, it considered the role of patent disclosure requirements in relation to inventions that are based on access to genetic resources.

The operational principles for intellectual property clauses of contractual agreements concerning access to genetic resources and benefit sharing were considered. The main objectives of this exercise were to provide information about possible licensing practices to the parties needing such information; and to develop this guidelines or principles on the IP aspects of licensing access to genetic resources.

The Committee further considered a technical study prepared by WIPO on disclosure requirements in patent law that were relevant to traditional knowledge or genetic resources used in the course of developing a claimed invention. These documents considered the interaction between legal systems governing access to TK and genetic resources on the one hand and established patent law in line with existing international standards, and aim at providing input for policymakers.

The discussions at WIPO have highlighted the expectation of a number of countries that specific steps should be taken to strengthen TK protection, including the development of specific new international instruments. The significance of the issues, and their complexity mean that further analysis and clarification is needed before crystallizing formal outcomes and more work needs to be done to explore the full potential of existing IP rights and systems to protect TK.

## 9.7 TOOLS FOR PROTECTING TK

The role of intellectual property (IP) systems in relation to traditional knowledge (TK), and how to preserve, protect and equitably make use of TK, has recently received increasing attention in a range of international policy discussions. These address matters as diverse as food and agriculture, the environment, notably the conservation of biological diversity, health, including traditional medicines, human rights and Indigenous issues and aspects of trade and economic development.

While the policy issues concerning TK are broad and diverse, the IP issues take two key directions:

- **Defensive protection** of TK prevents others from seeking IPR to one's TK. These are measures which ensure that IP rights over TK are not given to parties other than the customary TK holders. These measures include the amendment of WIPO-administered patent systems (the International Patent Classification system and the Patent Cooperation Treaty Minimum Documentation). Some countries and communities are also developing TK databases that may be used as evidence of prior art to defeat a claim to a patent on such TK; and

- **Positive protection** of TK establishing IPR to one's TK, with the resulting possibility of preventing others for using the TK without permission. This is creation of positive rights in TK that empower TK holders to protect and promote

their TK. In some countries, *sui generis* legislation has been developed specifically to address the positive protection of TK. Providers and users may also enter into contractual agreements and/or use existing IP systems of protection.

### 9.7.1 Defensive Protection of TK

A main tool for defensive protection is requiring relevant patent applications to include disclosure of the source of the genetic resources and associated TK, as well as evidence of PIC and benefit sharing. A few countries have recently started to implement this at the national level. As has been mentioned earlier, developing countries have also repeatedly proposed at the international level to include this requirement in the TRIPS Agreement. Such a measure would facilitate traceability and benefit sharing.

The Group of Like Minded Megadiverse Countries (LMMC), rich in biological diversity and associated traditional knowledge, have agreed to join efforts for effectively negotiating the development of an international regime on access and benefit sharing (ABS). The 17 members are Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela. These countries possess 60-70% of the world's biodiversity.

The Megadiverse countries have agreed to ensure that the proposed ABS includes prior informed consent of the country of origin and mutually agreed upon terms between the country of origin and user country.

TK existing in public domain, for example, the codified Indian Systems of Medicine, needs to be made available to patent examiners in format and language understandable by patent examiners, preferably in patent application format. Such a database could help establish the existence of prior art and therefore prevent the granting of *bad patents*.

### 9.7.2 Positive Protection of TK

Many TK-holding communities complain that their knowledge and cultural heritage are treated as common property and as free for commercial use by anyone anywhere. Often such use is not patented, and therefore, defensive protection measures as those outlined above would have little impact. These communities would like to exert their claim to their knowledge and to have this recognized in national and international law.

A legislative tool that could lay foundations for this would be a declaration of rights of indigenous and local communities, including the ownership of their TK.

Another tool would be the recognition of customary laws in national legislation. In most TK-holding communities, the use of TK is governed by a wide variety of customary laws. Within the communities, this approach may work well. However, outside the communities, the laws have little effect, unless they are recognized in national legislation or the formal judicial system. This approach is widely supported by indigenous and local communities, as it respects their values and beliefs and allows them to continue their traditional lifestyles.

The use of tort for misappropriation, whereby remedies can be sought for the unauthorized, improper or unlawful use of property for purposes other than that for which it was originally intended, is a potential tool which could be explored.

