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Protection of Traditional Knowledge under Indian Patent Regime

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Abstract:
International attention has turned to the use of Intellectual Property Laws to preserve, protect and promote Traditional Knowledge. Three broad approaches have been developed. The first emphasizes protecting Traditional Knowledge as a form of cultural heritage. The second looks at the protection of Traditional Knowledge as a collective human right. The third, taken by the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) investigates the use of existing or novel measures to protect Traditional Knowledge. The challenges faced by the traditional knowledge holder regarding the protection of the ancient knowledge and the benefit sharing can be improved if Cataloguing of the TK- The Indian Government has already undertaken an affirmative, concrete and ambitious project, and created the Traditional Knowledge Digital Library (TKDL), a database of the traditional knowledge acknowledges and provides recognition to the traditional knowledge holders. It is assumed that if the material/ knowledge is documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such materials/knowledge are readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom the benefits of commercialization of such materials/ knowledge has to be shared
Key words: documentation, Intellectual Property, traditional knowledge

1. Introduction

During the recent past, the developments of Intellectual Property Rights can be seen in the field of biotechnology, biodiversity and the traditional knowledge. Patent law has been extended to the Traditional Knowledge of tribal population in the third world countries like human life, animals, plants, micro-organisms, etc. The new technological developments, particularly in biotechnology, clearly demonstrate the significance and usefulness of Traditional Knowledge for the development of new product of commercial importance. Traditional Knowledge (TK), Indigenous Knowledge (IK), and local knowledge generally refer to the matured long-standing traditions and practices of certain regional, indigenous or local communities. Traditional Knowledge also encompasses the wisdom, knowledge and teaching of these communities. In many cases, Traditional Knowledge has been orally passed from person to person for generations. Some Traditional Knowledge is expressed through stories, legends, folklores, rituals, songs and even laws. Other forms of Traditional Knowledge are often expressed through different means.

Traditional Knowledge was treated as Knowledge in the public demeans for free exploitation without showing any respect or concern for the effort taken by the communities to preserve and promote the same. There must be free access to these resources for the survival of mankind on

the globe. Protections of the Traditional Knowledge of the local and indigenous communities seem to be one of the most contentious and complicated issue. The Traditional Knowledge is to be preserved and protected from outside agencies from being utilized at the cost of the possessor of such knowledge.

Recently, international attention has turned to the use of Intellectual Property Laws to preserve, protect and promote Traditional Knowledge. Three broad approaches have been developed. The first emphasizes protecting Traditional Knowledge as a form of cultural heritage. The second looks at the protection of Traditional Knowledge as a collective human right. The third, taken by the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) investigates the use of existing or novel measures to protect Traditional Knowledge.

Traditional Knowledge

Traditional knowledge (TK) may be described as knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. As such there is no definition of TK, it is integral to the identity of most local communities and is an ever evolving body of knowledge.

The attempts by a US Company to get Indian traditional products such as the active element of Turmeric and the anti fungal properties of Neem patented raised much hue and cry. All of these instances and many more raised eye brows of the common people because what was being exploited was the Traditional Knowledge (TK) of particular communities. Moreover, such acts also posed to be great economic threats as well to these people

Basically TK can be provided two types of protection:

Defensive protection- this aims to stop people who are not a part of the community from acquiring Intellectual Property Rights (IPR) over traditional knowledge. One of the excellent examples of defensive protections is India's Traditional Knowledge Digital Library which is formed after collaboration between Council of Scientific and Industrial Research (CSIR) and Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (Dept. of AYUSH), Ministry of Health & Family Welfare.

Positive protection- this is the granting of rights that empower communities to use and benefit from their TK.

Recently, attempts have been made to exploit TK for industrial and commercial benefits often leading to misappropriation of knowledge. Problems are not always commercial in nature and often involve ethical, cultural, historical, spiritual and moral considerations. For example, inappropriate use of sacred cultural artefacts, processes, or designs may be offensive to the community. Since as of now TK is not recognized as a separate IPR therefore one has to resort to other forms of Intellectual Property to protect it. It is hereby contended that patent is one of the most desired form of IPR to protect TK.

