CHAPTER 6

COMPARATIVE STUDY OF SUI- GENERIS AND OTHER TECHNIQUES OF PROTECTING TRADITIONAL KNOWLEDGE IN FOOD AND MEDICINES AND THE EXISTING PROTECTION MECHANISM.

The previous chapter explores the national and international legal mechanisms for protecting traditional knowledge in relation to food and medicines. Thus it points to the absence of a strong legislation in India. After exploring the legislations it becomes clear that a strong legislation alone cannot deal with problems of bio-piracy or other related indigenous issues.

Therefore there is the need for some special techniques of protection. These special techniques are some of the innovative methods of giving justice and protection from bio-piracy to the indigenous communities and traditional knowledge in relation to food and medicines. They exist in the form of Access and Benefit sharing, Prior Informed Consent, Material transfer Agreements and *Sui-generis* System. These alternatives can be implemented properly only through a legislation incorporating all or some of these alternatives. Each alternative has been explored in depth here as under:

6.1 **SUI GENERIS SYSTEM**

What does a *sui generis* system mean? *Sui generis* plainly means “of its own kind” and includes a group of generally recognized laws and ways of implementing them, for example, implementation of a law like plant variety protection (PVP) not through patents or other IP mechanisms. Though TRIPS introduced the term *sui generis*, it never defined or explained it. UPOV (International Union for the Protection of New Varieties of Plants) is followed by many countries even though TRIPS does not talk about it. UPOV is appreciated because it has met the requirements of *sui generis* system. On the other hand to comply with TRIPS and to implement *sui-generis* system, countries do not have to join UPOV. A *sui-generis* system may have a combination of some recognized forms of intellectual property protections and other forms of protections or will be based on a totally different protection mechanism, for genetic resources.

For instance, a nation may come up with patent protections under IPR for innovations, plant variety certificates (PVC) for plant varieties or some other varieties and as a basis of *sui- generis* exclude plants from any form of intellectual property protections although it may or may not contradict with TRIPS. Probably a *sui-generis* system may differ in its definition, implementation and from the way it is used in one country to another country.
It depends upon the way a *sui-generis* system is defined as it may create legal rights that will help to recognize any associated traditional knowledge relating to genetic resources. It may help in promoting access and benefit sharing. Thus there exists a choice for the government in extending protection to genetic resources and knowledge of a community under IPR in the form of patents, trade secrets, copyrights, farmers and breeder’s rights or any new kind of creative protection mechanism that does not currently exist in the intellectual property regime. *Sui-generis* system can become a very strong mechanism by adopting all measures of protection suitable for traditional knowledge, and capable enough to invalidate improper patents.

6.1.1 **NATURE OF THE SUI – GENERIS SYSTEM:**

All those *sui generis* system existing in this world by their nature of protection for traditional knowledge against bio-piracy, misappropriation and misuse can generally be classified into two:

i. A *Sui generis* system either with new intellectual property based protection, or rights, would generally be referred to as *sui generis* intellectual property protection. The WIPO-UNESCO Model provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions 1982 (the ‘Model Provisions 1982’) provide *sui generis* IP protection for expressions of folklore/traditional cultural expressions. Other examples are the Tunis Model Law on Copyright for Developing Countries 1976 (the ‘Tunis Model Law 1976’) and the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defence of their Cultural Identity and their Traditional Knowledge of Panama 2000 (the ‘Panama Law 2000’).

ii. *Sui generis* systems of protection deals with customary laws or traditional protocols of traditional knowledge holders and bearers of cultural traditions.¹ Thus systems have been developed in a different manner and do not exactly resemble intellectual property protection. For example, a separate legislation for the protection of traditional knowledge with customary rights of the community incorporated within it. It may look like IP law but may not be IP based protection.

6.1.2 SUBJECT MATTER OF SUI-GENERIS SYSTEM:

Sui generis systems of protection will depend upon the subject matter of protection that is covered. It may become difficult to incorporate all the traditional knowledge-related subjects under a single legislation. If the subject matter of protection is too diverse then it becomes difficult to draft a sui-generis law. For example traditional knowledge has different areas and therefore is diverse. For practical application, different laws based on different areas of traditional knowledge can be made. Some particular type of communities or some specific type of subject matter may require a different law. At times law may differ based on region or type of community. Thus a law that is general in nature cannot be applied, or if applied may not be adequate. The difference in legal protection is due to their different nature. For example, Folklore, cultural practices, traditional designs or traditional medicines and food may require different legal protection just like the manner in which intellectual property rights function.

When the subject matter of this system is ascertained carefully, one can divide it into three types:

1. TCE/traditional cultural expressions or expressions of culture - examples include the Tunis Model Law 1976 and the Panama Law 2000;
2. Traditional Knowledge based on biodiversity and it includes examples like the Peru Law of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (the ‘Peru Law 2002’) and Brazil’s Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge (‘Brazil’s Provisional Measure 2001’); and
3. Traditional knowledge in general and it includes the Philippines Indigenous Peoples Rights Act 1997 (the ‘Philippines Law 1997’)

A sui generis system may legally acknowledge and protect knowledge related to the use of genetic resources even when it is not officially documented, but instead exists in the form of oral information, traditional and historic use. Even though protections might be extended here, the

---

government’s intellectual property office needs to know about the knowledge or practice in order to enforce protection. Therefore, if a country has some form of a *sui generis* system in place, it is important for local communities to establish a working relationship with the intellectual property office. In addition, these offices may privately maintain inventories or registries of locally held knowledge, and can assist in its protection. For example, this office can deny a patent application if the knowledge that is based on is already held in the registry.

