ABSTRACT

God has bestowed man with the unique quality of thinking and intellect distinguishing him from all other creatures made by God. Man has utilized his intellectual mind for his own benefits as well as benefits at all society at large intellectual property is one such outcome of the exercise of intellectual faculty by human beings and it is because of his unique faculty from individual to individual which has been accepted from personal property of the individual exercising his intellectual faculty for a particular purpose which needs protection by law.

The grant of IPR and their proper enforcement facilitated fair trade and access of consumers to quality products while ensuring the safety to human and animals, product’s price shelf life and degradation etc. The new technology developments, particularly in biotechnology, demonstrate the significance and usefulness of traditional knowledge for development of new products of commercial importance. Research and creativity originating from research institutions in the field of science and technology like institutions of technology, university and industrial Houses engaged in R&D activities.

The fast technological metamorphosis and globalization require constant exploration of emerging issues in IPR. The WIPO Agenda on the Global Intellectual Property issue aims at enhancing of the coterminous, proximate and reciprocal relationships between intellectual property and traditional knowledge, bio-technology and biological diversity and collateral aspects of economic, social, cultural and technological development. The overall objective of the Global Intellectual Property Issue Division (Global Issues Division-GID) is promoted the constant viability, enhanced efficiency and broader coverage of the intellectual property system. In a world increasingly epitomized as the “global information society”, the rapid emergence of modern information technologies, an increasing awareness about
Abstract

Traditional knowledge and its spiritual, cultural and economic values have become central to human discourse.

Traditional knowledge (TK) is a collectively owned property and is integral to the cultural or spiritual identity of the social group in which it operates and is preserved. Traditional Knowledge is now at the centre of the discussions on intellectual property rights and has assumed immense significance. India does not have any specific legislation for protecting traditional knowledge. But the Patents Act, Plant Variety Protection and Farmers Rights Act, Biological Diversity Act, 2002 and Geographical Indication of Goods (Registration and Protection) Act, 1999 have provisions that can be utilized for protecting traditional knowledge. The concept of benefit-sharing, which is an integral part of protecting traditional knowledge, has been analysed in detail with specific reference to the Biological Diversity Act and also the Plant Variety Protection and Farmers Rights Act. The case study of Jeevani drug gives an insight into the concept of benefit sharing. The importance of traditional knowledge is highlighted in the revocation of patent granted to derivatives of neem on the ground that they were part of the traditional knowledge of our country and that fungicide qualities of the neem tree and its use had been known in India for over 2,000 years. A discussion of the patent granted to turmeric that was effectively challenged by the CSIR based on the ancient Sanskrit text also figures in the work. Along with this, a case study of Basmati has also been done. The thesis also focuses on the international initiatives at protecting traditional knowledge including the Convention on Biological Diversity, International Undertaking on Plant Genetic Resources for Food and Agriculture and the Agreement on Trade Related Aspects of Intellectual Property Rights. But there are no uniform norms regarding the protection of different types of traditional knowledge owned by local communities. The reason for this divergence of laws is that the international community never had an occasion to look at the protection of
traditional knowledge in its entirety. Measures to ensure that traditional knowledge is protected should be taken at the auspices of the World Trade Organization which should lay down general mandatory provisions to be complied by member countries.

With the advent of Trade Related Aspect of Intellectual Property (TRIPS) Agreement in the international scenario, all the countries signatory of WTO and TRIPS Agreement, become bound to mandate certain drastic changes in the patent systems throughout the world. Under the TRIPS Agreement it is the obligation of the member countries where their patent laws are not consistent with the TRIPS provisions of the agreement, to take steps to modify their legislation to make them consistent. The TRIPS Agreement provide a period of 5 years from 1995 for developing countries to implement the TRIPS provisions further it also provide a additional period of 5 years to developing countries like India to comply with the TRIPs Agreement.

Patents in India have their origin by the 1856 Act. After independence, relative inaccessibility and affordability, or even non availability of essential life saving medicines led to the government to appoint two committees: the Tek Chand Patents Enquiry committee (1948-50) and the Ayyangar Committee (1959). Consequent to the recommendations of these committees the Indian Patents law was enacted in 1970. The Indian Patent Act, 1970 was also enacted with a view to make patents serve the needs of economy as well as to make them a vehicle of rapid growth.