As per the news article of Times of India published on 11th January, 2014,[1] a Centre for research on traditional knowledge was launched. The research centre will undertake integrative and transdisciplinary research based on traditional knowledge. The main aim is to

create an interface for research and education in traditional systems and modern sciences using biomedical sciences like molecular biology, immunology, biochemistry, nutrition, pharmacology and genomics.

2.1 Examples of Traditional Knowledge

India is basically a country endowed with vast cultural and ethnic diversity. India is a hub of TK and indigenous culture and ethnicity. The diversity which is a basic fabric of Indian society gives rise to innumerable number of cultural, ethnic, religious, traditional and indigenous issues and activities. These are various activities which are cultural or traditional blessed with some indigenous spirit, which can be validly called as part of traditional or indigenous knowledge. The following types of knowledge could be formed as TK.

- Spirituality, spiritual knowledge, ethics and moral values.
- Games, sports, music dances, ceremonies, ritual performances and practices.
- All material objects movable cultural property.
- The delineated forms parts and details of visual compositions.
- Cultural environmental resources traditional resources.
- Documented aspects of traditional indigenous cultures in all forms.

2. Patents and Traditional Knowledge

Under current Intellectual Property Law, there is no obligation for companies, which utilize the traditional medical knowledge of indigenous peoples to provide any compensation to recognise their equality in the commercial application of this knowledge. In broad terms, patents can be defined as exclusive rights granted for an invention - either a product or a process - that offers a new technical solution to a specific problem. A patent implies the grant of a "monopoly" to an inventor who has used his knowledge and skills to produce a product or process which is new, involves an inventive step and is capable of industrial application. Patents can also be claimed on TK. For example, patents protect inventions which are considered to be new, involving inventive step, and capable of industrial application. Even the individual holder of TK can also acquire patent, which is passed on from generation to generation, provided they fulfil the necessary requirements. But in reality it is difficult to fulfil, as it is very difficult to identify the inventor of the TK or the specific community to which it belongs.

To be patentable, an invention has to be novel, involving an addition to the existing state of relevant technology. Novelty is assessed by reference to the prior art. Novelty will be destroyed by prior publication. A problem with the patent claims of indigenous peoples in relation to traditional medicine remedies is that it has been the practice of ethno botanists and ethno pharmacologists to publish accounts of the uses of plants by indigenous people. Another obstacle to the recognition of the contribution of indigenous peoples to the development of new drugs, are the fairly strict rules that apply to the concept of joint invention. The economic faction has played an important role in the agitation for the protection of traditional cultural works.

The TRIPS Agreement also has some provisions having limited application to the protection of TK. The obligation to protect geographical indications can be used to protect traditional knowledge if associated with the indication used for

production and sale of goods. It is made clear that a given quality, reputation or other characteristics of the goods essentially attributable to its geographical origin are to be considered in identifying the geographical indications for protection. Thus it may be possible for protection through geographical indication the traditional knowledge associated with goods.[2]

Disclosing traditional knowledge which forms part of an invention and of the state of the art or prior art will promote the progress of science by creating an incentive for the maintenance of traditional knowledge systems . This will happen by traditional knowledge being widely and universally accepted within "western" or "modern" innovation protection systems and becoming a reference point within the regular operations of the international patent system.

As per the news article of Times of India published on December 27, 2013[3]: Traditional knowledge, culture can be patented. Traditional Knowledge (TK) and Traditional Cultural Expression (TCE) reflecting a community's cultural and social identity, handed down generations, may soon be recognized as a form of intellectual property. TK and TCEs are innovations and creative expressions of local communities and products of creative intellectual activity, which need to be protected and safeguarded to prevent their misuse. The move has a special relevance for India in its pursuit of protecting and safeguarding its traditional healthcare and rich cultural heritage, given the fact that it has faced such disputes in the past. Several patents based on Indian TK have been unduly granted to third parties throughout the world. Calls for the protection of traditional medical knowledge are often based on a number of cases involving misappropriation by unauthorized third parties, who have patented compounds derived from traditional medicines without the prior consent of traditional medical knowledge holders, and without fair compensation. Examples of patents based on traditional Indian medicine have included the use of turmeric for healing wounds, the anti-fungal properties of neem, and a diabetes medicine made from extract of jamun. All three patents were subsequently revoked.