Under a *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 of the indigenous peoples who possess the knowledge in question, unless the knowledge is already in the 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 or persons wishing access to lands held by indigenous communities or a conservation area, its biological resources, and knowledge associated with either would need to present evidence of this consent to the intellectual property office or proper authority.

*Sui- generis* system does not exempt state from responsibility. The traditional, local or indigenous communities are not aware of laws and regulations. They are not party to international agreements and to treaties. State is a party to them. So when the rights of the communities are recognised internationally, it is the duty of the state to grant it and protect them. It is quite challenging and uncertain as to how *sui generis* laws that goes beyond intellectual property rights, provide rights different from IPR and the way it will function in a world increasingly dominated by IPR. It is important to note that in many countries the discussion on rights related to biodiversity for grassroots communities is not linked to TRIPS and therefore many Latin American countries that have notified WTO of their plant variety protection laws to comply with the *sui generis* option, are working towards a legislation with broader rights to deal with plant varieties as part of biodiversity. Professor Santasombat advocates the use of a *sui generis* system similar to the common property regime to ensure adequate protection to the people concerned. Dr. Williams, on the other hand opines that *sui generis* rights could result in the watering down of community rights. He discusses the option of a single alternate system, or a system designed under TRIPS or CBD individually, or a combination of both. The International
and other Conventions do not seem to disfavor *sui generis* rights, but have not even adopted a
definition of the same yet.

TRIPS allowed for the protection of plant varieties an effective *sui generis* system without
defining what a *sui generis* system is. TRIPS when incorporated the sui generis system expected
the developing countries will have an effective *sui generis* system by January 2000 and the least
developed countries by January 2006. The word effective has also not been defined. It is as if the
world bodies have decided that this problem does not require attention beyond the grant of
recognition. It is now left for the indigenous people to decide the modus and the laws in which
they would like to protect their knowledge. An example of the sui generis system in India is as
follows:

### 6.1.3 PROTECTION OF PLANT VARIETIES AND FARMER’S RIGHTS ACT 2001:
(PPVFRA)
The PPVFR Act though not directly related to traditional knowledge, is mentioned here as
example of the sui generis system.

**Important features of this Act:**
- It has important provisions on benefit sharing and farmers rights.
- The plant varieties which are not patentable under the Patents (Amendment) Act are
  specifically dealt in this Act.
- This legislation simultaneously attempts to achieve some balance between commercial
  breeders and traditional small scale and subsistence farmers.
- According to Sec 39 of PPVFRA, there are farmer’s rights to new varieties and to
  ‘farmers’ varieties.

The farmers’ varieties are defined as a variety which:
1. Has been traditionally cultivated and evolved by the farmers in their fields or,
2. Is a wild relative or land race of a variety about which the farmers posses the common
   knowledge.

Rather confusingly farmer’s varieties turn up again under the definition of, “extant varieties” and
are apparently understood as a sub- category of those. The PPVFRA allows for the registration of
such varieties. In the case of farmer’s Varieties, the registration mechanism can be used by ‘any
farmer or group of farmers or community of farmers claiming to be the breeder of the variety.
However there is no provision for royalty payments. Instead the legislation foresees the formation of a National Gene Fund into which benefit sharing payments, annual fees, money from compensation claims and contribution from other organizations and sources are to be paid. The amount of benefit sharing will be determined by a newly formed Protection of Plant Varieties and Farmer’s Rights Authority. Farmer’s are then entitled to recognition and reward from the National Gene Fund. 3

In common with many other countries India has adopted many of the requirements from UPOV Convention 1978, although the legislation contains the elements of 1991 UPOV Convention which is more favorable to the commercial plant breeders.

The traditional right of farmers to reuse saved seed has been safeguarded in S. 39 (1) (iv) but in accordance with UPOV 1991, the farmer is no longer allowed to sell branded seed of a protected variety. The authority will further decide about two types of compensation claims by farmers against commercial breeders. They can claim compensation, should the performance of the commercial variety remain below what the farmer had expected and the breeder promised. There is also the collective claim of a community against a breeder for the contribution the community has made to the evolution of a variety used in the breeding process.

To give effect to the rights of village or local communities and for benefit sharing, the Central Government may devise one or more schemes as provided in the Act. This shows that India is interested in traditional agricultural knowledge although there is also a Biodiversity Act with an even more centralized approach than the PPVFRA. In accordance with the international understanding on farmer’s rights, the Indian legislation only establishes an equitable claim to compensation, which will be mitigated by the national authority. 6

The example of Monsanto's terminator seeds, a patented item marketed to farmers in India that lasted only one growing season. When the patent on the seed expired, Monsanto attempted to

---

3 Christoph Antons, Traditional Knowledge and Approaches in the Asia-Pacific region, in TRADITIONAL KNOWLEDGE, TRADITIONAL CULTURAL EXPRESSIONS AND INTELLECTUAL PROPERTY LAW IN THE ASIA-PACIFIC REGION, Vol 14, 63 (2009); MAX PLANCK SERIES ON ASIAN INTELLECTUAL PROPERTY LAW
4 Chapter VI of the Act is devoted to farmers rights, which protects the traditional right of the farmers to save, use, exchange, share or sell their farm produce of a protected variety.
5 Supra
6 Id note 3,at 65.
extend the life of the patent by contractually restricting the ability of Indian farmers to save seeds for the next growing season. Farmers who did save the seed would be denied future seeds or other benefit because they would have been deemed to breach the contract. Monsanto removed these contractual restrictions after farmers violently protested in the streets of Bangalore. As this example illustrates, even though the patent had expired, the invention had not fallen into the public domain. Monsanto attempted to use contract law to extend its rights.