Another possible tool is the creation of a TK Registries, where putting TK into the database actually constitute establishing a legal claim over TK. This idea also merits further exploration. Activities such as People's Biodiversity Register (PBR), which was initiated for some Indian villages is an example. PBR is aimed at promoting sustainable use and equitable benefit sharing while conserving the biological diversity. It generates village level biodiversity management plans eventually to occupy

legislative and political spaces for de-centralised governance. Besides protection of immediate natural resource rights of villagers, broader objectives is also to include protection of their intellectual property rights, by creating documentary evidences useful in litigation.

For both types of protection, there have been cases where TK holders have been able to use conventional IPR instruments to protect their TK. However, since these instruments were not developed with TK in mind, but rather modern industrial intellectual property, the fit is not always perfect. This is due to the fact that: (i) for TK holders, most of whom have quite limited resources, enforceability of IPR will always be a major problem, (ii) the origin of oral traditional knowledge is difficult to be ascertained, (iii) most often the TK is a community knowledge and may not be of an individual and (iv) the duration for which such knowledge may be given protection.

## 9.8 INDIAN EFFORTS TOWARDS TK PROTECTION

India has developed a database known as **Traditional Knowledge Digital Library** (TKDL) with an objective of defensive protection of the codified traditional knowledge on Indian Systems of medicine of our country. Before understanding the effort made by India, let us understand about the structured classification of Traditional Knowledge.

### 9.8.1 Structured Classification of TK

Any area of industrial application, which has to be examined by the Patent Offices needs to have a structured classification basically for the retrieval of the data. For this reason the International Patent Classification (IPC) exists which categorises the entire industrial application related information qualifying for grant of patents into Sections, Classes, Subclasses, Main Groups and Subgroups. The entire industrial application related information qualifying for grant of patents have been divided into 69,000 Subgroups for the convenience of patent examiners, so that the patent search and examination gets restricted to the documents coming under the specified subgroups.

However, the TK lacked a structured classification, and the existing IPC just contained a single Subgroup i.e., A61K 35/78 for entire information on TK. Hence, the search and examination process by patent examiners becomes extremely difficult.

To address the above issue, Traditional Knowledge Digital Library (TKDL) classified the entire TK related information in a modern system as per the format of IPC, into Sections, Classes, Subclasses, Main Groups and Subgroups. This classification system evolved by India is known as Traditional Knowledge Resource Classification (TKRC). TKRC has been developed for Ayurveda, Unani and Siddha systems of medicine where about 8,000 subgroups have been created for classifying the codified (published) TK information particularly with respect Indian systems of medicine.

The novelty of the classification scheme was well recognised by the experts of the IPC Union. WIPO constituted a Task Force to further study the possibility of linking and/or integrating TKRC developed by India with IPC. Task Force consisted of United States Patent Office, European Patent Office, China, Japan and India. Subsequently, the Task Force recognised the need of having more detailed level of classifications relating to medicinal plants and have created about 200 sub-groups which will be included in IPC under A61K 36/00 instead of single sub-group on medicinal plants. The TKRC developed by India will be linked with the IPC. This is likely to have significant impact on the system of search and examination while granting patents in the area of traditional knowledge whereby the possibilities of grant of wrong TK patents shall get significantly reduced.

### 9.8.2 Traditional Knowledge Digital Library (TKDL)

Standing Committee on Information Technology (SCIT), World Intellectual Property Organisation (WIPO) at the 3rd Plenary Session held at Geneva in June 1999 and attended by 170 member states of WIPO was held under the Chairmanship of Dr. R. A. Mashelkar, Director General, CSIR, India. SCIT strategic plan for 21st century recognized the concern by WIPO Member States regarding the granting of intellectual property rights due to a lack of traditional knowledge being documented in the public domain. The SCIT suggested taking the initiative by including activities in its work program to support WIPO Member States, in particular developing countries in their creation of databases in the area of traditional knowledge available in public domain so that *prior art* gets established.

An Approach Paper was prepared by India and was sent to SCIT in Dec.1999. In the discussions by 170 member states of WIPO at Geneva, SCIT agreed to the India's approach.