3. Issues of Bio-Piracy and Traditional Knowledge

Bio-piracy refers to unauthorized use of

(a) Biological resources such as plants, animals' micro-organisms, etc.

(b) Traditional communities' knowledge on biological resources.

Bio-piracy also denotes unequal share of benefits between a patent holder and the indigenous community whose knowledge or resource has been used. This clearly shows that the person who commits bio-piracy enjoys the maximum benefit at the cost of the indigenous people's knowledge, as these people are unaware of the importance of their TK. It also indicates misappropriation and monopolization of TK and biological resources unlawfully. Normally, biotechnology companies commit bio-piracy when their work is based on natural varieties, which are found in developing countries among indigenous people. Whenever they commit such acts they have to pay royalty for them. In most of the time, the multinational companies use the country's biological and intellectual wealth without getting permission from the communities who have developed this knowledge. This amounts to bio-piracy.

There are various traditional products, which are subjected to bio-piracy by the multinational companies such as neem, turmeric, colgate, basmati rice etc.

4.1. Cases of Bio-Piracy

Following are few cases of bio-piracy in India:-

- **Neem: Common Heritage:** In 1994, a US Department of Agriculture granted a patent to a US based company WR Grace, for a fungicide made from Neem oil. The decision was later opposed by many of the NGOs and environmental organizations considering it as 'bio-piracy'. Subsequently, the European Patent Office agreed to withdraw the patent in May, 2000 confirming that "nothing has been invented, and that knowledge and use of Neem have been widespread in India and elsewhere for many decades".[4]
- **Basmati rice: Geographical Indication Act:** In September, 1997, a Texas company named, 'RiceTec Inc.', was granted a patent by the US Patent Office to call the aromatic rice grown outside India as 'Basmati'. As a result of which the company was entitled to not only call its rice as 'Basmati' within US, but also label it Basmati for its export purposes. This gave rise to a great repercussion for India and Pakistan as the patent would result into India not only loosing US import market but also its position in significant markets like Asia, Europe and UK. This brief diplomatic crisis between US and India with the later threatening the former to take the matter to WTO for a clear violation of TRIPs, as the Geographical Indication products cannot be patented under the provisions of TRIPS, ultimately came to an end with the US Patent Office deciding against RiceTec.[5]
- **Maca: The Revitaliser:** Considered to be a plant that 'revitalises', Maca acts as a tonic, helps in consolidating fractures, rebalances the menstrual cycle and is especially renowned as an 'aphrodisiac' for both men and women. Since the Aphrodisiac market is highly lucrative, it has attracted the attention of many Western health food companies. Subsequently, in 2010, the European Patent Office, following an action taken by the Peruvian National Anti-Biopiracy Commission, cancelled several patents on Maca.
- **Sacha Inchi:** The Sacha Inchi, because of its highly concentrated nutritional nature and very high fatty acid content, is considered of great interest in the cosmetic and food industries of developing countries. The Peruvian National anti- Biopiracy Commission and the Collective for an Alternative to Biopiracy in France marshaled and worked together to fight the illegitimate patents being sought on this plant. The outcome was the total definitive cancellation of the Greentech patent in October, 2009.
- **Novartis v. UOI :**Supreme Court in a Landmark Judgment in Novartis AG v. UOI[6] delivered on April 1, 2013, dismissed the appeal of the Swiss drug maker Novartis for grant of a patent over its anti-cancer drug Glivec in India. The judgment was a massive blow to the pharma major, and came down strongly on 'ever greening' of drugs. Supreme Court accepted the existence of "imatinib mesylate" as prior art by looking into Zimmerman patent and thus declared it not to be a 'invention' under section 2(1)(j) and section2(1)(j a) of the Patents Act, 1970.[7]
- In 1997, the US patent office revoked the patent of Turmeric (Curcuma Longa Linn.) given to the University of Mississippi Medical Center, after ascertaining that there was no

novelty; the findings by innovators having been in India for centuries.