A correction to the law of intellectual property could resolve the problem. Under United States law, the contract term would have been most likely pre-empted by patent law because the contract conflicts with the limited terms provision of patent law. Preemption, however, is unique to the federalist structure in the United States and would have no basis in Indian jurisprudence. However, principles of unfair competition could have served as legal tools to invalidate the contract. Alternatively, vesting a breeder's rights in the farmers could also redress the problem. Intellectual property rights, provide countervailing power in the global marketplace. Sui generis system for traditional knowledge in food and medicines is an excellent approach of protection. This system will become more powerful if it has access and benefit sharing mechanism incorporated within.

6.2 ACCESS AND BENEFIT SHARING
Access and Benefit sharing are two different concepts put together where the aim is conservation of bio-diversity involving the indigenous community. When this technique of protection is analyzed the term ‘Access’ explains the granting of permission by the indigenous community to enter an area for the purpose of sampling, collecting, and removing genetic or other resources. ‘Benefit sharing’ specifies that all forms of compensation for the use of genetic resources, whether monetary or non monetary would be provided to indigenous community. In benefit sharing mechanism, the indigenous or local community would share the benefits arising out of the use of genetic materials and traditional knowledge. Thus the indigenous community is motivated to protect and use the knowledge to the fullest extent. In doing so they may participate in scientific research and development of genetic resources. They can also share the results of their prospective benefits arising from the work.

7 Shubha Ghosh, Globalization, Patents and Traditional Knowledge, in COLUMBIA JOURNAL OF ASIA LAW (2003), WESTLAW.
Articles 1 and 8(j) of the CBD promotes the unbiased sharing of benefits arising from traditional knowledge for conservation and sustainable use of biological diversity.

So in simple words, for the indigenous community it means sharing of traditional knowledge and resources with contracting parties and other people who are interested in doing research and creating new products based on this knowledge. For the contracting parties it means, in return they would share any advancement, benefit may be monetary or non monetary or product that is made from the traditional knowledge.

Protection exists in two ways, one is positive and the other is defensive. There exists a narrow difference between the two. Positive protection is the manner in which the rights of traditional knowledge holders and enforcement of those rights is done through intellectual property rights or through any other *sui generis* system. Thus it includes law, rules and regulations. Defensive protection is through any other manner or method, may be legal or other way to avoid misappropriation or unauthorized use and claims to cultural expressions, traditional knowledge associated with certain practices, product derived from traditional knowledge and protecting this traditional knowledge present in the public domain. The law that has positive protection can also have defensive protection. Two techniques can be linked together. They jointly can be linked to the existing law. For example the access and benefit sharing when linked with prior informed consent, it has been possible to develop a system of protection where the rights on the indigenous community is recognized and also guarantees that such a system of protection are based on some conditions on misappropriation and grant of source.

The positive protection when applied by a state, would grant rights to the indigenous community or the traditional knowledge holders. These rights may include right to refuse access. Thus indigenous knowledge holder will be the authorized user, they can determine terms of access and means to enforce these rights. If others can claim patent rights on the knowledge that vest with the community, then even the community should be entitled to patent rights.

However, it becomes difficult when the traditional knowledge holders are not known. In a community based economy, for traditional knowledge holders or indigenous community the conception and continuance of traditional knowledge has innate value that gets primacy to sharing for a monetary gain.

*The Biological Diversity Act 2002 on Access and Benefit sharing:*
Section 36(v) grants for protection of knowledge through means such as registration of such knowledge and creating a *sui-generis* system for local people relating to biodiversity.

It warrants impartial sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 specifies prior approval of the National Biodiversity Authority (NBA) before their access.

National Biodiversity Authority, while granting approval, will inflict terms and conditions, which provides impartial sharing of benefits. Section 6 presents that there is a need to obtain prior approval of the NBA by anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge acquired from India. The NBA will inflict benefit-sharing conditions.

Section 18(iv) demands to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource. To oppose the grant is one of the functions of NBA.

Thus protection for traditional knowledge in relation to food and medicines through Access and Benefit sharing is possible only if there is prior informed consent of the community.

### 6.3 PRIOR INFORMED CONSENT

In this technique also there is a combination of three different concepts. If defined in general, ‘Prior informed consent is the sanction from the indigenous community before hand for the use of one’s genetic resources and any associated traditional knowledge. So the term “Prior” means the sanction that must come before access is allowed or others use the knowledge. “Informed” means that information is provided on how the resource and knowledge will be used. “Consent” means permission to use the resource or knowledge.

Indigenous community must be well informed about the threats or repercussions of using the knowledge, including the importance and potential commercial value, by the other stakeholders like intellectual property office, government or any other party involved.

Consent must be evident in a clear and unambiguous manner. For example, it should be obtained in writing, by a clear agreement that explains the details in plain language. It should not be forced on the community. Thus it should be free consent.

---

8 The Biological Diversity Act 2002, supra. Ch 5.
Protection that forms its path through prior informed consent will be strong if Material Transfer agreements exist.

6.4 MATERIAL TRANSFER AGREEMENTS:

To avoid bio-piracy or bio-prospecting, it is better that the developing countries or any other party or country that has rich traditional knowledge should opt for Material transfer Agreements. This was introduced by CBD. Basically it is an agreement or a contract between two countries or companies for transfer of some bio-diversity related materials which one of the parties intends to use for further research and development. The ownership of the material will always remain with the resource owner. Ownership is not transferred but some rights with respect to that property or knowledge is transferred. Generally this transfer aims at further research and development of the knowledge.

Every Material Transfer Agreements should have:

1) Details of the Materials: Proper description of the material or knowledge is important, so that it can be used for future research or can be traced if there are any bio-piracy related issues.

2) Terms and Conditions: All the terms and conditions to use a particular knowledge for the recipient country or company to use it should be mentioned in the agreement. In case of a conflict, dispute settlement measures like arbitration or negotiation should also be incorporated.