Mr. Robert Saifer, Director, International Liaison Staff, US Patent and Trademark Office emphasised in August 1999 the need of creating more easily accessible non-patent literature databases that deal with traditional knowledge. He suggest doing this by documenting TK with the help of the developing countries, capturing it electronically, and placing in the appropriate classification within the IPC so that it can be more easily searched and retrieved. This, in his opinion, would help prevent the patenting of turmeric, as well as karela, jamun, brinjal and other traditionally used remedies.

TKDL Task Force was established in January, 2000 after the interdepartmental meeting attended by Secretaries of Department of Industrial Policy & Promotions (DIPP), Department of Indian Systems of Medicine & Homoeopathy (D/o ISM&H) and Department of Scientific & Industrial Research (DSIR). The task force comprises of membership of Council of Scientific and Industrial Research, NIC, Patent Office, Ayurveda Experts, Central Council of Research in Ayurveda and Siddha, and Department of Indian Systems of medicine and Homoeopathy (ISMH).

The TKDL report along with TKRC was prepared in May 2000. The main aim of TKDL is to bring the knowledge in public domain in international languages to prevent the grant of wrong patents.

Traditional Knowledge Task Force created by the Department of AYUSH, Ministry of Health and Family Welfare randomly studied selected 762 US patents, which were granted under A61K 35/78 and other International Patent Classification (IPC) classes, having a direct relationship with medicinal plants in terms of their full text. Out of these 762 patents, 374 (49%) patents were found to be based on traditional knowledge. 408 patents were granted by USPTO during March, 2000 itself on several medicinal plants. A further study by a team of experts of TKDL studied the USPTO, EPO and UKPO patent databases in respect of medicinal plants (with respect to Unani system of medicine) in April, 2003 and found more than 15,000 patent references against 4896 references found in 2000, clearly demonstrating three-fold increase.

The work on creation of TKDL began in October 2001. Initially the team of 12
Ayurveda Experts and 4 scientists started the work on transcription of Sanskrit Slokas
into TKRC. The complete team at present consists of 29 Ayurveda Experts, 5
Information Technology (IT) Specialists, 2 Patent Examiners, 4 scientists and 3
Technical Officers.

TKDL (Ayurveda) has been created on the codified traditional knowledge on Indian Systems of medicine and in the first phase information present in 14 *Ayurvedic* texts listed in Indian Drugs and Cosmetics Act was taken. 36,000 formulations have been transcribed in patent application format in five international languages, viz. English,

French, German, Spanish and Japanese. The images from the original texts that have been transcribed have also been incorporated into the database. TKDL Ayurveda is presently being extended by inclusion of additional formulations. TKDL is also being created for Unani System of Medicine for 77,000 formulations from 42 Unani texts, which are in Arabic, Persian and Urdu.

TKDL software with its associated classification system, i.e. TKRC converts verses into multiple languages mentioned above. It may be noted that the software does not do translitration, rather it does smart translation, where data abstracted once is converted into several languages by using Unicode, Metadata methodology. Software also converts traditional terminology into modern terminology, for example *Kumari* (local name) to *Aloe vera*, *Masurika* (Sanskrit name of a disease) to small pox etc.

TKDL includes a search interface providing full text search and retrieval of traditional knowledge information on IPC and Keywords in multiple languages. Traditional Knowledge Classification shall be integral to TKDL database along with background on concepts and definitions on Indian system of medicines, scientific basis of Indian system of medicines, details on practitioners, hospitals and dispensaries.

TKDL database shall act as a bridge between ancient Sanskrit/Unani verses and a patent Examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent Examiners. It is expected that the gap on lack of prior art knowledge shall be minimized. The database has sufficient details on definitions, principles, and concepts to minimize the possibility of minor/insignificant modifications.

TKDL has been able to set international specifications and standards for setting up of TK databases and registries based on TKDL specifications. This was presented at the at the 4$^{th}$ Session of Intergovernmental Committee (IGC) of WIPO on Intellectual Property and Genetic Resources, Traditional Knowledge and expression of folklore. The technical standards presented by India were adopted by the Committee in the fifth session of the IGC held in 2003.

TKDL being a maiden effort has become a model for other countries for protecting their TK from misappropriation. Countries like South Africa, regional organizations like SAARC countries, African Regional Industrial Property Organization (ARIPO) have already been interacting with India to build TKDL for their own region.

