CHAPTER I

INTRODUCTION

The rise of technology and industry may have distanced us superficially from nature, but it has not changed our reliance on the natural world. Most of what the human use and consume on a daily basis remains the product of multitudes of interactions within this immensely bio-diverse nature, and many of those interactions are imperilled\(^1\). Biodiversity forms the web of life of which the human beings are an integral part and upon which we so fully depend.

Biological diversity, or biodiversity, encompasses the variety of all life on earth. The present biodiversity is the outcome of over 3.5 billion years of evolutionary history, shaped by natural processes and increasingly, by the influence of humans. Biodiversity is not distributed evenly or uniformly across the globe. Certain countries, lying wholly or partly within the tropics, are characterized by high species richness and more number of endemic species\(^2\). These countries are known as Megadiverse countries. India, along with sixteen other megadiverse countries, which are rich in biological diversity and associated Traditional Knowledge, (TK) has formed a group known as the Like Minded Megadiverse Countries (LMMC).

India is one of the identified megabiodiverse countries of the world. With only 2.4 per cent of the land area, India already accounts for 7-8 per cent of the recorded species of the world. Over 45,500 species of plants and 91,000 species of animals have been recorded so far. The wide variety in physical features and climatic situations have resulted in a diversity of ecosystems such as forests, grasslands, wetlands, coastal and marine (mangroves and coral reefs), deserts\(^3\).
India is also one of the 8 primary centres of origin of cultivated plants and is rich in agricultural biodiversity\textsuperscript{4}. India is an acknowledged centre of crop diversity, and harbours 320 wild varieties of crop relatives mainly of rich, maize, millets, barley and brinjals. About 114 breeds of domesticated animals (buffaloes, cattle, sheep, goat, camel, horses, donkeys, etc.) are also found in the country\textsuperscript{5}.

The rich biodiversity in India is also paralleled by the equally rich cultural diversity, what call it as TK especially regarding Traditional Medicine. Besides the 2500 odd endogamous communities that are outside the caste system, there are about 500 odd tribes who largely inhabit the remote hill and foothill areas of central, west, south, and northeast India, who hold their own package of Traditional Knowledge especially Traditional Medicine\textsuperscript{6}.

Human communities have always generated, refined and passed on knowledge from generation to generation. Such TK is often an important part of their cultural identities. TK has played, and still plays, a vital role in the daily lives of the vast majority of people.

Traditional Knowledge (TK), Indigenous Knowledge (IK), Traditional Environmental Knowledge (TEK) or Local Knowledge (LK) generally refer to the long-standing traditions and practices of certain regional, indigenous, or local communities\textsuperscript{7}. TK also encompasses the wisdom, knowledge, and teachings of these communities. In many cases, TK has been orally passed for generations from person to person. Some forms of TK are expressed through stories, legends, folklore, rituals, songs, and even laws.

Traditional Knowledge is essentially culturally oriented or culturally based, and it is integral to the cultural identity of the social group in which it operates and is preserved\textsuperscript{8}. Traditional Knowledge is an open-ended way to refer to tradition-based literary, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed
information, and all other tradition-based innovations and creations resulting from intellectual activity.

The definition of TK used by the World Intellectual Property Office (WIPO) includes Indigenous Knowledge relating to categories such as agricultural knowledge, medicinal knowledge, biodiversity related knowledge, and expressions of folklore in the form of music, dance, song, handicraft, designs, stories and artwork. Process leading to the creation of TK may not be formally documented in the way that much scientific and technological information is recorded. The apparent non-systematic manner of creation of TK does not diminish its cultural value, or its value from the point of view of technical benefit.

Traditional Knowledge, especially Traditional Medicine (TRM) is essential to the food security and health of millions of people in the developing world. In many countries, TRM provide the only affordable treatment available to poor people. In developing countries, up to 80 per cent of the population depend on TRM to help meet their healthcare needs. In addition, knowledge of the healing properties of plants has been the source of many modern medicines.

The effectiveness of traditional, plant and herb based medicine was appreciated early in India. Charaka Samhita, an ancient Ayurvedic text mentions in a verse that the remedies for the diseases prevalent in a given region can be found in the herbs growing naturally in that region. Again, the development of specialized branches of medicine has also often taken place in response to nature’s biodiversity especially the inherited TRM. For instance, an estimated 427 plant species are used in the treatment of snakebites, scorpion and centipede stings and similar afflictions, which are treated by specialist medicine men called Visha Vaidyas in south India and Ojhas in eastern and northeastern India. Another unique group are the traditional bonesetters found in many tribal and other communities. In northeast India, especially south Assam, a group of traditional bonesetters called Khandals enjoy great reputation and have a flourishing trade in setting fractured bones.
Besides splints and other mechanical supports, the bonesetters also use various herbal oils for massage and external application\textsuperscript{13}.

