MEDICINAL PLANTS AND THEIR PROTECTION AS TRADITIONAL KNOWLEDGE: A STUDY OF THE LEGAL FRAMEWORK WITH SPECIAL REFERENCE TO COOCH BEHAR DISTRICT OF WEST BENGAL

INTRODUCTION

Knowledge has always been an essential component of all human progress. The pursuit of knowledge has motivated the people to do new things, to bring new ideas, to find long standing solutions, to enlighten the people's mind in so many aspects. As a result, there is change, revolution, evolution and development in the society. Apart from other virtues of knowledge, the practical importance of knowledge has increased immensely as the concept of knowledge based economy is evolving nowadays. Knowledge has become an instrument to bring economic development and prosperity in the country. It can be the sustainable and continuous source of huge national income of a country, enriched with knowledge. A country's ability to protect the century old existing knowledge and new knowledge acquired through invention and innovation together with convert them into wealth will decide its future. In this respect India has a huge potentiality to utilise its century's old knowledge-individual knowledge and traditional collective knowledge.

India is the blessed country in the world that is enriched with golden treasures of knowledge. Apart from diverse cultural expressions there is associated traditional knowledge on a variety of subjects' especially medicinal properties of the plants, at every corner of this country. This traditional knowledge with a strong scientific base is unique in the world i.e. ayurveda, siddha, unani etc. The plants, more specifically its genetic resources can do wonders, by curing small or serious types of illness. Since time immemorial India has possessed a rich traditional knowledge of methods and means to treat diseases afflicting people and to cure ailments. Not only this, it also includes methods and means to have healthy lives and precautionary measures to remain disease free, by applying the herbal medicines made of the various parts of the medicinal plants.

A pertinent question is what is traditional knowledge? There are several attempts to define traditional knowledge by various organisations or by many experts on this subject. In most of the definitions traditional knowledge means the century old knowledge of the indigenous communities or tribal communities who are the holders and preservers of such knowledge. Keeping in mind the Indian experience this definition does not cover all. There is huge traditional knowledge which is not identified with any particular tribal or indigenous community. Rather it is the knowledge of the whole Indian society or the country itself. Hence, traditional knowledge refers to the century old knowledge-innovations and practices of indigenous and societies in general around the world. This is developed from

experience and research gained over the centuries, preserved or sometimes added value to the existing knowledge and transmitted orally from generations to generations, either through document or oral description. The present generations are the protectors, preservers and sometimes adapters of this great traditional knowledge. India is lucky to have such huge collection of traditional knowledge for the great works of ancient sages which very few countries in the world have.

Prof N.S.Gopalakrishnan opines that "(a) traditional knowledge can be generally described as information existing in the society which has been passed on by the previous generations. This includes *inter alia* the information regarding the product, its use, the manner of use and the method or manner of its manufacture. All these information were in use and majority are still being used by the members of the society. The peculiar characteristics of this knowledge base are the inability to identify in many cases the original creator of the information. In many cases the holder of the information in the previous occasion must have modified it to suit the then existing requirements. This information is available in all most all fields diversified and scattered over India with or without documentation. For the purpose of examining the scope of patent protection it can be conveniently classified into the following four categories. (b) Information commonly known to the society with or without documentation and is in constant use by the people. e.g. the common use of *neem, tulasi, termeric* etc.,(c)Information that is well documented and is available to the public for examination and use. e.g. the *ayurvedic* texts, information in the *palm leaves* etc., (d) Information that is not documented or commonly known but known only to small groups of people and not revealed to others outside the group. e.g. the tribal knowledge. (e) Information known only to individuals or members of the families and none else. e.g. the information used by the village medicinal practitioners for treatment."[1] Traditional knowledge passed on from one generation to another generation through socialisation process. The unwritten rule was that the knowledge would be used for the welfare of all the members of the society. By the constant use there was also value addition that made this system of knowledge relevant and useful even today.

Traditional knowledge for the purpose of the present research work is the knowledge which exclusively vests in a community or race or family or small groups or the society in general as their exclusive possession and includes the know-how, informations, innovations, applications, common practices and adaptations etc. It also embodies the traditional lifestyles of indigenous village communities or the societies in general regarding the TK, which may be informal or contained in codified or formal knowledge systems passed to the next generations, through socialisation process.

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[1] Prof N. S. Gopalakrishnan, "Impact of Patent System on Traditional Knowledge", Cochin University Law Review, 1998, Page 219.

This traditional knowledge is obviously the intellectual property. Hence deserves effective legal protection like other intellectual properties. This knowledge is the intellectual property either of these communities and sometimes societies in general, as being the expressions of idea. This is due to the reason that it is the result of so much of toil, hard work, study, research and experimentation, observation, trial, error, success and failure-an intellectual and cognitive exercise of mind and brain. It is completely a learned behaviour of a group of people i.e the tradition of the people, and collective programming of the mind that distinguishes the members of one group or society from another. This unique knowledge, Indians have not lost so far and kept in its treasures for the future generations, for the whole world. The Traditional Knowledge associated with biological resources is an intangible component of the plant generic resource itself. This traditional knowledge of India on biological resources of the plants, especially about medicinal plants is also an inalienable part of the culture of the particular community or Indian society in general. Due to this cultural ethos, this great knowledge was not monopolised exclusively for commercial purposes either by obtaining patent or otherwise by any indigenous community or by Indians collectively. It was also not commercially exploited, the way foreign multinational corporations promoted by developed countries in this globalised economy, have started doing, only with the motive of profit.

Medicinal plants of India are the species of the bio-diversity of this country. Simply biodiversity means different forms or species of lives in this world. Medicinal plant is one of the species. Biological diversity encompasses all species of plants, animals and micro-organisms and the variation between them, and the eco-systems of which they form a part. It occurs at three levels, namely: (i) species level - refers to number and kinds of living organisms; (ii) genetic level - refers to genetic variation within a population of species; and (iii) eco-system level - refers to the variety of habitats, biological communities and ecological processes that occur in such habitats. Biological diversity means the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of eco-system.[2] "It is the degree of variation of life forms within a given ecosystem and is a measure of the health of an ecosystem. Life on earth to day consists of many millions of distinct biological species and India is one of the seventeenth identified mega bio-diverse countries of the world. With only 2.4 percent of the total land area of the world, the known biodiversity of India contributes 8 percent to the known global biodiversity."[3] From about 70 per cent of the total geographical area are surveyed so far, 45, 000 plants and 91, 000 animal species, representing about 7 per cent of the world's flora and 6.5 per cent of the world's fauna, respectively, have been identified.[4] It states the fact that India is

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[2] Section 2(a), The Biological Diversity Act, 2002.
[3] Environment Audit Report, Report No. 17 of 2010-2011, Chapter-3, THEME: BIODIVERSITY.
[4] Ibid, Pp 29-30.

exceptionally rich in biological diversity. Among the 45, 000 plant species, most of them have medicinal properties in them. But what matters most is the associated centuries old traditional knowledge with those medicinal plants. India is equally rich in traditional and indigenous knowledge, both coded and informal. These plants are famous for their inherent medicinal properties to cure ailments or to resist diseases. Examples like haldi is for wound healing capacity, neem for bacteria resistance power, marrie-gold for stopping bleeding of wound etc. Though, huge numbers of species have been identified in the country by systematic surveys, covering all the ecosystems, by BSI and GSI, from the remaining areas, it has been estimated that another 400,000 species may still exist in India which remain undescribed. It is anticipated that some of the remaining areas (e.g. Himalayan Region, A & N Islands) may be far richer in biological diversity than most of the areas already surveyed. And India's position would go up.

What is more important about the plants is that the traditional knowledge associated with those that these plants are enriched with medicinal properties. As it was said earlier that traditional Knowledge associated with biological resources is an intangible component of the biological resource itself. Though it is within biological diversity, as the plants are associated with traditional knowledge, it goes beyond the limits of biological diversity and gives them a distinct biological- legal status. Sometimes the knowledge is held by some small tribal or other communities and sometimes the knowledge is held by all the members of the society including the indigenous communities. There are basically two types of traditional medicinal knowledge. One is codified traditional medicine and another is un-codified traditional medicinal knowledge. In India, the latter through folk traditions are handed over orally from generation to generation. The codified tradition consists of medical knowledge with sophisticated foundations expressed in thousands of manuscripts covering all branches of medicine. Take for example Ayurveda. Ayurveda is a documented knowledge system and the information is of about 36,000 compositions of medicines practiced for centuries available in *Sanskrit* language scattered in 14 texts. So traditional knowledge includes both the codified (documented) as well as non-codified information (not documented but may be orally transmitted). Not only this system has its own way of using medicinal plants but also unique method of diagnosis and treatment. The medicinal plants and genetic resources associated with traditional knowledge, has a very strong scientific base. The latter refers to those medicinal plants which are being used and applied by the indigenous communities. People in general do not have any access to those knowledge and method. Some of the medicinal plants are in the public domain in India which people use and apply to cure from different kinds of ailment or to enhance resistance power of the bodies. The comprehensive method of diagnosis and treatment in Ayurveda and application of extracts from the different parts of the medicinal plants and other systems to cure ailment and to ensure healthy life is the result of extensive research, study, experimentation and experience about anatomy, physiology, botany and bio-chemistry etc. This level of scientific progress with so much of study and research was there in

ancient India. Without that level of study, research is it possible to find out or invent the medicinal properties of the plants or to cure ailments without side effects and to ensure healthy life? And the Indians have been holding, preserving, adding value to it and applying to their day to day life. Now it has become an integral part of life, very natural, vary easy.

Traditional knowledge of medicinal plants has acquired its importance. Firstly, it is the result of the applications of intellects and analysis of the experiences about the medicinal values of the biological resources to cure different types of ailments and ensuring healthy lives of the human beings, obviously it is the intellectual property rights on scientific knowledge, invented with a lit of dedication, hardworking, study and research. It has got the status of a statutory right where the nature and scope of this right is recognized in a written document. Secondly, as it has become the tradition, culture and heritage of this communities-right to preserve own tradition, culture and heritage are integral part of 'Right to Life' guaranteed by article 21, Constitution of India. Hence it is also a fundamental right enforceable against the state, because, without the right to preserve heritage, culture and tradition, it is not the quality of life which was envisaged. Thirdly, important economic activity: it has the immense potentiality to create new job opportunities, open up new area of different types of business in the national economy as well as in the international economy. As a result, globalised economy would be immensely benefited by adding value to it. And finally it is the unique type of natural medicine without side effects. As demand for herbal medicines is growing up in developing countries, there are indications that consumers in both developing and developed countries are becoming disillusioned with modern healthcare and are seeking alternatives in traditional medicines, because it is purely natural, without side effects. It can cure the ailments and ensure healthy lives unbelievably and miraculously in the best way. Apart from that according to the World Health Organisation (WHO), the goal of health for all' cannot be achieved without herbal medicines. "Meanwhile, as recognition of the ecological failure of the chemical route to pest control, the use of plant-based pesticides is becoming popular in the industrialised world. Corporations that have promoted the use of chemicals are now looking for biological options."[5] As a result of increasing public awareness of the side effects of hazardous drugs and the rise of strains resistant to antibiotics, the western pharmaceutical industry is increasingly turning to the plant-based system of Indian and Chinese medicine. In the last few years, growing opposition to chemical products in the west, in particular to pesticides, has led to a sudden enthusiasm for the pharmaceutical properties of neem which do not have harmful long term bad side effects on human body and environment. Indigenous medical systems are based on over 7000 species of medicinal plants and on 15000 medicines of herbal formulations in different systems. The Ayurvedic texts refer to 1400 plants, Unani texts to 342, the Siddha system to 328. Homeopathy uses 570, of which approximately 100 are Indian

[5] Vandana Shiva, "Patents: Myths & Reality", Penguin Books, 2001, New Delhi, Page 52.

plants.[6] Traditional knowledge has the capacity and potentiality to give commercial benefits by providing leads for development of useful products and processes. These valuable leads save time for tireless and long research, energy, intellectual exercise, study and huge investment. This immensely helps the researchers in the modern pharmaceutical research laboratories to get the know-how for developing new products, new processes or new use of existing products. The modern manufacturing industries can commercially exploit the traditional knowledge based products using new modern technology. "It is possible today to bring out new products or find out new use of existing products based on traditional knowledge utilizing the technological developments in the field of biotechnology. This is proved beyond doubt particularly in the field of medicines[7], agriculture etc. "Particularly in the post TRIPs era, there has been the growing interest in alternate ways of healing, etc. A growing number of scientists and policy makers are aware of the contribution that traditional knowledge can make to a more sustainable development, protection of biodiversity etc. Traditional knowledge is being lauded as alternative wisdom relevant to a society which is increasingly confronting the limits of its science. That western science alone provides biological and ecological insights is no longer accepted unequivocally. As Berks puts it, TK is being regarded as an alternative collective wisdom relevant to a variety of matters at a time when existing norms, values and laws are called in question. There is thus felt a pressing need to access this wealth so that the world at large can benefit from their wisdom and the resources. This initiated the intensified search for commercially profitable substances and resources among the ecosystems of indigenous people, in part compelled by the limits of the western medical science."[8]

As medicinal plants are so important, there are laws also to deal with them, to protect the rights over them at the national level. Whether the laws are fair or have appropriate and sufficient safeguard are very important issues, to be discussed later on. Medicinal plants and related traditional knowledge can also be subject matters of some other important things i.e. intellectual property. The Patents Act 1970 is one such- a comprehensive law so as to ensure more effectively that patent rights are not worked to the detriment of the consumer or to the prejudice of trade or the industrial development of the country keeping in mind the WTO obligations and commitments. The another one is The Biological Diversity Act 2002- a law to provide for conservation of Biological Diversity, sustainable use of its components and fair and

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[6] Ibid, 52.

