

I) INTRODUCTION:

Knowledge means acquaintance or familiarity or conversance with facts, truths, or principles, gained by sight, experience, or report as from study or investigation on a particular subject. It is the perception of fact or truth of a fact or circumstance.

Knowledge is a familiarity with someone or something, which can include facts, information, descriptions, or skills acquired through experience or education. It can refer to the theoretical or practical understanding of a subject. It can be implicit (as with practical skill or expertise) or explicit (as with the theoretical understanding of a subject); it can be more or less formal or systematic.

A tradition is a ritual, belief or object passed down within a society, still maintained in the present, with origins in the past. Traditions can persist and evolve for thousands of years—the word "tradition" itself derives from the Latin *tradere* or *tradere* literally meaning to transmit, to hand over, to give for safekeeping. While it is commonly assumed that traditions have ancient history, many traditions have been invented on purpose, whether that be political or cultural, over short periods of time.

Tradition can also refer to beliefs or customs that are Prehistoric, with lost or arcane origins, existing from time immemorial. Originally, traditions were passed orally, without the need for a writing system. There are various origins and fields of tradition; they can be referred to:

1. The forms of artistic heritage of a particular culture.
2. Beliefs or customs instituted and maintained by societies and governments,
3. Beliefs or customs maintained by religious denominations

Many objects, beliefs and customs can be traditional, rituals of social interaction can be traditional, .tradition can also refer to larger concepts practiced by groups, organizations, or societies, and it can also include material objects, such as buildings, works of art or tools.

Traditional knowledge generally refers to the long-standing traditions and practices of certain regional, indigenous, or local communities. Traditional knowledge also encompasses the wisdom, knowledge, and teachings of these communities. In many cases, traditional knowledge has been orally passed for generations from person to person. Some forms of traditional knowledge are expressed through stories, legends, folklore, rituals, songs, and even laws. Other forms of traditional knowledge are expressed through different means.

Traditional knowledge (TK) is often cited as being relevant to intellectual property, and it is sometimes even argued that TK justifies some kind of sui generis IP right. Whether TK could in any sense be considered to be an IP right is contentious, and is not the subject of this post. It is less contentious that TK would at least be considered to be prior art.

“The indigenous people of the world possess an immense knowledge of their environments, based on centuries of living close to nature. Living in and from the richness and variety of complex ecosystems, they have an understanding of the properties of plants and animals, the functioning of ecosystems and the techniques for using and managing them that is particular and often detailed. In rural communities in developing countries, locally occurring species are relied on for many - sometimes all - foods, medicines, fuel, building materials and other products. Equally, peopleís knowledge and perceptions of the environment, and their relationships with it, are often important elements of cultural identity.”

“Traditional knowledge is employed to mean knowledge, innovations and practices of indigenous and local communities embodying traditional life-styles; the wisdom developed over many generations of holistic traditional scientific utilization of the lands, natural resources, and environment. It is generally passed down by word of mouth, from generation to generation and is, for the most part, undocumented. . Traditional knowledge is valid and necessary, and awaits its currently relevant wider application for human benefit.”

The adage of the good olden days that ‘knowledge is power’ is in recent times referred to as ‘knowledge is power and also a property’. Thus it has become necessary to see that the knowledge, more particularly the traditional knowledge is given protection as a form of property created either by individuals or by communities. The traditional forms of IP like patents, trademarks, copyrights and designs fall into the categories of individually created IP where the beneficiaries of the Protection of such IP are primarily the individuals, at least during the limited period for which they are granted monopoly rights. Such forms of Intellectual Property like patents, trademarks, copyrights and designs shift to public domain from private domain after the limited statutory period during which the property owner enjoys monopoly rights to use such Intellectual Property. On the other hand, the Traditional Knowledge is one such form Intellectual Property, which is generally the result of knowledge practiced and passed on from one generation to the other from time immemorial, requiring statutory recognition and protection.

WIPO currently uses the term "traditional knowledge" 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 in the industrial, scientific, literary or artistic fields. "Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation

to generation; are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment. It should be emphasized, however, that a precise definition of traditional knowledge is not a crucial requisite for establishing a system for its protection.

Traditional Knowledge is a knowledge, which is held by members of a distinct culture and/or sometimes acquired by “means of inquiry peculiar to that culture, and concerning the culture itself or the local environmental in which it exists

The growing importance attached to TK, and related concerns about preserving cultural and biological diversity, have raised policy, ethical and legal questions at the national, regional and international levels. TK arises as an issue in relating to food and agriculture, biological diversity and the environment, biotechnology innovation and regulation, human rights, cultural policies, and trade and economic development. The working concepts of TK in each forum tend to be shaped by the policy framework of that forum, leading to a decentralized and disintegrated set of approaches, in which the issues are subjected to differing policy considerations, cultural and ethical environments, analytical tools and legal concepts. Different terms can therefore be used for overlapping subject matter and the same term may be used in contrasting ways.

Since time immemorial, India has possessed a rich traditional knowledge of ways and means practiced to treat diseases afflicting people. This knowledge has generally been passed down by word of mouth from generation to generation. A part of this knowledge has been described in ancient classical and other literature, often inaccessible to the common man and even when accessible rarely understood. Documentation of this existing knowledge, available in public domain, on various traditional systems of medicine has become imperative to safeguard the sovereignty of this traditional knowledge and to protect it from

being misappropriated in the form of patents on non-original innovations, and which has been a matter of national concern.

Traditional knowledge is therefore the totality of all knowledge and practices whether explicit or implicit, used in the management of socio-economic and ecological facets of life. It is based on past experiences and observations and is usually a collective property of a society. This knowledge is transmitted from one generation to other generation.

The unique nature of Traditional Knowledge is that the common property resources are not used by single person/entity. Access to these resources is limited to members of an identifiable community. Each user has a separate entitlement to the common property and no single user has the right to abuse or dispose of it. The net result of such customs and practices are that the users perceive themselves mainly as possessors of their habitat but not as resource owners. In other words, the members of the community have only community rights.

The local people embodying traditional lifestyles and knowledge have devised and deployed various technologies to conserve the environment in general and bio-diversity in particular.

Traditional Knowledge is a multifaceted concept that encompasses several components. What characterizes traditional knowledge is the fact that, generally, it is not produced systematically, but in accordance with the individual or collective creators' responses to an interaction with their cultural environment. Traditional Knowledge, as representative of cultural values, is generally held collectively and most of the Traditional Knowledge practices are transmitted orally from generation to generation and thus remain undocumented.

Traditional knowledge, which is always banded to the native culture and spirituality of the communities, normally refers to a long term practices in a certain regional, indigenous area. It is a multifaceted concept, which is not produced systematically, but in accordance with the individual or collective creators' responses to and interaction with their cultural environment.

“The content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.”

Indigenous vs. Traditional Knowledge – This dichotomy may be more in some societies than others. They are often non-dominant sectors of society and are particularly concerned about the preservation, development and transmission to future generations of their ancestral territories and ethnic identities in accordance with their cultural patterns, social institutions and legal systems.

TRADITIONAL KNOWLEDGE AND RELATED TERMS:

The growing importance attached to TK, and related concerns about preserving cultural and biological diversity, have raised policy, ethical and legal questions at the national, regional and international levels. TK arises as an issue in relating to food and agriculture, biological diversity and the environment, biotechnology innovation and regulation, human rights, cultural policies, and trade and economic development. The working concepts of TK in each forum tend to be shaped by the policy framework of that

forum, leading to a decentralized and disintegrated set of approaches, in which the issues are subjected to differing policy considerations, cultural and ethical environments, analytical tools and legal concepts. Different terms can therefore be used for overlapping subject matter and the same term may be used in contrasting ways. This naturally reflects differences in the respective policy focus of each forum. Such differences are likely to be reflected in specific legal instruments, with variations applying in different jurisdictions and responding to different policy objectives.

International IP policy discussions have directly addressed the general concept of traditional knowledge relatively recently, although the broader debate is long-standing. The earlier focus of IP-related discussions was on the concept of “expressions of folklore,” a more limited term typically associated with the system of copyright and related rights. The WIPO/UNESCO Model Provisions characterized this term in 1982. Discussions on further characterization of this term took place during the four Regional Consultations on the Protection of Expressions of Folklore organized by WIPO and UNESCO in 1999, and this was also an issue in the attempts to establish an international agreement on protection of expressions of folklore in the 1980s.

The increasing attention to traditional knowledge as such reflects a more recent broadening of the IP policy focus, and TK accordingly covers a much broader range of subject matter and of policy fields – such as medicinal remedies and practices, biodiversity related knowledge and agricultural knowledge related to plant genetic resources for food and agriculture. The international dimension of this discussion has brought with it calls for clarity in terminology, a concern that was raised, for instance, by many of those who were consulted in many of the countries visited during the WIPO fact-finding missions in 1998 and 1999. Informants stressed the need for clarity both to identify the subject matter for which protection is sought, and secondly to clarify the relevance and role of IP in

respect of TK. This led to the conclusions that an “appropriate term or terms describing the subject matter for which protection is sought should be selected” and that “from an IP perspective, a clear definition or description of what is meant (and not meant) for IP purposes by the term or terms selected is desirable.” Many other writers and commentators have discussed related terminological issues in relation to IP and TK.

The terms in general use in international debate include:

- “traditional knowledge, innovations and practices,” in the context of conservation and equitable use of biological resources;
- “heritage of indigenous peoples” and “indigenous heritage rights”;
- “traditional medicinal knowledge” in the context of health policy;
- “expressions of folklore” in the context of IP protection;
- “folklore” or “traditional and popular culture” in the context of safeguarding traditional culture;
- “intangible cultural heritage”;
- “indigenous intellectual property” and “indigenous cultural and intellectual property”;
- “traditional ecological knowledge”; and
- “traditional and local technology, knowledge, know-how and practices.”

The protection of TK is important for communities in all countries, particularly in developing and least developed countries. First, TK plays an important role in the economic and social life of those countries. Placing value on such knowledge helps strengthen cultural identity and the enhanced use of such knowledge to achieve social and development goals, such as sustainable agriculture, affordable and appropriate public health, and conservation of biodiversity. Second, developing and least developed countries are implementing international agreements that may affect how knowledge associated with the use of genetic

resources is protected and disseminated, and thus how their national interests are safeguarded. Patterns of ownership of TK, cultural, scientific and commercial interest in TK, the possibilities for beneficial partnerships in research and development, and the risk of the misuse of TK, are not neatly confined within national boundaries, so that some degree of international coordination and cooperation is essential to achieve the goals of TK protection. A comprehensive strategy for protecting TK should therefore consider the community, national, regional and international dimensions. The stronger the integration and coordination between each level, the more likely the overall effectiveness. Many communities, countries and regional organizations are working to address these levels respectively. National laws are currently the prime mechanism for achieving protection and practical benefits for TK holders.

Traditional knowledge has been defined as "a cumulative body of knowledge, know-how, practices and representations maintained and developed by peoples with extended histories of interaction with the natural environment. These sophisticated sets of understandings, interpretations and meanings are part and parcel of a cultural complex that encompasses language, naming and classification systems, resource use practices, ritual, spirituality and worldview."

Traditional knowledge typically distinguishes one community from another. For some communities, traditional knowledge takes on a personal and spiritual meaning. Traditional knowledge can also reflect a community's interests. Some communities depend on their traditional knowledge for survival. This is particularly true of traditional environmental knowledge, which refers to a "particular form of place-based knowledge of the diversity and interactions among plant and animal species, landforms, watercourses, and other qualities of the biophysical environment in a given place". An example of a society with a wealth of TEK is the South American Kayapo people, who have developed an

extensive classification system of ecological zones of the Amazonian tropical savannah (i.e., campo / cerrado) to better manage the land.

Some social scientists conceptualise knowledge within a naturalistic framework, and emphasize the gradation of recent knowledge into knowledge acquired over many generations. These accounts use terms like "adaptively acquired knowledge", "socially constructed knowledge," and other terms that emphasize the social aspects of knowledge. Local knowledge and traditional knowledge may be thought of as distinguished by the length of time they have existed - decades to centuries versus millennia. A large number of scholarly studies in the naturalistic tradition demonstrate that traditional knowledge is not a natural category, and may reflect power struggles and relationships for land, resources and social control rather than adherence to a claimed ancestry or heritage.

Traditional knowledge, on the other hand, may be perceived very differently by indigenous and local communities themselves. The knowledge of indigenous and local communities is often embedded in a cosmology, and the distinction between "intangible" knowledge and physical things is often blurred. Indigenous peoples often say that "our knowledge is holistic, and cannot be separated from our lands and resources". Traditional knowledge in these cosmologies is inextricably bound to ancestors, and ancestral lands. Knowledge may not be acquired by naturalistic trial and error, but through direct revelation through conversations with "the creator", spirits, or ancestors.

Indigenous and local communities often do not have strong traditions of ownership over knowledge that resembles the modern forms of private ownership. Many have clear traditions of custodianship over knowledge, and customary law may guide who may use different kinds of knowledge at particular times and places, and obligations that accompany the use of knowledge. From their perspective, misappropriation and misuse of knowledge may be offensive to traditions, and may have spiritual and physical repercussions in their

cosmological systems. Subsequently, indigenous and local communities argue that others' use of their traditional knowledge warrants respect and sensitivity. Critics of "traditional knowledge", however, maintain that such demands for "respect" are really an attempt to prevent unsubstantiated beliefs from being subjected to the same scrutiny as other knowledge claims. This has particular significance for environmental management because the spiritual component of "traditional knowledge" can be used to justify any activity, including the unsustainable harvesting of resources.

Over the centuries since the evolution of mankind and development of civilization, technology has been the principal tool that has fashioned to alleviate the mankind from its beastly conditions. Most of the industrial advancement of the developed countries can be traced to technological experimentation and innovation which have been considered as the most dynamic factors in the growth of their national economies. Such technological advancement more aimed at improving the quality of the life of the inhabitants and supplying to the greatest extent possible the needs of the majority of the population by making maximum use of local resources having due regard of the local environment.

Over the past decade biotechnology, pharmaceutical and human health care industries have increased their interest in natural products as sources of new biochemical compounds for drugs, chemical and agro-product development. This has brought about the resurgence of interest in traditional knowledge and medicine. This interest has been stimulated by the importance of traditional knowledge and a lead in advancing the frontiers of science and technology. Traditional knowledge has been extensively used to gain useful understanding of how ecological systems generally work and interrelate. It has been estimated that of the 119 drugs developed from higher plants, 74% were discovered from a pool of traditional herbal medicine.

On the whole, a significant part of the global economy is based on the appropriation and use of traditional knowledge. It has contributed to the production in modern economy and played significant role in the Research and Development programs of industry.

However, this knowledge has been and continues to be an element in the commercialization of natural products. It is currently supplied to commercial interests through databases, academic publications or field collection. This undue exploitation needs to be paid for in some form. Concern over the growing interest in and economic importance of traditional knowledge has generated a wide range of public policy issues including those associated with intellectual property protection.

More recently, many scientists have begun to understand that such traditional knowledge extends far beyond what in western science would be called description biology, beyond knowing how to identify different species of animals or describe them feeding, reproduction or migratory behaviour. The knowledge possessed by such tradition-based, non industrial societies is essentially of an ecological nature, that is to say, it seeks to understand and explain the workings of ecosystem or at the very least biological communities, containing many interacting species of animals and often plants, and the determinative role played by certain key biological and physical parameters in influencing the behaviour of the total biological community.

In order to understand the role that traditional knowledge and indigenous technologies play in the socio-economic development of societies, it is important to understand the concepts of traditional and indigenous knowledge system. The concepts of indigenous knowledge and traditional knowledge are widely used yet their meanings are rarely provided. This usage is often subject to confusion and used inter-changeably. There have been various efforts to define these concepts but there are so far no universally adopted definitions.

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 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, triggering lively debate about ways to preserve, protect, further develop and sustainably use TK. Documenting and digitizing TK-related information in the form of a TKDL is proving to be an effective means of preserving TK and of preventing its misappropriation by third parties. India is a pioneer in this field. Globalization and the knowledge economy have opened up the world and facilitated the flow of information and knowledge. However, the flow of knowledge has been governed by uneven economic and political power between the developed countries and the developing countries. This has a number of ramifications for Indigenous Knowledge. The dilemma faced is that whichever method is taken to protect Indigenous Knowledge (Intellectual Property Rights regimes, documenting Indigenous

Knowledge etc) exposes INDIGENOUS KNOWLEDGE to some misappropriation. Protecting it through IPR is also fraught with problems. Documenting Indigenous Knowledge exposes Indigenous Knowledge to the public domain and makes it that much easier to be misused. However, not protecting Indigenous Knowledge runs the danger of having it disappear as the custodians holding it die off, or as communities become swamped by the effects of globalization. The conclusion therefore is that governments have to take more interest in protecting, promoting and using Indigenous Knowledge than they have been doing.