The practice of TRM is based on the theory, belief and experiences indigenous to different cultures. TRM has maintained its popularity in a number of Asian countries, such as China, India, Japan and Pakistan.

Medicinal plants are the oldest known health-care products. Their importance is still growing although it varies depending on the ethnological, medical and historical background of each country. Medicinal plants are also important for pharmacological research and drug development, not only when plant constituents are used directly as therapeutic agents, but also when they are used as basic materials for the synthesis of drugs or as models for pharmacologically active compounds.

A large proportion of the population in a number of developing countries still relies on traditional practitioners, including traditional birth attendants, herbalists and bone-setters and on local medicinal plants to satisfy their primary health care needs. World Health Organization (WHO) estimates that traditional birth attendants assist in up to 95 per cent of all rural births and 70 per cent of urban births in developing countries\textsuperscript{14}.

A genuine interest in various traditional practices now exists among practitioners of modern medicine and growing numbers of practitioners of traditional, indigenous or alternative systems are beginning to accept and use some of the modern technologies. This will help foster teamwork among all categories of health workers within the framework of primary health care. The reasons for the inclusion of traditional healers in primary health care are manifold. The healers know the sociocultural background of the people, they are highly respected and experienced in their work, economic considerations, the distances to be covered in some countries, the strength of traditional beliefs, the shortage of health professionals, particularly in rural areas, to name just a few.
Due to globalisation of production systems, increase in population, destruction of forests for agriculture and timber purposes and decreased motivation amongst the local communities to conserve and protect the nature, our bio-diversity and associated TK is declining at a rapid pace. This is happening also because of change in their life style as well as misappropriation of their resources and their knowledge.

On the one hand, habitat destruction and unsustainable harvesting of medicinal plants (and trapping/hunting of animals) pose a grave threat to biodiversity, as well as the indigenous medicinal resources in India, where many states and regions, including the North Eastern region and the other tribal areas, are progressively losing their forest cover\textsuperscript{15}. On the other hand, the rapid spread of consumerist philosophy and aggressive advertisement of mass-produced drugs are leading to erosion in the TK base, especially the folk medicinal knowledge transmitted orally. Homogenization of cultures is also contributing to a loss of faith in age-old practices that were environment-friendly. All these factors perhaps lead to an ecological-ethical crisis in cultural diversity, biodiversity and TRM.

Certain challenges faced by TRM, due to its adoption by the new population include\textsuperscript{16};

- **International Diversity:** Traditional Medicine practices have been adopted in different cultures and regions without the parallel advance of international standards and methods for evaluation.

- **National Policy and Regulation:** Not many countries have national policies for Traditional Medicine. Regulating Traditional Medicine products, practices and practitioners is difficult due to variations in definitions and categorizations of TRM therapies. A single herbal product could be defined as a food, either a dietary supplement or an herbal medicine, depending on the country. This disparity in
regulations at the national level has implications for international access and
distribution of products.

➢ **Safety, Effectiveness and Quality:** Scientific evidence from tests done to evaluate
the safety and effectiveness of TRM products and practices is limited. While
evidence shows that acupuncture, some herbal medicines and some manual therapies
(e.g. massage) are effective for specific conditions, further study of products and
practices is needed. Requirements and methods for research and evaluation are
complex. For example, it can be difficult to assess the quality of finished herbal
products. The safety, effectiveness and quality of finished herbal medicine products
depend on the quality of their source materials (which can include hundreds of
natural constituents), and how elements are handled through production processes.

➢ **Knowledge and Sustainability:** Herbal materials for products are collected from
wild plant populations and cultivated medicinal plants. The expanding herbal
product market could drive over-harvesting of plants and threaten biodiversity.
Poorly managed collection and cultivation practices could lead to the extinction of
endangered plant species and the destruction of natural resources. Efforts to preserve
both plant populations and knowledge on how to use them for medicinal purposes is
needed to sustain TRM.