[7] Michael J. Huft, "Indigenous People and Drug Discovery Research: A Question of Intellectual Property Rights", *North Western University Law Review"*, Vol.89, 1678 (1995), referred by Prof. N.S.Gopalakrishnan in his research paper which was presented in the WIPO Symposium on Teaching Intellectual Property held at Peking University, Beijing, June 1999.

[8] Rajshree Chandra, 'Knowledge as Property' in "Indigenous Knowledge Rights: Neem Patent Claims," Oxford University Press, New Delhi, 2010, Page-280.

equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto.

At the international level also there are some mechanisms for protection of medicinal plants. There are recommendations of Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore established by WIPO. [9] The sole purpose of WIPO is the maintenance and further development of the respect of intellectual property throughout the world. There are also the guidelines of the Convention on Biological Diversity.[10] 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. "The objectives of this convention, to be pursued in accordance with its relevant provisions, are the conservation of the biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by a appropriate funding."[11] More recently there are WTO obligations-Trade Related Intellectual Properties (TRIPS).[12] According to the WTO-TRIPS it is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. When there are trade disputes over intellectual property rights, the WTO's dispute settlement system is now available. The three major components of TRIPS are standards, enforcement, and dispute settlements. WTO is there to implement all national systems of intellectual property rights following an agreed set of minimum standards. "The medicinal plants have huge potentialities to cure ailments or to enhance immunity power so that human beings can have disease free healthy lives as was mentioned earlier. Some of the medicinal properties are already known and used either documented or non-documented. Basing on that information with the aid of modern science and technology, researchers have come up with herbal medicines in new forms or in traditional forms. Here are some of the examples in recent times. Experts in Ayurveda claim to have come up with medicines which can make life more comfortable for suffering from HIV/AIDS, cancer and several physical deformities.

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[9] WIPO is a specialized agency of the United Nations of Organizations. With a history dating back to 1883, it is the international body that oversees all intellectual property concerns.

[10] The first international agreement addressing rights to biological materials were the CBD (CONVENTION ON BIOLOGICAL DIVERSITY), adopted in 1992 which recognizes the rights of the originators and holders of traditional knowledge. The CBD was adopted at the 1992 Earth Summit in Rio de Janeiro.

[11] ARTICLE 1, OBJECTIVES, CBD,

[12] The agreement on TRIPS (Trade-Related Intellectual Property) went into effect January 1, 1995.

The Central Council for Research in Ayurveda and Siddha, the apex body that oversees research in Ayurvedic medicine, has developed drugs. The council has also begun clinical trials in different hospitals across the country. Director General of CCRSA, G.S.Lavekar said, "The traditional system in association with modern technology can do wonders in medical science. The age-old practice has been adopted by developing countries and our medicines are in much demand abroad. Diseases such as HIV/AIDS, cancer and mental illness may not be totally cured but the drugs can definitely improve the standard of life of the patients." Mr. Lavekar said that they have the credit of obtaining as many as 22 patents including one international patent right on drugs. "After vigorous clinical trials, seven drugs developed by the council are in the market while seven others are on the pipeline. These include one for HIV/AIDS, cancer, psoriasis and disabled persons," he added. For cancer treatment, the council has developed QUOL2C, which aims to increase the quality of life for those undergoing chemo and radio therapy. Clinical trial for the drug is conducted in four major hospitals including St John Medical College and Hospital in Bangalore, AIIMS-New Delhi and Tata Institute of Cancer, Mumbai. Similarly, QOL2A, a medicine for HIV infected and AIDS patients, has been launched for multi-centric clinical trials. "We developed this medicine in association with Indian Council of Medical research's two frontal organisations National AIDS Research Institute and National Institute of Virology" he said. Ayush-Manas, a medicine for mentally disabled people is being tested in Ram Manohar Lohia Hospital in New Delhi and NIMHANS in Bangalore. The council has also developed Triple 7 oilfor cure of psoriasis, a chronic skin disease, Ayush-64 for treatment of malaria, Balgutti-a tonic for children. The council is also working on different metabolic diseases such as hyper-tension, stress, anxiety, fatigue and others.[13]

Moreover, new and modern researches on those Indian medicinal plants are shown that those plants with their medicinal properties can cure some other diseases which were not known before. Here are some of the examples of these kinds of research outcomes:

"(A) Karela or bitter gourd has now been found to be a giant slayer of breast cancer cells. Scientists from Saint Louis University have for the first time found that an extract from bitter gourd not only killed human breast cancer cells but also prevented from multiplying. Karela has been known to be highly rich in all essential minerals and vitamins, including vitamin A, B1, B2 and C besides iron. Till now, it was known to be highly beneficial about diabetes, high blood pressure, heartburn, cholesterol levels and ulcers." Our result is encouraging. We have shown that bitter gourd extract significantly induced death in breast cancer cells and decreased their growth and spread," said Prof Ratna Ray, who published her findings in the latest issue of the medical journal "Cancer Research" She conducted research using human breast

[13] "Ayurvedic 'Salve' for Cancer, AIDS Patients" as reported in Times of India, 9th July, 2009.

cancer cells in vitro or in a controlled lab setting. The next step, she says is to test the extract in an animal model to see if it plays a role delaying the growth or killing of breast cancer cells. If those results are positive, human trials could follow. This finding comes as a special interest for women in India. While breast cancer cases have started to surge in the country, the karela is a commonly available that does not cost much. "Cancer prevention by the use of naturally occurring dietary substances is considered a practical approach to reduce the ever-increasing incidence of cancer. Studying a high risk breast cancer population where bitter gourd is taken as a dietary product will be an important area of future research." Ray said."[14]

(B) The root of the mulethi-licorice is used to treat sore throat, ulcers and eczema. Now research suggests that it may have a greater use-preventing the growth of cancer of the colon, the last section of the digestive system. Scientists have found that the compound that imparts the sweet taste to licorice, Glycyrrhyzic Acid, prevents cancerous growth in the colon. Studies have found different compounds of licorice effective against cancer of the skin, prostrate and stomach but the mechanism of the action was not known. The colon cancer is one of the five deadliest forms of the disease in Western countries, though its incidence in India is low. The only way to reduce colon cancer deaths is to prevent the growth of cancer cells. But the few drugs that can do this have severe side effects. Aspirin and Ibuprofen are used in colon cancer treatment. They control the growth of cancer cells by suppressing the enzyme hydroxysteroid dehydrogenase type 2, found in the colon and kidneys. This in-turn blocks the activity of another enzyme, cyclooxygenase (cox-2). Controlling cox-2 by suppressing the enzyme prevented the development of cancerous polyps-bud shaped tissues. These cannot be used for long periods as they damage the organs like the heart and stomach. Using the extract of the licorice-Glycyrrhiza Glabra is a safer way of suppression. The enzyme is present in high amounts only in the kidney and the colon and blocking its production with Glycyrrhizic Acid affents only these two organs. On the other hand other cox-2 inhibitors affect other organs too. In their commentary accompanying the study, Paul M Stewart, University of Birmingham, London and Stephen m Prescott, Oklahoma medical Research Foundation, USA said, "If the findings are confirmed, locally acting inhibitors may be the way forward in colon cancer treatment."[15]

Finding this huge potentiality in these medicinal in giving huge profits without doing less efforts, less investment, study and research and realising that this traditional knowledge of the Indians is legally unprotected and vulnerable at the national and international level, individuals and small and big companies round the world including India, have jumped into this field and started manufacturing the herbal

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[14] Karela may be giant cancer slayer, shows US study, published in Times of India, 27th February, 2010.

[15] Journal of Clinical Investigation, 23rd March, 2009 as published in The Statesman, 29th April, 2009.

medicines and selling them also in national and international market. In the recent past, there have been several cases of biopiracy of traditional knowledge of medicinal plants of India, by the foreign companies, supported by their respective countries through legal process. Now the question is what is biopiracy? According to Dr. Vandana Shiva, "Biopiracy refers to the use of intellectual property systems to legitimise the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized countries. Patent claims over biodiversity and indigenous knowledge that are based on the innovation, creativity and genius of the people of the Third World are acts of biopiracy. It refers to the collection, study and commercialization of biological and genetic resources without the free and prior informed consent of source communities and countries, and the application of intellectual property rights on these resources in their favour. Since a 'patent' is given for invention, a biopiracy patent denies the innovation embodied in the indigenous knowledge. Biopiracy occurs because of the inadequacy of western patent systems and the inherent western bias against other cultures. Western patent systems were designed for import monopolies, not for screening all knowledge systems to exclude existing innovations and establish prior art cultures. Western culture has also suffered from the 'Columban Blunder" of the right to plunder by treating other people, their rights, and their knowledge as non-existent. *Terra nullius* has its contemporary equivalent in 'Bio-Nullius'- treating biodiversity knowledge as empty of prior creativity and prior rights, and hence available for 'ownership' through the claim to 'invention".[16]

As it was earlier mentioned that traditional knowledge is of two type's i.e. traditional knowledge of a particular community of different types and the traditional knowledge of the society in general. Dr V.K. Gupta, Director, CSIR, observes about the former: "Traditional knowledge (TK) is integral to the identity of most local communities. It is a key constituent of a community's social and physical environment and, as such, its preservation is of paramount importance. Attempts to exploit TK for industrial or commercial benefit can lead to its misappropriation and can prejudice the interests of its rightful custodians. In the face of such risks, there is a need to develop ways and means to protect and nurture TK for sustainable development that are in line with the interests of TK holders. The preservation, protection and promotion of the TK-based innovations and practices of local communities are particularly important for developing countries. Their rich endowment of TK and biodiversity plays a critical role in their health care, food security, culture, religion, identity, environment, trade and development. Yet, this valuable asset is under threat in many parts of the world. There are concerns that this knowledge is being used and patented by third parties without the prior informed consent of TK holders and that few, if any, of the derived benefits are shared with the communities in which this knowledge originated and exists. Such concerns have pushed TK to the forefront of the international agenda,

[16] Vandana Shiva, "Patents: Myths & Reality", Penguin Books, 2001, New Delhi, Page 49.

triggering lively debate about ways to preserve, protect, further develop and sustainably use TK."[17]

WIPO is really concerned for the preservation and protection of traditional knowledge and to stop its misappropriation and bio-piracy. "The call for protection of TK against misuse or misappropriation raises deep policy questions and practical challenges alike. The changing social environment, and the sense of historical dislocation, that currently affect many communities may actually strengthen resolve to safeguard TK for the benefit of future generations. Just as the technological value of TK is increasingly recognized and its potential realized, the challenge is to ensure that the intellectual and cultural contribution of traditional communities is appropriately recognized. This means taking greater account of the needs and expectations of TK holding communities concerning the intellectual property system. Its traditional qualities and frequent close linkage with the natural environment mean that TK can form the basis of a sustainable and appropriate tool for locally-based development. It also provides a potential avenue for developing countries, particularly least-developed countries, to benefit from the knowledge economy.'[18]

Here are some of the examples of bio-piracy of Indian traditional knowledge in other countries of the world. A. Ginger is patented to treat obesity. However it is found that in a Siddha preparation, extracts of ginger-root are used in a treatment for obesity. B. Citrus-peel extract is patented to treat skin disorders and injuries. It is recorded in Ayurvedic texts as a key ingredient to treat skin diseases. C. Phyllanthus-amarus (Himalayan stem herb) is patented "for the inhibition of the replication of a nucleosidic inhibitor resistant retrovirus and/or a non-nucleoside inhibitor-resistant retrovirus, wherein said retrovirus is an HIV". Indian traditional texts show the drug is used for immuno-supressive emaciating diseases. D. Brassica-rapa (mustard) is patented to normalize bowel function or for the prevention of colonic cancer. Unani has for years prescribed it for stomach ailments.[19] Researchers found that in Europe one company had patented an Indian creeping plant-Brahmi-Bacopa Monnieri for memory enhancer. F. Another patent was awarded for Aloe Vera for its use as a mouth ulcer treatment.[20] These are not the ends. There are patents on Kumari-(Aloe

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[17] Dr V.K.Gupta on "Protecting Indian Traditional Knowledge from Biopiracy". Available at http://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/pdf/tkdl_gupta.pdf. Visited on 12th January 2011, at 11.30 AM.