3) Rights of the owner: The ownership of the country or party is always intact. Therefore the Agreement should clearly express the rights and future benefits of the owner through this contract.

4) Disclaimer: The ownership country or party should always be safe as there are chances of fraud, misrepresentation that can happen. Owner should not be held responsible for any unlawful or unwanted activities of the recipient country or company.

Thus Material Transfer Agreements help in protecting the ownership of the genetic or biological or traditional knowledge materials. It may act as a check on bio-piracy related cases.

---

9 Role of Material Transfer Agreements in Intellectual Property Rights Regimes; in Trade Notes; 26, April 2010
A sui-generis protection mechanism, for traditional knowledge in relation to food and medicines should incorporate access and benefit sharing with prior informed consent of the indigenous community and should be based on material transfer agreements. Then the protection cannot be challenged. It will become even stronger if there is a database like Traditional Knowledge Digital Library, (TKDL).

6.5 **TRADITIONAL KNOWLEDGE DIGITAL LIBRARY:**

India is known as the land of spices and is well known for the herbal medicines, making it rich in traditional medicine and other valuable knowledge like Ayurveda, Homeopathy, Naturopathy, Siddha, Unani, and Yoga. It becomes difficult to trace the origin of many of this ancient wealth of knowledge and it is still difficult to access the present existing knowledge which is written in diverse traditional language. India witnessed lot of bio-piracy cases and thus Indian experience of bio-piracy is representative of a general trend in many developing countries with rich genetic resources and a traditional knowledge heritage. Therefore the decision was taken to digitally document codified forms of its rich traditional medicinal heritage.

The Government of India has already undertaken a affirmative, concrete and ambitious project, the Traditional Knowledge Digital Library (TKDL), a database of the Traditional Knowledge.

During the 1990’s, the issue of bio-piracy and unethical bio-prospecting made headlines when the Government of India could successfully obtain revocation of turmeric and basmati rice patents provided by the United States Patent and Trademark Office (USPTO) and also the Neem patent provided by European Patent Office (EPO). Since the traditional medicinal knowledge was in various languages like Sanskrit, Hindi, Arabic, Persian, Urdu, and Tamil, making it impossible to check the claims by the patent examiners at the international patent offices became one of the prime reasons for the increase in cases of such patent claims. This cases and reasons encouraged the Department of AYUSH, Government of India to create Traditional Knowledge Digital Library with the help of the task force of experts in the field of traditional medicinal systems of India. The experts were people belonging to Ayurveda, Unani, Siddha as well as Yoga, patent examiners, IT experts, scientists and technical officers. Thus TKDL came into
force in 2001. Main duty of TKDL was translating Sanskrit shlokas which describe an Ayurvedic formulation in text form, using Traditional Knowledge Resource Classification (TKRC) devised for the purpose. The aim was that this knowledge should be easily understood by the patent examiner anywhere in the world. Thus efforts were initiated to document the knowledge in five different languages English, German, French, Spanish and Japanese, thus the entire text has in all 34 million pages.

It reflects the dialectics of developing countries relationship with intellectual property and other knowledge protection systems. For instance, as a defensive mechanism, the TKDL's principal objective is to thwart potential or existing bio piracy patents or the tendency by second-comers or strangers to exploit India's traditional medicinal knowledge. India has already two task force programmes relating to creation of a Traditional Knowledge Digital Library (TKDL) and designing a Traditional knowledge Resource Classification (TKRC). The Department of Indian Systems of Medicine and Homeopathy (ISMH) spearheaded the initiative. The ISMH set up the TKDL task force, by drawing experts from Central Council of Research of Ayurveda and Siddha, Banaras Hindu University, National Informatics Centre, Council of Scientific and Industrial Research, and Controller General of Patents and Trademarks.\(^{10}\)

Since there are many threats like bio-piracy, India is alert and cautious of the prospective intellectual property follow up of the projects, particularly when it involves research and joint investment with foreigners interested in the use of the knowledge. Theoretically therefore, the traditional knowledge digital library is not essentially limited to a patent-related prior art search but an advanced search. Authorities of TKDL are working consciously against any kind of misappropriation or misuse of the information available at the digital library. Due to easily available information there is a risk of bio-piracy involved. Therefore the authorities have implemented the need of an agreement for all those who want an access and use the TKDL database. This agreement sets restrictive conditions on those who have a legitimate possession of the database and are in position to make it available for the third parties. The legitimate possession of TKDL database is with national and regional patent office. They need the database to help them in conducting prior art searches.

Within a short span of coming into existence the traditional knowledge digital library project, has

---

a remarkable achievement of positive integration of the valuable information through its database. Thus helping the international intellectual property office activity of search and examination of the prior art search systems. TKDL is continuously improving its systems, for example it has progressed on the problem of the classification system that deals with the documentation of traditional knowledge. The improvement is done by creating a modern classification system that is based on the framework of the International Patent Classification (IPC). The Traditional Knowledge Resource Classification (TKRC) includes in it the Unani and Ayurveda medicinal systems after the improvement of the classification system.

**International Patent Classification (IPC):** This was created as a result of the World Intellectual Property Organization (WIPO) -administered multilateral treaty, the Strasbourg Agreement Concerning the International Patent Classification. The IPC has rigidly graded in order whereby the technological or innovation categories are divided into a range of sections, classes, and subclasses. This helps in easy identification during the prior art examination. The important feature of IPC is that it is relied upon for prior art searches by patent offices of more than one hundred countries, other intellectual property regional offices and also by International Bureau of the WIPO and the Patent Corporation Treaty (PCT).