➢ **Patient Safety and Use:** Many people believe that because medicines are herbal
(natural) or traditional they are safe (or carry no risk for harm). However, Traditional
Medicines and practices can cause harmful, adverse reactions if the product or
therapy is of poor quality, or it is taken inappropriately or in conjunction with other
medicines. Increased patient awareness about safe usage is important, as well as
more training, collaboration and communication among providers of traditional and
other medicines.
Traditional Knowledge including TRM has always been an easily accessible treasure and thus has been susceptible to misappropriation. Misappropriation of knowledge not only violates the rights of communities who conserved TK but also adversely affects the conservation and sustainable use of the TK and that of bio-diversity\textsuperscript{17}.

The TK, particularly, related to the treatment of various diseases has provided leads for development of biologically active molecules by the technology rich countries. In other words, TK is being exploited for bio-prospecting or bio-piracy. Also TK is often misappropriated, because it is conveniently assumed that since it is in public domain, communities have given up all claims over it. TK includes both the codified (documented) as well as non-codified information (not documented but may be orally transmitted).

There is no accepted definition of ‘bio-piracy’. The Action Group on Erosion, Technology and Concentration (ETC Group) defines it as\textsuperscript{18};

\begin{quote}
\textit{“…the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge”}.
\end{quote}

Bio-piracy of codified Indian Traditional Knowledge continues, since, this information exists in regional languages, and there exists a language barrier due to which the patent offices are unable to search this information as prior art, before granting patents. Formulations used for the treatment of human ailments from TK are time-tested since they have been in practice for centuries. The reliability of the TRM systems coupled with the absence of such information with patent office’s provides an easy opportunity for interlopers for getting patents on these therapeutic formulations derived from TRM systems.
Traditional medicinal knowledge associated with biological resource is an intangible component of the resource itself. Traditional Medicine has the potential of being translated into commercial benefits by providing valuable leads for development of useful products and processes. The valuable leads provided by TRM save time, money and investment of modern biotech industry into any research and product development. Hence, a share of benefits must accrue to creators and holders of TRM.

Prior to the commencement of the Convention on Biological Diversity (CBD) in 1992, access to genetic resources and associated TK was free for all mankind. Genetic resources and knowledge were often taken from communities and countries by organisations, food, pharmaceutical, perfume and other industries and individuals who monopolised the benefits. The research and commercialisation of genetic resources and associated TK has existed in many forms for hundreds of years. From the beginning of 18th century systematic exploration begun. In the 18th Century, European colonial explorers travelled to different parts of the world seeking exotic plants. They brought back decorative flowers, medicinal herbs, and new types of food. These expeditions were a one-way transfer of knowledge, with biological explorers taking knowledge from local communities. There was little or no exchange of knowledge and no offer of compensation to such communities.

During the latter part of the 1900’s, a few countries developed legal provisions for Access and Benefit Sharing (ABS). However, benefits were usually narrowly defined as tangible benefits (such as royalties) and benefit sharing was largely carried out at the government level. Benefits did not reach the traditional owners of genetic resources and associated TK. Local communities and countries of origin were often not informed about the use of their genetic resources and associated TK, limiting their bargaining power and preventing them from sharing in the benefits of their own resources.
Growing concern over the monopolisation of benefits led genetic-resources providing countries to restrict access to genetic resources and associated TK. This led to the negotiation of an international regime to regulate ABS known as the CBD. The CBD integrates the objectives of conservation, sustainable use, and benefit sharing. It balances the right of resource-providing countries to share in benefits, with the right of technology-rich countries to access biodiversity resources in biodiversity rich countries. The CBD recognises the importance of the knowledge, practices, and innovations of indigenous and local communities, and makes provision for Prior Informed Consent to be obtained by any public or private enterprise seeking access to biodiversity resources (Article 15). The CBD is supported by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which commenced in 2001.

Today, genetic resources are no longer considered the common heritage of mankind and cannot be treated as freely accessible commodities. The CBD and the ITPGRFA recognise the sovereign right of countries to regulate access to their genetic resources and associated TK. The CBD provides a framework for national governments to implement ABS mechanisms to regulate and protect knowledge and genetic resources in order to facilitate access and ensure the fair and equitable sharing of benefits. One hundred and ninety-three countries are party to the CBD, including all Himalayan countries, and 116 countries are party to the ITPGRFA.

Despite this however, the ABS has been a contentious issue. Many things are unclear therefore a protocol of CBD is being developed which hope fully facilitate to resolve many of the issues related to ABS.

Faced with these concerns, the representatives of indigenous and tribal communities around the world called for the legal protection over their knowledge of medicine and their rights to decide over the end use of their knowledge. Many groups have also called for a moratorium on ‘bio-
prospecting’ (the commercial use of biodiversity) until such time as effective TK protection systems are in place and for the banning of all patents on life forms.