[18] INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE, Booklet No-2. This is one of the series of booklets dealing with intellectual property and genetic resources, traditional knowledge and traditional cultural expressions/folklore. Available at http://www.wipo.int/freepublications/en/tk/920/wipo_pub_920.pdf. Visited on 12th January, 2011, at 11. 45 AM.

[19] "India protects remedies from foreign patents" as reported in Times of India,27th February, 2009.

[20] Ibid.

Barbadenis), Amaltas- (Cassia Fistula), Kala Jeera- (Cuminum Cyminum), Harad- (Terminalia Chebula), Aswagandha- (Withania Somnifera), Kali Marich- (Piper Nigrum), Erand- (Ricinus communis), Amla- (Phyllanthus Emblica), Jar Amla- (Phyllanthus Amarus), Anar-(Punica Granatum), Dudhi- (Euphoria Hirta), Gulmendhi, Bagbherenda, Karela- (Momordica Charantia), Rangoon-Ki-Bel, Shallaki- (Boswellia Serrato), Garden Balsam- (Impatiens Balsamina), Jangli Erand-, (Jatropha Curcus) Mustard- (Brassica Rapa), Bhu Amla- (Hillanthus Niruri), Rangoon Creeper- (Quisqualis Indica), Arjun- (Terminalia Arjuna), Guruchi- (Tinospora Cordifolia), Vilayeti Shisham- (Sapium Sebiferum), Chhotagokhuru- (Tribulus Terrestris), Ritha- (Sapindus Mukorossi) Ber- (Zizyphus Jujuba), Adarakha- (Zinziber Officinale), Latjira- (Achyranthes Aspera), Dhaya- (Woodfordia Floribunda), Khatal- (Artocarpus Integrifolia), Black Nightshade- (Solonum Nigrum), Neem- (Azadirachta Indica) etc. This has become a serious headache for India to revoke these already granted patents all over the world-USA, UK, JAPAN, GERMANY so on and so forth. Even if, it can be revoked, how to get back the huge unauthorised and illegal profit, it is also to be looked into. "The scientists in Delhi noticed an alarming trend-the bio-prospecting of natural remedies by companies abroad. After trawling through the records of the global trademark offices, officials found 5,000 patents had been issued-at a cost of at least 150 million dollars for 'medical plants and traditional systems'. More than 2,000 of these belong to the Indian systems of medicine."[21] "The USPTO had already granted fourteen patents on mustard, seven on castor, four on amla, three each for cassia and kumara and two for kerela, black cumin, jatropha and black nightshade for their various properties, says the report by Afsar H. Jafri, Deputy Director of RFSTE."[22] Apart from the patents or other types of business rights on the documented medicinal plants, here are thousands and thousands of medicinal plants in different remotest parts of India, where villagers or tribal communities have the golden treasures of traditional knowledge. Though there is no written document, as these are all oral descriptions, these are more prone to be bio-pirated. Because this public use of this traditional herbal medicine has also not been documented and the process also has not been initiated. There might be more patents or different types of commercial exploitation of this knowledge, not been traced so far.

In future there could be cases of biopiracy of traditional knowledge on medicinal plants by national or multi-national companies in India or even foreign countries. Though, recently, patents on turmeric and neem were revoked by USPTO and EPO respectively after a well fought legal battle by Indians. Three patents US Patent No. 5,124,349 for 'Storage Stable Azadirachtin Formulation', European Patent No. 0436257 for 'Hydrophobic Extracted Neem Oil' and US Patent No. 5,401,504 'use of turmeric in wound healing'are significant cases because on them converged the symbolic fight against appropriation of traditional knowledge made possible by TRIPs

[21] Guardian newspapers Limited, 2009.

[22] Afsar H. Jafri, People's Commission on Biodiversity, Indigenous Knowledge and People's Rights: A Report, New Delhi: RFSTE.

laws. They became the focal point of the assertion of the right of the Indians over their knowledge. The patent battles came to question the conceptual and moral premises of intellectual property rights which assert the primacy of one kind of knowledge right over the other. Though later on, the patents on neem and turmeric were revoked, that does not necessarily mean traditional knowledge on them gets protection. It would get protection without any utility or usefulness.There are thousands and thousands of patents on Amla, Jar Amla, Anar, Salai, Dudhi, Gulmendhi, Bagbherenda, Karela, Rangoon-ki-bel, Erand, Vilayetishisham, and Chamkurastill are still there, indifferent countries. This is because the right over this special type of intellectual property is not well protected in some important areas and remains unrecognized in some major areas.The implications of bio-piracy are economic, legal, constitutional and ethical. As this traditional knowledge of medicinal plants can be exploited economically by national and multinational corporations without much expenditure for research works to get the idea or lead, original holders of the traditional knowledge as well as country of origin get no share of profits from the multi-billion dollar business. The original holders do not get any recognition for preserving, adapting, developing the resources and knowledge on it. India's battle to protect traditional treatments is rooted in the belief that the developing world's rich biodiversity is a potential treasure trove of starting material for new drugs and crops. Dr. V. K. Gupta again says that "if you can take a natural remedy and isolate the active ingredient then you just need drug trials and the marketing traditional medicine could herald a new age of cheap drugs".[23] Hence, it might result violation of statutory right in different ways and is the root cause of different problems for which, the country would be losing economically entire profits would go in other countries.

One of the main concerns of India is that "this in turn led to the race by the scientific community particularly from the corporate R&D units for identifying and collecting materials and information from the existing products based on traditional knowledge. The result is the illegal transfer of the knowledge base from the communities in the developing countries to the corporate houses of the developed countries for scientific analysis and creation of new products for global exploitation[24]. It is the lack of technological capabilities, scarcity of capital, political inertia etc., existing in the developing countries that seem responsible for the erosion of this knowledge base. The opening up of the markets of these developing countries through the process of globalization enable the corporate houses to sell these new products for huge profits and in some cases substantially affecting the production and sale of the existing products based on traditional knowledge. The net result is not only the destruction of the traditional knowledge base but also the creation of a perpetual technological dependence. The challenges India face in this context are on the one hand to prevent

[23] Times of India, 27th February, 2009.

[24] See Darrell A. Posey, "Protecting Peoples Bio: Indigenous Rights to Diversity", 38 *Environment* 6 (1996); Edger J. Asebey & Jill D. Kempenaar, "Biodiversity Prospecting: Fulfilling the mandate of the Biodiversity Convention", 28 *Vanderbilt Journal of Transnational Law* 703 (1995).

the illegal transfer of the traditional knowledge base and on the other to develop appropriate measures including technological and industrial capabilities to exploit these resources for creating new products for global market.[25] There is threat of the extinction of some of the rare medicinal plants of India. The concern was raised by D.N.Dutta, Director of North-East Business Finance Organization's Research and Development Centre in a seminar in February at Guwahati. He says that "a large number of medicinal plants of the region find way to international market and these are extracted from the forest sources most unscientifically by unscrupulous traders at very nominal price. Unless we stop this practice, we will lose some very rare species belonging to herbal medicinal group"[26]

Since the traditional knowledge, except those in secret use, are in the public domain as per the TRIPs based patent system, it has been considered as common property without any ownership. This enables any one to use it for further scientific analysis and bring out new products claiming patent protection depriving the custodians of this knowledge without any returns and in some cases go out of business and even from traditional occupation. The labour and efforts taken by the generations to keep this information alive and use it for social benefit is thus taken away without any recognition. 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 traditional knowledge. [27] This is absolutely true; there is no doubt about it. But this is not the whole part of the story. Some of the important matters are left. The fact remains that blame cannot be put only on the foreign multinational corporations and developed nations. Due to this legislative vacuum the transfer of traditional knowledge is also happening to the Indian big or small companies as well in the form of granting of patents based on TK without any such obligations to the custodians of knowledge-either indigenous community or larger society as a whole, which would be discussed in detail in subsequent chapter.

Obtaining of patents where there is existing knowledge (traditional knowledge) either by way of suppression of facts or by not recognising them as prior art in that subject is the worst form of bio-piracy in the world. Apart from these forms of umpteen number of bio-piracy incidents of Indian traditional knowledge all over the world, there are also some other forms of misappropriation of Indian traditional knowledge in India and abroad. These are also posing challenges to the protection and utilisation of the knowledge in a rightful way of medicinal properties of the plants associated with

[25] Prof. N.S.Gopalakrishnan, "IMPACT OF PATENT SYSTEM ON TRADITIONAL KNOWLEDGE", Cochin University Law Review, 1998, P 219.
[26] Reported in Times of India, February 2011.
[27] Prof. N.S.Gopalakrishnan, "IMPACT OF PATENT SYSTEM ON TRADITIONAL KNOWLEDGE", Cochin University Law Review, 1998, P 219.

traditional knowledge in India. A number of medicinal plant based products (medicines) have come on the Indian market and have become one of the booming sectors, doing billion dollar business. Though various companies or trusts have not obtained patents for the manufacture and sell those medicinal plant based products (medicines) in national and international market, but as they are commercialising traditional knowledge for profit, first of all, they have not taken permission for using the knowledge from any national or provincial authority and any indigenous society so far (there is no authority as such at the national or provincial level); nor they are paying for the traditional knowledge. This is also one type of absence of protection of traditional knowledge of medicinal plants in India. It has become accessible for economic purpose. This is also as serious as bio-piracy incidents. Can it be called another form of bio-piracy? As a result, without having obtained patent, many Indian companies and trusts are doing business on traditional knowledge and for utilising this traditional knowledge, no benefit is going to the society. What they can do with patents, they are doing the same things without the patents.

This is not the end of the story of the plight of the medicinal plants and associated traditional knowledge in India. It is presumed that there is no effective, more specifically no protection of medicinal plants and related traditional knowledge. It is also true that there is no protection of the existing knowledge as per present intellectual property framework. Misappropriation of existing knowledge in different ways in India and abroad is one of the consequences of its vulnerability. Apart from this there is one more serious threat to the existing traditional knowledge and medicinal plants. It is due to the fact that so much of knowledge was lost in the past and is being lost day by day and would be lost in future. The holders of this traditional knowledge are not willing to disclose or do not disclose this knowledge for fear of losing it to the others and keep it secret in them. They disclose this knowledge only to their own descendants or their faithful disciples. In this way it goes on generations after generations. Sometimes lack of interest, sometimes lack of efficiency, sometimes lack of dedication and commitment to keep the knowledge alive, sometimes absence of takers of this knowledge, sometimes lack of understanding capacity and knowledge of those to whom it was transmitted, this traditional knowledge has been lost. This is a great loss to the society. If this goes on like this, this country would be losing this traditional knowledge in near future. There is one more serious threat to this traditional knowledge. So many species of medicinal plants have been lost from this world of biological diversity due to lack of sustainable preservation and conservation. Nowadays these plants are not seen. If steps are not taken immediately for the in-situ and ex-situ preservation and conservation of these endangered medicinal plants, just these would vanish one day. Modern research with clinical trials of the use of the medicinal plants based on traditional knowledge is also not happening to confirm the medicinal value either to prevent the disease or to cure the disease and enrich the existing level of knowledge or to find new knowledge. This is also a threat.

There would also be violation of sacrosanct fundamental rights of the holders of the traditional knowledge on medicinal plants as: A. Right to preserve culture, heritage and tradition guaranteed under Article 21. Supreme Court in Ramsharan Autyanuprasi vs. Union of India case says that "it is true that life in its expanded horizons includes all that gives meaning to a man's life including his tradition, culture and heritage".[28] Hence, right to protect and preserve traditional knowledge of medicinal plants is an integral part of right to life of Indians which carries with same basic nature and characteristics of life.

B. Right not to be discriminated ensured under Article 14 and C. Right to carry on business, trade etc., mandated by Article 19 of the Constitution of India. The State has the obligation to protect it under the Constitution of India. This right is enforceable against the state if due to state action either in national or international territory, it is denied except by the procedure established by law, which is fair, good, just and reasonable under Article 21. Under Article 14, there must be an intelligible differentia between the two classes (Indians and Non-Indians) and rational nexus between the object sought to be achieved and the basis of classification. In case of article 19 (g), it can not impose or prevent the state from making any law imposing reasonable restrictions on such right.

Most importantly, as the law is dealing with an important area of human activity which has international ramifications, apart from the validity of the law (because it violates some other laws-national or international), there is a substantial question of fairness of the law itself also. Not only, the fairness of the national laws in IPR protection in different countries are to be achieved, but also the fairness of IPR protection in the international law which mandates member countries to conform to it. If the international IPR jurisprudence is not sound enough to show the ideal way and the effective mechanism for the harmonisation, really it would be disastrous. There are also serious concerns to preserve, protect and fairly utilise the traditional knowledge on medicinal plants of India. And the laws which are there to give direct or indirect protection at the national level are insufficient and unfair. Actually there is no law specially to protect the traditional knowledge of medicinal plants or genetic resources in India and there is no national policy.