SCOPE OF THE STUDY:

“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 present topic studies the protection of rights in Traditional Knowledge as Intellectual Property Rights in India with reference to the Traditional Knowledge Digital Library. It also explains the relationship between traditional knowledge and intellectual property and the trends and scenarios in the legal protection of TK.

The present study is confined to the importance of rich traditional knowledge based in India and the need to protect the same from being wrongly appropriated through Intellectual Property Rights Regime by people not only in India but across the world.

HYPOTHESIS:

After going through the available literature the following hypothesis is formulated:

- 1) The Significance and Importance of Traditional Knowledge was not known in India till the beginning of TRIPS Agreement.
- 2) The Traditional Knowledge i.e. knowledge which has been known in India for generations together and which is known elsewhere has been misused by patent regime.
- 3) Traditional Knowledge Digital Library has helped in curbing the misuse of Traditional Knowledge through the process of wrong patenting.

METHODOLOGY FOLLOWED:

The researcher has followed the doctrinal method of research for which the researcher has used primary sources like commentaries and various reports of WIPO and secondary sources like articles on the subject.

OBJECTIVES OF THE STUDY:

The following are the objectives of the dissertation:

1. To study the meaning, nature and scope of Traditional Knowledge.
2. To study about the protection of rights in traditional knowledge as intellectual property rights.
3. To study about the recent trends and scenario in the legal protection of Traditional Knowledge.
4. To study about the tools and mechanism of protection of traditional knowledge in India with reference to Traditional Knowledge Digital Library

CHAPTERIZATION: The dissertation contains the following chapters:

- I) INTRODUCTION**
- II) TRADITIONAL KNOWLEDGE – CONCEPTUAL ANALYSIS**
- III) MISUSE OF TRADITIONAL KNOWLEDGE IN IPR REGIME**
- IV) PROTECTION OF TRADITIONAL KNOWLEDGE IN IPR REGIME**
- V) TRADITIONAL KNOWLEDGE DIGITAL LIBRARY – A METHOD OR MECHANISM FOR PROPER USE OF TRADITIONAL KNOWLEDGE**
- VI) CONCLUSION**

II TRADITIONAL KNOWLEDGE – CONCEPTUAL ANALYSIS:

Traditional knowledge can be defined as a cumulative body of knowledge and beliefs handed down through generations by cultural transmission, about the relationship of the living beings with one another and with their environment. It includes an attribute of societies with historical continuity in resource use practices, such as the use of non-industrial or less technologically advanced societies many of them indigenous or tribal. Traditional knowledge and practices, whether explicit or implicit used in the management of socio-economic and ecological facets of life. This knowledge is established on past experiences and observation.

As a first step into the snarl of legal and policy issues that surround Traditional Knowledge, and its complex linkages with IP law and policy, it can be helpful to dwell on the distinctive characteristics of Traditional Knowledge, before the debate moves into legalism. Many conceptual difficulties arise in policy and legal debate when limiting preconceptions are imposed on the notion of Traditional Knowledge.

Knowledge is not traditional because of its object, or its subject matter or content, or its age or antiquity, or its aesthetic qualities. What makes it traditional is the way it has been preserved and transmitted between generations within a community. Its nature relates to the manner it develops rather than to its antiquity. By virtue of this traditional context, Traditional Knowledge has a profoundly local quality. The social structures that create, use, preserve and pass down Traditional Knowledge between generations and the customary laws and protocols that govern these processes are deeply rooted in their traditional location and community setting, and indeed may be conceived as integral to the land and environment itself.

There are three distinct ways that globalization is interpreted: as economic interdependency across vast distances; information availability and movement across vast distances; and reduction of the world into a global village. Two forms of globalization can be identified: economic globalization and cultural globalization.¹ Globalization is also viewed as the opening up and interconnectedness of the world. This openness and interconnection has been given impetus by the need to open up economic and trade markets as well as developments in information and communication technologies culminating in the so called “knowledge economy”. Many people assert that globalization is characterized by a mismatch of political and economic power, and that it is the more powerful countries in the north that benefit from globalization.

Indigenous knowledge is the knowledge, ideas and practices that are peculiar to a particular community and embody the community’s identity and ways of surviving and maintaining the environment they find themselves in. IK is often associated with rural based communities that possess limited or no education and who still live as one with nature, using IK to survive the vagrancies of nature. However, it is the contention that IK is not only a preserve of indigenous people or rural communities; IK is the knowledge that is held communally by communities that have lived in a particular area a significant amount of time. These communities may be indigenous, rural or urban. IK therefore represents a strategy that is used by communities to deal with everyday issues of life, be it food production, health, education, the environment, etc. Most IK, especially in developing countries, is not documented and is transmitted orally from generation to generation. As such, it is vulnerable to gradual disappearance due to the influence of globalization and as individuals who lived life in the old way departs this life.

¹ Pan Africanism and the Origins of Globalization - Mazrui Ali

Arguments have been raised that undocumented IK is considered to be in the public domain and therefore available for all with the possibility of being easily misappropriated. It is for these reasons that the documentation of IK has been advocated; the creation of digital libraries is seen as a way that ownership of IK can be articulated and the databases used to check whether the IK is new or has always existed and therefore cannot be patented to individuals wishing to own it. The importance of IK has been acknowledged as crucial for health, agriculture and for commercial value in many other products. Arts and crafts emanating from indigenous knowledge have also attracted a lot of attention. The products of IK therefore are part of a multimillion trade and investment in the world. The issue is that since such information is undocumented and is thus in the public domain, it has been used to produce goods and products from which the communities who own the IK have not benefited. It is for these reasons that people have advocated documentation to guard against the disappearance and misappropriation of IK. In spite of this interest and the money that is being made from IK, communities who own it are sliding further and further into poverty. IK is also important for the world as a whole, and should be shared as long as communities are consulted and acquiesce to its use and most importantly, benefit from such use.

Economic globalization is characterized by transnational and multinational corporations seeking to extend their markets and sources of raw materials and ideas. Generally they tend to look for such in less developed countries. Although the contention is that biological resources are meant for the good of the entire world, the irony is that the finished products such as drugs are patented and are out of reach for poor countries and communities.

Globalization has commoditized and privatized knowledge, resulting in the knowledge economy. Indigenous knowledge has not been exempt from this privatization. Knowledge that was in the public domain, owned by communities and passed down from

generation to generation, has been privatized by applying intellectual property rights that confer rights on individuals, effectively robbing whole communities.

Developments in information and communication technologies have fuelled what is now commonly referred to as the knowledge economy. The basis of this economy is that we live in a world where the major currency is information and knowledge just as much, if not more than capital and land. It is posited that whoever has access to information and knowledge and uses it effectively can expect to develop and generate wealth. A major argument is that developing nations are not progressing because they do not have access to knowledge that they would use to improve production and generate wealth. However, knowledge is available for use by developing countries, but it is not attractive because it is said to be unscientific, and can only be useful if subjected to the scientific methods which are mainly a western construct that the rest of the world adheres to. The development of information communication technologies has however, brought IK into focus as a knowledge system worth having – hence the clamour to obtain IK and develop products and services of value. The knowledge economy has had a number of influences and impact on indigenous knowledge and communities who own it.

In the knowledge economy, intellectual property has been given a very high profile and represents greater economic value. Indeed, much of the intellectual property of knowledge products is not vested in those who created it, but rather in global corporations that become the content providers and therefore command the greatest profits. The efforts being made to apply intellectual property rights, which are by nature individualistic, to knowledge that is communally owned, such as IK, has created a myriad of problems, especially for the communities who own the IK.

Globalization or neo-colonialism as some refer to it, has played a large role in dispossessing communities of their knowledge and identity. Many ideas and knowledge have

been removed from communities through agreements for bilateral aid. Research organizations and governments in developing countries benefit from donor funding as long as they will accept foreign students and researchers to come and conduct research and invariably take home all the data and findings which eventually find their way back to developing countries as products developed in the West and patented there. Clearly there is dire need for intervention aimed at protecting IK and ensuring that the economic gains of communities and the protection of their sacred and confidential knowledge is assured.

Traditional knowledge accumulated over generations to help people protect their health and manage their habitats. If traditional knowledge vanishes with economic development, then economic development comes at the cost of losing humanity's heritage and diversity. The possibility that traditional knowledge may be rapidly and widely lost in response to globalization has become a major concern of scholars and policy-makers. The loss of traditional ecological knowledge concerns policy-makers because it represents the irreversible loss of information about different ways to manage natural resources.

Traditional ecological knowledge resembles scientific knowledge developed through inductive methods and that it can contribute to the conservation of biological diversity, agriculture health, nutrition, and the management of natural resources.

"The protection of knowledge, innovations and practices of indigenous and local communities (hereafter referred to as "traditional knowledge", TK) has been receiving increasing attention on the international agenda in recent years. This is due to several factors. First, it has been recognized that TK plays a key role in the preservation and sustainable use of biodiversity. Second, many activities and products based on TK are important sources of income, food, and healthcare for large parts of the populations in many developing countries, including the least developed countries (LDCs). However, TK is being rapidly lost as local ecosystems are degraded and traditional communities are integrated into the wider society.

Third, concerns have been raised about how the benefits derived from the use of biodiversity and associated TK are appropriated and shared. The vast majority of plant genetic resources and other forms of biodiversity are found in – or originate from - developing countries. Access to these resources and the associated TK can provide substantial benefits to companies and scientific research centres in both developed and developing countries. However, there is concern that TK is at times appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent.

Fourth, while the need to protect TK and to secure fair and equitable sharing derived from the use of biodiversity and associated TK has been fully recognized, there is no agreement on what would be the most appropriate and effective ways to achieve these objectives. There have been calls for a better understanding of the needs of TK holders and exchanges of information on the effectiveness of existing systems of protection such as customary law, intellectual property rights (IPRs), sui generis systems, access and benefit sharing mechanisms, voluntary measures and documentation. Fifth, the long term sustainable economic development of many indigenous and local communities may depend on their ability to harness their TK for commercial benefit. Traditional technologies and innovations, which are by their very nature adapted to local needs, can contribute to a viable and environmentally sustainable path to economic development. It is therefore important to encourage TK-based innovations and, if desired by the communities concerned, explore the commercialization of TK-derived products. From a trade and development perspective, systems for the protection of TK should seek to preserve TK to ensure that the benefits of cumulative innovation accrue to TK holders, while at the same time allowing developing countries to utilize their TK to promote development and trade. This inter alia raises the question of responsibilities of both TK holders and users in ensuring equitable sharing of

benefits deriving from the use of biodiversity resources and associated TK. It is also important to ensure that the commercialization of TK-based products contributes to the long-term socio-economic viability of indigenous and local communities, as well as the creation of new trading opportunities for developing countries. This could be done, for example, through partnerships or other benefit sharing arrangements aimed at promoting innovation and the production of value-added products, or by seeking to ensure that TK-based products are traded as distinct products, based on their long-term uses and traditional know-how. Similarly, the promotion of innovation and capacity building play important roles in developing country efforts to ensure that their TK contributes to their socio-economic development.

UNCTAD's member States decided to address the protection of TK as part of UNCTAD's work in the area of trade and environment. "UNCTAD should also, in full cooperation with other relevant organizations, in particular and where appropriate WIPO and WHO, promote analysis and consensus building with a view to identifying issues that could yield potential benefits to developing countries"¹. It specifies that this work should inter alia focus on: "Taking into account the objectives and provisions of the Convention on Biological Diversity and the TRIPS Agreement, studying ways to protect traditional knowledge, innovations and practices of local and indigenous communities and enhance cooperation on research and development on technologies associated with the sustainable use of biological resources".² In preparing this Expert Meeting, the UNCTAD secretariat has been working closely with the secretariats of other intergovernmental organizations, in particular the CBD and the World Intellectual Property Organization (WIPO).

¹ The Plan of Action adopted by UNCTAD's tenth Conference - (UNCTAD, 2000)

² (paragraph 147, third bullet)supra

Access to and use of TK within and outside communities is generally governed by wide variety of unwritten customary laws. This seems to be true whether or not notions of ownership and property would be strictly applicable to traditional societies. Indeed many traditional communities express preference for words like stewardship and custodianship, which imply responsibilities as well as rights. Proprietary systems exist in many traditional societies. But any assumption that there is a generic form of customary regulations governing TK use and dissemination ignores the intricacies and diversity of traditional systems.

TK is valuable not only to those who depend upon it for their survival but also to modern industry and agriculture, and to sustainable development more generally. Up to 80 per cent of the world's population depends on traditional medicine for its primary health needs.¹ In India, for example, there are 600,000 licensed medical practitioners of classical traditional health systems and over one million traditional community-based health workers. "Possibly two thirds of the world's people could not survive without the foods provided through indigenous knowledge of plants, animals, insects, microbes and farming systems."² Over 90 per cent of food in sub-Saharan Africa is produced using customary farming practices.³ For those comprising the poorest segments of societies, particularly women, indigenous people and rural inhabitants of developing countries, traditional knowledge is indispensable for survival. This is especially true in many LDCs.

A number of TK-derived products are traded internationally. These include handicrafts, medicinal plants, traditional agricultural products, and non-wood forest products

¹ According to the World Health Organization (WHO, 1993),

² "(Rural Advancement Foundation International, 1994)

³ (Dakora, 1997)

(NWFPs). Biogenetic resources and their associated TK also provide significant inputs into other markets including pharmaceuticals, cosmetics, agriculture, food additives, industrial enzymes, bio-pesticides, and personal care. However, the future of bio-prospecting is difficult to predict. While enhanced abilities to screen huge quantities of natural products and analyse and manipulate their DNA structures might suggest that bio-prospecting will become more popular, it is also possible that advances in biotechnology and new drug discovery approaches based, for example, on combinatorial chemistry and human genomics will in the long term reduce industrial interest in natural product research for food, agriculture and health, as well as associated TK. Concerns about food safety and other unknown side effects of DNA-modified products may promote interest in natural product research, especially in organic agricultural products. The recent interest in biodynamic agriculture which is based on TK is one such example of agricultural uses of TK.

There have been some attempts to estimate the contribution of TK, particularly biodiversity-related TK, to modern industry and agriculture. For pharmaceuticals, the estimated market value of plant-based medicines sold in OECD countries in 1985 was US\$ 43 billion.¹ That many of these would have used TK-leads in their product development is borne out by biochemist Norman Farnsworth's (1988) estimation that of the 119 plant-based compounds used in medicine worldwide, 74 per cent had the same or related uses as the medicinal plants from which they were derived. It is particularly difficult to estimate the contribution of traditional crop varieties (landraces) to the global economy. However, a study on the use and value of landraces for rice breeding in India² estimated that rice landraces acquired from India and overseas contributed 5.6 per cent, or US\$ 75 million, to

¹ (Principe, 1989)

² (Evenson, 1996)

India's rice yields. Assuming that landraces contribute equally to other countries where rice is cultivated, the global value added to rice yields by use of landraces can be estimated at US \$400 million per year.

Estimating the full value of TK in monetary terms is difficult if not impossible. First, TK is often an essential component in the development of other products. Second, as many and possibly most TK-derived products never enter modern markets, they are excluded from sectoral or GNP indices. However, if those who depend on TK-derived products were deprived of them, the cost of replacing them through purchases of substitutes in the market would probably be quite high, particularly as a portion of their incomes. And third, a great deal of TK is likely to have cultural or spiritual value that cannot be quantified.”¹

Indigenous knowledge provides the basis for problem-solving strategies for local communities, especially the poor. It represents an important component of global knowledge on development issues. IK is an underutilized resource in the development process. Learning from IK, by investigating first what local communities know and have, can improve understanding of local conditions and provide a productive context for activities designed to help the communities. Understanding IK can increase responsiveness to clients. Adapting international practices to the local setting can help improve the impact and sustainability of development assistance. Sharing IK within and across communities can help enhance cross-cultural understanding and promote the cultural dimension of development. Most importantly, investing in the exchange of IK and its integration into the assistance programs of the World Bank and its development partners can help to reduce poverty.