In this situation it is necessary to contrive effective legal measures to prevent bio-piracy and misappropriation in the field knowledge of TRM. Without such regulation the proper arrangement of ABS in a fair and reasonable manner to the real holders of such knowledge will be in peril. Because this very knowledge is necessary for the continued survival of the community.

The impact of Intellectual Property protection on TRM is also worth mentioning in today’s context.

Intellectual Property is a term referring to a number of distinct types of creations of the mind for which a set of exclusive rights are recognised and the corresponding fields of law. Under Intellectual Property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works, discoveries and inventions, and words, phrases, symbols, and designs. Common types of Intellectual Property Rights (IPR) include copyrights, trademarks, patents, industrial design rights and trade secrets in some jurisdictions.

Although many of the legal principles governing Intellectual Property have evolved over centuries, it was not until the 19th century that the term Intellectual Property began to be used, and not until the late 20th century that it became commonplace in the majority of the world.

While Intellectual Property protection for TRM has multiple and diverse objectives, the priorities are often not clear and the strategies which could be deployed may interfere with each other, as well as with the prioritization of objectives. This is further aggravated by differences in stakeholders’ concepts on ownership of knowledge and by uncertain or paradoxical effects of some potentially useful strategies. Thus, policymakers should address the multiple, multi-layered issues and questions, and try to develop a range of solutions in order to address and balance the various
objectives and interests. Thus, the things have turned out to such a situation that, now the TK including TRM is under the threat of IPR and a new legal framework is needed to protect our treasure.

A range of legal and policy developments at the intergovernmental, national, institutional, company, and community levels create the new framework within which biodiversity research and bio-prospecting take place.

At the intergovernmental level, the CBD, The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the ITPGRFA formalised principles of Prior Informed Consent, Mutually Agreed Terms (MAT) and benefit–sharing associated with the use and exchange of genetic resources.

The Biological Diversity Act (BDA), The Protection of Plant Varieties and Farmers’ Rights Act, The Geographical Indications Goods (Registration and Protection) Act, The Patent (Amendment) Act, to name a few were formulated in the national level with the aim of protecting Traditional Knowledge as well as TRM from exploitation. Another Government of India initiative to protect its rich and varied TK package is the setting up of a digital database formulated by the Council of Scientific and Industrial Research (CSIR) called the ‘Traditional Knowledge Digital Library (TKDL)’. TKDL is expected to help in combating the bio-piracy. If this apprehension comes true, it will unequivocally protect the indigenous knowledge.

Giving TK better legal protection will help to secure the cultural and economic future of indigenous and local communities.

The 21st century has ushered in new debates and social movements that aim to structure how culture is produced, owned, and distributed. At one side, ‘open knowledge’ advocates seek greater freedom for finding, distributing, using, and reusing information. On the other hand, ‘TK’ rights
advocates seek to protect certain forms of knowledge from appropriation and exploitation and seek recognition for communal and culturally situated notions of heritage and Intellectual Property.

There is an ethical vacuum as old systems are not being replaced by equally value-oriented modern ones. Unless there is a conscious attempt to fill in this ethical vacuum, no long-term goal in conserving and perpetuating culture-biodiversity-Traditional Knowledge-TRM can be achieved. It is also to be realized that these four aspects cannot be addressed in isolation, but warrant a holistic and pro-active, and most importantly, people-oriented approach for resolving the crisis.

1. **Scope of the Study**

One of the basic features of TRM is that it is unwritten and exists in the minds of the local people. It is transmitted orally from one generation to another. TRM plays a significant role in the lifestyle of the members of the local community and hence an essential resource for any human development process. They form the basis for human and animal health, natural resource management and other vital activities. Local communities in many developing countries are applying TRM knowledge to respond to and manage many endemics and pandemic as well as in the treatment of other opportunistic infections. TRM forms an integral part of the culture and history of local communities and hence their common asset in their effort to gain control of their own lives.

The TRM in a few developing countries tend to stagnate through not exploiting the rapid discoveries of science and technology for its own development, it has kept a slow pace of change in comparison with medicine as practiced in the industrialised countries, which keeps abreast of scientific and technological innovations to extent that it is often exclusively referred to as modern medicine.

On the other hand TRM, as well as associated TK is subjected to high rates of misappropriation and bio-piracy understanding its high commercial value. One of the best modern
approaches to preservation of TRM against bio-piracy is documentation in some permanent form and public accessibility using information and communication technologies. In addition to preservation, documentation and online accessibility of TRM knowledge provides an effective tool for research and innovation.