The enactment of the Patents Act, 1970 has proven a boon for Indian pharmaceutical industry (especially the generic pharma segment). The traditional medicine continues to play an important role in health care but the general lack of research on safety and efficacy of traditional medicines is of great concern. Fortunately in many developing countries, traditional medicine offers a major and accessible source of health care. India has also focused on
the role of traditional medicine in national health care strategies, supporting the development of clinical research into the safety and efficacy of traditional medicine, advocating the rational use of traditional medicine. Indian Pharmaceutical Industry also has a significant contribution of Indian System of Traditional Medicine. The newly enforced product patent regime would be in favour of the traditional medicinal knowledge of India. Taking the product patent on traditional herbal drug will certainly work to prevent misappropriation of traditional herbal drugs and its knowledge by the western countries.

Medicinal plants the world’s oldest known health care products, play a key role in traditional medicine. But these plants are not only used for primary health care; many widely used pharmaceuticals are derived from plants and other natural sources. Traditional medicines is used the world over but is particularly relied on in developing countries. In the South, some 80% of people endeavor to protect or restore health using methods that have been handed down from generation to generation.

In India medicinal plants have made a good contribution to the development of ancient India Materia Medica. One of the earliest treatises on Indian medicine, the Charak Samhita (1000 B.C.) records the use of over 340 drugs of vegetable origin. Medicinal plants have curative properties due to the presence of various complex chimerical substances of different composition, which are found as secondary plant metabolites in one or more parts of these plants.

The Indian traditional medicines also have a significant presence in the Indian Pharmaceutical Industry. The Indian system of medicine was prevalent about 1500 years over Southeast Asia. It comprises of 3 major systems namely Ayurveda, Siddha and Unani this traditional medicines now comes under the Indian system of Medicine. In 1995 to boost the growth of traditional
medicines The Department of Indian system of Medicine and Homeopathy (now has been known as \textit{AYUSH}) was established by the Ministry of Health & Family welfare.

An insight to India pharmaceutical industry tells the position of IPI. It rank $4^{th}$ in terms of volume and $13^{th}$ in terms of value. Indian firms produce approximately 1.5\% of the global pharmaceutical market of $480$ billion. The Indian pharmaceutical industry meets around 70\% of the country's demand. IPI provides direct employment to 5, 00,000 people. And indirect employment to approximately 24, 00,000 people.

"\textit{The Indian pharmaceutical industry is a success story providing employments for millions and ensuring that essential drugs at affordable prices are available to the vast population of this subcontinent.}" said Richard Grester.

India is emerging favoured destination for level of expenditure on R \& D is about 5\% of turnovers, which is much lower compared to most of the developed countries which is 15 to 20\%. Some of the leading firms who take the initiative in the investment in R \& D are Dr. Reddy's and Ranbaxy. Today contract research contract manufacturing formation alliances in research \& development between the Indian and foreign pharmaceutical companies have strengthened the prospects of the Indian pharmaceutical sector in post Jan, 01.2005 regime. The Indian pharmaceutical companies' mergers and acquisitions of foreign companies is another evidence of its rise of Indian Pharmaceutical Industry.

India being a member of WTO also realized the need to protect the interests of plant breeders, farmers and promote conservation of genetic resources and seed industry. TRIPS under Article 27.3(b) of the TRIPS agreement provides that member states may exclude essentially biological processes for the protection of plants or animals other than non-biological and
variety protection, Article 27.3(b) gives Member countries an option to protect plant varieties by patents or an effective *sui-generis* system or both.

India's first *sui-generis* law Protection of Plant Varieties and Farmers' Rights Act, 2001 tries to strike a balance between the monopoly rights granted to the intellectual property rights holders and the benefits of society through the provisions of compulsory licensing, researcher’s rights, exclusion of certain varieties from registration etc. Though certain loopholes are also present in the Act such as to avail the monopoly right registration of the variety is necessary and for retaining registration they have to pay royalty to the Government on the other hand it can also be consider as a check on the breeder's monopoly right. In the absence of this provision, obligation relating to benefit sharing and payment of compensation will not be workable by amending the provisions of the Act these loopholes can be closed. By the enactment of Protection of Plant Varieties Act, legislators tried to maintain the equilibrium between the Indian dual goals of protection of agrarian economy and protection of private investment in the development of new plant varieties and also recognizing the protecting the rights of plant breeders and farmers.