- Disputes related to Kava patent rights- a cash crop grown in the pacific; Ayahuasca patent rights- a ceremonial drink throughout the Amazon basin; Quinoa case- a staple food crop grown in the Andes; Hoodia cactus case in Africa and many more other instances when the developed countries have tried to infringe the rights of developing countries over their own resources guaranteed under different international conventions and treaties.

4. Traditional Knowledge Protection in India

India is a country, which has been nurturing a tradition of civilization over a period of about 5,000 years. India's ancient scriptures consist of the four Veda, 108 Upanishads, 2 epics, Bhagavad-Gita, Brahma sutras, eighteen Puranas, Manusmriti, Kautilya Shastra and Smritis. Biologically speaking, India is one of the 12 most biodiverse countries of the world. With only 2.4 percent of the world's land area, India accounts for 7 to 8 percent of the recorded species of the world. India's diversified agro-climatic nature is a blessing. The whole world has 26 agro-climatic zones and India alone has 16 agro-climatic zones. India's diversified agro-climatic zones start from the Trans-Himalayan region to the coastal areas of Kerala, Andaman and Nicobar, which are home to a varied range of medicinal plants like herbs, shrubs, tubers, mangroves and rhizomes. The Botanical Survey of India and the Zoological Survey of India have recorded over 47,000 species of plants and 81,000 species of animals.

This multitude of natural wealth has created a renewed interest in the traditional medicinal system, which includes the Unani, Yoga, Ayurveda, Homeopathy and Siddha systems. The Ayurveda is the oldest and most effective of these alternative systems of medicine. The ancient scriptures of the Ayurveda are full of instances where herbs with medicinal properties were used not only for curative purposes but also for increasing physical and mental efficiency.

India is a party to the Convention on Biological Diversity (CBD), which came into force on 29 December, 1993. It has three main objectives, namely, the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources. CBD envisages that the benefits accruing from commercial use of TK have to be shared with the people responsible for creating, refining and using this knowledge. Article 8(j) of the CBD provides for respecting, protecting and rewarding the Knowledge, Innovations and Practices (KIP) of local communities.

Traditional knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, and forestry. Many widely used products, such as plant-based medicines and cosmetics, are derived from traditional knowledge. Other valuable products based on traditional knowledge include agricultural and non-wood forest products as well as handicrafts. Realizing the need to ensure that the holders of TK, which is not still in public domain, should be able to get the benefits arising from the use of such knowledge, an enabling provision has been made for protecting the TK in the Bio-diversity Act, 2002. Indian Patents (Amendment) Act, 2005 also deals indirectly with the protection of TK.

5.1. India, Traditional Knowledge and Bio-Piracy

Prior to the amendments the Patent Act provided only process patents for food, medicine or drug substances. But after the amendment, Indian Companies are given a right to manufacture products (drugs) patented elsewhere by employing a non-infringing process under exceptional cases.[8] The TRIPS agreement also has some provisions to protect TK. The obligation to protect geographical indications under the agreement can be used to protect TK associated with the goods. Doha Declaration of 2001, in WTO ministerial conference, says that, TRIPS council should examine the relation between the TRIPS agreement and the UN convention on Biodiversity, the protection of TK and folklore, etc. Besides, International Labour Organisation's Convention: 169 also recognize and protect the social, cultural, religious and spiritual values and practices of indigenous and tribal people.