The International Patent Classification has adequately improved International Patent Classification structure relating to traditional medicine due to the Indian initiative on the classification of traditional knowledge.

This incorporates the excellent example of the decision in 2003 by the International Patent Classification Union to extend the classification of medicinal plants by something like two hundred subgroups through the formation of a brand new group (A61K36) and, maybe above all, the linkage of IPC with the TKRC through a concordance table set up by India.

As of now, the TKRC incorporates about 500 subgroups for medicinal plants, inasmuch as IPC held one and only subgroup (i.e., A61K35/78). In its operational modem framework, the TKDL programming joins the novel classification framework, TKRC, and proselytes archived information into target dialects. Fundamentally, medicinal details systematized in antiquated messages on Indian systems of medicine are translated or decoded into patent application formats in five purported global dialects under the minute supervision of researchers, specialized officers, and recognized specialists in the particular system of medicine.

The software of traditional knowledge digital library is designed in a special manner
whereby it can translate the unreachable and hard to find information hidden in Indian traditional medicinal knowledge heritage and convert them into the modern scientific co-relation. This helps the patent examiners to use it readily in prior art searches.

In numerous ways the digital capture of customary traditional medicinal knowledge has given new force to traditional knowledge. It is only the practical force of TKDL initiative that has changed the situation a bit. As the accepted and longer standing policy responses to intellectual property’s tricky relationship with traditional knowledge is always unclear and has never yielded any better results. Particularly, the TKDL has powered an epistemological experience and dialogue between traditional medicine as a local data form and its more cosmopolitan Western partner through the immediate endeavor to build traditional medicine's stake inside the patent arrangement. Despite the fact that digitization of traditional medicine through the TKDL fundamentally points at establishing aspects of its standing as prior art, it must be noted that, all those prior existing patents, like those connected with Western medicine, are prima facie prior art. Traditional knowledge digital library has raised itself to that degree whereby it has standardized and leveled up traditional medicine with the Western medicinal knowledge counterpart. Thus under the patent system it creates an impression of psychological similarity towards traditional medicinal knowledge in respect of the present significance to Western scientific medicine. The dissimilarity between both the traditional medicine and western scientific medicine is that, the traditional medicinal knowledge is freely accessible in theory as it is a part of the rich Indian literature and is in public domain, whereas the Western scientific medicinal knowledge is protected for a term of any applicable patent. Traditional knowledge digital library does not directly deal with the exclusive and proprietary aspects of traditional medicine like the traditional patent system. Nevertheless TKDL has initiated to build a bridge between modern science, modern medicines and traditional knowledge by creating a new classification system based on traditional medicine under the TKRC and by updating the IPC and global patent literature. Beyond TKDL’s function to bridge the gap, it also adopts the similarity methodology to establish traditional medicinal knowledge in the IPC system. At present both these systems cannot stick to their rigid classification because TKDL facilitates in bringing the interaction, interrelationship and correlation between Western medicine and traditional medicine. As a permanent and growing face of the global patent process, TKDL deals with codified
information on traditional medicine in the public domain and it also aims to play a very important part of checking into the patentability of non-codified and independent traditional medicinal innovations.

In spite of being 13 years old, TKDL has remarkably progressed even if it is not a very old institution. It has its own limitations, for example its part, the TKRC at present has only incorporated Ayurveda and Unani data. It is trying to focus on codified as well as non-codified systems of Indian traditional medicinal system. Comparatively the focus is more on codified aspects. TKDL has come into existence in collaboration with Council of Scientific and Industrial Research (CSIR) and other departments like Yoga, Naturopathy etc. The manner in which it functions as a government sponsored department it is not clear whether it involves the indigenous holders of the knowledge in any of its research activities. TKDL has its own limitations. It has its merits and demerits. TKDL will be considered more significant as it has the potential to reach out to the other developing countries whereby it will further allow traditional knowledge to go deep into the patent system.

*How does TKDL function outside India?*

TKDL is an excellent initiative by the Indian government and is well appreciated outside India. It acts as a source of inspiration to many countries and other regional intellectual property organizations that are continuously trying to curb the menace of misappropriation of their traditional knowledge resources especially in food and medicines like the interest shown to create an African regional traditional knowledge digital library by the Cameroon-based African Regional Industrial Property Organization (ARIPO) and also by South Africa, Mongolia, and Thailand. Recently, it is seen that India has been instrumental in supporting to create TKDL for the South Asian Association for Regional Cooperation (SAARC) comprising Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, and Sri Lanka.

In this manner, in spite of its available and characteristic functional and applied limits, the TKDL is a potential instrument to help the liberation of traditional knowledge and drive it into the conventional intellectual property system. The Indian TKDL initiative creates a wave length with majority of the gene rich developing countries as it plays an important role in targeting and controlling the nation from bio-piracy. Other countries are taking initiatives in creating a system whereby engaging the local knowledge with their intellectual property system. They want to make their national patent laws and other systems stronger and tackling bio-piracy is not the only
reason but to make traditional medicine powerful.\textsuperscript{11}

For preventing bio-piracy, there is a need for developing digital databases of prior art related to herbs which is already under public domain. In India an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as Traditional Knowledge Digital Library (TKDL). Such digital database would enable Patent Offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents and bio-piracy.

As the database project reached its completion, the government in 2006 decided to allow access to the library to international patent offices, including European Patent Office (EPO), Japan and the UK, subject to a non-disclosure clause. This allowed patent examiners to evaluate patent applications and stop attempts to patent traditional knowledge as "new" inventions. Subsequently, agreements were signed with European Patent Office (EPO) in February 2009, with United Kingdom Trademark & Patent Office (UKPTO) in January 2010, apart from an agreement with the U.S. Patent and Trademark Office (USPTO) after the Summit meeting between US President Barack Obama and Prime Minister, Manmohan Singh, also in January 2010. With patent examiner getting access to TKDL database, legal cases regarding unethical patent claims, which in the past have taken years and vast expenditure for bringing each case to fruition, could be avoided.