Moreover, what is the use of it if the knowledge on medicinal plants is not utilised for the betterment of the original holders of the traditional knowledge? Or if is not used for the betterment of the society? Or it is not commercialised for the economic development of the country? Before that is done, traditional knowledge of medicinal plants and genetic resources must have a very positive and comprehensive intellectual property protection. The question is pertinent because the concept of knowledge society is evolving nowadays. Only knowledge can bring development, transformation, change, and modernisation. Revoking patent is not the full solution.

[28] AIR 1989 SC. See also Maneka Gandhi vs. Union of India, AIR 1979 SC.

What the holders would do if they could not utilise the knowledge fairly for their betterment? The appropriate solution lies in the fact that traditional knowledge associated with medicinal plants must get a new type of effective protection through which the knowledge can be utilised for economic benefits of the society and the country without anyway getting misappropriated. Obviously present legal framework of intellectual property laws is lacking in that direction and dimension.

STATEMENT OF THE PROBLEM

The present research work wants to critically analyse the national and international legal framework of Intellectual Property Rights with a specific objective to highlight India's weakness and strength to protect the traditional knowledge of medicinal plants. This research work is also an attempt to recommend a model legal framework so that India can take the advantage and meet the challenges for the protection of its own century old unique traditional knowledge of medicinal plants, for the benefit of the beholders by stopping unfair and legally sanctioned bio-piracy.

SIGNIFANCE OF THE STUDY

In the emerging world order where intellectual knowledge and right is protected by the boundaries of intellectual property rights, indigenous knowledge is not yet protected and is pirated by unscrupulous countries. This work has the potential for preventing such unscrupulous abuse.

OBJECIVE OF THE STUDY

The objective of the study is to propose a legal framework to prevent piracy and abuse of indigenous knowledge relating medicinal plants and ensuring that in the event of transactions the benefit cascades upon the community that posses the knowledge.

HYPOTHESIS

Under Trade related aspects of Intellectual properties (TRIPS) exploitation of bio-diversity on medicinal plants and the available traditional knowledge over them is encouraged. However there is no mechanism for benefit sharing under the WTO schemes. The patent law has been so far proved ineffective and unfair in this regard. TRIPS and CBD are not mutually complimentary or supplementary. The existing IPR regime is inadequate to offer protection to traditional knowledge, particularly medicinal plants. The national and international laws also conflict. Moreover international laws are in conflict with each other. Though at the macro level, there is conformity between national laws of two countries, but at the micro level, there is no uniformity. These situations have affected the right of equality, right to trade and right to life of those communities (including the country) which possess the traditional knowledge. As, firstly, the present IPR system to protect traditional knowledge on medicinal plants is not fair, just, good and reasonable, and secondly, the legal

framework to protect traditional knowledge is not appropriate, a new type of PRO-TRIPS AGREEMENT is must to make an effective legal regime.

RESEARCH QUESTIONS

Traditional knowledge faces tremendous challenge in this globalization era. The protection of traditional knowledge raises several questions, mainly

A. What is the scientific analysis of medicinal plants- its biological properties and chemical components?
B. What should be jurisprudential theory for IPR protection?
C. What is the analysis of this problem from constitutional perspective?
D. As it has become the tradition, culture and heritage of these communities, is there any constitutional protection?
E. Is the state action violative of right to equality of the traditional knowledge holders, guaranteed by Article 14, Constitution of India which is the basic structure of the Constitution? Or, right to freedom of trade?
F. Is TRIPS Agreement aiding, encouraging and paving the way for the exploitation of biodiversity on medicinal plants from the traditional knowledge of some Indian communities (in the form of the foreigners obtaining based on Indian biological materials)?
G. What should be the solution where there is conflict between two international laws?
H. Are TRIPS agreement and the CBD mutually supportive or supplementary to each other resulting in systematic conflicts of objectives, systems of rights and obligations? This is because TRIPS imposes private intellectual property rights while CBD recognizes the collective rights of the local communities on the biological resources.
I. What would be the ways or methods of such protections- types and standards of protection-duration of such protection- nature and form of ideal protections?
J. How to ensure that economic benefit for Indian economy from IPR protection of traditional knowledge?
K. Is there any such mechanism for sharing of benefits arising out of the commercial exploitation of biological resources using such traditional knowledge in the WTO agreement?
L. As patents are granted in India with territorial applications only, due to this, effective mechanism to prevent the bio piracy from the traditional knowledge on medicinal plants, are ineffective at the international level in different countries. How much truth lies in it?
M. Is there any appropriate legal and institutional means under WTO regime for recognition of the rights of various communities on their traditional knowledge based on biological resources?

N. Is TRIPS agreement also lacking in the field IPR protection of bio-diversity while allowing patenting of genetic resources of bio-diversity from the traditional knowledge?

O. As protection of knowledge, innovations and practices associated with biological resources do not seem to fall in the conventional legal systems of IPR protection (individual rights), are conventional forms of IPRs inappropriate and inadequate to protect Indigenous knowledge being collective in nature?

P. Is there any conflict between national law and the international law over the IPR protection, because TRIPS provides minimum standards of protection, while WTO members are free to grant a higher level of protection under the national laws subject to certain conditions?

Q. What should be the future steps to have a strong and fair IPR protection of traditional knowledge?

R. What should be the contents and procedure of future IPR protection on traditional knowledge?

S. Is there any alternative and viable solution to this problem?

T. What should be strategy of India for future negotiations?

U. Why the initiative was successful to challenge and revoke the granting of patents to the foreign companies?

V. Is there scope of interpretation of TRIPs in a more favourable way to suit India's interest, because, there are provisions in the TRIPs agreement which can be taken as advantages?

W. What is the meaning of protection?

X. What is the scope of protection?

Y. What would be a model law to protect the medicinal plants and traditional knowledge?

Z. What would be the principles over which new law would be based?

CHAPTERISATION

INTRODUCTION

CHAPTER I deals with traditional knowledge digital library: a rich scientific heritage of India.

CHAPTER II deals with patents on medicinal properties of Indian plants associated with Indian traditional knowledge, in India and foreign countries.

CHAPTER III deals with misappropriation of traditional knowledge in India without obtaining patent.

CHAPTER IV deals with analytical study of the IPR law regime in U.S.A., U.K., Germany, Australia, Japan, India and some other countries for protection of traditional knowledge of medicinal plants.

CHAPTER V deals with international legal framework relating to traditional knowledge of medicine from biological resources.

CHAPTER VI deals with a case study of turmeric and neem patent revocation and thereafter.

CHAPTER VII deals with march to evolve a legal framework for the protection of traditional knowledge associated with medicinal plants.

CHAPTER VIII deals with medicinal plants of Cooch Behar

CHAPTER IX: CONCLUSION

LITERATURE SURVEY

Before undertaking this proposed work a literature survey was undertaken. It is found that there is not much work done in this area but optimal data is available, together with some very important scholarly articles and booklets. Basically the works are done by Dr. Vandana Shiva, Prof. N.S.Gopalakrishnan, Prof. R.A.Mashelkar and WIPO in the area of traditional knowledge vis-a-vis medicinal plants of India. Followings are the review of the literature i.e. chapters of the books, articles of journals and booklets are perused and reviewed for the purpose of this research work.

1. Biopiracy: The Plunder of Nature and Knowledge- Vandana Shiva[29]

A. In the introduction the author spoke about the evil of bio-piracy of India's traditional knowledge associated with medicinal plants by the foreign multinational corporations supported by their respective countries. The nomenclature of the introduction is "Piracy through Patents: The Second Coming of Columbus". She wrote that a more secular version of the same process of colonization continued through patents and intellectual property rights (IPRs). The Papal Bull, the Columbus Charter, has been replaced by the GATT and subsequently by GATT treaty i.e. WTO. The principle of effective occupation by Christian princes has been replaced by effective occupation by the transnational corporations supported by modern-day rulers. The vacancy of targeted lands has been replaced by the vacancy of targeted life forms and species manipulated by the new bio-technologies. The duty to incorporate savages into Christianity has been replaced by the duty to incorporate local and national economies into the global market place, and to incorporate non-Western systems of

[29] Dr. Vandana Shiva, "Biopiracy: The Plunder of Nature and Knowledge", Research Foundation for Science, Technology and Ecology, New Delhi, 1998.

knowledge into the reductionism of commercialised Western science and technology. The creation of property through the piracy of other country's wealth remained the same as five hundred years ago as she analysed the unfair trade and business policy of the Western countries dealing with the developing countries in the name of globalisation. On the justification of this sort of exploitation and misappropriation of the intellectual property of India in the form of bio-piracy, the author went back and rightly referred John Locke's treatise on property which effectually legitimised this process of theft and robbery during the enclosure movement in Europe. Locke says that only those who own the capital have the natural right to own natural resources, a right that supersedes the common rights of others with prior claims and capital is a source of freedom that at the same time denies the freedom to the land, forests, rivers and bio-diversity that capital claims as its own and to others whose rights are based on their labour. Hence returning private property to the common people is thus perceived as depriving the owner of the capital of their freedom. According to Vandana Shiva these European notion of property and piracy are the bases on which the IPR laws of the GATT and WTO have been framed. She is of the view that same logic is now used to appropriate bio-diversity from the original owners and innovators by defining their seeds, medicinal plants and medical knowledge as nature, as non-science and treating the tools of genetic engineering as the yardstick of 'improvement', by defining the commercialised Western science as the only science and all other knowledge systems as primitive. She opines that at the heart of Columbus's 'discovery' was the treatment of piracy as a natural right of the colonizer, necessary for the deliverance of the colonized. At the heart of the GATT treaty and its patent laws is the treatment of bio-piracy as a natural right of the Western corporations, necessary for the 'development' of Third world communities and bio-piracy is the Columbian 'discovery' after Columbus. Patents are still the means to protect this piracy of the wealth of non-Western people as a right of Western powers. Vandana Shiva concludes by sayings that through patents and genetic engineering, new colonies are being carved out. The land, the forests, the rivers, the oceans and the atmosphere have all been colonised, eroded and polluted. Capital has now to look for new colonies to invade and exploit for its further accumulation. These new colonies are the interior spaces of the bodies of women, plants and animals. Resistance to bio-piracy is a resistance to the ultimate colonisation of life itself-of the future of evolution as well as the future of non-Western traditions of relating to and knowing nature. It is a struggle to protect the freedom of diverse species to evolve. It is a struggle to protect the freedom of diverse cultures to evolve. It is a struggle to conserve both cultural and bio-logical diversity. In this introduction i.e. Piracy through Patents, the basic business policy or marketing strategy and exclusivity of attitude or mindset of the Western nations are highlighted dating back of the era of Columbus to historically trace out the root causes of bio-piracy in the form of patents of the medicinal properties of the plants associated with traditional knowledge not only of India but also of other countries in the world. This is also another form of intellectual colonisation of India and other bio-diversity rich countries which give rise to discrimination and deprivation of the colonised

B. Chapter one is on "Knowledge, Creativity and Intellectual Property Rights". While discussing about 'Intellectual Property Rights and the Destruction of Intellectual Diversity', she shows her reservation about the narrow limit of modern Western science which gets its reflection in IPRs: "Intellectual property rights are supposed to reward and provide recognition for intellectual creativity. Yet knowledge and creativity have been so narrowly defined in the context of IPRs that the creativity of nature and non-Western knowledge systems has been ignored. IPRs are theoretically property rights to products of the mind. People always innovate and create everywhere. If IPRs regimes reflected the diversity of knowledge traditions that account for creativity and innovation in different societies, they would necessarily be pluralistic-also reflecting intellectual modes of property systems and systems of rights-leading to an amazing richness of permutations and combinations." According to her, individual profit is not the only motivating factor for creativity and invention as TRIPS or modern IPR laws project it in this way. It is partially true. Social commitment and responsibility is another motivating factor for individual and collective creativity and invention, where individual profit does not matter. That is why, she says that "this interpretation of creativity as unleashed only when formal regimes of IPR protection are in place, is a total negation of creativity in nature as well as the creativity generated by non-profit motives in both industrial and non-industrial societies. It is a denial of the role of innovation in traditional cultures and in the public domain." Hence it is wrong to say that without IPR protection in country creativity, innovation, invention lies buried. On the issue of "Patents as a Block to Free Exchange" Vandana Shiva is also very much critical about the role of patent as the boosting factor for economic development of a country. She also has given some very good examples to substantiate her view. She strongly says that "A strong patent system has not been the main reason for economic development, even in industrially developed countries." She continues to say that "Patents are not necessary for developing a climate of invention and creativity. They are more important as instruments of market control. Indeed, existence of patents undermines the social creativity of the scientific community by stifling free exchange among scientists. Patents are the strongest form of IPR protection. Wherever patents have been associated with scientific research, the result has been closure of communication. While scientists have never been as open as popular mythology portrays, the threat to scientific communication posed by scientists working with commercial enterprises that seek patent protection is becoming a major cause for concern." She is deadly against the patent protection of creativity and invention. Her observation is that "The openness, the free exchange of ideas and information and the free exchange of materials and techniques have been critical to the creativity and productivity of the research community. By introducing secrecy to science, IPRs and the associated commercialisation and privatisation of knowledge will kill the scientific community, and hence, it's potential for creativity. IPRs exploit creativity while killing its very source." Her take on the subject is that it is the "Threats to the Tree of Knowledge". Through this process, the roots of the tree of scientific knowledge are being starved, even as they are being rapidly exploited and harvested for profits. As certain

disciplines and specialisations in science spin profits through commercialisation, other disciplines and streams are neglected, even though they are essential to the foundations of the knowledge system. As a result, IPRs lead to the skewing of research to targets of greater commercial interest only. According to Vandana Shiva "Once priorities shift from social need to potential return on investment, which is the main criterion for commercially guided research, entire streams of knowledge and learning will be forgotten and become extinct. While these diverse fields might not be commercially profitable, they are socially necessary." Hence the moment acquiring of useful and necessary knowledge are ignored and only concentration is on profitable things, the social conditions for the creation of intellectual diversity are destroyed. She describes it as the "enclosure of the intellectual commons".