The TRIPS agreement allows member states to exclude from patentability inventions which are contrary to public order or morality or detrimental to health and environment. Therefore, we cannot say that the TRIPS Agreement is in conflict with the Convention on Bio-logical Diversity (CBD), which recognizes the sovereign rights of states over their biological resources. India, having ratified Convention on Bio-Diversity tries to provide security for sovereign rights recognized under CBD. In fact the culture and tradition of indigenous people are very much threatened by IPR Regime as imposed by the TRIPS agreement. The Patent Act of India was amended latest in 2005. The main features of this amendment are:-

- Introduction of product patent protection in all fields if technology.
- Deletion of provisions relating to exclusive marketing rights.
- Introduction of a provision enabling grant of compulsory license of export of machines to countries which have insufficient or no manufacturing capacity to meet emergent public health situation.
- Makes biological processes as patentable, including biochemical, biotechnological and microbiological processes (sec. 5).
- Microorganisms are patentable (sec. 3(j)).
- For patent on biological material, specifications must disclose the source and geographical origin of the biological material used in the invention (sec. 10(d)).
- Non-disclosure a ground for opposition of the patent (sec. 25)
- A patent is refused or revoked for giving wrong information about the source of geographical origin of biological material (sec. 64(p)(q)).
- Plant varieties or essentially biological processes are non-patentable (sec.3).
- An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component/s is also non-patentable (sec.3 (p)).

Above all a sui generis legislation has to be developed for the purpose of protecting TK. India has already enacted a law to provide for protection of biological diversity[9], sustainable use of its components and equitable benefit sharing on the use of its components and equitable benefit sharing on the use of biological resources. The legislation also provides for a National Authority, which

will grant approvals for access and ensures equitable sharing of benefits. Following are the features of Biological Diversity Act of India, 2002:-

- Prohibits transfer of Indian genetic material outside the country without approval of the Indian Government.
- Prohibits patents or other Intellectual Property Rights over such material or over related knowledge can only be taken seeking permission in advance.
- Provides for the levying of approximate fees and royalty on such transfers and Intellectual Property Rights.
- Provides for sharing of benefits of various kinds including transfer of technology, monetary returns, joint Intellectual Property Rights ownership, etc.
- Provides measures for habitat and species protection.
- Provides for the protection of Indigenous knowledge through appropriate legislation at local, state and national levels.

Further, the TRIPS[10] agreement mandates protection for plant varieties; either by patenting the plants or through effective sui generis system. In our country farmers are not habituated for patenting plant varieties, as they are ignorant about the long patent process. The process of drawing up a new plant variety protection Act in India started in 1993. Dr. M.S. Swaminathan, a renewed agriculture scientist drafted the Bill and said at the M.S. Swaminathan Research Foundation that the draft plant variety protect Act should recognize the rights of the farmers and breeders. He said, farmers and breeders are allies in the struggle for sustainable food security and hence their rights should be protected. The result is the Protection of Plant Varieties and Farmer's Rights Act, 2001. The main objectives of the Act are:

- To recognize and protect the rights of the farmers for their contribution made in conserving, improving and making plant genetic resource available for development of varieties.
- To protect plant breeders rights, to inspire for investment in research and development both in private and public sector for the development of new plant varieties.
- To facilitate growth of the seed industry in the country to ensure the availability of high quality seeds and planting material to farmers.

The Act also guarantees rights of the farmers to use, save, and re-sow exchange or share or sell their farm produce including seeds. The farmers can also seek protection under the Act if they develop new strains through selection and breeding, if they satisfy the conditions such as novelty, distinctiveness, uniformity and stability.

5. Documentation of Traditional Knowledge

India has woken up to the task of protecting her traditional knowledge from patent bio-piracy. Protection and preservation of traditional knowledge have been a matter of concern to the developing countries in general and India in particular. As a result of this, in 1999, the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy-(AYUSH), erstwhile Department of Indian System of Medicine and Homoeopathy (ISM&H) constituted an inter-disciplinary Task Force, for creating an approach paper on establishing a Traditional Knowledge Digital Library (TKDL).The project TKDL was initiated in the year 2001.