The initiative of TKDL will help in future to check the cases of bio-piracy as the entire traditional knowledge is properly documented. Though the TKDL does not relate to the custodians of the knowledge or call them to be a part of research programmes, by documentation of the traditional knowledge it leads to giving them a mark of respect. Only by documenting knowledge it may not help sharing of benefits arising out of the use of such knowledge. There is a need for separate mechanism for sharing of benefits. Thus documentation of traditional knowledge may only lead to defensive protection. Whereby people cannot patent this knowledge in the form in which it exists.

\textsuperscript{11}Chidi Oguamanam, Patents And Traditional Medicine: Digital Capture, Creative Legal Interventions, And The Dialectics Of Knowledge Transformation, in INDIANA JOURNAL OF GLOBAL LEGAL STUDIES, WESTLAW (2008)
If the world is taken into consideration most of the indigenous population exists in Asia, Africa and America. Therefore a few legislations based on access and benefit sharing from each region, are compared as below:

6.6 **COMPARATIVE STUDY OF LAWS IN ASIA, AFRICA AND AMERICAN COUNTRIES:**

6.6.1 **Philippines**\(^{12}\) **Indigenous Peoples Rights Act 1997:**

This legislation is appreciated because it deals with all the rights of the indigenous community and takes care of the welfare of its people. This law is necessary as major part of the population is indigenous community.

Significant features of the legislation in relation to traditional knowledge are as follows:

- The Act concentrates on land rights over ancestral domains; a considerable measure of Self-government within these territories; the right to freely pursue their economic, social and cultural development; right to preserve and protect their culture, traditions and institutions.

- Indigenous Peoples Rights Act in chapter six, S.34 clearly provides:
  
  “Right to Indigenous Knowledge Systems and Practices and to Develop own Sciences and Technologies. - ICCs/IPs are entitled to the recognition of the full ownership and control and protection of their cultural and intellectual rights. They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and hearth practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts.” Thus it covers the rights of the community in relation to indigenous knowledge.

- It confirms if prior informed consent of the community is not obtained, then that application for patent or IPR protection is considered illegal and will not be granted.

- It gives power to indigenous community to possess the right to regulate biological and genetic resources in their areas or territories.

\(^{12}\) Asia
Chapter 6, S. 35: “Access to Biological and Genetic Resources. - Access to biological and genetic resources and to indigenous knowledge related to the conservation, utilization and enhancement of these resources, shall be allowed within ancestral lands and domains of the ICCs/IPs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community.”

Thus the access to genetic resources is permitted only by prior informed consent. This prior informed consent should be free from external manipulation, coercion and can be obtained only after explaining the community in the language that they understand about the intention and scope of the activity. If they permit then only one can go ahead and not otherwise.

All the other rights (human rights and indigenous rights) of the community are considered in this Act. Thus it addresses all the basic issues of the community and is considered as a complete legislation. Therefore this is the best legislation that caters to the needs of its people.

The next law is of Andean Community. It is based non- IPR mechanism of protecting traditional knowledge:

6.6.2 **Andean Community** – Member Countries are Bolivia, Colombia, Ecuador, Peru and Venezuela.

- There is a common system on Access to Genetic Resources. Decision 391 establishes general and concrete rules on access. This system recognizes historical contribution to Bio-diversity, its conservation by traditional community.

- The most important aspect of this system is that it has introduced the concept of “Intangible component”. This concept provides legal support to indigenous people and local communities in contesting misappropriation of their knowledge.

---

13 Sarah A Laird; *Biodiversity And Traditional Knowledge, Equitable Partnerships In Practice*; in PEOPLE AND PLANTS CONSERVATION SERIES; (Earthscan, ed., 2002).

14 Susette Biber Klemm and Thomas Cottier; *Rights To Plant Genetic Resources And Traditional Knowledge, Basic Issues And Perspectives*; in CAB INTERNATIONAL, (2006).

15 South America


17 Decision 391 establishes both general principles and concrete access rules. Among the principles, it recognizes national sovereignty over genetic resources, the right of indigenous, Afro-American, and local communities to decision-making authority over their TK, the importance of regional cooperation among Andean countries, and the precautionary principle. The access regulations apply to genetic resources, their by-products, their intangible compounds (TK, innovations and practices) and the genetic resources of migratory species found within the national territory for natural reasons. The access procedure includes an application, a contract, an official resolution and registration in a public list. [http://cisdl.org/biodiversity-biosafety/public/CISDL_Overview_of_ABS_Measures_2nd_Ed.pdf](http://cisdl.org/biodiversity-biosafety/public/CISDL_Overview_of_ABS_Measures_2nd_Ed.pdf) (lat updated April 22, 2014)
“Intangible Component” means any knowledge, innovation or practice of an individual or collection of actual or potential value associated with genetic resources or derivatives whether or not it is protected by IPR System.

Example: An agreement between Aguarunas\(^{18}\) people of Peru and Searle demonstrates, a case of traditional knowledge\(^{19}\). The Aguarunas and their know-how agreement with Searle shows how traditional knowledge is respected through non-IPR system. In Peru the Aguarunas people have negotiated a know-how license with Searle (Pharmaceutical division of Monsanto).