C. Chapter Four is about Biodiversity and People's Knowledge. In the introduction of this chapter the author opined that the emergence of new intellectual property regimes, and new and accelerated potential for exploitation of biodiversity, created new conflicts over bio-diversity. On this issue of "Bio-Diversity: Whose Resources" she says that bio-diversity has always been exclusively a local common resource. This resource including the knowledge associated with the resources is common property of all the members of the society when social systems exist to use it on the principles of justice, equality, equity and sustainability which involve a combination of rights and responsibilities among users, a combination of utilisation and conservation. But as IPR is a protection of capital investment, there is a tendency for ownership of knowledge and the products and processes emerging from it, to move toward areas of capital concentration and away from poor people without capital. Knowledge and resources are therefore systematically alienated from the original custodians and donors, becoming monopoly of the transnational corporations. With this bio-diversity is converted from a local commons into an enclosed private property. This tendency of enclosure is being universalised through TRIPs and some interpretation of CBD. It is a conflict between private and common ownership, between global and local use. IPRs allows for the privatisation of bio-diversity and intellectual commons and the word 'bioprospecting' is to describe this new form of enclosure. After analysing the difference between non-Western medical systems and Western medical systems vis-a-vis IPRs, she points out two important historical tendencies surround the issue of knowledge. Firstly, there is a growing recognition that the Western paradigm of mechanistic reductionism is at the root of the ecological and health crises and that non-western systems of knowledge are better adapted to respect life. Secondly, when indigenous systems of knowledge could come in their own, TRIPs is reinforcing the monopoly of Western systems and devalue indigenous systems. On the issue of "Indigenous Knowledge and IPRs" Vandana Shiva observes that the patenting of products and processes derived from plants on the basis of indigenous knowledge has become a major issue of conflict in the IPR domain. The patenting of neem-Azadirachtica Indica is one such classic example. She fought very successfully the neem patent cancellation case before the EPO and got it cancelled by disproving the claim that there was non-obviousness in the claim. According to her, at the micro

level of the knowledge, knowledge may be involved in tinkering with technical process. The basis of patent claims to neem is illegal and invalid on two grounds. First, it claims nature's creativity and the creativity of other's cultures as its own. Second, in the case of neem, this leads to the false claims that the biopesticide property was created by the patentee. It treats petty tinkering as a source of creation, rather than acknowledging that specific species are the source of creation of specific properties and characteristics, and that communities are the source of knowledge that allows that property to be utilised. Moreover, the issue of value is very closely associated[30] with IPRs. In this case, the value is taken away from the source i.e. biological resources and indigenous knowledge is reduced to raw material. On the issue of Bioprospecting vs. People's Knowledge, she is against bioprospecting as it denies people's knowledge and supports that economy which is based on monocultures and non-sustainability. She says that "the challenge of bio- diversity conservation is to enlarge the scope of economics based on diversity and de-centralisation and shrink the scope of economies based on monoculture, monopolies and non-sustainability. While both kinds of economies use bio-diversity as an input, only economies based on diversity produce diversity."[31] Her opposition to bio-prospecting stems from her concern for the protection of traditional knowledge. According to her, "the metaphor of bio-prospecting hides the prior use, knowledge and rights associated with bio-diversity. Alternative economic systems disappear and the Western prospector is projected as the only source for medical uses of bio-diversity. With the disappearance of alternatives, monopolies in the form of intellectual property rights appear natural."[32] She continues to say that "When alternative and freely exchanged knowledge-such as the use of neem or medicinal plants-is eclipsed, corporations with IPR protection appear to the only source of biological pesticides or the cure for cancer, for example. Their exclusive claims to added value and monopoly rights to production are rendered legitimate in the absence of alternatives, which, even if kept alive, are recognised as illegitimate."[33] To sum up, it can be said that the concept of value adding in bio-prospecting negates the value of indigenous plants and knowledge and MNCs that prospect displace the economies of alternative values and knowledge systems to expand their markets for bio-pesticides, pharmaceuticals etc. After asking questions about the feasibility of patenting route to protect indigenous knowledge, her observation is very fundamental. She observes that "Protection of indigenous knowledge implies the continued availability and access to it by future generations in their practices of health care and agriculture. If the economic organisation that emerges on the basis of patents displaces the indigenous lifestyles and economic systems, indigenous knowledge is not being protected as a living heritage. Dominant economic system is at the root of the ecological crisis because it has failed to address the ecological value of natural resources, expanding the same economic system will

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[31] Ibid, Page 72.
[32] Ibid, Page 73.
[33] Ibid, Page 73.

not protect indigenous knowledge or bio-diversity."[34] Hence she advocates for an alternative economic paradigm that does not reduce all value to market prices and all human activity to trade and commerce. She talks about patents as the systems of protection for capital investment, without the ability to control the capital and neither do they protect people nor knowledge systems. Finally, she says about bio-prospecting that there is no space for respecting the rights of the people and communities who do not want the commons enclosed. Next, on the issue of "Recovery of the Biodiversity Commons" she advocates for a strong political and social movement to bring back the biodiversity to the common people from the hands of the MNCs-"The protection and recovery of the bio-diversity commons is, first and foremost, a political and social movement that recognizes the creativity intrinsic to the diversity of life-forms. It calls for common property regimes in the ownership and utilization of bio-diversity. Further, it works toward an intellectual commons- a public domain in which knowledge of bio-diversity's utility is not commodified."[35] She names it CIRs-Collective Intellectual Property Rights, which is very appropriate term. To protect CIRs, she talks about an effective sui-generis system- "A sui-generis system must effectively prevent the systematic exploitation of Third World biological resources and knowledge, while it maintains the free exchange of knowledge and resources."[36] This sui-generis system necessarily has to be based on 'bio-democracy'- the belief that all knowledge and production systems using biological organisms have equal validity. On the issue" of "Legalizing Bio-piracy", she says that TRIPs agreement is not the result of democratic negotiations between the larger public and commercial interests or between industrialised countries and the Third world. It is the imposition of values and interests by western transnational corporations on the diverse societies and cultures of the world resulting in legalising bio-piracy and commercial interests have displaced ethical, ecological and social concerns from the substance of the TRIPs agreement.

2. Patents: Myths and Reality: Vandana Shiva[37]

On the chapter of "Bio-Piracy" Vandana Shiva at first defines the term 'bio-piracy' According to her "Bio-piracy refers to the use of intellectual property systems to legitimise the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialised cultures. Patent claims over bio-diversity and indigenous knowledge that are based on the innovation, creativity and genius of the people of the Third World are acts of 'bio-piracy'. Since a 'patent' is given for invention, a bio-piracy patent denies the innovation embodied in indigenous knowledge." About the reason of bio-piracy, she is of the view that "Bio-piracy occurs because of the inadequacy of

[34] Ibid, Page 77.
[35] Ibid, Page 79.
[36] Ibid, Page 81.
[37] Dr. Vandana Shiva, "Patents: Myths and Reality", Penguin Books, New Delhi, 2001.

western patent systems and the inherent western bias against other cultures. Western patent systems were designed for import monopolies, not for screening all knowledge systems to exclude existing innovations and establish 'prior art' in other cultures. Western culture has also suffered from the 'Columban blunder' of the right to plunder by treating other people, their rights and their knowledge as non-existent. Terra nullius has its contemporary equivalent in "Bio-Nullius"-treating bio-diversity knowledge as empty of prior creativity and prior rights and hence available for 'ownership' through the claim to 'invention'. She comes down heavily on Western reductionist method of study and analysis. Reductionism basically isolates chemicals and genes from the biological resources. This isolation is considered as an act of invention and creation intellectually and materially. But the indigenous knowledge gives the information and the leads for useful traits in biological organisms. She says that "the appropriation of indigenous knowledge and of the uses of bio-diversity is not a creative act at either the intellectual level or at the material level. Intellectually, the innovation has already been done as part of indigenous knowledge systems. Materially, the traits and properties for which the patent has been claimed already exist in nature. Their isolation and separation cannot be claimed as creation. Treating translation and transfer of existing indigenous knowledge and isolation of useful traits of life forms as acts of 'creation' and 'invention' is rooted in the philosophical assumptions of the industrial society which defines non-Western cultures as inferior to the industrial west and perceives nature as inert and dead matter. The creativity of both nature and other cultures is negated and appropriation of that creativity is then interpreted as an act of creation." She is of the view that diversity of knowledge needs to be recognised and respected and pluralistic IPR regime needs to be evolved which would offer effective protection indigenous knowledge systems and practices. On the issue of "Stealing from the Pharmacy of the Poor" she elaborately discussed the bio-piracy incident of Indian medicinal plant-Phyllanthus niruri (Jar amla) to cure hepatitis. By isolating the application of Phyllanthus niruri for the treatment of one form of infective hepatitis only i.e. hepatitis B and treating this as a novel application, even though medicines derived from Phyllanthus niruri have been widely used all over India for treating all forms of hepatitis in traditional systems of medicine, scientists of Fox Chase Cancer Centre have falsely presented an act of bio-piracy as an act of invention before European Patent Office. Next on "Stealing Nature's Pesticide" she analysed in detail the most debated bio-piracy incident of Azadirachta indica-neem as bio-pesticide, where W.R.Grace obtained an EPO patent. W.R.Grace's justification for patent pivots on the claim that this modernised extraction process constitutes genuine invention. Although over 2000 years that neem-based bio-pesticides have been used in India and many complex processes have been developed to make them available for specific use of pest control. Hence it lacks novelty and inventiveness. About "Resolving Bio-piracy" Vandana Shiva sees bio-piracy and patenting of indigenous knowledge is a double theft because firstly it allows theft of creativity and innovation; secondly, the exclusive rights established by patents on stolen knowledge steal economic options of everyday survival on the basis of indigenous biodiversity and knowledge. IPR regime in the context of globalisation

becomes instruments of bio-piracy at three levels: 1. Resource piracy; 2. Intellectual and Cultural piracy; 3. Economic piracy. To stop this kind of bio-piracy, she advocates the changing the US and other IPR systems. She strongly says that "If a patent system which is supposed to reward inventiveness and creativity systematically rewards piracy, if a patent system fails to honestly apply the criteria of novelty and non-obviousness in the granting of patents related to indigenous knowledge, then the system is flawed and it needs to change." Next issue is "Bioprospecting as Legalised Bio-piracy". She opposes the present form of bio-prospecting and benefit-sharing formula and there are justified reasons in her approach. According to her, bio-prospecting in the present form is merely a sophisticated form of bio-piracy. There are two basic problems in it. Firstly, if knowledge already exists, a patent based on it is totally unjustified since it violates the principles of novelty and non-obviousness. Secondly, the appropriation of indigenous knowledge vital for medicine, its conversion into an exclusive right through patents and the establishment of an economic system in which people have to buy what they had produced for themselves in a system which denies benefits and creates impoverishment, not a process which promotes 'benefit sharing'. It actually leads to the enclosure of the biological and intellectual commons. When a community's bio-diversity knowledge is taken by a corporation for commercialisation protected by IPRs, some impacts are felt by the donor community. According to Vandana Shiva, these are 1.Free receiving but proprietary sales and prohibition of free exchange between individuals and communities leads to monopoly control over bio-diversity and knowledge; 2. As biodiversity gains commercial value globally i.e medicinal plant, leads to diversion of biological resource from meeting local needs to feeding non-local greed. 3. In case of over-exploitation, it can lead to extinction; 4. The local scarcity combined with IPRs on derived commodities eventually takes the resource and its products beyond the access of the donor communities etc. That is why, according to her, bio-prospecting paradigm needs to be examined in the context of equity, specifically its impacts on the donor community, the recipient communities and on bio-prospecting corporations. She concludes by saying that reclaiming the intellectual commons through asserting collective intellectual property rights represents the real model of equitable benefit sharing and outlawing bio-piracy and making patents based on the bio-piracy of indigenous knowledge illegal is necessary for guaranteeing equity and sustainability.