Indigenous knowledge is an integral part of the development process of local communities. Knowledge, not capital, is the key to sustainable social and economic

¹ <http://unctad.org/en/docs/c1em13d2.en.pdf>

development. Building on local knowledge, the basic component of any country's knowledge system, is the first step to mobilize such capital.¹ Indigenous knowledge is an important part of the lives of the poor. It is an integral part of the local ecosystem. IK is a key element of the "social capital" of the poor; their main asset to invest in the struggle for survival, to produce food, to provide for shelter or to achieve control of their own lives. Indigenous knowledge also provides problem-solving strategies for local communities and helps shape local visions and perceptions of environment and society.

IK is important for both the local communities and the global community. The development partners need to recognize the role of IK, understand its workings in the context of the local communities, and integrate systematically the most effective and promising of such practices into the development programs they support. Investing in the exchange of indigenous knowledge and its integration into the development process can help to reduce poverty.

Anywhere in the world people need protection for their properties; tangible property can be easily protected, but the case of intangible property is different. They require much more effective mechanisms like patents, copyrights, trademarks, geographical indicators etc. These mechanisms can be used to protect individual's intangible properties. Question raised is whether this mechanism is useful in protection of properties owned by the communities. Challenges to TK are diverse and far reaching and involves many areas of law and policy which is even beyond the expansive view of intellectual property.

Indigenous people have an immense understanding about their complex ecosystems, properties of plants and animals and regarding the techniques of using them based on their living close with nature for centuries. This knowledge when transformed into a formal

¹ 1998/99 World Development Report,

specification is sources of wealth. Generally these communities at large are in the grip of illiteracy and poverty and are unable to develop their own resources. Modern globalised World has witnessed the conversion of collective knowledge of the society into proprietary knowledge of a few.

Preservation of TK is intended to provide self identification to these indigenous communities and thereby provide continuous existence of indigenous people. The maintenance of the distinct knowledge systems that give rise to TK is vital for the future well being, development, cultural and intellectual vitality of indigenous communities.

In recent years patenting of traditional knowledge based products by MNC's have been a great concern. Bio-piracy can be regarded as double theft because firstly it allows theft of creativity and innovation and secondly it establishes exclusive rights on stolen knowledge and steal economic options of every day survival of indigenous communities on the basis of their common knowledge. Bio piracy happens in cases where patents are granted according to the existing national legislations which does not recognize certain forms of public disclosures as prior art as in the case of USA. The developing nations and NGO's are vigilant in preventing bio piracy and this can be witnessed from the results of several cases like turmeric, neem, ayahuasca etc.

Transmission and loss of traditional knowledge:

There are inherent linkages between TK protection, the maintenance of indigenous cultural identity, language, customary laws and rights over traditionally occupied lands¹. In relation to the latter, a study for the Ad-Hoc Working Group on Article 8(j) of the Convention on Biological Diversity adds that the political will to address land claims is

¹ As recognized in the 2005 United Nations Development Programme (UNDP) Practice Note on 'Traditional Knowledge, Access to Genetic Resources, and Benefit-Sharing - (UNDP 2005, p. 7; Thomas 2001)

essential to the retention and use of TK.¹ Importantly; it is the loss of opportunity to pursue the traditional practices that will result in the loss of the knowledge. Without opportunities to constantly review the traditional knowledge, innovation and practice, the indigenous way of knowing the earth will cease, except as a collection of data in reports such as this.²

Traditional indigenous knowledge is knowledge of a land. A pillar of the efforts to redress the decline in traditional knowledge, innovation and practice is to acknowledge the critical link between the land, the people, and the knowledge.³ Intellectual property protection is thus but one component in the complex social and environmental rubric influencing the future preservation of TK. As emphasized in the Composite Report, the state of TK ‘remains under threat’ and efforts to protect TK are ‘as yet insufficient’⁴. Along with persistent challenges facing indigenous peoples in retaining or recovering their land rights, the loss of TK is closely connected to other socio-economic factors including poverty, unemployment, rural-urban migration and the homogenizing effects of globalization on culture.⁵ Along with these factors, the transmission of TK is affected by declines or interruptions in the transmission of indigenous languages, which encode TK. Particular groups within indigenous societies, for example, women and elders, play important roles in the transmission of language and TK. The threat to TK can furthermore be seen within the

¹ United Nations Environment Programme [UNEP] & Secretariat of the CBD 2003, p. 52)

² Composite Report on the Status and Trends Regarding the Knowledge, Innovations and Practices of Indigenous and Local Communities (Regional Report for North America) - UNEP

³ Composite Report on the Status and Trends Regarding the Knowledge, Innovations and Practices of Indigenous and Local Communities (Regional Report for North America) - UNEP

⁴ (ibid.)

⁵ (UNDP 2004, p. 11; see generally Wood, Stedman-Edwards & Mang 2000)

larger phenomenon of biodiversity loss which includes bio-cultural loss – that is, the ‘extinction of experience’ – as well as genetic resource loss. Climate change has greatly exacerbated these concerns and poses one of the most pressing challenges to the physical and cultural survival of many people. In terms of integrated approaches towards rescuing bio-cultural diversity, there are projects such as those stemming from the agreement between the Association for Nature and Sustainable Development (ANDES) and the International Potato Centre (CIP), under which traditional potato varieties are being repatriated to the Quechua Communities. This is an interesting trend towards the recuperation of agrobiodiversity and associated TK, going beyond current debates centring on IP by focusing on transmission of TK and dynamic experimentation in relation to factors such as food security and climate change.

III) PROTECTION OF TRADITIONAL KNOWLEDGE IN IPR REGIME

Intellectual property (IP) is a term referring to a number of distinct types of expressions for which a set of rights are recognized under the corresponding fields of law. Under intellectual property law, owners are granted certain exclusive rights to various markets, machines, musical, literary, and artistic works; discoveries and inventions; and applications. Common types of intellectual property rights include copyrights, trademarks, patents, industrial design rights, and trade secrets in some jurisdictions.

The main objective of most intellectual property law (with the exception of trademarks) is to "Promote progress." By exchanging limited exclusive rights for disclosure of inventions and creative works, society and the patentee/copyright owner mutually benefit, and an incentive is created for inventors and authors to create and disclose their work. Some commentators have noted that the objective of intellectual property legislators and those who support its implementation appears to be "absolute protection." "If some intellectual property is desirable because it encourages innovation, they reason, more is better. The thinking is that creators will not have sufficient incentive to invent unless they are legally entitled to capture the full social value of their inventions." This absolute protection or full value view treats intellectual property as another type of 'real' property, typically adopting its law and rhetoric.

These exclusive rights allow owners of intellectual property to benefit from the property they have created, providing a financial incentive for the creation of an investment in intellectual property, and, in case of patents, pay associated research and development costs.

The WIPO treaty and several related international agreements are premised on the notion that the protection of intellectual property rights is essential to maintaining economic growth. There are two reasons for intellectual property laws:

*One is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations. The second is to promote, as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development.*¹

Legitimacy of the global intellectual property right systems is in question for its inability to generate symmetrical opportunities for traditional knowledge holders' vis-à-vis the inventors and innovators in formal sector. There is a widespread appreciation that IP systems have to reduce transaction costs of the various stakeholders involved in documentation, validation, value addition, IP Protection, dissemination through commercial or non-commercial licensing or otherwise and fair benefit sharing. There are several issues which are to be resolved if transaction costs have to be reduced reciprocally, i.e., not just for the well connected and resourceful formal sector but also for the disadvantaged informal sector. However, before the conceptual and empirical issues involved in online IP administration for traditional knowledge can be identified, it is desirable that we understand the institutional context of traditional ways of knowing, creating and innovating in various societies. The knowledge, innovation and practices produced through these ways may require different kinds of instruments for protection. The electronic administration of these instruments would have to contend with the challenges of linguistic, cultural and socio-economic diversity of communities around the world. The central thesis of this paper is that given the inadequacies in the technical competence and infrastructural capabilities of most of the developing, international registry administered electronically by WIPO and/or its subsidiaries might provide the most effective tool for meeting the aspirations of grassroots

¹ *WIPO Intellectual Property Handbook*

innovators and traditional knowledge holders. This registry will help accomplish what I call as golden triangle of rewarding creativity, i.e., link innovation, investment and enterprise around the globe. Without a system of protection of knowledge globally, incentives for disclosure and dissemination cannot be provided to the holders of valuable traditional knowledge about biological and genetic resources as well as other resources. If erosion of knowledge has to be stemmed, on line intellectual property rights administration may provide a necessary, though not sufficient condition for the same.

The dimensions of traditional ways of knowing and generating the intellectual property:

Local communities have survived against all odds in various parts of the world through a constant process of experimentation, innovation and mutual learning. These processes helped some communities and individuals therein to make a transition to modern lifestyles and associated privileges of dealing with various constraints of managing survival. At the same time, for a very large number of communities and individual knowledge experts, the forces of globalization have reduced over a period of time, the opportunities for their continued expression of their values. Accordingly, a very large number of traditional communities have been impoverished precisely because their values encourage them to conserve biodiversity and other resources and associated knowledge systems and not exploit the same in a non-sustainable manner. while these impoverished communities have provided leads for modern pharmaceutical and seeds industry and many other commercial sectors, the benefit sharing has been almost totally absent. Because of asymmetrical recognition of the contributions of various actors in the value chain of knowledge in formal and informal sectors, this chain is not sustainable. It is obvious that this asymmetry is neither sustainable nor ethically justified. There is no reason to expect that communities and

individuals would continue to disclose their knowledge, innovations and practices to outsiders without any reciprocal recognition of the rights and entitlements of local communities and individuals. The illegitimate exploitation of the traditional knowledge of local communities by the formal sector without any acknowledgement and therefore benefit sharing cannot be stopped without putting in place traditional knowledge digital libraries (TKDL) as being attempted in India. The incentives not only for disclosure but also for further augmentation of traditional knowledge systems by communities and individual knowledge experts are necessary to sustain the positive elements of the knowledge systems. The underlying ethical and cultural values, which have contributed to the conservation of biological and other resources and associated knowledge systems, have a role to play in future. This will help in modifying and moderating the negative influences of market economy and enhance the positive elements of the modern market oriented exchange economies.

There is no doubt that technological knowledge exists in an institutional context. What kind of rules govern the evolution of knowledge and its dissemination are therefore important to determine the typology of incentives that will nurture or impair the processes of knowledge production and reproduction. The generation of creative and innovative solutions for local problems will also be influenced by these incentives. Therefore, the interaction among three sets of knowledge domains is important to understand the complexity of knowledge systems.

The knowledge could be produced by individuals, and or groups alone or in combination. Some of this knowledge may diffuse only locally to be characterised as community knowledge while other may diffuse widely among various communities in a region and some time across regions and countries to become public domain knowledge.

Within the community knowledge, there may be elements which are restricted in scope or in terms of accessibility while others may be in public domain. Similarly, individuals may also produce knowledge, which they may share widely with the community and outsiders in a manner that the knowledge might become public domain. However, some of the knowledge produced by the individuals may be kept confidential and accordingly may be accessed only with restrictions.

Within the community knowledge, there may be elements which are restricted in scope or in terms of accessibility while others may be in public domain. Similarly, individuals may also produce knowledge, which they may share widely with the community and outsiders in a manner that the knowledge might become public domain. However, some of the knowledge produced by the individuals may be kept confidential and accordingly may be accessed only with restrictions. Further, community knowledge may or may not be accessible to outsiders (K2-A and K2-NA). Different communities may have varying capability to produce, reproduce and practice the knowledge for individual or common good. Wider the sharing, greater is the probability of feedback coming from larger number of people and thus improving the knowledge. At the same time the incentives for individuals to improve such knowledge may go down because such individuals in view of widespread awareness cannot extract the rent. Some communities govern the access to biodiversity resource by different rules than the access to knowledge about such resources. The knowledge within a community is therefore not distributed symmetrically. The variability not only influences the power differentials but also the extent of efficiency gains that different members of a community make by using the same knowledge differently. The communities benefit from the individual knowledge and thereby revere the local knowledge experts or healers. But this reverence may not be the sufficient motivator to encourage young

people, to acquire this knowledge and take it forward with or without improvement. There may be other factors also such as public policy, media exposure, life style changes etc., which may affect the incentives for younger people to acquire particular knowledge. However, the point remains that the existing set of incentives may need to be modified if traditional knowledge has not only to be conserved but also augmented.

There is a strong need for protecting intellectual property rights of knowledge rich economically poor individuals and communities. However, to provide such a protection one would have to characterize such knowledge in the manner that the novelty and non-obviousness can be established. This would mean a comparison with available formal scientific knowledge. The present instruments of IPR can provide limited help in this manner. However, with modifications these instruments can indeed go a long way in protecting the intellectual property of individuals as well as communities. The greatest advantage of this system would be that the people will have incentives to disclose their traditional and contemporary knowledge and make it available to others for learning purposes. Once this knowledge becomes a basis for livelihood, conservation, lateral learning and social networking, a knowledge society starts emerging. Once this happens the public domain provides incentives and not disincentives for individual and communities to share their knowledge after due acknowledgement.

Intellectual property rights protection for traditional knowledge, innovation and practices:

The part of intellectual capital which is incorporated in the intellectual property systems requires clarifications of several aspects of interface between traditional knowledge system and modern IP arrangements.

a. Prior art

There are parts of traditional knowledge systems, which have been brought in public domain by the formal sector researchers, corporations and sometime the committees themselves by wider dissemination of their knowledge, innovation and practices. These parts of knowledge systems would need not only the copyright protection but also digitization so that various patent offices' do not issue patents inadvertently on such prior art. The traditional knowledge digital library (TKDL) being attempted in India provides one very useful model of establishing prior art. Issuance of patents on public domain knowledge as was the case in turmeric patent, which was subsequently invalidated, will thus be prevented. However, one of the most difficult questions to be resolved is: Should knowledge, innovation and practices not yet documented or disseminated widely be considered prior art? In the Indian Patent Amendment Bill, 1999 there is a provision that a patent can be denied if the claims can be anticipated by the oral knowledge systems of traditional and/or local communities. Such a provision would be highly inappropriate for recognizing the IP rights of local communities. It will imply that even if the knowledge is not documented and has unique features amenable for industrial applications, it will still constitute prior art. My contention is that we should the precedence of "reasonable accessibility" as a necessary condition for constituting the domain of prior art, i.e., if a particular practice of innovative way of managing any resource is known to a community and/or a knowledge expert, but is not reasonably accessible to an inventor in the formal sector, then it should not constitute prior art. Accordingly, it should be amenable for protection. The distinction between discoveries and inventions has already been blurred in the case of micro-organisms and plant varieties. Therefore, that cannot be a basis for

denying the novelty to a unique contribution of a community and/or individual knowledge experts.

b. Grace period

Related to the issue of prior art is the aspect of grace period, i.e., how much time should be permitted for a knowledge, innovation or practice to be revealed within which it retains the eligibility for IP protection. In the US, one year grace period is provided for any disclosure. However, certain kinds of disclosure in a specific context do not constitute a knowledge or innovation becoming a prior art. There are two issues, which we have to appreciate from the point of view of local communities. One, what should be the mechanism to deal with disclosure by people in good faith without being aware of the implications of the modern IP system; and second, what is the ethical basis of a very large body of ethno biological literature where outside researchers have documented local and traditional knowledge without any acknowledgement or reciprocity in terms of sharing. One possibility is that we give five-year grace period for traditional knowledge disclosed in good faith. The basis for five years is that the TRIPS coming into force in 1995. This provision will generate tremendous goodwill among the traditional communities though it will not satisfy all those who criticize and justifiably so, the historical bio piracy and usurpation of traditional knowledge systems.

c. Community intellectual property rights versus individual intellectual property rights:

The legitimate representatives of the communities should have the opportunity to protect their knowledge for a longer period or bring it in public domain or permit the individual members to keep it as trade secrets. In various countries, various customary or

constitutional institutions may exist which can execute the choices. In the Indian context, a village council could authorize anybody to sign on its behalf, the application representing all the community members who have contributed to the production and reproduction of knowledge systems. It will be difficult to isolate the contribution of each individual since these contributions may have been made through feedback processes, through conservation of resources or through direct experimentation. Just as we have collectors' societies for protecting the collective rights of individual performing artists, we should think of similar institutional innovations for protecting individual IP rights of grassroots innovators. This will further reduce the transaction costs of the innovators.