The Aguarunas agreed to pass on medicinal plants and knowledge to the company in exchange of know-how license fee. This fee will increase to reflect success in research and development even before a product reaches a market. This license is known to be exclusive, in that it does not affect the right of any Aguarunas communities to use, share or sell or otherwise transfer plants or knowledge whether or not they are parties to agreement. A Trust fund is created to distribute the benefits. A board is appointed to administer the fund with in the Aguarunas people including representatives of participating and non-participating communities. Legal ownership of biological resources is not a pre-condition for communities to benefit.

6.6.3 Costa Rica\(^{20}\) Bio-Diversity Act 1998:

The objective of this law among others is protection of scientific and traditional knowledge of biodiversity (through IPR system or sui generis), education and public awareness.

- The law aims at providing holder of each kind of knowledge with equal entitlement to protection.
- It is the duty of national seeds office and intellectual and industrial property Registries to consult National Biodiversity Management Commission to ensure that invention does not come within the exception of IPR regime.

\(^{18}\) Indigenous community from Peru

\(^{19}\) a 1996 five-party agreement among the Aguaruna people of northern Peru, the American drug company G.D. Searle, two Peruvian universities, and Washington University in St. Louis. The agreement allowed researchers from Searle and the universities to prospect for plants in the Aguarunas' native territory, in return for annual payments to the Aguaruna people. If and when a commercial product was ever manufactured as a result of the research, the agreement guaranteed that no less than 75 percent of the royalty income would be returned to Peru. [http://www.legalaffairs.org/printerfriendly.msp?id=929](http://www.legalaffairs.org/printerfriendly.msp?id=929) (last updated, April 23, 2014)

\(^{20}\) North America
Among others, one of the exceptions is invention essentially derived from knowledge associated with traditional, biological or cultural biological practices which is in the public domain.

A certificate of origin by the technical office of the commission and statement of prior informed consent will have to be presented with IPR application.

Indigenous Community and local people are fully entitled to refuse access to their resources and knowledge for any reason.

The state has recognized sui-generis community intellectual rights, i.e., the knowledge, innovations and practices of indigenous people and local communities. The indigenous people and peasants will determine the nature, extent and conditions of sui-generis community intellectual right.

An example of Access: Merck/INBio agreement provides for easing the tussel, where international arrangement is brought about despite the domestic protection of IPR being inadequate. Such quasi arrangement can be established by a contract that internalizes the external effects of lack of IPR protection. In 1991, a contract must widely publish and successful chemical prospecting agreement concluded between Costa Rica National biodiversity Institute (Instituto Nacional De Biodiversidad INBIO) and Merck and Co. ltd, a pharmaceutical firm achieving what neither the international law or the domestic law achieved the protection of IPRs, development concerns and the conservation of biodiversity. The contract provided the company with access to chemical extract and plant genetic resources collected by INBio for drug screening and others.²¹

Besides these provisions of Biodiversity law there is CAFTA, where disclosure of patented inventions is of prime importance. It directly does not deal with traditional knowledge.²²

---

²¹ Dr Shashikala Gurpur, *A Critical Study Of The Legal Regime Of The Biological Diversity*, 276 (2001) (unpublished manuscript)

²² US-Dominican Republic-Central America FTA: The U S-DR-CAFTA, often called CAFTA for short, was signed in 2004. It barely made it through US Congress the following year and still has not been ratified by Costa Rica. The text contains no direct reference to traditional knowledge, but many Central Americans see it as a precedent-setting obstacle to implementation of national policies on traditional knowledge. CAFTA does this in two ways: it puts walls around what governments can enforce as "disclosure" requirements for patents, and it makes clear that bioprospecting falls under its reach. The CAFTA text limits what the signatories can require in terms of "disclosure" of patented inventions by defining when that disclosure is "sufficiently clear and complete". A "mega diverse" country like Costa Rica therefore cannot add further conditions such as the disclosure of origin of a biochemical element or proof of prior informed consent from indigenous peoples. Broadening disclosure requirements, however, is precisely what developing countries which form the Mega diverse Group have been fighting for since years at
6.6.4 Kenya

Although Kenya is not culturally diverse as India, in large expanses of the country cultural communities follow traditional lifestyles that have changed little, at least until recent times. Since much of Kenya’s land surfaces are arid and semi-arid deep knowledge of the environment is highly essential for survival. It is difficult to survive in certain climatic conditions, for instance groups like the Turkana of the North Western Kenya has a highly primitive natural resource management system and so they survive in all extreme weather conditions.

Even though modernization has crept in people of this country follow and practice traditional system of health. The traditional healers are present in both the rural and the urban areas.

- These traditional healers or herbalist if want to be officially certified then they should qualify the requirements like to get registered with the ministry of culture and also to provide KEMRI’s center for traditional medicine and drug research with samples of all plants. Like an examination to KEMRI they have to provide information on each plant such as the part used, the method of preparation and the dosage.

- For sharing the knowledge with KEMRI the herbalists in return get some general scientific information on each sample. Information like if the prescribed dosages are safe and if they contain elements with genuinely medical effects.

Even though pharmaceutical development is needed, KEMRI’s main focus is to ensure that safe and standardized herbal treatment should be provided in rural communities.

- Until 1989, Kenya’s patent system was essentially an extension of that of the UK. Patent applications were examined in the UK. Rights and obligations were defined in conformity with the UK Patent Act of 1949 and Patents remained in force and expired in Kenya according to their status in UK. Provision for the public disclosure of the patent specification was completely inadequate.

international fora like the WTO, CBD and WIPO. Under CAFTA, failure to indicate the origin of a plant or show proof of consent for its use from a local community may never be grounds for rejecting a patent application.

http://www.grain.org/fr/article/entries/91-ftas-trading-away-traditional-knowledge (last updated, April 16th, 2014)

23 Africa.

24 According to Barrow, the people of Turkana have evolved well-managed and sound ecological strategies which enable them to utilize the vegetation on a sustainable basis. They exploit different ecological niches by having grazing life stocks, (cattle, sheep, donkeys) and browsing life stocks (camels and goats) and diversified food procurement strategies. Barrow also emphasizes their ‘well developed’ knowledge of their flora and its uses and goes on to explain how the Turkana take advantage of the full diversity of the woody species to meet their many subsistence needs through their use as sources of food, fuel, building materials and human and veterinary medicines.