CBD affirms the sovereign rights of the states over their biological resources and India being a member of CBD decided to bring a piece of legislation in the form of Biological Diversity Act, 2002. The Biodiversity Act also plays an important role in the conservation of biodiversity protection of traditional knowledge, equitable sharing of benefits and to regulate access to biological resources. Section 3, 4, 6 and 7 the key provisions relating to regulate access to biological resources and traditional knowledge and exemption to certain persons such growers and cultivator, *Vai ds & Hakims* make a good combination of access and denial at some extent it is being able to present biopiracy. Since it is an innovative legislation with adequate measures to safeguard biodiversity and protection of economic interest of local and traditional comminutes, it will work as a tool for protection of traditional
knowledge after the averseness of different state holders and its effective implementation.

The other pertinent question would be as to who are entitled to seek protection of which forms of traditional knowledge and who may confer recognition and status on the holders of traditional knowledge in a *sui-generis* modality raises a number of questions about the role of communities and functions of communally held knowledge in traditions that are part of heritage and culture as well as living traditions of habitat presentation and human interactions. At last to conclude it can be said that for the protection if traditional Indian knowledge, a separate *sui generis* system is required. Traditional knowledge is not an area of patent. Patent requires novelty essential elements of patentability which cannot be fulfill by traditional knowledge. The new patent regime does not directly affect the traditional knowledge. If the patent regime affect it would be at the extent of the aspect of traditional medicines. On one hand where for the protection of plant varieties a separate *sui-generis* law has been framed which was also not an area of patent on other hand the need of an hour is to frame a *sui-generis* law for the protection of traditional Indian knowledge. The below stated Hypothesis framed by researcher for the research work has been proved.

**Hypothesis**

There is no law for the protection of traditional knowledge but traditional knowledge is protected under other IPR legislation such as Patent, Copyrights, Trademarks, Geographical Indication, Biodiversity and Plant varieties and India also amended its municipal laws in consonance of TRIPS agreement and different international conventions, treaties and protocols. Now the pertinent question is that whether our traditional knowledge and indigenous knowledge ought to be protected under any else legislation or not?
1. It is hypothesized that thought he TRIPS agreement under Article 27 talks about a *sui-generis* legislation and also for the protection of traditional knowledge but this does not specifically give any guidelines to protect the T.K.

2. It is hypothesized that most of our traditional knowledge is patented by developed countries. On large scale our traditional knowledge has been patented by US, Germany and other developed countries, should we opt for such a strong legislation which can prevent our traditional knowledge from being patented by these western countries?

3. Though India has already placed a legislation for the protection of farmers' as well as breeder's rights. Even than question arises what are the farmers' rights to be enunciated in any sui-generis legislation for the protection of traditional knowledge, whether this legislation would be complementary to the protection of traditional knowledge?

4. It is hypothesized that India is among one of the twelve richest mega-biodiversity rich countries. Biopiracy is directly related to biodiversity and, a separate legislation has been framed to protect biodiversity of the country but the enactment and implementation of this law has no effective purview to prevent biopiracy.

5. It is hypothesized that along with biodiversity legislation to protect the traditional rights of the farmers and to protect the plant varieties, protection varieties Act is a significant form of *sui-generis* legislation.

6. It is hypothesized that India is the richest source of traditional knowledge not only in medicinal area but it has a rich heritage of folklore, Art, Music, Dance Handicrafts, and Skills etc. which needs protection through separate *sui-generis* legislation.

It is hypothesized that whether proposed *sui-generis* legislation would be recognized internationally in absence of international rules and guidelines for such a law?
The discussion carried out in five chapters of this research work has made it crystal clear that a lot of steps have been taken by the international community for the protection of valuable asset in the form of traditional knowledge yet there are certain gaps which need to be filled so as to make protection of traditional knowledge regime effective. It is necessary for the effective and integrated implementation of the three Acts, Protection of Plant Varieties and Farmers' Rights Act, 2001, Biodiversity Act, 2002 and Seeds Bill 2004, to protect the T.K. In India a National patent programme should be started to make masses aware of its benefits challenges and be ready to face global new patent regime. Patent literacy is a must for India. The following important suggestion may be advanced for taking certain initiatives for the protection traditional knowledge.