3.INTELLECTUAL PROPERTY RIGHTS AND THE THIRD WORLD: DR. R.A.MASHELKAR[38]

In Dr. R.A.Mashelkar's own language about the article "Issues of generation, protection and exploitation of intellectual property are increasing importance. The

[38] R.A.Mashelkar,"Intellectual Property Rights and the Third World", Vol.7,No.4, Journal of Intellectual Property Rights, July 2002, Pp 308-323.

new IP regimes will have wide ranging socio-economic, technological and political impact. As per the obligations under the Trade Related Intellectual Property Systems (TRIPS), all the members of WTO are supposed to implement national systems of intellectual property rights following an agreed set of minimum standards. However, there is an increasing feeling that harmonisation is demanded from those that are not equal, either economically or institutionally." In this backdrop, he discussed the major concerns of the third world countries about this process of harmonisation and the new challenges these countries are facing in diverse areas of intellectual property protection. He also suggested some measures which are to be taken and have been taken about the ways ahead. In this discussion and suggestion, the issue of protection of Indian traditional knowledge associating with medicinal plants comes naturally.

Dr. R.A. Mashelkar starts his article on "IPR & Third World Concerns" where he talks about the importance of 'knowledge economy vis-a-vis intellectual property right' in this twenty first century. "Twenty first century will be the century of knowledge, indeed the century of mind. Innovation is the key for the protection as well as processing of knowledge. A nation's ability to convert knowledge into wealth and social good through the process of innovation will determine its future. In this context, issues of generation, valuation, protection and exploitation of intellectual property are going to become critically important all round the world." But the issue is not simple as such. There is a need and increasing demand of new forms of intellectual property protection to deal with complexities linked to IP in traditional knowledge, community knowledge, access to IP related information as the author observes. He also stresses the need to have an ideal regime of IPR that strikes a balance between private incentives for innovators and the public interest of maximising access to the fruits of innovation. This balancing of the interest between the inventor and the society in an optimum way is very serious and important question. He is of the view that the battle today is between those countries which are not economically and institutionally equal. He is also of the view that as TRIPS is an agreement on a legal framework, its implications will be decided by resolving disputes. The power of the State parties is of great importance. The third world including India has a clear disadvantage here. Next issue he raises is "Traditional Knowledge Protection and Promotion." Over here, he equally recognises the contribution of informal innovators to enrich the existing knowledge likely to the formal system of innovation, though the latter system is generally considered and valued. India is such a country where formal and informal innovations, both have taken place significantly and these informal innovators have generated such a rich store of collective traditional knowledge in India. Then he points out some serious concerns about the collective traditional knowledge. "One of the concerns of the developing world is that the process of globalisation is threatening the appropriation of elements of the collective knowledge of societies into proprietary knowledge for the commercial point of view. And urgent action is needed to protect these knowledge systems through national policies and international understanding linked to IPR, while providing its development and proper use for the benefit of its holders." Then he

emphasises that need to have new models and new thinking on IP, to be envisioned to accomplish this. The present western model of IPR legal framework theoretically flawed and traditional knowledge associated with herbal medicine does not get any protection. Dr. Mashelkar is of the view that "the local communities or individuals do not have the knowledge or the means to safeguard their property in a system, which has its origin in a very different cultural values and attitudes." Moreover "the existing IPR systems are oriented around the concept of private ownership and individual innovation. They are at odds with indigenous cultures which emphasise collective creation and ownership of knowledge. There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use and that too without the fair sharing of benefits of the holders of this knowledge." He is also of the view that "it is only logical and in consonance with natural justice that they are given a greater say as a matter of right in all matters regarding the study, extraction and commercialisation of the bio-diversity. A policy that does not obstruct the advancement of knowledge and provides for valid and sustainable use and adequate intellectual property protection with just benefit sharing." He talks about two types of traditional knowledge protection. First type of protection is to exclude the unauthorised use by third parties. The second type of protection is to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities. While recognising the market-based IPRs, he also gives equal weightage and importance of non-market-based IPRs and sui generis IPRs which could be useful in developing models to protect traditional knowledge, innovations and practices. On "IPR & Traditional Medicine" part of the article, the author admits the fact that traditional medicine basically which come from medicinal plants associated with traditional knowledge, plays a crucial role in health care services of a vast majority of people in developing countries. Health care providers are turning to incorporate many of these traditional medicines into their commercial activities. "As traditional medicines are based on medicinal plants, the effort is on accessing them either directly or through the use of modern tools of breading and cultivation, including tissue culture, cell culture and transgenic technology, intellectual property issue linked to such endeavours remain unresolved" as Dr. Mashelkar points out. He also points out that "Protection of traditional medicine under IPRs raises two types of issues. Firstly, to what extent it is feasible to protect traditional medicine under existing IPR system. Certain aspects of traditional medicine may be covered by patents or other IPRs. There have also been many proposals to develop sui generis systems of protection. Such proposals are based on the logic that if innovators in the 'formal' system of innovation receive compensation through IPRs, holders of traditional knowledge should be similarly treated." According to him, one more concern is that the grant of patents on non-original innovations (particularly those linked to traditional medicines) which are based on what is already a part of the traditional knowledge of the developing world including India. In this context, he discusses the importance and role of Traditional Knowledge Digital Library in stopping the menace of bio-piracy of medicinal properties of the plants. "The TKDL on traditional medicinal plants and systems will lead to a

Traditional Knowledge Resource Classification. Linking this to internationally accepted International Patent Classification System will mean building the bridge between the knowledge contained in an old Sanskrit Shloka and the computer screen of a patent examiner in Washington. This will eliminate the problem of the grant of wrong patents since the Indian rights to that knowledge will be known to the examiner," as he sees the consequence of the functioning of TKDL in India. On "Bridging the Divide" part of this article the author stresses the need of bringing the divide between the developed and developing world of the third world countries which is the reason of bio-piracy, to a zero acceptance level. He has also given some examples of some laudable efforts taken by WIPO in this direction. Finally he says: "The industrial property systems were set up centuries ago for inanimate objects and that too in formal systems of innovation. The time has come to revisit them. The emerging challenge is to look at the systems that will deal with animate objects such as plants and animals and with informal systems of innovation. The standard intellectual property systems will certainly not suit such innovators and their innovations. Innovation is needed in the intellectual property system itself."

4.A. Protection of Traditional knowledge-Need for a Sui-Generis Law in India: Prof.N.S. Gopalakrishnan[39]

In the introductory remark, Prof N.S.Gopalakrishnan sets out the context to look at the international and national efforts in developing a jurisprudence and legal structure for protecting traditional knowledge. Firstly, The philosophy of the present intellectual property framework that consider the existing knowledge base in the public domain and the absence of any legal frame work to protect the valuable traditional knowledge facilitate the exploitation of them. Secondly, The new initiative to document and reveal this knowledge base particularly that were never the subject matter of documentation hitherto in the pretext of preventing patent protection made their position more vulnerable since the knowledge base that remained within the confines of community is slowly made available for plunder that too without their knowledge and consent. Thirdly, Demand for protection of traditional knowledge gained momentum at the international level in the wake of technological changes that took place towards the end of the last century. It is the ability of the new technology particularly biotechnology to churn out new products having high economic value in the global market by using traditional knowledge that spearheaded the demand for the protection of this knowledge base. Sudden chase for this knowledge base particularly based on genetic materials by global traders made the custodians of this knowledge base conscious of the economic potential of their knowledge.
On "International Initiatives – An overview" Prof. N.S.G discussed and critically analysed TRIPS-WTO, CBD, WIPO-UNO and UN Declaration on the Right of

[39] Prof. N.S.Gopalakrishnan, "Protection of Traditional knowledge-Need for a Sui-Generis Law in India", The Journal of World Intellectual Property, September 2002, Vol.5, No.5, Pp.725-742.

Indigenous People. He is of the view that "It is clear that there is a general agreement in the international community that there is need to recognize the traditional knowledge. It is also evident that wherever possible it must be identified with the community treating the members there of as the holders of such knowledge if it is confined to the community. It is the notion of collective enjoyment of property by the members of the community that is reflected in these norms. The concern is to recognize it, take measures to ensure that communities are involved in the preservation and development of it and proper benefits are given to them in case of commercial exploitation by others. But the method of achieving it is left to individual nations. There are no uniform norms regarding the protection of different types of traditional knowledge owned by local communities. The reason for this state of affairs is that the international community never had occasions to look at the protection of traditional knowledge in its entirety." It is evident from his analysis of the international legal framework that there is some scope for the traditional knowledge protection in it but the scope is very limited. Hence, these cannot offer effective and comprehensive protection of the traditional knowledge. The absence of uniform and enforceable and binding international norms clearly shows the vulnerability and lack of protection of the traditional knowledge associated with medicinal plants in the international arena.

On the issue of "Legislative Approach in India," Prof N.S.G analysed the various existing Indian IPR legislations (The Protection of Plant Varieties and Farmers' Right Act, The Geographical Indication of Goods (Registration and Protection) Act, The Patent Act and Biological Diversity Act) found flaws with these laws due to their ineffectiveness to protect traditional knowledge and felt the need for a comprehensive sui-generis law for that purpose. He says that facilitating scientific development and the commercialization of the new products based on traditional knowledge seems to be the clear agenda of these legislations and protection of traditional knowledge is just an incidental to this objective. These legislations address only traditional knowledge based on genetic materials and many other categories are left. Even the existing international obligations are not taken seriously by Parliament in protecting traditional knowledge. According to him these legislative provisions legalize the activities of the apostles of searching and documentation of traditional knowledge for commercial gains in the pretext of preventing patenting of traditional knowledge. This will facilitate them to go ahead with mass documentation of India's undocumented valuable traditional knowledge hither to customarily owned by the local and indigenous communities and trade on it without the benefits reaching the custodians of this knowledge. Very strongly he says that it is the failure of Parliament to appreciate the jurisprudential shift in protecting traditional knowledge and succumb to the pressure of industrial groups both Indian and foreign that resulted in the current scenario.

In the conclusion i.e Need for a Sui Generis Law, he felt the need to have a comprehensive and special legislation to protect the traditional knowledge. He

suggested some of the principle as useful guidelines for that purpose. These are: 1. All forms of traditional knowledge including folk science and technology must be included within the scope of the law. 2. The law must protect and preserve this valuable traditional knowledge of India available in the public domain from being commercially exploited without authorization. 3. The exclusive right to manage this knowledge base must be primarily with the representatives of the local and village communities along with representatives of the people, government, experts, etc., in the form of "Trusts". 4. Considering the diverse nature of this knowledge and the fact that a lot of knowledge had lost its community identity, the right of management must be vested with trusts and different level – from Community Trust to National Trust. 5. The legislation must aim at the local communities preserving the traditional knowledge/folklore and using the same for the social, cultural and economic growth of the communities by starting appropriate institutions for achieving the purpose. 6. The legislation must facilitate the interaction of traditional knowledge with the modern technological developments like biotechnology and digital technology so that the new knowledge developed can be adopted and used by the communities for their social, cultural and economic development. 7. Civil and Criminal remedies for unauthorized use of folklore for commercial exploitation.

B. TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System-Prof. N.S. Gopalakrishnan[40]

To protect traditional knowledge associated with genetic resources Indian Parliament took some positive and bold steps by amending the Patent Act. To prevent patenting of traditional knowledge in India section 3 says that traditional knowledge is not an invention. To make this a reality a new provision is added in the grounds of opposition and revocation regarding the prior art of traditional knowledge. Accordingly knowledge available with local and indigenous communities oral or otherwise with in India or elsewhere will be treated as prior art. Thus it is significant to note that oral knowledge of communities is recognized as valid for the purpose of considering prior art. This bold step is required to ensure that the vast undocumented knowledge of Indian local and indigenous communities is kept out of patent system.

Another amendment is regarding the disclosure. To find out whether traditional knowledge is included in the invention relating to generic resources it is made obligatory that the applicant must disclose the source and geographical origin of the biological material in the specification. It is clear that the obligation is to provide not only the details of the source from where the material is obtained but also the geographical origin. The information regarding the source will necessarily include the details of the person or institution from whom the material is obtained and the details of the information regarding the material. Even though it is not expressly stated that

[40] Prof.N.S.Gopalakrishnan, "TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System", European Intellectual Property Review, January 2005, Pp 1-18.

the details of the traditional knowledge associated with the material and its holder must be disclosed it is implied that this information must form part since one of the purposes of disclosure in the specification is to enable the patent office to find out the prior art and inventive step. This is evident from the fact that this requirement is part of the technical details to be included in the specification. To make this provision effective it is made clear that the patent application can be opposed or revoked if the information is not given or wrongly mentioned.