25 KENYA MEDICAL RESEARCH INSTITUTE.
This situation was obviously unsatisfactory for a sovereign nation and so in 1989, the government passed a law intended ‘to provide for the promotion of inventive and innovative activity and to facilitate the accusation of technology through the grant and regulation of patents, utility models, rationalization models and industrial designs and for connected purposes.

The Industrial property Act established a new institution called the Kenya Industrial Office (KIPO) whose functions were to: examine applications for and grant, industrial right; screen technology transfer agreements and licenses; provide patent information to the public and promote inventiveness in Kenya.

The extent of what may be considered to be an invention is far more expensive than India. Only the following are not considered patentable:

a) Plant varieties as provided for in the Seeds and Plant varieties Act but not parts thereof or products of biotechnology processes.

b) Inventions contrary to public order, morality, public health and safety, principles of humanity, and environmental conservation;

c) Any other invention that may be declared non patentable by the minister responsible for the supervision of the office (this could of course be construed quite broadly.)

In addition, the following are considered not to be inventions for the purposes of the Act:

a) Discoveries or findings that are products or processes of nature where humankind has not participated in their creation, including animals, plants and micro organisms and scientific and mathematical methods and theories;

b) Schemes, rules or methods for doing business, performing purely mental acts or playing games, and computer programmes;

c) Methods of treatment of the human or animal body by surgery or therapy as well as diagnostic method; except product, in particular substances or compositions, for use in any of those methods; or

d) Mere presentation of information.

Conclusion: Kenya is similar to India as it has no developed protection mechanism of traditional medicinal knowledge. Patent protection is remotely used. The concept of recognition to tribal herbalist is excellent. There is access and benefit sharing mechanism but it is not clear as to how
the benefit sharing mechanism work. In comparison the Philippines Act can be taken as an example for the access and benefit sharing mechanism. Andean community also reflects upon the well established access and benefit sharing. A proper procedure is laid down for access in the Decision 391 of Andean Law. Costa Rica Biodiversity Act 1998 takes care of the indigenous community and access and benefit sharing mechanism. It has already recognized the *sui- generis* system of protection. Thus except Kenya all the others have a developed access and benefit sharing mechanism. India has at least to some extent included the ABS mechanism though it is not satisfactory.

Through *sui- generis* system, a legal protection mechanism is developed. Through access and benefit sharing and prior informed consent, the protection mechanism is based on conservation of biodiversity and the active participation of indigenous community. Without the techniques of protection like the *sui- generis* system, access and benefit sharing, prior informed consent, material transfer agreements and the traditional knowledge digital library it is difficult to provide protection to the traditional knowledge in food and medicines. For a national legislation on protection of traditional knowledge in relation to food and medicines to be effective, it must include all these techniques given above. For the protection of the knowledge there is a need of *sui- generis* system of law like the Philippines Indigenous Peoples Rights Act which deals with all the rights and provides protection for the traditional knowledge. Through a *sui generis* mechanism, a nation can implement access and benefit sharing which is essential for the growth and development of the nation. For this, material transfer agreements can also be drafted. Here the community will get proper representation as the entire system is considered as incomplete if the prior informed consent is not obtained. All these techniques when put together, the protection system would be excellent. They cannot be compared to each other as they all are needed on equal basis for a nation to have proper protection mechanism.

With proper documentation through databases like TKDL, it will avoid further bio-piracy. In this era of globalization, there has been extreme misuse of traditional knowledge and more specifically knowledge in relation to food and medicines and companies move forward to obtain patents and create a monopoly even though the knowledge existed in the public domain.

Documentation activities undertaken by developing countries like India are worth recognition.

---

26 The Environmental Management and Co-ordination Act (No. 8 of 1999) provides for the regulation of biological resources and genetic resources for ensuring sustainable management and protection of the such resources.
However, unless there is awareness and strict measures about respecting and valuing traditional knowledge, corporations can always find a way to commercially exploit the traditional knowledge to their advantage. The main concern of protecting traditional knowledge should include equitable distribution of benefits, conservation concerns, preservation of traditional practices and culture, the prevention of misuse by unauthorized parties of traditional knowledge and promotion of its use and its importance in development. If laws are not stringent man will end up in bio-piracy or double theft and will forget to respect the knowledge of the country.

Thus the findings of this chapter are:

- Access and benefit sharing is not properly regulated. Biodiversity Act, 2002 provides for ABS. But the dealing of ABS is inadequate. Jeevani Case is good example of ABS but it lacks transparency and effective Monitoring.
- The documentation of TKDL if not done minutely it will lead to bio-piracy. There is still lot of knowledge to be documented. There is no mandatory provision in international patent offices to refer to TKDL before granting patent. Equal importance is not given to the custodians of the knowledge. It only aims at documentation does not aim at benefit sharing.
- Compared to the other countries Philippines law is better as it gives complete control to the indigenous community and it addresses all the basic issues of the community.

Today these alternatives are needed to protect the traditional wealth in the form of traditional knowledge beyond the profit-centered approach of IPR. The sui generis approach discussed here is justified as the best approach because of its adaptability to local situations in comparison to the other generic approaches.

After a detailed analysis of all the problems involved in protecting traditional knowledge, researcher has drawn certain conclusions and provided suggestions for the same in the next chapter.