With regards to the applicability of conventional IPR to TRM knowledge, it was observed that the concept of copyright and individual rights to privately own and control information is at odds with traditional notion that knowledge is collectively own and shared. Hence the difficulty in the application of western concept of IPR to TRM knowledge calls for a sustainable access framework that meets the unique characteristics of TRM knowledge.

A sustainable framework to this effect will be one which preserves the communal rights characteristic of TRM, enhance access to TRM for scientific discovery and innovation while at the same time granting traditional communities equitable access to any commercial benefit arising from the use of such knowledge. In appreciation of this fact, stakeholders in developing countries like India are currently embarking on effort to put in place sui generis legislation which ensures equitable access to TRM knowledge.

2. Objectives of the Study

The study entitled “Legal Protection of Traditional Medicine in the Neo-capitalist World- A Legal Analysis” was undertaken with the following objectives.

(1) To review the literature to examine the nexus between biodiversity and Traditional Knowledge and to evaluate the existing legal measures for the protection of the same at national and international level.
(2) To analyse in detail the existing legal measures and its effectiveness to protect the knowledge of Traditional Medicine both at national and international level.

(3) To critically evaluate the extent of bio-piracy and misappropriation of knowledge of Traditional Medicine and study the effectiveness of existing legal provisions in combating the same.

(4) To review the contemporary Access and Benefit Sharing Mechanisms and evaluate the need for an appropriate legal frame work for fair and equitable sharing of benefits.

(5) To critically examine and identify various flaws and lacunas in the protection afforded by Intellectual Property Rights for Traditional Medicinal knowledge.

(6) To study the role of supplementary efforts in the protection of knowledge of Traditional Medicine.

3. Methodology

The research work is mainly based on doctrinal research. The historical method also has been used for bringing out the history, development and legal aspects of TRM. In addition to this comparative method too is used whenever necessary. It comprised of appreciation of various documents of international, national, regional and subnational organizations which formed the basis for the issues and legal protection of TRM were analyzed. Various provisions in the Indian laws as well as international laws and cases which are significant for TRM and ABS also constituted the subject matter of the study. Contemporary national and international level working papers were analyzed to support the study. Various other statutes and reports of governments’ and non-governmental organisations’ were also formed tools for the study. Legal literature, journals, books, periodicals and newspaper reports formed the subject matter of appraisal.
4. Thematic Breakup

The topical division of the present study is as follows. It is divided into eight chapters of which the first chapter is an introduction to the work. The introduction chapter gives a bird’s eye view on the concept of TRM, its importance and present day issues.

Chapter II explains in detail about biodiversity, with special reference to its relation to TK and TRM, its importance, laws and various conservation strategies.

Chapter III deals with the concept of TK, various measures of conservation, preservation and protection strategies to prevent misappropriation, both at the national and international level.

Chapter IV presents in a nutshell all about TRM, the present trends, its role in public health scenario and challenges involved in its protection in an analytical way.

Bio-piracy in TRM, cases on bio-pirated medicinal knowledge all over the world is critically evaluated and presented in Chapter V.

Chapter VI looks at various national and international, governmental and non-governmental, regional and sub-national initiatives set for the protection of TRM. This Chapter is also devoted to the contribution of IPR in the field of TRM. That is how TRM is protected under IPR and its applicability is well explained.

Significance of ABS, importance of Prior Informed Consent, Material Transfer Agreement, national and international legal concepts of ABS, various contractual agreements for ABS are dealt in chapter VII.

Chapter VIII concludes the study and makes suggestions and recommendations.
5 Ibid
6 Ibid
9 Dr. N.S. Gopalakrishnan, “Traditional Knowledge, Information Technology and Development- The Challenges” 29 CULR 143 (2005)
11 G. Pranoto, “Traditional Medicine Knowledge as a Basic For The development of Allopathic Medicine: An Industry Perspective of Future Possibilities” ASEAN Workshop on the TRIPS Agreement and Traditional Medicine, organized by the Directorate General of Food and Drug Control Indonesia, Jakarta (2001)
12 M. Fuchs, “Use of Traditional Indian Medicine Among Urban Native Americans” 13(11) *Medical Care* 915 (1975)
19 Supra n. 12
20 Supra n. 10
22 Ibid
24 Article 15 of the Convention on Biological Diversity, 1992

27 See Ibid