6.1. Traditional Knowledge Digital Library (TKDL)

In the recent past, there have been several cases of bio-piracy of TK from India. For preventing such instances in future there is a need for developing digital databases of prior art related to herbs already in the public domain. Traditional Knowledge Digital Library (TKDL), an electronic database which provides information on traditional knowledge existing in the country. TKDL acts a bridge between the traditional knowledge information existing in local languages and the patent examiners at Indian Patent Offices. TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented at CSIR. An inter-disciplinary team of Traditional Medicine (Ayurveda, Unani, Siddha and Yoga) experts, patent examiners, IT experts, scientists and technical officers are involved in creation of TKDL for Indian Systems of Medicine.

The project TKDL involves documentation of the traditional knowledge available in public domain in the form of existing literature related to Ayurveda, Unani, Siddha and Yoga, in digitized format in five international languages, which are English, German, French, Japanese and Spanish. This database enables the Patent Office's all over the world to search and examine any prevalent prior art, and thereby prevent incorrect grant of patent on products/processes based on knowledge in public domain.

6.2. National Knowledge Commission and TKDL

The National Knowledge Commission, Government of India, in December 2007, recommended that the work on TKDL should be diversified and expanded. Further, the Commission suggested that steps should be taken for the use and incorporation of TKDL, with all pertinent sources of information, into the minimum search documentation lists of International Search Authorities and other offices while processing patent applications.

6.3. TKDL Present Status

Present status of transcription of the traditional medicine formulation in the TKDL is given in following table:-

Discipline	No. of Texts(including volumes) used for transcription	Transcribed
Ayurveda	75 books	97,203
Unani	10 books	1,70,990
Siddha	50 books	22,815
Yoga	15 books	1,654
Total	150 books	2,92,662

Source: http://tkdl.res.in/tkdl/langdefault/common/AboutTKDL.asp?GL=Eng#Present accessed on 28th Februrary 2014.

6.4. Traditional Knowledge Resource Classification (TKRC)

Traditional Knowledge documentation lacked a classification system. Therefore, a modern classification system i.e. Traditional Knowledge Resource Classification (TKRC), based on the structure of International Patent Classification (IPC) was been evolved for

Indian Systems of Medicine viz., Ayurveda, Siddha, Unani and Yoga. It is an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval has been evolved for about 25,000 subgroups against few subgroups that were available in earlier version of the International Patent Classification (IPC), related to medicinal plants, minerals, animal resources, effects and diseases, methods of preparations, mode of administration, etc.

TKRC is a structured classification consisting of sections, classes, subclasses, groups and subgroups, similar to that included in IPC system, relating to Indian traditional knowledge for facilitating the patent examiners in retrieval of information related to prior art, before granting a patent in the area of traditional knowledge.

7. Challenges Faced in Patent Regime

There are many problems faced by indigenous people when they try to protect their traditional knowledge under Indian Patent Act, 1970 (PTA) so as they fail to satisfy the requirements for the intellectual protections provided in the aforesaid Act. In order for inventions to be patentable generally there are three criteria's to be met which are: novelty, non-obviousness, and industrial application. In absence of any of these three criteria's, the patent cannot be approved. Since most of the traditional knowledge is ancient and has been used for long periods, it usually fails to meet the requirements of novelty and inventiveness and hence, deprived of the patent protection.

Further, traditional knowledge constitutes prior art, therefore it is already known and lies in public domain that destroys an invention's novelty or non-obviousness. The term "prior art" refers to the entire body of knowledge, which is available to the public before the filing date of an application. Section 102(a) of the US Patent Act[11] defines prior art as encompassing oral disclosures or use only if the acts occurred in the United States; written disclosures. The difficulty that narrow definitions of prior art pose is that they shift the burden to the holders of traditional knowledge to ensure that the knowledge is disclosed in a manner sufficient to be included in the prior art. Similarly, PTA rejects the patent application on the ground of anticipation by previous publication or by public display or by communication to government.

Many patents have been granted for traditional knowledge which has not met the criteria of patentability when compared with the relevant prior art. This prior art consisted of traditional knowledge which cannot be recognized by the patent granting authority during the examination of the patent application.