There are several other related issues concerning period of protection, multi community rights and grounds for revocation of patents. Without going into the detailed analysis which is beyond the scope of this paper, it may suffice to mention that justification for present generation to be given the right to protect and assign their intellectual property is very clear. It is the action and values of the present generation which would determine whether or not the traditional knowledge system or part thereof survive in future.

It is important to recognize that some of the traditional ways of knowing are similar to the modern ways though the motivation and values underlying those ways may be different. For example, a farmer spots an odd plant in the field and select the seed, tests them next year and if found superior to existing germ-plasm, retains as seed for future use. Many farmer-bred varieties have come up through this process. For instance, the cardamom variety by Sebastian Joseph; the pigeon pea variety by Dhulahbhai, chilly variety by Sundaram and Alibhai Abhvani were selected in the same way. Modern plant breeders also make selections of off type plants and develop varieties. Many varieties of pulses and oil

seed for rainfed regions have been developed in this manner. The traditional and modern methods converge in this case. Likewise, many herbal pesticides, veterinary medicines or farm implements may be developed through experimentation.

The Form of Protecting Traditional Knowledge:

As the value of the traditional knowledge has been recognized by modern world gradually, the steps into protecting traditional knowledge attract more and more attention. It is not only desirable but also important as well to take measures to give the protection and respect to traditional knowledge, and to make prevention from misappropriation, by the means of passive protection and defensive protection mutually. The former one mainly gives the holders the right to take action or search for a way of remedy, to prevent it from abusing. The latter one, on the other hand, aims to supply a safeguarding against the illegitimate right of IP by a third party over the traditional knowledge. To protect traditional knowledge properly, the two approaches should be applied complementally.

Positive Protections

The main way of exerting positive protection is through acknowledging the intellectual right on traditional knowledge. The key part of this thesis is to provide an appropriate choice for the holders of traditional knowledge to value their interest and protect traditional knowledge.

The Use of Current Intellectual Property Legislation:

It has to be accepted that the current intellectual property system on the TK part is limited to the desire and expect of TK holders. Nevertheless, the current intellectual property legislation is still playing a useful role in the way of preventing TK from misuse and

misappropriation. The following parts give some description of mechanisms in IP legislation on protecting TK.

1. In patent

When the practitioners make some improvement or renovation on the TK, the patent system plays its role to protect it. Another situation is that the patent also makes some effort to ensure illegitimate patent rights are not be applied over TK by a third party. (This will be discussed in the defensive part)

2. In unfair competition and trade practices

These allow making a declaration to make public aware of the fake or misleading products, which are under the name of TK or relating to TK but in essence is not.

3. In Distinctive signs

It aims to protect the signs, symbols and terms related to traditional knowledge, by the way of providing a safeguarded against an unreasonable third party to require for a trade mark right.

4. In the law of confidentiality and trade secrets

Their purpose is to protect the TK in non-disclosed area, including secret TK and confidential culture. In some countries, courts even make sentence of compensation, if someone broke the rule of confidentiality.

The Use of Sui Generis Exclusive Regime

Some countries believe that the current intellectual system is not sufficient to adapt the whole characteristics of TK or to protect it effectively. As a result, these countries assert

to use a sui generis system, which is, as they insist, the only one can protect TK effectively and appropriately. This essay takes sui generis regime in Peru and Portugal as examples.

In Peru, the sui generis regime was established through the law No. 27. 811 of 2002. The law entail the power to the local people that they could make the decision whether agree others to use their TK or not. What worth our attention is that the aim of this law is to ensure the informed consent by holders and reasonable and the fair benefit-sharing with the indigenous community. On the other hand, it also works on preventing others from the illegal use of the TK. As in Portugal, its sui generis Decree-Law No. 118, of April 20, 2002, involves in the problems that how to legally register, safeguard and supervise of TK. The objective of it is to provide a more effective protection to TK, especially to its commercial and industrial applications.

Defensive Protections:

The main difference between positive and defensive protection is that while positive protection aiming to stop misusing or misappropriating TK when not be granted, defensive protections aims at protecting TK from acquiring invalid intellectual property right. That means one could not apply for a patent for his invention, in the situation that the 'invention' has been acknowledged as TK in other community for a while. In other words, we need a more effective and wide instrument to provide a database to exam before application. The following sections explain this in details.

Amendment of the Legal System in WIPO:

In some countries and international organizations, a series of mechanisms for defensive protection of traditional knowledge have already been established and taken into practice. The work of WIPO (World Intellectual property organization) in the area of

defensive protection of TK includes modifying the administered systems and expanding the function of practical capacity-building tools.

There are many examples, all of which are serviced for making sure the TK used under the condition of the holders' permit or even preventing the third party from misappropriation or misuse. The international Patent Classification (IPC), whose function is to locate technical information for patent purposes, is one of the famous instances. It has taken more and more TK subject matters into account, such as medicinal products based on plants extracts. At the same time, intergovernmental committee will make more efforts in this direction of solving the problems. The Patent Cooperation Treaty is another typical example of WIPO administered treaty. It services the field of international cooperation, which regulates relative rules about international search and examination. Recently, an international search and examination has expanded to eleven information resources related to TK. This means that this system has been improved that relevant TK will be located at an early stage in patent area.

Practical Capacity-Building Tools---Database:

Taken Toolkit for IP Management and an Online Portal of Registries and Databases of TK and Genetic Resources as examples, WIPO is always working on develop a tool or an approach to protect traditional knowledge effectively. Another typical example is “Toolkit for IP Management When Documenting TK and Genetic Resources”, which is a practical cooperate instrument. It aims to provide stakeholders relative knowledge to help them decide whether to use their right or under what kind of situation to use their right to protect themselves and TK properly.

However, there is another question which is that though establishing a database is available for public to exam whether the TK is valuable, it is a risk for holders to offer all the information about the TK. Certainly, in the process of establishing the database, holders of TK need to collect information, register, write down all the secrets, and even arrange all of them to documents. The significant drawback of placing the core information into public is that it will be very hard to control to give the secret of community away. Therefore, when the holders do the database works of placing the information in public, they may be careful with their secrets related to TK, on the other hand, not revealing the secrets against the customary law and practice.

Under the background of comprehensive protection of TK, the defensive approach is on its own practical way to maximize its effect. In fact, the aim of this defensive protection, database, is to make the TK be used more effectively and practically by the business or non-indigenous users. This process needs holders of TK to understand sufficiently what result it will be after the information about the TK has announced to public. Therefore the defensive protection has its own advantages on the part of preventing others from individual application to complementary the positive protection, though it has its own shortcomings.

A Modified New Patent Application Procedure:

It is obvious that the whole system of protecting TK needs to be a practical and effective one. The current prevalent idea on global scale is that patent law can be modified by introducing sui generis elements to sufficiently protect TK more effectively. It is proposed that introducing procedural safeguards into the current system of protecting TK could get a much better result. The following parts will describe the three procedural safeguards separately.

Disclosure of Origin:

It should be mentioned that in Europe, it has been already introduced a procedure of disclosure of origin requirement for protecting TK, especially on the level of plant and animal genetic resources. This process should be adopted on global scale as well, for the reason that it could supply a more reasonable and available stage for TK protection.

It requires an applicant an obligation to disclose the origin of the knowledge or materials used. This process will not only help protecting the indigenous communities' knowledge or secrets, it also provides the convenient for other procedures, prior informed consent or benefit-sharing, to be administered more effectively. Therefore this procedure is highly recommended on the international level.

Prior Informed Consent:

Despite of disclosing the origin of the knowledge or materials it used, it is an important step to confirm whether an applicant has got the consent from the indigenous community to apply the traditional knowledge, as discussed in the former section. "Prior informed consent implies the right to stop the activity from proceeding, and for it to be halted if it is already underway."

The core element in this step is that it gives local communities the right of control over their traditional knowledge and materials, no matter plant or animals. Anyone who wants to use their TK or materials should ask their permit firstly or it will be seemed as against legislative. Therefore the party should make a negotiation with the holder of TK, and in the negotiation or agreement it should be stipulated whether or to what extent the third party could use TK. This on the other hand helps preventing from misuse and

misappropriation at the same time. What's more, this make more available for the holders of TK to share the benefits from using their TK.

Benefit-Sharing:

As in many legal systems, it is common that many include the concept of equitable balancing of benefits. It is also contained in the intellectual property law. When it comes to the field of TK, this principle should be adopted as well. After getting the consent of the local community, the party intending to use the TK or applying a patent involving the TK should start to make a negotiation with local community to discuss about the issue of benefit-sharing, which of course should be established on the level of fair and equitable.

According to this, the holder of the TK should be rational to share the benefits gained from the use of TK, which may be on the sake of compensation or other non-monetary benefits. This is considered as an equitable and rational payment to the holders of the TK or the indigenous community.

Diversity is the very essence of TK systems, precisely because they are so closely intertwined with the cultural identity of many diverse communities. It is therefore not surprising that practical experience so far with the protection of TK has shown that no single template or comprehensive “one-size-fits-all” solution is likely to suit all the national priorities and legal environments, let alone the needs of traditional communities in all countries. 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 key is to provide TK holders with an appropriate choice of forms of protection, to empower them to assess their interests and choose their own directions for the

protection and use of their TK, and to ensure there is adequate capacity to carry through protection strategies. The way in which a protection system is shaped and defined will depend to a large extent on the objectives it is intended to serve. Protection of TK, like protection of IP in general, is not undertaken as an end in itself, but as a means to broader policy goals. The kind of objectives that TK protection is intended to serve include:

- Recognition of value and promotion of respect for traditional knowledge systems
- Responsiveness to the actual needs of holders of TK
- Repression of misappropriation of TK and other unfair and inequitable uses
- Protection of tradition-based creativity and innovation
- Support of TK systems and empowerment of TK holders
- Promotion of equitable benefit-sharing from use of TK
- Promotion of the use of TK for a bottom-up approach to development.

International attention has turned to intellectual property laws to preserve, protect, and promote traditional knowledge. The reasons for this are complex. In 1992, the Convention on Biological Diversity (CBD) recognized the value of traditional knowledge in protecting species, ecosystems and landscapes, and incorporated language regulating access to it and its use (discussed below). It was soon urged that implementing these provisions would require revision of international intellectual property agreements.

This became even more pressing with the adoption of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which established rules for creating and protecting intellectual property that could be interpreted to conflict with the agreements made under the CBD. In response, the states who had ratified

the CBD requested the World Intellectual Property Organization (WIPO) to investigate the relationship between intellectual property rights, biodiversity and traditional knowledge. WIPO began this work with a fact-finding mission in 1999. Considering the issues involved with biodiversity and the broader issues in TRIPs (involving all forms of cultural expressions, not just those associated with biodiversity - including traditional designs, music, songs, stories, etc.), WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC-GRTKF).

The period of the early 1990s to the Millennium was also characterized by the rapid rise in global civil society. The high-level Brundtland Report (1987) recommended a change in development policy that allowed for direct community participation and respected local rights and aspirations. Indigenous peoples and others had successfully petitioned the United Nations to establish a Working Group on Indigenous Populations that made two early surveys on treaty rights and land rights. These led to a greater public and governmental recognition of indigenous land and resource rights, and the need to address the issue of collective human rights, as distinct from the individual rights of existing human rights law.

The collective human rights of indigenous and local communities has been increasingly recognized - such as in the International Labor Organization (ILO) Convention 169 (1989) and the Declaration on the Rights of Indigenous Peoples (2007). The Rio Declaration (1992), endorsed by the presidents and ministers of the majority of the countries of the world, recognized indigenous and local communities as distinct groups with special concerns that should be addressed by states.

Initial concern was over the territorial rights and traditional resource rights of these communities. Indigenous peoples soon showed concern for the misappropriation and misuse

of their "intangible" knowledge and cultural heritage. Indigenous peoples and local communities have resisted, among other things: the use of traditional symbols and designs as mascots, derivative arts and crafts; the use or modification of traditional songs; the patenting of traditional uses of medicinal plants; and the copyrighting and distribution of traditional stories.

Indigenous peoples and local communities have sought to prevent the patenting of traditional knowledge and resources where they have not given express consent. They have sought for greater protection and control over traditional knowledge and resources. Certain communities have also sought to ensure that their traditional knowledge is used equitably - according to restrictions set by their traditions, or requiring benefit sharing for its use according to benefits which they define.

Three broad approaches to protect traditional knowledge have been developed. The first emphasizes protecting traditional knowledge as a form of cultural heritage. The second looks at protection of traditional knowledge as a collective human right. The third, taken by the WTO and WIPO, investigates the use of existing or novel *sui generis* measures to protect traditional knowledge.

Currently, only a few nations offer explicit *sui generis* protection for traditional knowledge. However, a number of countries are still undecided as to whether law should give traditional knowledge deference. Indigenous peoples have shown ambivalence about the intellectual property approach. Some have been willing to investigate how existing intellectual property mechanisms (primarily: patents, copyrights, trademarks and trade secrets) can protect traditional knowledge. Others believe that an intellectual property approach may work, but will require more radical and novel forms of intellectual property

law ("sui generis rights"). Others believe that the intellectual property system uses concepts and terms that are incompatible with traditional cultural concepts, and favors the commercialization of their traditions, which they generally resist. Many have argued that the form of protection should refer to collective human rights to protect their distinct identities, religions and cultural heritage.

Current IP system considers only documented knowledge as prior art. This is contrary to the concept of TK which may not be available in a systematic and organized manner. Besides even if it is recorded it may be recorded in the local language like old manuscripts in Sanskrit which the foreign patent offices may find difficult to access.

The current IP system is based on granting exclusive rights to individual private property which is contrary to the concept of TK, a community based knowledge and granting exclusive rights to a particular individual or corporation for collective knowledge of the community would be against the nature of TK.

One can rightly say that current patent system provides stand for protecting the economic interests of big corporations that have slightly altered TK to bring out a commercial product and left out the entire community which developed this knowledge to the present stage. Basically the patent regime lacks the concept of community patent which can be used to protect collective knowledge of the society and this has led to the questions of who can be the owner of patents, based on TK and how benefits accruing from such patents can be distributed among the society who are the actual owners of that knowledge.

Current patent system is based on the principles of novelty, non-obviousness and industrial application and hence it cannot be invoked for giving positive protection to TK. Traditional Knowledge has evolved through generations by trial and errors and therefore

lacks the concept of novelty. Also TK as such may not be having any commercial application, it indeed requires certain changes and it is totally unjust to ignore the role of the entire society and grant economic rights to those who came out with the commercial application of community knowledge. So we can see that existing patent system is incapable of giving protection to TK as there is an essential difference between both the concepts.

Government of India efforts:

In 2001, the Government of India set up the Traditional Knowledge Digital Library (TKDL) as repository of 1200 formulations of various systems of Indian medicine, such as Ayurveda, Unani and Siddha and 1500 Yoga postures (asanas), translated into five languages — English, German, French, Spanish and Japanese. India has also signed agreements with the European Patent Office (EPO), United Kingdom Intellectual Property Office (UKIPO) and the United States Patent and Trademark Office (USPTO) to prevent the grant of invalid patents by giving patent examiners at International Patent Offices access to the TKDL database for patent search and examination.

IPR Policy of Kerala Govt.(India) - Intellectual Property Rights (IPRs) Policy for Kerala released in 2008 [17], proposes adoption of the concepts ‘knowledge commons’ and ‘commons licence’ for the protection of traditional knowledge. The chief architects of the Policy are Prof. Prabhat Patnaik and Mr. R.S. Praveen Raj. The policy seeks to put all traditional knowledge into the realm of “knowledge commons”, distinguishing this from the public domain. While codification of TK in digital libraries and sharing the same with patent offices’ prevents direct misappropriation, it is feared that it may provide an opportunity for private appropriation by making cosmetic improvements to such traditional knowledge that is not readily accessible otherwise.

Limitations of the Intellectual Property Rights Regime in Protecting Traditional Knowledge:

The difficulty experienced by indigenous peoples in trying to protect their traditional knowledge under intellectual property (IP) rights law stems mainly from its failure to satisfy the requirements for protection under existing IP law. For example, intellectual property must be new, original, innovative or distinctive to qualify for protection. These requirements make it difficult for traditional knowledge – generally handed down from generation to generation – to obtain IP protection.

Moreover, from an Aboriginal perspective, the emphasis of the existing western intellectual property rights regime on individual proprietary rights does not address the collective nature of traditional knowledge. Because western IP law is based on individual property ownership, its aims are often incompatible with, if not detrimental to, those of traditional communities. For many traditional communities, intellectual property is a means of developing and maintaining group identity and survival, rather than promoting individual economic gain.