### 9.8.3 PCT Minimum Journals

Patent Cooperation Treaty (PCT) is a multinational patent-application processing Treaty. Most of the countries in the world are PCT members. You know that the treaty provides for limited centralized pre-processing of an international patent application (PCT application) that will eventually be filed in multiple countries. PCT patent applications are administered by the WIPO. The Treaty is the result of an effort by many countries to provide some streamlining of patent applications across several countries at once.

In the Fifth Session of PCT Meetings in 1981, 169 periodicals were identified as PCT Minimum Journals for search and examination by the International Search Authorities (ISA). Of these 169, 168 were primary periodicals in various languages, and one secondary source, Chemical Abstracts. In 1995, the list was narrowed to about 135. In 2004 the list was further reduced to bring the number of periodicals in Non-Patent Literature (NPL) list to 131.

**Traditional Knowledge (TK) periodicals**

Recent developments in the area of traditional knowledge have made an impact on the definition of the PCT minimum documentation and this was considered by the

International Authorities. An effort that emerged in the work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which, at its first session in May 2001, expressed support for a work program comprising, *inter alia*, that the Member States may wish to consider revising existing criteria and developing new criteria which would allow the effective integration of traditional knowledge documentation into searchable prior art.

At its second session in December 2001, the IGC expressed support for the compilation of an inventory of existing traditional knowledge related periodicals and agreed that, once such inventory is compiled, it might recommend that certain of those periodicals be considered by the International Searching Authorities for integration as NPL into the PCT minimum documentation list.

At its Tenth Session held in September 2004 at the meeting of International Authorities under the PCT related to PCT Minimum Documentation on TK, five TK related periodicals were approved for addition to the NPL list. Further, six more journals were included in the NPL list, and the list was made available prior to the IPC Union meeting held in October 2004. None of the journals from Developing countries found its presence in the PCT minimum list, which included a total of 142 journals.

India made a strong representation in August, 2004 for including the prestigious science and technology journals brought out by Council of Scientific and Industrial Research in the NPL list. In the submission it was pointed out that the two journals brought out by NISCAIR, Indian Journal of Traditional Knowledge (IJTK) and Medicinal and Aromatic Plant Abstracts (MAPA) do meet the criteria of selection adopted by PCT/CTC.

Subsequently, the Eleventh Session of the Meeting of International Authorities under the PCT reviewed the inclusion of the journals IJTK and MAPA in the NPL and approved their inclusion in the NPL list which marks a major breakthrough since this is for the first time two periodicals from developing countries have been included in the NPL list.

## 9.9 NEED FOR *SUI GENERIS* FRAMEWORK FOR PROTECTION OF TK

*Sui generis* literally means *of its own kind* and consists of a set of nationally recognized laws and ways of extending the legal protection to traditional knowledge and genetic resources. Potentially, a *sui generis* system could be defined and implemented differently from one country to another. In addition, a *sui generis* system must be defined to create legal rights that recognize any associated TK relating to genetic resources and promote access and benefit sharing. The government may choose to extend protection to genetic resources and/or knowledge to a community in the form of patents, trade secrets, copyrights, farmers' or breeders' rights, or any other creative form not currently established in the intellectual property regime.

Under the *sui generis* system and as called for by the Convention on Biological Diversity, any person interested in gaining access to a community's biological resources or knowledge for scientific, commercial or industrial purposes would need to obtain the Prior Informed Consent (PIC) of the indigenous peoples who possess the knowledge in question, unless the knowledge is in public domain. This would allow the community to decide on access to and use of its genetic resources and knowledge, with the option to share or not to share them. If consent is granted, the person(s) wishing access to lands held by indigenous communities or a conservation area, its biological resources, and the knowledge associated with either would need to present evidence of this consent to the intellectual property office or proper authority.

However, there is a consensus building to protect traditional knowledge through *sui generis* rights. This must properly accommodate special characteristics to the subject matter, and the specific needs which may lead to a distinct system. Few national experiences of *sui generis* IP rights for protecting traditional knowledge are known. For example, the countries such as Peru, Costa Rica, Portugal and Thailand have their own *sui generis* regimes with their own defined objectives.

Table 9.1 summarizes the range of possible legal approaches.