It is unfortunate to note that there is no provision in the Patent Act making it obligatory on the part of patent applicant for inventions based on traditional knowledge to take prior informed consent to use the traditional knowledge and share the benefits derived out of such use before filing a patent application. It is worth mentioning that the Biological Diversity Act, 2002 has a provision making it obligatory on the part of the patent applicant for an invention based on the genetic materials of Indian origin to take prior informed consent from the National Biodiversity Authority. This has to be obtained before the grant of patent. The failure to take PIC or satisfy the conditions stipulated in the PIC is actionable under the Act. But this has no impact on the grant of patent or enjoyment of the patent rights. There is no obligation under the Biodiversity Act or under the Patent Act to produce the PIC in the Patent Office before grant of patent nor is there a provision to oppose or revoke the patent on the ground of failure to produce the PIC or satisfy the conditions stated in the PIC. This makes the provision meaningless. Since India from the very beginning is arguing in the TRIPS Council that this obligation must be built into the TRIPS to prevent the conflict between TRIPS and CBD it is reasonable that we include this in our Act at the earliest.

In the context of facilitating patenting of biotech inventions in India there is an urgent need to make the Indian Patent Office equipped with necessary documentation and experts to examine these applications and ensure that India is not going to repeat the mistake USPTO has committed in case of 'turmeric' and 'basmathi' patents. As of now the patent examiners are not experts in traditional knowledge associated with genetic resources. It may not be possible for the Office to find such persons in all the fields. So it is necessary that the Indian Patent Office develop institutional links with institutions having documentation and experts in the field of TK. The Office must also develop elaborate guidelines to be followed in case of examining patent application linked to TK to find out prior art and inventive step. Only then we could effectively prevent the conversion of TK of local and indigenous communities into private property of a few modern scientists and corporations using biotechnology and patent law.

C. PROTECTION OF TRADITIONAL KNOWLEDGE - THE CHALLENGES: PROF. N.S.GOPALAKRISHNAN[41]

In the introduction Prof N.S. Gopalakrishnan says that there is an urgent need to set some international standards for the protection of traditional knowledge. Here he identifies some important issues about traditional knowledge which are to be addressed while doing that. He is of the view that protection of the traditional knowledge is one of the most contentious and complicated issues. The development of intellectual property and its jurisprudential justifications based on individual private property rights pushed the traditional knowledge outside the scope of the formal IP protection regime. Traditional knowledge is treated as existing knowledge in the public domain for free exploitation without any respect and sincerity for the efforts of these communities to preserve and promote it. The modern biotechnological development has become an instrument to utilise the traditional knowledge for the development of new products of commercial importance. The formal IP system does not give any scope the traditional knowledge holders to enjoy and share the benefits of the new commercial exploitation of their knowledge. The absence of international standards causes serious concerns for the protection of traditional knowledge.

Next on "Concept of Traditional Knowledge" the author tries to define traditional knowledge. According to him traditional knowledge is useful information that is passed on by the members of the society from generation to generation. The important feature of this knowledge base is the difficulty and impossibility to identify the person who has created or developed it. Some of these informations were documented and others remain undocumented and passed to the next generation orally. The custodians or the possessors of this traditional knowledge use it for the benefit of the community. They were also collectively owned. On "Commercial exploitation of Traditional Knowledge" he points out that the modern cultural industries as well as the manufacturing industries commercially exploit the traditional knowledge based products using new technology without the permission and sharing of profits with the communities. The development of new products enables the industries to get protection for these products from the formal intellectual property laws. About "Traditional Knowledge and formal IPR system" his analysis is based on the jurisprudential basis of formal IP framework. The concepts especially used to find out the items to be protected through the formal intellectual property system address only the scientific developments based on the western understanding of science. Similarly the insistence of the identity of the creator of the new knowledge for the purpose of affording protection also reflects the individual private property jurisprudence underlying the protection of intellectual property. These concepts kept the traditional knowledge and the products based on it outside the scope of formal intellectual

[41] Prof.N.S.Gopalakrishnan on "Protection of Traditional Knowledge-The Challenges". This paper was presented in the WIPO Symposium on Teaching Intellectual Property held at Peking University, Beijing, June 1999.

property system and treated it as knowledge in the public domain without owners for exploitation without authorization. Thus the knowledge base of the community remain without any legal protection where as the creators of new knowledge based on it using modern science were afforded protection by the formal system. The provisions in the TRIPs Agreement are a clear indication in this direction. This calls for a different jurisprudential approach for the protection of traditional knowledge. On "International norms for protection of Traditional Knowledge" he analysed various international declarations, agreements i.e. United Nations Draft Declarations on the Rights of Indigenous People-1994, Convention on Biological Diversity or Agreement on Trade Related Aspects of Intellectual Property Rights. He commented that the international community on different occasions made some weak attempts to protect traditional knowledge. At last he discussed "Protection of Traditional Knowledge in India". Over there he finds the utility of traditional knowledge: "TK has the potential of being translated into commercial benefits by providing leads for development of useful products and processes. The valuable leads provided by TK save time, money and investment of modern biotech industry into any research and product development".

On Indian legislation to give effect to Convention on Biological Diversity, he is of the view that the problem of bio-piracy may not be resolved with this alone. "There is a need to provide appropriate legal and institutional means for recognizing the rights of tribal communities on their TK based on biological resources at the international level. There is also a need to institute mechanisms for sharing of benefits arising out of the commercial exploitation of biological resources using such TK. This can be done by harmonizing the different approaches of the Convention of Biological Diversity on the one hand, and the TRIPS Agreement on the other, as the former recognizes sovereign rights of States over their biological resources and the latter treats intellectual property as a private right." He finds merit with Indian legal framework for patent which incorporates 'disclosure of the source of biological material" in the patent application as mandatory. It is a ground for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource of knowledge in the patent application, and anticipation of knowledge, oral or otherwise. In this regard, he supports the Indian proposal to WTO where the patent applicants are to disclose the source of origin of the biological material utilized in their invention under the TRIPS Agreement and to obtain prior informed consent of the country of origin. If this is done, it would enable institutional mechanisms of all countries to ensure sharing of benefits of such commercial utilization by the patent holders with the holders of the knowledge i.e. indigenous communities whose traditional knowledge is used. Lastly, he finds that Geographical Indication Act, 1999 may offer some kind of indirect protection to traditional knowledge. It is possible that the holders of the traditional knowledge in goods produced and sold using geographical indication can register and protect their traditional knowledge under this law.

D. IMPACT OF PATENT SYSTEM ON TRADITIONAL KNOWLEDGE: N. S. GOPALAKRISHNAN[42]

In the introduction, Prof. Gopalakrishnan talks about the most complex and socially sensitive challenge as India has to face in the field of intellectual property protection in the context of TRIPs agreement. It is the issue of granting patents to inventions based on the traditional knowledge of Indian origin as India is bound to protect inventions both product and process emerging from all over the world based on existing traditional knowledge that were not commercially exploited in the global market. The patent law is used to afford protection to the investments made and the corporate R&D units of the developed countries are racing for identifying and collecting materials and information from the existing traditional knowledge. One of the results is the illegal transfer of the knowledge from the communities of developing countries to the corporate houses of the developed countries for scientific analysis and creation of new products for global exploitation. It is the lack of technological capabilities, scarcity of capital, political inertia etc., existing in the developing countries, are responsible for the erosion and destruction of this knowledge base. Uphill tasks for India are to prevent the illegal transfer of the traditional knowledge base and to develop appropriate measures including technological and industrial capabilities to exploit these resources. On "Patenting of Traditional knowledge", at first he gives a definition of traditional knowledge and then categorises it into four types. According to him traditional knowledge is the information existing in the society which has been passed on by the previous generations. Four categories of traditional knowledge are as follows: 1. Information commonly known to the society with or without documentation and is in constant use by the people. 2. Information that is well documented and is available to the public for examination and use. 3. Information that is not documented or commonly known but known only to small groups of people and not revealed to others outside the group. 4. Information known only to individuals or members of the families and none else. Then he peruses the definition and exemption clause of patent under TRIPs agreement. He comes to the conclusion that it will put considerable limitation on countries like India for denying patent protection to new products based on traditional knowledge on the ground of public interest. He also says that from the analysis of the TRIPs provision it is clear that a product or process based on the traditional knowledge is patentable only if it is an invention i.e., new, involves inventive step and with industrial application, and not expressly exempted by the national legislation. On "Concept of Novelty and Traditional Knowledge" he discusses the elements of novelty to find out whether an invention based on traditional knowledge is novel.The concept of novelty presupposes that there should not be any prior knowledge of the invention by the public. The two requirements to find out whether an invention is disclosed or not are (a) prior

[42] Prof.N.S.Gopalakrishnan, "Impact of Patent on Traditional Knowledge", Cochin University Law Review, 1998, Pp.219-228.

publication and (b) prior use. The prior publication include (1) the publication of the information through the patent claims already filed before the authorities anywhere in the world or (2) the existence of the information in any publication or document available for public examination irrespective of whether any member of the public including the person claiming the invention has read it or not. The prior use is the use of the information in the course of the trade by a person or is within the common knowledge of the public or those involved in the trade. Thus it is only those informations in the form of a product or process not already in the public domain that is qualified for patent protection. "On an examination of the classification of the traditional knowledge, it is clear that in all most all cases the information is in the public domain. It is also not necessary that all these information are concerning a product or process. In the first case the novelty is lost in as much as the common public is aware of the invention and it is in use i.e., there is prior knowledge and prior use of the invention. In the second case the novelty is lost by prior publication since the invention is already documented and available to the public for examination irrespective of whether it is read by the public or not." In this context one can categorically argue that majority of the existing products and processes based on traditional knowledge will not satisfy the test of novelty. The lack of novelty will disqualify the products based on the knowledge to be treated as invention for the purpose of patent protection. About "Concept of Inventive step and Traditional Knowledge" he says that "requirement of inventive step is to demonstrate that the invention is the creation of the individual or individuals claiming monopoly. This is to ensure that substantial intellectual labour of the inventor is involved in the creation of the new invention. The quantum of application of independent thought, ingenuity and skill of the inventor is the matter of inquiry in this regard. This is achieved by asking whether the invention is obvious to a person skilled in the same field. The standard applied is that of a normally skilled but unimaginative person in the art at the relevant time." The traditional knowledge is passes on to the present generation by the previous generation. It is thus obvious that the present claimants have not contributed any independent thought, ingenuity or skill to establish a valid patent claim. Hence it is ample clear that traditional knowledge will not fulfil the requirements of patenting under TRIPs. Moreover, the traditional knowledge, except those in secret use, is in the public domain according to TRIPs, it has been considered as common property without any ownership. This enables any one to use it for further scientific analysis and bring out new products claiming patent protection depriving the custodians of this knowledge without any returns. The labour and efforts taken by the generations to keep this information alive and use it for social benefit is thus taken away without any recognition. Lastly, he advocates for a sui-generis law to protect traditional knowledge in India and emphasises India to acquire the technological and industrial capabilities to exploit traditional knowledge base after giving due share to the custodians of it, to take the advantage of the new patent system. "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 traditional knowledge. This is in clear violation of the basic human rights - cultural, social and economic - of these people. If one is really concerned about the rich traditions of this country not being looted again and the protection of human rights, such legislation is the desideratum."

E. INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE: BOOKLET NO. 2[43]

In the "Introduction", this booklet of WIPO talks about the significance of traditional knowledge, raises some concerns due to its misappropriation and suggests appropriate measures to prevent it. It says that the traditional knowledge of the indigenous and local communities is the key to a diverse and sustainable future of these communities and their intellectual and cultural vitality. One of the challenges posed by modern age is to find ways of strengthening and nurturing the roots of traditional knowledge. This is due to the reason that this knowledge is being misappropriated worldwide for huge commercial gains. Traditional knowledge should not be used by others inappropriately without their consent and arrangements for fair sharing of the benefits. There must be greater respect and recognition for their values, contributions and concerns of traditional knowledge holders. In the "Key Concepts" part, definitions and use of terms, challenges confronting TK holders and legal protection for TK are discussed.

The Booklet did not define 'traditional knowledge'. There are so many reasons for that. Firstly, the astonishing diversity of indigenous and local intellectual traditions and cultural heritage cannot be bundled together in to one single definition without losing the diversity that is its lifeblood. Secondly, it is not feasible or even desirable to find one form of international protection for traditional knowledge etc. Moreover, according to the Booklet, no form of legal protection system can replace the complex social and legal systems that sustain traditional knowledge within the original communities. It is only one form of protection i.e. the application of laws to prevent unauthorised or inappropriate use of traditional knowledge by third parties beyond the traditional circle and it is the IP form of protection. The basic question is-how can those qualities which make the knowledge traditional gain greater recognition and legal protection beyond the traditional circle, indeed worldwide, but in a way that remains appropriate, useful and beneficial for the holders of the knowledge. According to the Booklet, this traditional knowledge is dynamic in nature. It is not the old knowledge only. 'Traditional knowledge is being created every day, and evolves as individuals and communities respond to the challenges posed by their social environment. This contemporary aspect is further justification for legal protection.