**SUGGESTIONS**

No doubt, protection of T.K is a global problem demand globals solution. This T.K should be respected in all patent laws. Since T.K is often owned by an entire community, the entire community should have some share in the patent rights. This is one of the surest ways to fight biopiracy. This is also proposed that traditional communities should be integrated mainstream of the country origin. It is submitted that the TRIPS trade treaty needs to be revised to protect traditional knowledge and prevent bio-piracy. Further the TRIPS and CBD treaties should made workable to altercate contradictions and inconsistencies in the two agreements.

Public awareness campaign should be lunched by the government as there is an urgent need to educate the T.K holders, and communities. The effect of product patent would be more profound on pharmaceuticals but India should set up a new agenda as new challenges are a head. It is well recognized fact that there exist basic human rights to a clean and safe natural environment. The effects of Bio-piracy and industrial agriculture also clearly threaten. These human rights surveying the existing material on protection of T.K researcher
reached on the conclusion that the jobs, livelihood, employment, food security and safety, equity, the precautionary principle should not be ignored for IP regime in biodiversity.

1. In India, in order to check bio-piracy an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants, known as Traditional Knowledge Digital Library (TKDL). However, documentation of TK is only one of the means of giving recognition to knowledge holders. Mere documentation may not enable sharing of benefits out of the use of such knowledge unless it is backed by some kind of mechanism for protecting knowledge. Documentation of TK may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form of which it exists.

2. The Bio-Diversity Act, 2002, which regulates access to genetic resources and associated knowledge, contains no provision for the involvement of communities in decision-making. The Act is very much influenced by Bonn Guidelines. The National Bio-Diversity Authority (NBA) is the principal body for granting access to genetic resources. Thus, there is a need to include more stakeholders from amongst the traditional communities so that its representative nature may be improved.

3. National level mechanisms and legal provisions to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to TK holders should also be given international recognition for their effective implementation and for their enforcement in other countries. Thus, there is a need for development of an international mechanism for protecting TK.

4. Considering the fact that TK also needs international protection, it is imperative to define the characteristics of the international mechanism,
which must include the following:-

(a) Local protection of the rights of the TK holders through national *sui generis* regimes including customary laws.

(b) There is an urgent need for the effective enforcement of municipal level *sui generis* regimes through positive comity of protection of TK which include co-ordination and co-operation amongst national authorities of various countries in undertaking measures for protection of TK.

(c) A procedure whereby the use of TK from one country is allowed particularly for seeking IPR protection, or commercialization, only after such use is disclosed and PIC is obtained from the competent national authority of the country of origin.

5. That patent must not be granted without prior consent of the country, origin should be incorporated. No patenting plants should be carried out without prior informed consent of government and communities holders in country origin.

6. Prior informed consent for the use of TK is necessary whether the use of TK is commercial or non-commercial. The right to TK should be treated as basic Human Rights.

7. Since development of an appropriate form of protection for the knowledge of local communities is of great importance, therefore, there is a need for various bio-diversity rich developing countries to work together inter-governmental expedition towards developing an international instrument for the recognition of diverse national *sui generis* system. Thus, various bio-diversity rich countries should take steps for the preservation and protection of TK, and should come together for making concerted efforts in order to obtain international
recognition of their national level systems of protection of TK.

8. There is a long felt need to harmonize the provision of TRIPS and CBD. The CBD while reaffirming the sovereign rights of nations over their biological resources, calls for equitable sharing of benefits arising out of the utilization of these resources and associated TK. TRIPS agreement, on the other hand, recognizes IPR to be private rights and provides for rewarding inventions without referring to the source of biological material and associated TK and without commitment for fair and equitable sharing of benefits with the country of origin of such knowledge. The adverse implications of the TRIPS Agreement on protection and sustainable use of TK needs to be rectified. The TRIPS Agreement should be used not only to reward the inventors but also the local people and community who have conserved and developed the TK, which provide valuable base for such inventions. Therefore, the developing countries must utilize the mandate given by Doha Ministerial Declaration on the relationship between CBD and TRIPS, which needs to be harmonized.

9. An action may be taken on the following three broad fronts: -

(a) To put into place well considered legislations and complimentary arrangements which would help address the needs of the holder of TK.