Another key concern shared by indigenous peoples worldwide is that the present intellectual property rights regime favours multinationals and other non-indigenous interests. Where IP protection may apply, the prohibitive costs of registering and defending a patent or other intellectual property right effectively limit its availability to the vast majority of indigenous communities, primarily in developing countries. In this way, the existing intellectual property rights regime is seen to help corporate interests and entrepreneurs lay claim to indigenous knowledge without appropriate acknowledgement or compensation for the communities who have developed that knowledge.

PROTECTING TRADITIONAL KNOWLEDGE OF INDIGENOUS AND LOCAL COMMUNITIES:

Article 8(j) of the Convention on Biological Diversity requires Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" and promotes the "wider application" of traditional knowledge with the approval and involvement of the holders of traditional knowledge. Article 10(c) similarly provides that CBD Parties "shall...protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements."

The TRIPS Agreement and other international agreements on intellectual property rights, by contrast, fail to recognize the value of traditional knowledge as a source of innovation. These instruments were designed mostly to protect "western" forms of innovation and do not provide adequate mechanisms that address the special nature of traditional knowledge. Current trends show an increasing number of national laws providing direct or indirect protection for traditional knowledge. Direct protection is provided by establishing mechanisms exclusively designed for protecting traditional knowledge, including sui generis systems. Indirect protection occurs as a consequence of more general laws oriented towards the protection of indigenous rights or laws regulating access to genetic resources. These particular trends should be supported by the international community because they favour a bottom-up approach when providing protection and permit more direct participation of indigenous and local communities in their national context.

Principal international agreements relevant to the legal protection of traditional knowledge

The international agreements relevant to the legal protection of TK range from those that are essentially aspiration in character to those that impose on parties concrete legal obligations backed by international enforcement mechanisms. In the former category are such agreements as the International Covenant on Economic, Social and Cultural Rights, the International Labour Organization's Convention (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries and the Convention on Biological Diversity (CBD).¹³ Some aspects of the CBD, the first international agreement to make explicit reference to the protection of TK, are discussed in Box 4.2. Significantly, the UN General Assembly adopted on 17 September 2007 the UN Declaration on the Rights of Indigenous Peoples, which includes provisions relating to TK. At the other end of the spectrum is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement'). This Agreement requires its members to adhere to specific minimum standards for the protection and enforcement of IPRs, and establishes an international dispute settlement process to resolve disputes among members and to authorize the imposition of sanctions on members who fail to carry out their obligations under the Agreement. Falling between these two extremes is the Food and Agriculture Organization (FAO) International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), which creates a formal 'Multilateral System' – that is, a system of 'common-pool goods' – in thirty-six genera of crops and twenty-nine genera of forages, guaranteeing both 'facilitated' (i.e. free or low-cost) access to these genetic resources and a system for equitable sharing of the benefits derived from any commercialized products that incorporate materials from the Multilateral System.

An important TRIPS-related development with respect to the protection of TK was the 2001 Doha Ministerial Declaration of the WTO, which instructed the WTO's Council for TRIPS 'to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore' Of particular significance to the implementation of the CBD was the 2003 promulgation of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization ('Bonn Guidelines'). These Guidelines are designed to assist parties, governments and other stakeholders in developing an overall access and benefit-sharing (ABS) strategy and in identifying the steps relevant to ABS. Some guidance on the elements and basic principles of a prior informed consent (PIC) system, in accordance with Article 15 of the CBD, are provided in the Guidelines . An International Regime on Access and Benefit-Sharing is also being negotiated at the CBD and is discussed later in Section 4.3. In September 2007, the UN General Assembly adopted the UN Declaration on the Rights of Indigenous Peoples, following twenty years of negotiations involving indigenous peoples and national governments. The Declaration was adopted with an overwhelming majority of 143 votes in favour, only 4 negative votes cast (Canada, Australia, New Zealand and US) and 11 abstentions. While the UN Human Rights Council had endorsed the Declaration on the Rights of Indigenous Peoples in 2006, the process for its formal adoption by the UN General Assembly had come to a halt in November 2006, when the UN General Assembly's Third Committee adopted a non-action resolution, apparently at the behest of a number of African states. But this turned out to be a temporary hitch. As further considered in Chapter 5 of this book ,the future of indigenous rights, including the protection of their TK, depends a great deal on the political will of governments to recognize these important rights, connected ultimately to historically rooted questions of indigenous peoples' self-determination. A provision of particular significance to the IP protection of TK

from the UN Declaration on the Rights of Indigenous Peoples is Article 31(1) which states that:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

Article 31(2) provides that ‘States shall take effective measures to recognize and protect the exercise of these rights’, in conjunction with indigenous peoples. These rights are rather broad and could be better defined. Consequently, there are many possible ways to interpret and uphold them in national laws and policies. With respect to IP and the TRIPS Agreement, one can anticipate considerable debate on the question of whether certain provisions of TRIPS, or ways that these provisions tend to be implemented, would impinge on the full enjoyment of these indigenous peoples’ rights. The TRIPS Agreement takes legal precedence over the non-binding Declaration. Nonetheless, some countries may still choose to give priority to the Declaration irrespective of what the international law of treaties indicates. Significantly, Bolivia has adopted provisions reflecting the UN Declaration on the Rights of Indigenous Peoples in its national law. The UN Declaration on the Rights of Indigenous Peoples makes explicit reference, furthermore, to the right of indigenous peoples to their ‘traditional medicines’ and to maintain their health practices, including ‘the conservation of their vital medicinal plants, animals and minerals’ (Article 24).

National and regional traditional knowledge protection models:

The CBD's affirmation of the 'sovereign right' of states to exploit their own genetic resources pursuant to their own environmental policies has stimulated a variety of national and regional measures for regulating access to genetic resources and promoting benefit-sharing. These measures may promote, tolerate or discourage the practice of 'bio prospecting'. If a country (or region) wishes to encourage bio-prospecting, it would do well to follow the example of Costa Rica, and put in place a system that is: (1) relatively simple and attractive to the private sector and research institutions; and (2) adds value to its stock of genetic resources, which involves investing in building scientific capacity. One of the important objectives of the Costa Rican Biodiversity Law is to 'provide compensation for the knowledge, practices and innovations of Indigenous Peoples and local communities in the conservation and sustainable ecological use of the components of biodiversity'. Other examples of how this approach can be used to provide affirmative legal protection for TK are to be found among the International Cooperative Biodiversity Group (ICBG) projects sponsored by the US National Institutes of Health, although some difficulties have been experienced in their practical application.

More and more national and regional legislative frameworks are being established to guard against misappropriation of genetic resources and associated TK, and to implement the principle of PIC. A WIPO document notes that almost all national sui generis laws for TK protection apply the principle of PIC to TK.¹ For example, the African Model Law, the Brazilian Provisional Measure,⁴⁸ the sui generis TK provisions under the Costa Rican Biodiversity Law, the Indian Biodiversity Act, the Peruvian sui generis law, the Indigenous

¹ WIPO 2006b, p. 18 of Annex

Peoples' Rights Act of the Philippines, and the sui generis law of Portugal make access and acquisition to TK subject to PIC. Some elements of the Peruvian sui generis law are described alongside the Andean Community regional framework for the protection of TK.

As national and regional systems give increasing weight to protecting against 'bio-piracy' and safeguarding interests and values such as there may be a 'race to the bottom', with bio-prospecting activities shifting to those countries with the least restrictive legislation. Regional agreements may ameliorate the latter problem, but only if coherent regional benefit sharing arrangements are included and if such agreements are widely adopted throughout the various regions of the world. It is the need for protection of TK beyond national and regional jurisdictions which has led increasingly to discussions of international frameworks for the protection of TK. A joint paper published by the Southern Africa Development Community (SADC), International Union for the Conservation of Nature (IUCN) and United Nations Development Programme (UNDP) has called for the development of a SADC sub-regional legislative and policy framework on ABS in line with the socio-economic realities of the region. In this paper, Chishakwe and Young highlight the need to develop standards promoting the interests of source countries especially, and to explore a regional or multi-regional 'collective' approach under which source countries could band together to increase their bargaining power 'in the face of the lack of credible information from genetic resource users on the value, markets, and mechanisms relevant to ABS'. Some have, indeed, argued that nothing short of a 'biodiversity cartel' will effectively combat biodiversity loss and promote equitable benefit sharing.¹

¹ Vogel 2007, p. 115)

IV. MISUSE OF TRADITIONAL KNOWLEDGE IN IP REGIME

Traditional knowledge holders face various difficulties. In some cases, the very survival of the knowledge is at stake, as the cultural survival of communities is under threat. External social and environmental pressures, migration, the encroachment of modern lifestyles and the disruption of traditional ways of life can all weaken the traditional means of maintaining or passing knowledge on to future generations. There may be a risk of losing the very language that gives the primary voice to a knowledge tradition and the spiritual world-view that sustains this tradition. Either through acculturation or diffusion, many traditional knowledge practices and associated beliefs have been irretrievably lost. Thus, the primary need is to preserve the knowledge that is held by elders and communities throughout the world. Another difficulty facing traditional knowledge holders is the lack of respect and appreciation for such knowledge. For example, when a traditional healer provides a mixture of herbs to cure a sickness, the healer may not isolate and describe certain chemical compounds and describe their effect on the body in the terms of modern biochemistry, but the healer has, in effect, based this medical treatment upon generations of clinical trials undertaken by healers in the past, and on a solid empirical understanding of the interaction between the mixture and human physiology. Thus, sometimes the true understanding of the value of traditional knowledge maybe overlooked if its scientific and technical qualities are considered from a narrow cultural perspective. With the gradual recognition of the value of traditional knowledge and an exponential growth in the use of traditional knowledge products the greatest threat against it is that of usurpation over-exploitation by commercial entities in derogation of the rights of the original holders.

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lifestyles and the disruption of traditional ways of life can all weaken the traditional means of maintaining or passing knowledge on to future generations. There may be a risk of losing the very language that gives the primary voice to a knowledge tradition and the spiritual world-view that sustains this tradition. Either through acculturation or diffusion, many traditional practices and associated beliefs and knowledge have been irretrievably lost. Thus, a primary need is to preserve the knowledge that is held by elders and communities throughout the world.

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utilization and protection of Traditional Knowledge, results in these populations often being placed at a decided disadvantage in using existing IP mechanisms. At the same time, the lack of understanding and clear rules concerning the appropriate use of Traditional Knowledge creates areas of uncertainty for those seeking to use Traditional Knowledge in research and development of new products. There is a common need for well-established, culturally appropriate and predictable rules both for the holders and legitimate users of Traditional Knowledge. A further challenge is to address the international dimension of the protection of Traditional Knowledge and benefit-sharing for associated genetic resources, while learning from existing national experiences. Only through the participation of communities and countries from all regions can this work go forward to produce effective and equitable outcomes that are acceptable to all stakeholders. These challenges are diverse and far reaching, and involve many areas of law and policy, reaching well beyond even the most expansive view of intellectual property. Many international agencies and processes are engaged on these and related issues. But responses to these problems should be coordinated and consistent, and need to provide mutual support for broader objectives. For instance, IP protection of Traditional Knowledge should recognize the objectives of the CBD concerning conservation, sustainable use and equitable benefit-sharing of genetic resources. In general, the preservation and protection against loss and degradation of Traditional Knowledge should work hand-in-hand with the protection of Traditional Knowledge against misuse and misappropriation. So when Traditional Knowledge is recorded or documented with a view to preserving it for future generations, care needs to be taken to ensure that this act of preservation doesn't inadvertently facilitate the misappropriation or illegitimate use of the knowledge.¹

¹ WIPO-Intellectual Property and Traditional Knowledge

Because IK has a wide range of commercial and scientific uses, it is becoming increasingly valued by people outside Aboriginal communities. In recent years, interest in his knowledge has greatly increased, often stimulated by the search for Aboriginal peoples' knowledge of medicines, sustainable use of the environment and their cultural practices and arts. This has led to situations where IK has been gathered and used without contacting the source of the knowledge; for example, the use of traditional medicines as a basis for developing western pharmaceutical products and herbal remedies, or the unauthorized use of Aboriginal designs on T-shirts and other commercial goods.

The nature of traditional knowledge is such that more of it is transmitted orally than written down. This poses particular problems when parties not authorised by the holder of that knowledge seek to obtain IPRs over it. In the absence of any accessible written record, a patent examiner in another country is unable to access documentation that would challenge the novelty or inventiveness of an application based on traditional knowledge. The only option for an aggrieved party, be it the holders of the knowledge, or someone representing them, is to challenge the patent during the granting process or after grant, where national laws permit. For instance, this is what the Indian Government achieved by overturning the patents on basmati and turmeric in the US. The presence of administrative or quasi-judicial patent opposition or re-examination procedures has facilitated the overturning of these patents. In the absence of such procedures it would have been necessary to instigate proceedings before the relevant court with the inherent cost and time implications. Even with such procedures, it is extremely difficult and costly for developing countries to monitor and challenge IPRs issued all around the world. We suggest later in this chapter a possible way of assisting countries to monitor patents granted on inventions consisting of, or developed from, acquired biological material and associated knowledge.

Abuses of IK include:

- Unlicensed and unauthorized commercialization of IK
- Taking images, such as photographs, film and video of Aboriginal people, their way of life, etc.
- Using, reproducing or copying Aboriginal names, images and arts without permission
- Use and misuse of symbols without permission
- Disclosing secret knowledge and cultural property
- Publishing research without recognition or reward for the knowledge holders
- Entering into community research without fully explaining how the research will be used or who owns the results.

Patent applications claiming traditional knowledge already in the public domain should not be granted. The problem is that the knowledge tends not to be documented, or if it is, it is unlikely to be easily accessible to a patent examiner. In particular, information on traditional knowledge is not likely to be found in the type of patent-based information that patent offices' rely most on when assessing novelty and inventiveness. To address this problem, WIPO and a number of developing countries led by India and China are seeking to develop traditional knowledge digital libraries. These digital libraries will not only detail in writing considerable amounts of traditional knowledge already in the public domain, but will do so taking into account international classification standards (the WIPO International Patent Classification (IPC) system) so that the data will be easily accessible to patent examiners.

Because of these types of abuses, protecting IK from unauthorized use by others is a growing concern for Aboriginal communities. Historically, Aboriginal peoples have willingly shared their knowledge, often joking that a typical Aboriginal family consisted of parents, children, in and an anthropologist. However, interest in their knowledge by outsiders

has often been based on relationships that have not always been fair, equitable or beneficial for the community. This is changing today. If Aboriginal peoples decide to share their knowledge, they should be able to share it in a way that is consistent with their traditions and social values as well as in a way that reflects its economic value. Protecting against the abuses and misuses of the present and past is essential to establishing a balanced, consent-based system for sharing IK.

Traditional knowledge has always played an important role and will continue to do so in vital areas such as agriculture and medicine. For example, knowledge about medicinal use of Neem and Turmeric exists in indigenous groups of India since hundreds of years. To this day, these herbs continue to be widely researched for providing cures to a number of diseases. However, attempts by some individuals and corporations to make a quick buck by exploiting the traditional knowledge of a community, has raised the hackles of the communities that originated the knowledge. The concern stems from the fact that a large number of patents have been granted (although some of them have been revoked) for traditional knowledge-related inventions that do not fulfil the novelty criteria if the “traditional knowledge” is taken into consideration as prior art. The term “prior art” refers to any published content available in the public domain before the filing date of a patent application. An intensive search to find such prior art is conducted as a part of examination process of the patent application before it is granted. But, the problem is that content can only be considered “prior art” if it is in a documented form. Most of the traditional knowledge has been orally transferred down over a number of years and there may not necessarily be documented evidences for it. This has led to the granting of a number of erroneous patents due to lack of prior art. Use of these erroneously granted patents for commercial gain by individuals and corporations without proper sharing of benefits obtained from such use with the originators of the traditional knowledge has led to blatant exploitation

of the rights of indigenous peoples. Thus, concerns regarding protection of traditional knowledge are growing around the world.

Bio-prospecting is an umbrella term describing the process of discovery and commercialization of new products based in biological resources, typically in less-developed countries. Bio-prospecting often draws on indigenous knowledge about uses and characteristics of plants and animals. In this way, bio-prospecting includes bio-piracy, the exploitative appropriation of indigenous forms of knowledge by commercial actors, as well as the search for previously unknown compounds in organisms that have never been used in traditional medicine.