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[43] This is one of a series of Booklets dealing with intellectual property and genetic resources, traditional knowledge. Available at http://www.wipo.int/freepublications/en/tk/920/wipo_pub_920.pdf. Visited on 12th January, 2011, at 11.45 PM.

This contemporary aspect is further justification for legal protection. It is not only desirable to develop a protection policy that documents and preserves TK created in the past, which may be on the brink of disappearance; it is also important to consider how to respect and sustain the development and dissemination of further TK that arises from continuing use of TK systems." On "Challenging Confronting TK Holders" this Booklet is of the view that due to some challenges the very survival of the knowledge is at stake. The challenges are external social and environmental pressures, migration, encroachment of modern lifestyles and disruption of traditional ways of life. These can all weaken the traditional means of maintaining or passing knowledge on to the future generations. Either through acculturation or diffusion, many traditional practices, associated beliefs and knowledge have been irretrievably lost. The Booklet mentions that the lack of respect and appreciation for such knowledge is one challenge. Another challenge is the commercial exploitation of their knowledge by others, which raises questions of legal protection of TK against misuse, the role of prior informed consent, and the need for equitable benefit-sharing. A further challenge is to address the international dimension of the protection of TK and benefit-sharing for associated genetic resources, while learning from existing national experiences. About "Kind of Legal Protection" the Booklet has explored some important points. These are as follows: 1. A comprehensive strategy for protecting TK should consider the community, national, regional and international dimensions; 2. Protection should reflect the aspirations and expectations of TK holders and should promote and respect for indigenous and customary practice, protocols and laws; 3. Economic aspects of development need to be addressed and the effective participation by the TK holders is also important in line with the principle of prior informed consent; 4. TK protection should also be affordable, understandable and accessible to TK holders. Holders of TK should be entitled to fair and equitable sharing of benefits arising from the use of their knowledge etc. Lastly, on "Forms of Protection" the Booklet talks about two forms of IP related protection. These are: 1. Positive protection: giving TK holders the right to take action or seek remedies against certain forms of misuse; 2. Defensive protection: safeguarding against illegitimate IP rights taken out by others over TK subject matter. Then the Booklet goes on to discuss the TK protection related important policy issues beyond the domain of IP. In 'Environment', these are United Nations Environment Programme, Convention on Biological Diversity and United Nations Convention to Combat Desertification. In 'Health' it is Primary Health Care Declaration of Alma Ata. In 'Trade and Development' it is Agreement on Trade Related Aspects of Intellectual Property Rights. In 'Food and Agriculture' these are International Understanding on Plant Genetic Resources and International Treaty on Plant Genetic Resources for Food and Agriculture. In 'Indigenous Rights' it is the Declaration on the Rights of Indigenous People etc.

Next issue of the Booklet is "Positive Protection – Recognition of IP Rights in TK". It says that as no single template or comprehensive "one-size-fits-all" solution is likely to suit all the national priorities and legal environments. Instead, effective protection may be found in a coordinated "menu" of different options for protection. This could

perhaps be underpinned by an internationally agreed set of common objectives and core principles that could form part of the international legal framework. The objectives include: 1. Recognition of value and promotion of respect for traditional knowledge systems; 2. Responsiveness to the actual needs of holders of TK; 3. Repression of misappropriation of TK and other unfair and inequitable uses; 4. Protection of tradition-based creativity and innovation; 5. Support of TK systems and empowerment of TK holders; 6. Promotion of equitable benefit-sharing from use of TK; 7. Promotion of the use of TK for a bottom-up approach to development etc.

On 'Use of existing intellectual property laws' it opines that the policy debate about TK and the IP system has underlined the limitations of existing IP laws in meeting all the needs and expectations of TK holders. Even then, existing IP laws can be successfully used against some forms of misuse and misappropriation of TK, through the laws of patents, trademarks, geographical indications, industrial designs, trade secrets etc. On 'Adaptations of existing IP through *sui generis* measures' it gives the idea of adaptations of existing intellectual property systems with examples of some countries to protect traditional knowledge and the need of the TK holders. On 'Use of *sui generis* exclusive rights' the Booklet says that as adaptations of existing IP rights systems also are not sufficient to cater to the holistic and unique character of TK subject matter, TK protection through sui-generis rights can be a better alternative. It also gives examples and explains the salient features of some of these sui-generis measures including the key issues of sui-generis measures. The key issues of sui-generis measures are: 1. What is the (policy) objective of the protection? 2. What subject matter should be protected? 3. What criteria should this subject matter meet to be protected? 4. Who are the beneficiaries of protection? 5. What are the rights? 6. How are the rights acquired? 7. How are the rights administered and enforced? 7. How are the rights lost or how do they expire? Lastly, on 'Other legal concepts for the protection of TK' it explains and discusses a broader range of legal concepts apart from the kind of exclusive rights used in most forms of IP law. These alternative concepts are 'prior informed consent', 'equitable benefit-sharing', 'unfair competition' and 'respect for customary laws and practices'.

On "Defensive Protection – Safeguarding against Illegitimate IP Rights over TK", the booklet discusses about the defensive protection. It says that "TK is protected "defensively" by steps that prevent third parties from obtaining or exercising invalid IP rights over the TK." Defensive protection has two aspects: 1. legal aspect: to ensure that the criteria defining relevant prior art apply to the TK, for example, this could mean ensuring that orally disclosed information must be taken into account and 2. practical aspect: to ensure that the TK is actually available to search authorities and patent examiners, and is readily accessible, for example, can ensure that it is indexed or classified, so that it is likely to be found in a search for relevant prior art. The booklet is of the view that defensive protection has some limitations, cannot solve the problem alone and then suggests a comprehensive approach. "Defensive protection can be valuable and effective in blocking illegitimate IP rights, but it does not stop others from actively using or exploiting TK. Some form of positive protection is needed to prevent unauthorized use." Hence, a comprehensive approach to protection

needs to consider positive and defensive protection as two sides of the same coin. On 'Amendment of existing WIPO administered patent systems' it briefly discusses the practical mechanisms for the defensive protection of TK which have been developed and implemented within countries and international organizations. In this regard, WIPO's work on defensive protection has included amendment of WIPO-administered systems and the development of practical capacity-building tools.
The "Conclusion" says: "The call for protection of TK against misuse or misappropriation raises deep policy questions and practical challenges alike. The changing social environment, and the sense of historical dislocation, that currently affect many communities may actually strengthen resolve to safeguard TK for the benefit of future generations. Just as the technological value of TK is increasingly recognized and its potential realized, the challenge is to ensure that the intellectual and cultural contribution of traditional communities is appropriately recognized. This means taking greater account of the needs and expectations of TK holding communities concerning the intellectual property system. Its traditional qualities and frequent close linkage with the natural environment mean that TK can form the basis of a sustainable and appropriate tool for locally-based development. It also provides a potential avenue for developing countries, particularly least-developed countries, to benefit from the knowledge economy. It requires respect for the values and concerns of traditional communities, as well as consideration of the full international policy and legal context, including a range of current international debates. Even new or expanded forms of IP protection would be inadequate to meet all the needs and expectations that have been voiced, but various forms of IP mechanism have been found to be practically useful. The current WIPO process aims at distilling the practical and policy lessons of a wide range of experience in many countries, with a view to building a shared policy perspective and effective practical tools. The WIPO work is framing the core principles that should underpin the protection of TK. This offers a potential foundation for international legal development in the form of precise policy and legislative options for enhanced protection of TK through adapted or expanded conventional IP systems, or through *sui generis* systems. This may in turn facilitate further development of an international consensus on the more detailed aspects of protection, as the lessons of practical experience in achieving these principles are better understood and shared. This should lead to strengthened linkages between the needs and interests of traditional communities, and the core public policy principles of the IP system."

The articles and booklets surveyed above, have been delved deeper into the problem of bio-piracy and the misappropriation of the traditional knowledge associated with medicinal plants and found the ineffectiveness and loopholes of the present national and international legal frameworks, had shown the consequences and offered various legal and non-legal solutions to the problem from different angles and perspectives. No doubt, these analyses bring out some astounding facts about the facts of misappropriation. But these analyses altogether touches some of the areas, do not touch all the issues related to this problem and some important areas are left out.

Moreover, some of the analyses are partial in nature. After discussing the causes, while suggesting some solutions for the protection of the traditional knowledge, these have not advised complete solutions. These are not comprehensive in nature. Take for example: (A.) The definition of traditional knowledge. All most all the research works define TK as the knowledge of the traditional communities. This cannot be so in India's context. There are traditional knowledges associated with medicinal plants in India which cannot be identified with any specific community, rather it is the knowledge of the whole society, where each and every community-linguistic, ethnic, religious, social have equal right. (B). Traditional knowledge is being misappropriated in different forms in India and in foreign countries. But these analyses have identified only IPR sector and foreign countries. But there are umpteen number of examples which clearly show that there are commercialisation of the traditional knowledge without having IPR right over it and India is a country where there is commercialisation of the traditional knowledge is occurring for which the country or the society is not getting any benefit. This aspect has not been discussed.(C). The concept of protection is narrowly analysed in these research works. Protection does not necessarily mean negative protection; it does not only mean taking measures to stop misappropriation of the knowledge by way of obtaining wrongful patents i.e. bio-piracy but there only these aspect has been emphasised. It also has so many positive aspects-preservation of the medicinal plants, augmentation, continuous and systematic research works etc, sustainable use are also important. But these are not focussed. (D). There is no discussion as to how to protect and preserve the huge undocumented traditional knowledge about herbal medicine, many of which are lost and going to be lost in near future.

Here lies the significance and importance of the present research work. The present research work attempts to make a comprehensive analysis of the problem by taking into account all the major areas with national and international experience, for example, there are other ways of commercial exploitation of traditional knowledge happening in India but was not attracted the notice of anyone or the definition of traditional knowledge etc. It also attempts to offer a viable and wide range of full protection mechanism-positive and negative, for the traditional knowledge of India about the medicinal properties of the plants, which was not envisaged and explored ever before.

METHODOLOGY OF THE RESEARCH

Basically, the research methodology is theoretical and empirical. The methodology in some of the chapters is theoretical when it follows the process of analysis of the national legislations and international agreements. This analysis includes descriptive and comparative methods. While doing that, the steps which have been followed are: **1.(A).** Selection of national legislations of India. **1.(B).** Collection of national legislations of some developed and developing countries. **1.(C).** Selection of international agreements. **1.(D).** Selection of international declarations; **2.(A).** Study of the Indian laws and the laws of other countries. **2.(B).** Study of the international agreements and international declarations. **3.(A).** Explanations of the national

legislations of India and some other countries. **3.(B).** Explanations of the provisions of the international agreements and other international declarations. **4.(A).** Analysis of the provisions of the Indian laws and the laws of other countries. **4.(B).** Critical analysis of the various provisions of the international agreements and international declarations. **5.** Conclusion and comment about the nature of those provisions in those agreements and legislations. **6.** Suggestions for the enactment of a model set of binding international or national legislations for the protection of traditional knowledge associated with medicinal plants. Before doing that firstly it follows the descriptive and then it follows the analytical method of construction and interpretation. Moreover, while interpreting and construing the various Articles and Sections of International Agreements and National Laws, it follows the golden rules and mischief rules, to find out the actual and intended meaning of all of them, with the objective to know the consequences of these agreements and legislations in national and international IPR field associated with traditional knowledge vis-a-vis medicinal plants of India.

The methodology in some of the chapters becomes empirical when it takes into account the secondary data i.e. USA, Indian and EPO patent documents or the documents about the various ayurvedic products of various Indian companies and trusts. The steps which are taken to do research in these areas are: **1.** Selection and collection of the above mentioned secondary data from the internet (most of the cases) and books. **2.** Study of those above mentioned secondary data to have a general and specific idea about those. **3.** Explanation of these above mentioned information of the data to give a general and specific idea about these. **4.** Critical analysis of these above mentioned secondary data by following the proper and appropriate tools and techniques to find out the relevant and necessary informations for the purpose of the research. **5.** Conclusion and comment on those above mentioned secondary data related to existing facts **6.** Suggestions for the future course of action to have a comprehensive policy and protection through national and international legislations legislation for the protection of traditional knowledge associated with medicinal plants.

For the purpose of collecting data about the medicinal plants of Cooch Behar, West Bengal, it relies on primary data. The data about the medicinal plants which are grown and used as herbal medicines, has been collected through conversation or discussion method.