**Table 9.1: Legal approaches for protection of traditional knowledge**

| **Existing formulations** | **Modifications/ supplements to existing formulation** | ***Sui generis* alternatives** |
|---|---|---|
| Customary law | Codification/ national recognition of customary law | New intellectual property categories |
| Intellectual property, rights:<br>- Patents<br>- Utility models<br>- Plant variety rights<br>- Copyrights<br>- Trademarks<br>- Trade secrets<br>- Geographical indications<br>- Performers' rights | - Certificates of origin<br>- Traditional Knowledge Digital Library<br>- Inclusion of Identifiability criteria in plant variety right legislation | Access and benefit-sharing/ biodiversity management regulations with TK-related provisions |
| Civil and common law concepts, such as:<br>- Breach of confidence<br>- Privacy<br>- Unfair competition<br>- Trust funds | | |
| Contracts:<br>- know-how licenses<br>- Material transfer agreements | | |

Table 9.2 includes some existing and possible legal solutions along with some other, essentially non-legal solutions.

**Table 9.2: Legal and policy measures for protecting traditional knowledge**

| Measures | Examples and Models |
|---|---|
| Legislative – IPR | ➢ Kenya Industrial Property Act.<br>➢ Peru Regime of Protection of the Collective Knowledge of Indigenous Peoples<br>➢ OAU African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources<br>➢ UNESCO/ WIPO Model Folklore Provisions<br>➢ Convention on Farmers and Breeders (Gene Campaign) Community Intellectual Rights (TWN) |
| Legislative – non-IPR | ➢ Costa Rica Biodiversity Law<br>➢ Brazil Medida Provisósria no.2.052-1<br>➢ Andean Community Decision 391<br>➢ Philippine Indigenous Peoples Rights Act |
| Existing legal concepts and principles | ➢ Unfair competition<br>➢ Privacy<br>➢ Trust funds<br>➢ Confidentiality<br>➢ Passing off |
| Existing private legal arrangements/ contracts | ➢ Aguaruna-Searle know-how licence<br>➢ TBGRI-Arya Vaidya-Kani licence |
| Institutional reforms | ➢ Certificates of origin<br>➢ Traditional Knowledge Digital Library<br>➢ Ombudsman (complaint redressal mechanism) |
| Existing legally non-binding instruments | ➢ Voluntary agreements/ codes of conduct |
| Local/ NGO initiatives | ➢ Community-controlled TK databases |

**SAQ 3**

*Spend 5 min.*

What are the key issues that need to be considered for developing the *sui generis* system for protection of TK?

Let us summarize the points discussed in this Unit.

## 9.10 SUMMARY

- Protection of TK against misuse or misappropriation raises deep policy questions and practical challenges alike.
- The changing social environment, and the sense of historical dislocation, that currently affect many communities may actually strengthen resolve to safeguard TK for benefit of future generations.

- The challenge is to ensure that the intellectual and cultural contribution of traditional communities is appropriately recognised.
- Protection of TK can be defensive or positive.
- Examples of defensive protection include Traditional Knowledge Digital Library, which needs to be replicated by the developing countries which are rich in TK.
- The journals included under PCT minimum also provide defensive protection to the knowledge contained therein.
- Positive protection can benefit from the core principles on protection of TK framed by WIPO.
- It can be obtained through adapted or expanded conventional IP systems, or through stand-alone *sui-generis* systems.

## 9.11 TERMINAL QUESTIONS

*Spend* 15 *min.*

1. From your own experience, give five examples of traditional knowledge that you may have observed.
2. What is defensive mechanism of protection of TK? Give one example of defensive mechanism of protection of TK.
3. What do you understand by Prior Informed Consent? When this consent is required to be obtained and for what purpose?

## 9.12 ANSWERS AND HINTS

**Self Assessment Questions**

1. Refer Sec. 9.2 and 9.3.
2. Refer Sec. 9.7.1.
3. i) Policy objective of protection, ii) Subject matter to be protected, iii) Criteria of this subject matter which needs be protected, iv) Beneficiaries of protection, v) Rights, vi) Acquiring of rights, vii) Administration and enforcement of rights, and viii) Loss or expiry of rights.

**Terminal Questions**

2. Refer Sec. 9.7.1.
3. Refer Sec. 9.5.2.