Bio-piracy is a situation where indigenous knowledge of nature, originating with indigenous people, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves. For example when bio-prospectors draw on indigenous knowledge of medicinal plants which is later patented by medical companies without recognizing the fact that the knowledge is not new, or invented by the patentee, and depriving the indigenous community to the rights to commercial exploitation of the technology that they themselves had developed. Critics of this practice such as Greenpeace, claim these practices contribute to inequality between developing countries rich in biodiversity, and developed countries hosting companies that engage in 'bio-piracy'.

Bio-piracy:

There is no accepted definition of “biopiracy.” The Action Group on Erosion, Technology and Concentration (ETC Group) defines it as “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.”

The following have been described as “bio-piracy”:

a) The granting of ‘wrong’ patents. These are patents granted for inventions that are either not novel or are not inventive having regard to traditional knowledge already in the public domain. Such patents may be granted due either to oversights during the examination of the patent or simply because the patent examiner did not have access to the knowledge. This may be because it is written down but not accessible using the tools available to the examiner, or because it is unwritten knowledge. A WIPO led initiative to document and classify traditional knowledge seeks to address some of these problems.

b) The granting of ‘right’ patents. Patents may be correctly granted according to national law on inventions derived from a community’s traditional knowledge or genetic resources. It could be argued this constitutes “bio-piracy” on the following grounds:

- Patenting standards are too low. Patents are allowed, for instance, for inventions which amount to little more than discoveries. Alternatively, the national patent regime (for example, as in the US) may not recognise some forms of public disclosure of traditional knowledge as prior art.

- Even if the patent represents a genuine invention, however defined, no arrangements may have been made to obtain the prior informed consent (PIC) of the communities providing the knowledge or resource, and for sharing the benefits of commercialisation to reward them appropriately in accordance with the principles of the CBD.

CASE STUDIES

1. TURMERIC: On March 28, 1995 the United States Patent and Trademark Office (USPTO) granted a patent (US 5401504) to two expatriate Indians of the University of Mississippi Medical Center for a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound. Turmeric is a plant yielding saffron-colored rhizomes and has been used by the people of India for ages as a flavor for cooking. It has

also been used widely as a color dye and for cosmetics. Most importantly, turmeric has been used for its medicinal qualities to heal wounds and rashes. The Indian Council for Scientific and Industrial Research (CSIR) filed a case with the USPTO challenging the patent by providing evidence of “prior art”. CSIR presented an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association to support their claim that the use of turmeric for medical purposes was known in India for many years and hence its use as a medicine was not a new invention. The USPTO upheld the objection and cancelled the patent on the grounds that it failed to meet the novelty criteria.

2. NEEM: In a landmark decision on March 8, 2005, the European Patent Office (EPO) ended a decade long battle over the ownership rights of Neem as an anti-fungal product. A patent had been granted to the United States Department of Agriculture (USDA) and the multinational corporation W.R. Grace for a fungicide derived from seeds of the Neem tree, a tree indigenous to the Indian subcontinent. A challenge was first mounted against the patent when it was granted in 1995. Leading the campaign in the Neem case against the US multinational was the EU Parliament's Green Party, India-based Research Foundation for Science, Technology and Ecology (RFSTE) and the International Federation of Organic Agriculture Movements (IFOAM). The mainstay of RFSTE's challenge was that the fungicidal qualities of the Neem tree and its use had been known in India for over 2,000 years. The RFSTE contested that various parts of the Neem tree (bark, leaves, seeds, etc) had been used traditionally to make insect repellents, soaps, cosmetics, tooth cleaners and contraceptives. In addition, documented evidences were also presented by India that included research done by two scientists prior to 1995 on use of Neem for making several products including fungicide. This was used as prior art to revoke the patent granted to USDA and W.R. Grace. In addition to the Turmeric and Neem cases cited above, a patent on a variety of Basmati rice and a number of patents on the different asanas or positions of yoga

have been embroiled in long litigation proceedings. India scored a significant victory in the Basmati case by successfully contesting 15 out of the 20 claims of the patent.

3. BASMATI RICE: Rice Tec Inc. had applied for registration of a mark "TEXMATI" before the UK Trade Mark Registry. It was successfully opposed by Agricultural and Processed Food Exports Authority (APEDA). One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the U.S. Patent 5,663,484 (hereafter referred to as '484 patent) granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest.

This US utility patent '484, was in a unique way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The patent was granted to Rice Tec by the U.S. Patent Office on September 2, 1997. The said patent covered 20 claims covering not only a novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced. The grant of this patent created a stir in the public, government, business circles and academics.

In the wake of this controversy, the Government of India set up a Task Force under the Chairmanship of Secretary, Ministry of Industrial Development, to examine the possibilities of filing a re-examination request against the above mentioned US Patent. The Task Force, in turn, set up a Technical Committee comprising primarily the ICAR & CSIR scientists to examine the Patent specification in detail and to collect necessary documentary evidence that may be required to file the re-examination request against the US Patent.

Evidence from the IARI Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. The various grain characteristics were evaluated by CFTRI scientists and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics.

Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15 to 17 along with claim 4. Although RiceTec did withdraw these claims, the US Patent Office on its own judged that 'a substantial question of patentability has been raised in respect of the remaining claims. Based the exhaustive office action, Ricetec has now surrendered the claims 1 to 3, 5 to 7, 10, 14 and 18 to 20.

As such, the claims that Ricetec now intends to protect are 8,9,11,12 & 13. These claims pertain to specific rice lines and the progeny and the grains of the specific crosses. This means that as against the Indian attack on 3 claims, Ricetec is withdrawing 15 claim.

In summary, Ricetec having withdrawn claims 15-17, the threat of infringement by the export of Basmati grains to US has been averted. And now, with the surrender of all the other broad claims, even the alleged threat to the export of grains of insensitive rice lines from India has been averted. In short, the objective for which India had filed the re-examination case has been fulfilled.

V) TRADITIONAL KNOWLEDGE DIGITAL LIBRARY – A METHOD OR MECHANISM FOR PROPER USE OF TRADITIONAL KNOWLEDGE

Traditional knowledge has always been an easily accessible treasure and thus has been susceptible to misappropriation. The traditional knowledge, 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, traditional knowledge is being exploited for bio-prospecting. Also Traditional knowledge is often misappropriated, because it is conveniently assumed that since it is in public domain, communities have given up all claims over it. Traditional Knowledge includes both the codified (documented) as well as non-codified information (not documented but may be orally transmitted).

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 traditional knowledge are time-tested since they have been in practice for centuries. The reliability of the traditional medicine systems coupled with the absence of such information with patent offices, provides an easy opportunity for interlopers for getting patents on these therapeutic formulations derived from traditional medicine systems.

Misappropriations of Traditional Knowledge :

The grant of patents on non-patentable knowledge (related to traditional medicines), which is either based on the existing traditional knowledge of the developing world, or a minor variation thereof, has been causing a great concern to the developing world.

A large number of bodies including WIPO, the CBD, UNCTAD and WTO are discussing the protection of traditional knowledge. These debates have rightfully focused on understanding the issue rather than on developing international norms. Only with a deeper

understanding and greater practical experience at national or regional level would it be realistic to develop an international system of protection for traditional knowledge. It is essential that all of the agencies considering the issue work together to avoid unnecessary duplication and to ensure that the debate includes as many different views as possible. In this respect it has been suggested to us that an organisation such as WIPO, which deals exclusively with intellectual property matters, may not be the most appropriate forum to consider traditional knowledge in all its aspects. It is believed however that no single body is likely to have the capacity, expertise or resources to handle all aspects of traditional knowledge. Indeed it is our view that a multiplicity of measures, only some of them IP-related, will be necessary to protect, preserve and promote traditional knowledge.

Protecting Codified Traditional Knowledge :

Patent examiners, in the international patent offices, while examining the patentability of any claimed subject matter, use available resources for searching the appropriate non-patent literature sources. Patent literature, is usually wholly contained in several distinctive databases and can be more easily searched and retrieved whereas non-patent literature prior art is often buried somewhere in the many and diverse sources. Therefore, a need was felt to create more easily accessible non-patent literature databases on traditional knowledge of India.

Traditional Knowledge Digital Library - A tool for prevention of misappropriations of traditional knowledge - How it all began:

India's TKDL, a collaborative project between the Council of Scientific and Industrial Research (CSIR), and the Department of AYUSH³, is a home-grown effort to ensure patent offices around the world do not grant patents for applications founded on India's wealth of age-old TK. The idea to establish a TKDL came to the fore amid India's efforts to revoke the patent granted by the United States Patent and Trademark Office

(USPTO) on the wound healing properties of turmeric, and the patent granted by the European Patent Office (EPO) on the antifungal properties of neem. These endeavors, while successful, proved extremely costly and time-consuming.

Around the time the TKDL was established in 2001, the TKDL expert group estimated that, annually, some 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world.

For a patent to be granted, an applicant must satisfy certain criteria as defined by national patent law, in particular, an applicant must prove that a claimed invention is novel and not previously known. Why then had patents been granted for so many applications relating to Indian medicinal systems? When patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India's traditional medicinal knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil. These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted.

The fact that so many patents had been wrongfully granted in the U.S. and Europe caused a great deal of national distress. The people of India felt that knowledge belonging to India was wrongfully being taken away from them. On top of this, these "wrong" patents conferred exclusive rights to exploit the technology in the country in which patent protection was granted. This posed a very real economic threat to Indian producers and to their freedom to operate in foreign markets.

Bridging the divide:

The TKDL has overcome language barriers and is bridging the gaps in TK information in major patent offices. Using information technology tools and a novel Traditional Knowledge Resource Classification System (TKRC), the TKDL has converted

and structured ancient texts into 34 million A4-sized pages along the lines of a patent application. These have been translated into English, French, German, Japanese and Spanish.

Today, thanks to its TKDL, India is capable of protecting some 0.226 million medicinal formulations and at zero direct cost. Access to the database helps patent examiners root out those applications that clearly do not satisfy the novelty requirement at an early stage. Without a TKDL database, the process of revoking a patent can be a costly and time-consuming affair. It takes, on average, five to seven years and costs between 0.2-0.6 million US dollars to oppose a patent granted by a patent office. Multiply this by India's 0.226 million medicinal formulations and it is clear that the cost of protection, without a TKDL, would be prohibitive.

An innovative classification system:

India's innovative TKRC is modeled on WIPO's International Patent Classification (IPC). It consists of some 27,000 subgroups for Ayurveda, Unani, Siddha and Yoga and, like the IPC, is indispensable for the retrieval of relevant information.

The TKRC has prompted the reform of the IPC – an essential tool in enabling effective search and examination of patent applications – as it relates to TK. The IPC divides technology into eight sections with approximately 70,000 subdivisions each of which is assigned a symbol consisting of Arabic numerals and letters of the Latin alphabet. Until 2005, only one subgroup – A61K35/78 – existed for medicinal plants, meaning that patent examiners were ill equipped to examine traditional medicine-based patent applications.

India took up the lack of recognition for traditional medicines in the IPC's Committee of Experts. Following the establishment of a five-nation 'Traditional Knowledge Classification Task Force' – comprising China, the European Union, India, Japan and the United States – the number of IPC subgroups relating to medicinal plants rose to 207

bringing about a fundamental and far-reaching reform of the international patent system. In 2004, it was agreed to link the TKRC's 27,000 subgroups to the IPC.

Connecting TK holders and patent examiners:

The TKDL is a unique, proprietary database that integrates diverse knowledge systems and languages. It is based on 148 books of prior art relating to Indian systems of medicine, available at a cost of around US\$1,000. The TKDL connects patent examiners around the world with these books of knowledge.

The TKDL is available to all patent offices that have signed a TKDL Access Agreement which has built-in, non-disclosure mechanisms to safeguard India's interests and counter any possible misuse. Under such an agreement, patent examiners may use the TKDL for search and examination purposes only and its contents may only be revealed to third parties for the purposes of citation.

So far, India has signed TKDL Access Agreements with the EPO and the patent offices of Australia, Canada, Germany, the United Kingdom and the United States. Negotiations are also ongoing with the patent offices of New Zealand and Japan where agreement in principle has already been reached.

TKDL targets Indian Systems of Medicine, viz., Ayurveda, Unani, Siddha and Yoga available in public domain. This is being documented by sifting and collating the information on traditional knowledge from the existing literature existing in local languages such as Sanskrit, Urdu, Arabic, Persian and Tamil in digitized format, which will be available in five international languages which are English, German, Spanish, French and Japanese. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval was evolved for about 5,000 subgroups against few subgroups available in International Patent Classification (IPC), related to medicinal plants. The information is being structured

under section, class, subclass, group and subgroup as per the International Patent Classification (IPC) for the convenience of its use by the international patent examiners. Information comprising about 2 lakh formulations has been transcribed for realizing the objective of TKDL Project.

Each Sloka is read and converted into a structured language using Traditional Knowledge Resource Classification by subject (Ayurveda, Unani, Siddha or Yoga) experts. The codes are then filled into the data entry screen. The Slokas are also saved in the database. The translated version of all the TKRC codes is ported in the database. The abstraction is done by the subject experts. The codes once saved in meta data directory are converted in different languages based on Unicode technology. The formulations are presently being converted into English, German, French Japanese and Spanish languages. The converted format of the formulation is readable and can be understood by a layman though it is targeted towards a patent examiner.

TKDL software with its associated classification system i.e., TKRC converts text in local languages into multiple languages as mentioned above. It may be noted that the software does not transliterate, rather it does a knowledge-based conversion, where data abstracted once is converted into several languages by using Unicode, Metadata methodology. Software also converts traditional terminology into modern terminology, for example, Jwar to fever, Turmeric to Curcuma longa, Mussorika to small pox etc.

TKDL includes a search interface providing full text search and retrieval of traditional knowledge information on IPC and keywords in multiple languages. The search features include single or multiple word searches, complex Boolean expression search, Proximity search, Field search, Phrase search, etc in the form of simple and advance search options. Simple search lets the user search a combination of keywords. Advance search lets

the user search using Boolean expressions, using the expressions like “near”, “and”, “and not”. Searches are also available on IPC and TKRC codes.

TKDL acts as a bridge between formulations existing in local languages and a Patent Examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to Patent Examiners. It is expected that the issue of the gap on lack of access to prior art traditional knowledge shall get addressed.

Since time immemorial, India has possessed a rich traditional knowledge of ways and means practiced to treat diseases afflicting people. This knowledge has generally been passed down by word of mouth from generation to generation. A part of this knowledge has been described in ancient classical and other literature, often inaccessible to the common man and even when accessible rarely understood. Documentation of this existing knowledge, available in public domain, on various traditional systems of medicine has become imperative to safeguard the sovereignty of this traditional knowledge and to protect it from being misappropriated in the form of patents on non-original innovations, and which has been a matter of national concern. India fought successfully for the revocation of turmeric and basmati patents granted by United States Patent and Trademark Office (USPTO) and neem patent granted by European Patent Office (EPO). As a sequel to this, in 1999, the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy- (AYUSH), erstwhile Department of Indian System of Medicine and Homoeopathy (ISM&H) constituted an inter-disciplinary Task Force, for creating an approach paper on establishing a Traditional Knowledge Digital Library (TKDL). The project TKDL was initiated in the year 2001.

TKDL provides information on traditional knowledge existing in the country, in languages and format understandable by patent examiners at International Patent Offices (IPOs), so as to prevent the grant of wrong patents. TKDL thus, acts as a bridge between the

traditional knowledge information existing in local languages and the patent examiners at IPOs.

TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented at CSIR. An inter-disciplinary team of Traditional Medicine (Ayurveda, Unani, Siddha and Yoga) experts, patent examiners, IT experts, scientists and technical officers are involved in creation of TKDL for Indian Systems of Medicine.

The project TKDL involves documentation of the traditional knowledge available in public domain in the form of existing literature related to Ayurveda, Unani, Siddha and Yoga, in digitized format in five international languages which are English, German, French, Japanese and Spanish. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval has been evolved for about 25,000 subgroups against few subgroups that was available in earlier version of the International Patent Classification (IPC), related to medicinal plants, minerals, animal resources, effects and diseases, methods of preparations, mode of administration, etc.