Another significant issue is the "possession" of the intellectual property which is one of the most important basis to seek patent protection. In case of traditional knowledge, it is common knowledge and a product of collective experience without an individual act of creation; therefore it gets precluded from getting protection. Additionally, it faces challenge to get patent as the locus of ownership cannot be clearly identified for knowledge systems that are essentially inter-generational and products of communal endeavour. It is known that traditional knowledge is either originated within a community or procured from outside, and when the knowledge has been derived from outside the community then it may not be subject to any IPR protection and remains in public domain.

If the knowledge is from within the community, then it becomes difficult to ascertain who is the owner or inventor of that particular knowledge and tricky to find out the ownership and therefore traditional knowledge denied patent protection.

Due to the above barriers mentioned, the traditional societies have been kept outside the 'loop' of the patent protection regime. Nonetheless, the large pharmaceutical companies are actually trolling the tropical rainforests searching for commercially valuable traditional knowledge from indigenous populations and applying for the patents.

However, in order to protect "traditional knowledge" practitioners believe that adoption of practices such as

- Documentation of traditional knowledge;
- Registration and innovations patent system; and
- Development of a sui generis system would help to extend protection to knowledge, innovations in India.

They are also of the view that proper documentation of associated traditional knowledge could help in checking bio-piracy.

8. Conclusion

The present legal regime in the field of TK is inadequate and incomplete. The fact remains is that, the tribal people are placed in the disadvantaged position and they are not in a position to enjoy the benefit derived out of their TK. There must be adequate sharing of profit for utilizing the TK for commercial purposes. Trusts are to be constituted, through which awareness on the importance of TK should be promoted and documentation of different kinds of TK should be undertaken. Committees are to be constituted to promote and preserve TK. Prior informed consent of knowledge holders must be obtained before they can use their knowledge. There must be an involvement of indigenous and local communities in applying and utilizing their knowledge to the development of new products. In the area of biodiversity, Convention on Biological Diversity must take primacy over Trade Related Intellectual Property Rights. Protection of biodiversity and Traditional Knowledge is the inevitable task before the nations in the interest of mankind. There are many challenges before the third world countries posed bu the IPR Regime, which needs to be addressed:

- Protection and preservation of Traditional Knowledge.
- Access to and benefit sharing of the traditional resources knowledge developed by the indigenous communities.
- No alteration of indigenous and tribal community from their TK and habitat.

Now, it is high time to protect and preserve the rich heritage from the clutches of the new international patent regime, which is adverse to the tribal communities. As TK, is not only more valuable for those who depend on it, but equally important for the modern industry and agriculture, and for sustainable development. Today, more traditional products are being sold at international market, like medicinal plants, traditional agricultural products and handicrafts, etc.

9. Recommendations for Protection of Traditional Knowledge

The challenges faced by the traditional knowledge holder regarding the protection of the ancient knowledge and the benefit sharing can be improved if following measures are adopted:

- Cataloguing of the TK- The Indian Government has already

undertaken an affirmative, concrete and ambitious project, and created the Traditional Knowledge Digital Library (TKDL), a database of the traditional knowledge acknowledges and provides recognition to the traditional knowledge holders. It is assumed that if the material/ knowledge is documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such materials/knowledge are readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom the benefits of commercialization of such materials/ knowledge has to be shared.

- Bringing together the local innovators and entrepreneurs so that the entrepreneurs can exploit the traditional knowledge and the local innovators will get the royalties, which leads to the establishment of benefit sharing system. Any benefits, profits or royalties realized from the plants and knowledge recovered should be shared within the community.
- An international fund needs to be set up to promote filing of patents by grassroots innovators and traditional knowledge holders internationally. This will encourage the grassroots innovators to contribute more in the area of traditional knowledge and would also get the actual monetary benefit from its commercial use.
- The government should establish the traditional medicines resources centre which should work with local healers to document details of all traditional medicines with a view to promote a sharing of practices within the country.

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