(b) To establish the institutional structure needed for effective implementation of the legislations; and

(c) To review various legislations enacted both by the Central Government and different State Governments, with a view to amend those that may undermine the rights of the traditional communities over the resources they have been using.
10. Institutional structures should be established to provide the traditional communities with an opportunity to partake of the benefits arising out of the biological diversity and/or associated knowledge. The need for an institutional structure arises from the fact that the use of contracts for the sharing of benefits suffers at least two limitations which need to be taken into consideration. In the first place, they are voluntary agreements between the parties concerned. Given their nature, contracts cannot be relied upon as a way of realizing the objectives of the CBD. The second and the more important limitation of contracts is that it would prevent fair and equitable sharing of benefits which may arise when the parties involved are of vastly unequal bargaining strengths, as usually large companies having significant market power and the traditional communities, are at the fringe of the market system.

11. If bio-piracy has to stop, then the U.S. patent laws must change, and Article 102 must be redrafted to recognise prior art of other countries. This is especially important given that the U.S. patent laws have been globalizing through the TRIPS agreement of the WTO. Article 102 lays down that "A person shall be entitled to a patent unless:

A. The invention was known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by the applicant for patent: OR

B. The invention was patented or described in a trade publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States."

Thus, use in a foreign country does not constitute 'prior art' in U.S. patent law. This is the basis of bio-piracy of traditional Indian knowledge systems,
and indigenous uses of biological resources being patented. The U.S. style patent laws can only pirate indigenous knowledge. They cannot recognize or protect it.

The issue of providing legal protection on TK in line with the existing IPR regime is a complex one because of the very nature and clustered pattern of distribution of TK held within and between various communities across the world. Positive and defensive protection measures along with development of sui- generis laws may perhaps be the best and immediate options for countries like India to provide intellectual property rights to TK holders.

Thus, it can aptly be said that unless India, acquires the R&D along with industrial capabilities in order to use its knowledge base after giving due share to the custodians of these knowledge, the nation will not be in a position to take the advantage of the new patent system. This makes a strong case for a sui generis law in India to recognize and protect the interest of the custodians of TK. If the TRIPS Agreement is designed to promote industrial growth based on the western technological development, the sui-generis legislation must be one to protect and promote traditional knowledge for the revival and growth of the village industries in India for the economic prosperity of the down trodden lots of these villages. It is this legislative vacuum and the technological and industrial backwardness in India that are responsible for the transfer of the traditional knowledge to scientific community in the developed nations to reap the new fortunes without any obligations to the custodians of TK. This is in clear violation of the basic human rights-cultural, social and economic -of these people. As India leapfrogs into this new century of knowledge based industry and growth, its growth and development may not be determined only by its strategies of generation of new knowledge and innovation but also by the protection and exploitation of existing traditional knowledge and intellectual property. Thus, in India there exists an urgent need to both protect and utilize the existing traditional knowledge.
Abstract

To mitigate the problem of protecting traditional knowledge, the Government of India has taken steps to create a Traditional Knowledge Digital Library (TKDL) on traditional medicinal plants and systems, which will also lead to a Traditional Knowledge Resources Classification (TKRC). Though linking this to an internationally accepted International Patent Classification (IPC) System will mean building a bridge between the knowledge contained in an old Sanskrit *shloka* and the computer screen of a patent examiner in Washington. Even then the traditional knowledge existing in this vast population of India needs more attention to protect not only the medicinal knowledge but every aspect of the traditional knowledge. Hopefully this will eliminate the problem of the grant of wrong patents since the examiner, all over the world will be aware of the Indian rights to that knowledge. There is an urgent need for a timely legislation so that Traditional Knowledge in India may be protected without wasting any more time because delay can cause big national loss. The researcher therefore proposes the model law to be adopted in our country.

For the suggestions to be meaningful it has to be implemented to serve the interests of different groups. The government should do a great service by amending or enacting a new and appropriate legislation on the lines suggested by the researcher. It is submitted that the universities, Bio-technological institutions lawyers, and academicians can debate over the suggested action plan and remedies and help in benefiting the community and T.K. holders.

Lastly our submission is that India needs to protect the Traditional Knowledge by enacting suitable legislation on the line of African Model or it must be *sui-generic* in character as Traditional Knowledge has different characters.