In just under two years, in Europe alone, India has succeeded in bringing about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations. The key to this success has been its Traditional Knowledge Digital Library (TKDL), a database containing 34 million pages of formatted information on some 2,260,000 medicinal formulations in multiple languages. Designed as a tool to assist patent examiners of major intellectual property (IP) offices in carrying out prior art searches, the TKDL is a unique repository of India's traditional medical wisdom. It bridges the linguistic gap between traditional knowledge expressed in languages such as Sanskrit, Arabic, Persian,

Urdu and Tamil, and those used by patent examiners of major IP offices. India's TKDL is proving a powerful weapon in the country's fight against erroneous patents, sometimes referred to as "biopiracy".

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 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, triggering lively debate about ways to preserve, protect, further develop and sustainably use TK. Documenting and digitizing TK-related information in the form of a TKDL is proving to be an effective means of preserving TK and of preventing its misappropriation by third parties. India is a pioneer in this field.

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Global IP-watch systems:

The national patent laws of most countries allow for third parties – any member of the public – to file a submission questioning the novelty and non-obviousness of a patent application before a patent is granted. There is a need, therefore, to ensure that patent applications that wrongly claim rights in prior art are readily identifiable so that such “third party observations (TPOs)” can be filed and made easily searchable. Global IP-watch monitoring systems have an important role to play in enabling the identification of published TK-related applications on which third parties – in accordance with the patent law of the country concerned – may file observations.

To date, the submission of TPOs has proven the only cost-effective way of preventing misappropriation of TK at the pre-grant stage. The TKDL database has enabled the submission of TPOs that have resulted in the successful opposition of hundreds of patent applications filed around the world. Without documenting and digitizing TK and making these databases easily accessible to patent examiners operating in the major languages of commerce, this would not have been possible.

The TKDL has an integrated global bio-piracy watch system that allows monitoring of patent applications related to Indian medicinal systems. It enables effective detection of attempts to misappropriate this knowledge by third parties filing applications with patent offices around the world. It means that immediate corrective action can be taken, and at zero direct cost, to prevent bio-piracy. India is the only country to date to have put such a system in place.

Impact of TKDL on bio-piracy :

The TKDL's impact is already being felt at the EPO. Since July 2009, 215 patent applications relating to Indian medicinal systems for which third party TKDL evidence has been filed have been identified. In two such cases the EPO has already reversed – on the strength of TKDL evidence – its earlier intention to grant the patents. In one case the applicant modified the claims submitted and, in 33 other cases, the applicants themselves withdrew their four to five-year-old applications upon presentation of TKDL evidence.

It is expected that in the coming months some 179 cases that are currently in the balance will either be rejected by the EPO or withdrawn by the applicants. A recent study by a TKDL expert team at the EPO shows a sharp decline (44 percent) in the number of patent applications filed concerning Indian medicinal systems, particularly in relation to medicinal plants. The TKDL is clearly proving to be an effective deterrent against biopiracy.

Misappropriation of TK and bio-piracy of genetic resources are of great concern to many countries and indigenous and local communities. While these issues have been taken up within various multilateral forums such as the Convention on Biological Diversity (CBD), the TRIPs⁴ Council of the World Trade Organization (WTO) and at the World Intellectual Property Organization (WIPO), a global framework to protect TK has not yet been established. WIPO's IGC⁵ is, however, making progress and it is hoped that in the near future consensus will emerge on an internationally legally binding instrument to effectively protect TK.

A success story:

India is the only country in the world to have set up an institutional mechanism - the TKDL - to protect its TK. The TKDL enables prompt and almost cost-free cancellation or withdrawal of patent applications relating to India's TK.

To date the TKDL has enabled the cancellation or withdrawal of a large number of patent applications attempting to claim rights over the use of various medicinal plants. India's TKDL is a unique tool that plays a critical role in protecting the country's traditional knowledge.

Need for Traditional Knowledge Digital Library:

It has been observed that in the past years patents have been wrongly granted to traditional knowledge related inventions which do not fulfill the requirement of novelty and inventive step, particularly due to existence of relevant prior art. For instance, this has happened in the case of Turmeric, Neem, Basmati etc.

The practical obstacle underlying the issue was that patent examiners could not search relevant traditional knowledge as prior art, because they did not have access to traditional knowledge information in their classified non-patent literature. The reasons for this non-accessibility were that the Indian traditional knowledge exists in local languages

such as Sanskrit, Urdu, Arabic, Persian, Tamil, etc. which either was not available or not understood by patent examiners. TKDL breaks the language and format barrier and makes available this information in English, French, Spanish, German and Japanese in patent application format, which is easily understandable by patent examiners. TKDL is thus a tool providing defensive protection to the rich traditional knowledge of India.

TKDL is a database with a tool to understand the codified knowledge existing for the Indian Systems of Medicine including Ayurveda, Siddha, Unani and Yoga as prior art. It is not a diagnostic or usage database. TKDL is also not the prior art in itself; the Books on Indian Systems of Medicine are the prior art which act as the source of information for TKDL. However, TKDL contains the scanned images of medicinal formulations from the original books. TKDL covers over two lakh formulations which have been taken from Ayurveda, Unani, Siddha and Yoga texts. It is pertinent to note that TKDL does not contain the entire information existing in the Indian Systems of Medicine. Rather than comprehensive, TKDL is a dynamic database, where formulations will be continuously added and continuously updated according to the inputs from the users of the database. The information on traditional medicines appears in a standard format in TKDL. For example, formulations on Indian Systems of Medicine appear in the form of a text, which comprises the following main components:

- Name of the drug
- Origin of the knowledge
- Constituents of the drug with their parts used and their quantity
- Method of preparation of the drug and usage of the drugs
- Bibliographic details

TKDL, gives modern names to plants (e.g., *Curcuma longa* for Turmeric), diseases (e.g., fever or jwar), or processes, mentioned in the literature related to Indian Systems of

Medicine, and establishes relationship between traditional knowledge and modern knowledge.

Traditional Knowledge Resource Classification (TKRC) :

Traditional Knowledge documentation lacked a classification system. Therefore, a modern classification based on the structure of International Patent Classification (IPC) was evolved. This has been developed for the Indian Systems of medicine, viz., Ayurveda, Unani, Siddha and Yoga and named as Traditional Knowledge Resource Classification (TKRC). The TKRC has gained international recognition and linked with the International Patent Classification.

TKRC is likely to facilitate greater awareness on the traditional knowledge systems by leveraging the modern system of dissemination i.e. Information Technology, in particular, the Internet and Web technologies. It is anticipated that TKRC structure and details will create interest in those countries that are concerned about prevention of grant of wrong patents for non-original discoveries relating to traditional knowledge systems.

Misappropriation of traditional knowledge and bio-piracy of genetic resources are the issues of great concern for all the developing countries. These issues are being pursued at several multilateral forums, such as Convention on Biological Diversity, TRIPs Council, World Trade Organization and World Intellectual Property Organisation. However, so far a 'global framework' for traditional knowledge protection system has not been established. It is mainly for this reason that Mexico had to fight a legal battle for 10 years to get the patent on Enola bean at the United States Patent & Trademark Office (USPTO) cancelled in July 2009. Similarly, the cancellation of Monsanto Soybean patent in July 2007 at the European Patent Office (EPO) took 13 years of legal battle.

India is the only country in the world to have set up an institutional mechanism – TKDL, to protect its traditional knowledge and to prevent grant of wrong patents. A

collaborative project between CSIR and Department of AYUSH, Ministry of Health and Family Welfare, TKDL is a maiden Indian effort to help prevent misappropriation of traditional knowledge belonging to India at International Patent Offices. It enables cancellation/withdrawal of wrong patent applications concerning India's traditional knowledge at zero cost and in few weeks time. In sharp contrast, in the absence of TKDL, it took 10 years (1995-2005) to get Neem patent invalidated for antifungal properties at EPO.

The genesis of TKDL dates back to the Indian effort on revocation of patent on wound healing properties of Turmeric at the USPTO and anti-fungal properties of Neem at EPO. In 2000, the TKDL expert group estimated that about 2000 wrong patents concerning Indian systems of medicine were being granted every year at international level, mainly due to the fact that India's traditional medical knowledge existing in languages, such as Sanskrit, Hindi, Arabic, Urdu, Tamil etc. was neither accessible nor comprehensible for the patent examiners at the international patent offices.

The TKDL technology integrates diverse disciplines (Ayurveda, Unani and Siddha), languages (Sanskrit, Arabic, Urdu, Persian and Tamil), modern science and modern medicine. It has created a unique mechanism for overcoming the language and format barriers by scientifically converting and structuring the available information contents of 34 million A4 size pages of the ancient texts into five international languages, namely, English, Japanese, French, German and Spanish. Through TKDL, a Sanskrit verse can now be read in international languages by an examiner at any International Patent Office on his computer screen enabled by two important features of TKDL: Relevant information technology tools and a novel classification system - Traditional Knowledge Resource Classification (TKRC). Today, through TKDL, India is capable of protecting about 0.226 million medicinal formulations similar to those of Neem and Turmeric. On an average, it takes five to seven years for opposing a granted patent at international level which may cost 0.2-0.6 million

US\$. One could only imagine the cost of protecting 0.226 million medicinal formulations in the absence of TKDL!

India has already signed TKDL Access Agreement with (i) European Patent Office (Feb 2009), (ii) United State Patent & Trademark Office (Nov 2009), (iii) Canadian Intellectual Property Office (Sep 2010), (iv) German Patent Office (Oct 2009), (v) United Kingdom Patent & Trademark Office (Feb 2010) and (vi) Intellectual Property, Australia (Jan 2011). In-principle Agreement has been reached with the Japan Patent Office while negotiations are under way to conclude the Access Agreement with the Intellectual Property Office of New Zealand.

These unique international Access Agreements are expected to have long-term implications on the protection of both traditional knowledge and global intellectual property systems in view of the fact that in the past, patents have been granted at various patent offices on the use of over 200 medicinal plants due to the lack of access to the documented knowledge in public domain. Also, 40-50 patent applications based on Indian traditional knowledge are awaiting grant of patent at any point of time.

Significant impact has already been realized at EPO during the last one year after the signing of the Access Agreement. Beginning July 2009, TKDL team has so far identified about 230 patent applications at EPO which concern Indian systems of medicine and filed third party TKDL evidences at EPO. In two such cases, EPO has already set aside its earlier intention to grant patents after it received TKDL evidence. In one case, the applicant modified its earlier claims. In other thirty three cases, the applicants themselves decided to withdraw their four-to-five year old applications on being confronted with TKDL evidence which is a tacit admission of bio-piracy by applicants themselves. It is expected that in the balance 200 plus cases, either EPO would reject these applications or applicants themselves would withdraw their wrong claims/patent applications in coming months. In addition,

TKDL evidences against misappropriation in 400 more cases have been submitted at other International Patent offices. Similar outcomes are also expected at the other International Patent Offices.

More than 40 countries from different regions of the world would participate in this international event, including 35 developing countries (17 from Asia Pacific region, 4 African, 4 Latin American, 3 Arabian, 4 from Division for certain countries in Europe and Asia such as Bulgaria and Russian federation and 3 Least Developed Countries- Mali, Uganda and Zambia) and 7 developed countries who are signatories of TKDL Access Agreement, viz., European Union, United States of America, Germany, United Kingdom, Canada, Australia and Japan.

Impact of TKRC on International Patent Classification:

TKDL has been responsible for the reform of International Patent Classification (IPC) by enhancing the IPC on Traditional Knowledge from one subgroup to 207 subgroups which enables effective search and examination process on the patent applications related to traditional knowledge subject matter. IPC reforms in the context of TK are fundamental reforms in the International Patent System which would have long term implications. TKDL breaks distance, format and language barriers between TK holder(s) Knowledge and International Patent Examiners. TKDL is a proprietary and original database. TKDL is based on 148 books of Indian Systems of Medicine, which are available at a cost of Rs. 50,000. These books are the prior art and can be sourced by any individual/organisation at national/international level. TKDL acts as a bridge between these books and international patent examiners. It is the TKDL technology which has created a unique mechanism for a Sanskrit sloka to be read in languages like German, Japanese, English, Spanish and French by an examiner at EPO or any other International Patent Offices on his computer screen.

Access to TKDL under TKDL (non-disclosure) Access Agreement:

Access of TKDL to International Patent Offices' is available under TKDL Access (Non-disclosure) Agreement. Under the agreement, examiners of patent office can utilise TKDL for search and examination purposes only and can not reveal the contents of TKDL to any third party unless it is necessary for the purposes of citation. TKDL Access Agreement is unique in nature and has in-built safeguards on non-disclosure to protect India's interest against any possible misuse. India has signed TKDL Access Agreements with: (i) European Patent Office (Feb 2009) (ii) United State Patent & Trademark Office (Nov 2009) (with the sideline of the state visit of the Prime Minister to United States) (iii) Indian patent Office (July 2009), (iv) Canadian Intellectual Property Office (Sep 2010) (v) German Patent Office (Oct 2009) (vi) United Kingdom Patent Office (Feb 2010) (vii) Intellectual Property Australia (Jan 2011) and (viii) Japan Patent Office (April 2011).

TKDL search and retrieval capabilities for protection of Traditional knowledge:

TKDL is one such database that has proven its efficacy and has succeeded in opposing hundreds of patent applications at various International patent offices' through the route of filing of third party observations which exists in most of the National Patent Laws of the countries, wherein a submission may be filed by any member of the public on state of art / prior art at the patent office questioning the novelty and non-obviousness of a patent application after the publication of the patent application and before the grant of patent. Challenging the patents at International Patent Offices' is a long drawn process and is expensive. For example, Mexico, only after more than 10 years of legal battle, was able to get the patent on Enola bean at USPTO cancelled in July 2009. Similarly, cancellation on Monsanto Soybean patent happened in July 2007 at EPO after 13 years of legal battle. India

is the only country in the world which has set up an institutional mechanism (TKDL) to protect its Traditional Knowledge and is able to prevent grant of wrong patents. TKDL enables cancellation / withdrawal of wrong patent applications concerning India's Traditional Knowledge at zero cost and in time period of few weeks. In sharp contrast, in the absence of TKDL it took 10 years (1995-2005) to get Neem patent invalidated for antifungal properties at EPO

Impact of TKDL against bio-piracy:

Significant impact has already been realised during the last two years. Beginning July 2009, TKDL team has submitted 571 third party observations out of which so far 53 patent applications of the pharma companies of United States, Great Britain, Spain, Italy, China, etc. have been either set aside or withdrawn/cancelled or declared as dead patent applications based on the information present in the TKDL database.

TKDL - A model for other Countries:

Considering the novelty, utility and its effectiveness in preventing the grant of wrong patents several countries and organizations such as South Africa, Mongolia, Thailand, Malaysia, ARIPO, Nigeria, Indonesia, etc. have expressed their keenness in replicating the TKDL model for their own countries. World Intellectual Property Organization including the global community has recognized India's leadership in the area of Intellectual Property Rights and Traditional Knowledge. WIPO in collaboration with CSIR organized an international conference on utilizing TKDL established by India as a model for protection of traditional knowledge was held in New Delhi in March 2011 where 35 countries rich in traditional knowledge participated to understand the methodology for creation of TKDL and to apply such model for protection of TK in their own country

Some examples of bio-piracy of traditional knowledge

Turmeric (*Curcuma longa* Linn.): The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and dyes. As a medicine, it has been traditionally used for centuries to heal wounds and rashes. In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric in wound healing. The Council of Scientific & Industrial Research (CSIR), India, New Delhi filed a re-examination case with the US PTO challenging the patent on the grounds of existing of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

Neem (*Azadirachta indica* A. Juss.) : Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis. In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995, a group of international NGOs and representatives of Indian farmers filed legal

opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and therefore, was unpatentable. In 1999, the EPO determined that according to the evidence all features of the present claim were disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000. EPO, in March 2006, rejected the challenge made in 2001 by the USDA and the chemicals multinational, W. R. Grace to the EPO's previous decision to cancel their patent on the fungicidal properties of the seeds extracted from the neem tree.

Basmati Rice (*Oryza sativa* Linn.) : Rice Tec. Inc. had applied for registration of a mark "Texmati" before the UK Trade Mark Registry. Agricultural and Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest.

This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The US PTO granted the patent to Rice Tec on September 2, 1997. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced. Evidence from the IARI (Indian Agricultural Research Institute) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of

Rice Research, Hyderabad since 1978. CFTRI(Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics. Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15-17 along with claim 4. Biopiracy of traditional knowledge is not limited to India alone. In fact, there have been several examples from other countries where traditional knowledge bio-piracy has become a concern. Some of these examples are given below:

Kava (*Piper methysticum* Forster) : Kava is an important cash crop in the Pacific, where it is highly valued as the source of the ceremonial beverage of the same name. Over 100 varieties of Kava are grown in the Pacific, especially in Fiji and Vanuatu, where it was first domesticated thousands of years ago. In North America and Europe, Kava is now promoted for a variety of uses. French company L'Oreal - a global giant with US \$10 billion a year in sales - has patented the use of Kava to reduce hair loss and stimulate hair growth.

Ayahuasca (*Banisteriopsis caapi* Mort.) : For generations, Shamans of indigenous tribes throughout the Amazon basin have processed the bark of *B. caapi* Mort. to produce a ceremonial drink known as "Ayahuasca". The Shamans use Ayahuasca (which means "wine of the soul") in religious and healing ceremonies to diagnose and treat illness, meet with spirits, and divine the future. American, Loren Miller obtained US Plant Patent (no. 5,751 issued in 1986), granting him rights over an alleged variety of *B. caapi* Mort. which he had collected from a domestic garden in Amazon and had called "Da Vine", and was analyzing for potential medicinal properties. The patent claimed that Da Vine represented a new and distinct variety of *B. caapi* Mort., primarily because of the flower colour.

The Coordinating Body of Indigenous Organisations of the Amazon Basin (COICA), which represents more than 400 indigenous tribes in the Amazon region, along with others,

protested about a wrong patent that was given on a plant species. They protested that Ayahuasca had been known to natives of the Amazon rainforest and it is used in traditional medicine and cultivated for that purpose for generations, so Miller could not have discovered it, and should not have been granted such rights, which in effect, appropriated indigenous traditional knowledge. On reexamination, USPTO revoked this patent on 3rd November 1999. However, the inventor was able to convince the USPTO on 17th April 2001, the original claims were reconfirmed and the patent rights restored to the innovator.

Quinoa (*Chenopodium quinoa* Willd.) : Quinoa is a staple food crop for millions in the Andes, especially Quechua and Aymara people who have bred a multitude of quinoa varieties. One traditional quinoa variety, Apelawa, is the subject of US patent 5,304,718 held by two professors from Colorado State University who claim the variety's male sterile cytoplasm is key to developing hybrid quinoa. The patent claims any quinoa crossed with male sterile Apelawa plants.

Hoodia (*Hoodia gordonii* (Masson) Sweet ex Decne) : For thousands of years, African tribesmen have eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips. The Kung bushmen, San who live around the Kalahari desert in southern Africa used to cut off a stem of the cactus about the size of a cucumber and munch it. Hoodia is now at the centre of a bio-piracy row. In 1995, South African Council of Scientific & Industrial Research (CSIR) patented Hoodia's appetite-suppressing element (P57) and hence, its potential cure for obesity. In 1997 they licensed P57 to British Biotech Company, Phytopharm. In 1998, Pfizer acquired the rights to develop and market P57 as a potential slimming drug and cure for obesity (a market worth more than £ 6 billion), from Phytopharm for \$ 32 million. The San people eventually learned of this exploitation of their traditional knowledge, and in June 2001, launched legal action against South African CSIR and the pharmaceutical industry on grounds of bio-piracy. They claimed that their traditional

knowledge has been stolen, and the South African CSIR had failed to comply with the rules of the Convention on Biodiversity, which requires the prior informed consent of all stakeholders, including the original discoverers and users.

Phytopharm conducted extensive enquiries but were unable to find any of the knowledge holders. The remaining San were apparently at the time living in a tented camp 1500 miles away from their tribal lands. The South African CSIR claimed that they have planned to inform the San of the research and share the benefits, but wanted to make sure that the drug proved successful.

The two sides entered into negotiations for a benefit-sharing agreement, despite complications regarding who should be compensated: the person who originally shared the information, their descendants, the tribe, or the entire country. The San are nomads spread across four countries.

However, in March 2002, a landmark was reached in which the San will receive a share of any future royalties. The settlement will not directly affect Phytopharm or Pfizer since the San would be paid out of the CSIR's royalties, as South African CSIR is the patent holder. South African CSIR will probably receive a royalty of around 10% from Phytopharm, which itself will receive royalties from sales from Pfizer. Thus San are likely to end up with only a very small percentage of eventual sales.

Other examples :

To cite some more examples of biopiracy, the plant *Phyllanthus amarus* Schum. et Thonn. is used for Ayurvedic treatment for jaundice, a US patent has been taken for use against Hepatitis B. The plant *Piper nigrum* Linn. is used for Ayurvedic treatment for vitiligo (a skin pigmentation disorder). A patent has been taken in UK for the application of a molecule from *Piper nigrum* Linn. for use in treatment of vitiligo.

VI CONCLUSION:

The appropriation of elements of this collective knowledge of societies into proprietary knowledge for the commercial profit of a few is one of the concerns of the developing world. An urgent action is needed to protect these fragile knowledge systems through national policies and international understanding linked to IPR, while providing its development and proper use for the benefit of its holders. What is needed is a particular focus on community knowledge and community innovation, enterprise and investment is particularly important.

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 very different cultural values and attitudes. The communities have a storehouse of knowledge about their flora and fauna, their habits, their habitats, their seasonal behavior and the like-and 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 commercialization of the biodiversity. 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 is what is needed.

Protection of Traditional Knowledge in Indian Patent act:

The new millennium poses serious challenge to the international legal community to set new international legal standard for tackling the problem of intellectual property protection throw open by the technology developments. Protections of the Traditional Knowledge of the local and indigenous communities seem to be one of the most contentious and complicated issue. The historical development of the protection of intellectual property in the wake of individual private property rights, pushed, the traditional knowledge and the innovative practice based on the it outside the purview of the formal intellectual property protection regime. Traditional Knowledge was treated as Knowledge in the public demans

for free exploitation without showing any respect or concern for the effort taken by the communities to preserve and promote the same. The new technological developments, particularly in biotechnology, clearly demonstrate the significance and usefulness of traditional knowledge for the development of new product of commercial importance. The formal intellectual Knowledge base. The need to protect the traditional knowledge captured the attention of the international community only recently but the standard setting was left to the national governments. The absence of the international standards, that causes serious negligence for the protection of the traditional knowledge and the benefits of new technology.

Traditional Knowledge (TK), variously referred to as ‘traditional knowledge’, ‘traditional ecological knowledge’, ‘local knowledge’, ‘folk knowledge’ is knowledge developed by local and indigenous communities over time in response to the needs of their specific local environment. The World Intellectual Property Organization (WIPO) defines traditional knowledge as “indigenous cultural and intellectual property,” indigenous heritage,” and customary heritage rights”.

All other innovations and creations that is “tradition-based”. Tradition-based” refers to knowledge systems that have been transmitted from generation to generation; pertain to a particular people and their territory; and are constantly evolving in response to a hanging environment. Categories of traditional knowledge include agricultural knowledge, scientific knowledge, technical knowledge, ecological knowledge, medicinal knowledge and biodiversity-related knowledge. It is imperative to protect this TK because it is under serious threat today from the callous neglect visible in national and international policy. A central problem s that while knowledge created in laboratories is acknowledged as the property of the innovator; that created in fields and forests is not recognized as the property of its creators. The main arguments for granting protection to TK include equity

considerations, conservation concerns, the preservation of traditional practices and culture, the prevention of appropriation by unauthorized parties of components of TK; and promotion of its use in development.

Over the past few years, the patent system has come under considerable criticism of its failure to prevent the misappropriation of traditional knowledge. While there is wide agreement that positive protection of traditional knowledge can not be successively accomplished through the patent system, increasingly, consideration is being given to suggestions to use the patent system as a defensive measure against misappropriation of traditional knowledge. Traditional knowledge also constitutes much of the world's medicinal knowledge and agricultural knowledge. Indigenous and local communities around the world rely on this knowledge for their survival, daily life, healing and nutrition needs. In Africa alone, 80% of the population relies on traditional remedies to combat disease. The "value" of traditional knowledge is being applied in the fields of botanical, pharmaceutical, agricultural, biotechnological and genetic research.

The Communities survived on their traditional knowledge base. The product they manufactured formed part of their livelihood. Even today many local and indigenous communities in the Asian countries meet their basic need from the product they manufacturing and sell based in their traditional knowledge. Maintenance of there health even now based traditional medicine derived from plants and other natural products. The development of new technology and the new of technology and the survival of many of these communities. The modern culture industries as well as the manufacturing industry (textile, handicraft, pharmaceutical, seed etc,) now commercially exploit the traditional; knowledge based product using new technology without the permission and sharing of profits with the communities. It is possible today to bring out new products or find out new of existing product based on traditional; knowledge utilizing the technological in the field of

biotechnology. This is provided beyond doubt particularly in the field of medicines, agriculture, etc. The Bio- prospecting helps the scientists in the modern pharmaceutical research laboratories to get that know that how to developed new product or new use of existing product.

The legal norms relating to the formal intellectual property rights based on copyright, patent, design, etc., were developed to tackle the social problems that emerged due to the scientific developments during industrial revolution in the West. The legal norms crystallized to protect the new Knowledge have a significant bearing on the manner in which the western system looked at science and scientific developments. Thus the concept of ‘originality’, ‘novelty’, ‘utility’, ‘non-obvious or inventive step’ etc., used to find out the items that are to be protected through the formal intellectual property system addressed only the scientific developments based on the western understanding of science. In the same way the insistence of the identity of the creator of the new Knowledge - author or inventor as the case may be - 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 property system and treated it as Knowledge in the public domain for exploitation without authorization.

The Knowledge based on the community remains 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.

Patents and Traditional Knowledge:

In broad terms, patents can be defined as exclusive rights granted for an invention - either a product or a process - that offers a new technical solution to a specific problem. A patent implies the grant of a “monopoly” to an inventor who has used his knowledge and skills to produce a product or process which is new, involves an inventive step and is capable of industrial application.

The TRIPS Agreement also has some provisions having limited application to the protection of Traditional Knowledge. The obligation to protect geographical indications can be used to protect traditional knowledge if associated with the indication used for production and sale of goods. It is made clear that a given quality, reputation or other characteristics of the goods essentially attributable to its geographical origin are to be considered in identifying the geographical indications for protection. Thus it may be possible for protection through geographical indication the traditional knowledge associated with goods.

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

Traditional Knowledge in Danger:

a) Devolution: As demand for commercialization of biodiversity and traditional knowledge increases at a rapid pace and as the world globalizes, develops and modernizes, indigenous societies are being encroached upon faster than traditional knowledge can be protected. Their cultures and knowledge are being lost. In many parts of the world, the very existence of indigenous societies is under threat.

b) Encroachment, Bio-prospecting and Bio-piracy:

One of the biggest threats to biodiversity and related traditional knowledge is ever-increasingly bioprospecting activities on behalf of entomologists, pharmaceutical companies and others who wish to profit from the rich biodiversity and traditional knowledge in indigenous territories.

Current legal systems are inadequate, allowing for the biopiracy of biodiversity and traditional knowledge. “Legislation is required and it is required yesterday,” says Noiwazi Gcaba, a South African patent attorney.

c) Inadequacy of Legal Systems that Address Traditional Knowledge:

This point is divided into two major sections:-

1. General issues relating to the protection of traditional knowledge.

Devolution, encroachment, the bio prospecting rush, lack of appropriate legal systems and a clash of systems all make traditional knowledge highly vulnerable to Biopiracy. Several traditional plants and related knowledge in Asia, specifically India, have also been allegedly falsely patented by the US patent office, including: Neem’, Haldi’, pepper, Harar’, Mustard, Basmati rice, Ginger, Castor, ‘Jaramla’, ‘Karela’ and ‘Jamun’. The African continent has too been plagued by biopiracy —with the case of West Africa’s sweet genes and one of the most recent cases involving “Hoodia” still unresolved. Some cases have been resolved but clearly demonstrate the problems with the intellectual property system.

Traditional knowledge is generally associated with biological resources and is invariably an intangible component of such a biological resource. Traditional knowledge has the potential of being translated into commercial benefits by providing leads/clues for development of useful practices and processes for the benefit of mankind. The valuable leads/clues provided by TK save time, money and investment of modern biotech and other industries into any research and product development. Reasonably, we can say that a share of

such benefits should accrue to the creators and/or holders of such Traditional Knowledge. Some countries have specific legislation protecting this kind of knowledge while some other countries feel their existing IPR regime protects such knowledge. As of now, India does not have a specific sui generis legislation to protect such TK and folklore but is in the process of developing such legislation.

In the recent past, there have been several cases of bio-piracy of TK from India. First it was the patent on wound-healing properties of haldi (turmeric); now patents have been obtained in other countries on hypoglycaemic properties of karela (bitter gourd), brinjal, etc. An important criticism in this context relates to foreigners obtaining patents based on Indian biological materials without acknowledging the source of their Knowledge or sharing the benefits. There is also the view that the TRIPS Agreement is aiding the exploitation of biodiversity by privatizing biodiversity expressed in life forms and knowledge.

Granting of patents in respect of traditional knowledge:

Concern that has been expressed in the discussion in the council for TRIPS is about the grant of patents or other IPRs covering traditional knowledge to persons other than the indigenous peoples or community who have originated the knowledge and legitimately control it. Several patents have been cited as ex. including in regard to turmeric, Neem and Athabasca vine. The view has been expressed that the granting to patents on traditional knowledge already in the public domain or without the content of indigenous peoples and local communities amount to unauthorized appropriation of the knowledge. It has been said that this occur particularly in the case where members do not appropriate definition of the criteria for penetrability or appropriate procedure.

It is felt that there are two areas where patent system is not working well enough in connection with the granting of patent covering traditional knowledge like firstly “Definition of prior art” used to determine whether a claimed invention meets the novelty standard for

patentability and second concerning the “adequacy of the information on prior art” available to patent examiners.

Consent and benefit sharing:

Traditional knowledge is being used without the authorization of the indigenous peoples or communities who have originated and legitimately control it and without proper sharing of the benefit that occurs from such use.

Use of the existing system of IPR:

It has been suggest theta starting point should be explore possibility for making more effective use of the exciting IPR system for protecting the traditional knowledge of indigenous peoples and local communities.

Contracts:

It has been suggest that the beat way of dressing this concern would be through system based on bilateral contract between holder of traditional knowledge and persons or companies wishing to access and use the knowledge.

Disclosure requirement:

It has been suggested that applicant for patent for indentations that used traditional knowledge associated with genetic resources should be required to disclose the course. Or the origin of the source of the traditional knowledge in their patent applications.

Sui generis system of protection:

It has been suggested that only a system of protection of traditional knowledge which provides proprietary rights can insure that market forces will be operate to generate fairness and equity. The suggestions concerning contracts and disclosure, which have also been made in regarded to genetic material used in invention that are the subjects of patent application, are discuss in more detail in the secretariat’s revised summery note on the relationship between the TRIPS agreement and convention on biological diversity.

The Indian legislation for the Protection of Plant Varieties and Farmers' Rights Act 2001 also acknowledge that the conservation, exploration, collection, characterization, evaluation of plant genetic resources for food and agriculture are essential to meet the goals of national food and nutritional security as also for sustainable development of agriculture for the present and future generations. It also acknowledges that the plant genetic resources for food and agriculture are the raw material indispensable for crop genetic improvement. The concept of effective benefit sharing arrangement between the provider and the recipient of the plant genetic resources forms an integral part of our Act. The protection provided to a plant variety bred by a breeder can be cancelled if there is an omission or wrongful disclosure of such information.

Strategies to Increase Protection of Traditional Knowledge:

International Efforts:

There are several international legal platforms and instruments that currently address intellectual property protection as it relates to traditional knowledge. Some of the most prominent include.

The UN Draft Declaration on Rights of Indigenous Peoples:

“Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts.”¹

Global Guidelines: A recent positive initiative is the drafting of a set of corporate guidelines for businesses that want to use native plants and traditional knowledge from

¹ Article 29 - UN Draft Declaration

indigenous communities to make commercial drugs. In April 2002 in The Hague, delegates of the UN Biodiversity Congress from 166 countries negotiated and adopted global guidelines during a two- week long U.N. sponsored CBD conference that was designed to encourage pharmaceutical companies to make responsible agreements with countries whose resources they use.

Regional Initiatives:

In February 2002, Environmental Ministers from 12 countries met in Cancun, Mexico met to discuss issues related to biodiversity in their countries, identifying a need to establish terms governing the granting of patents.¹ At the WSSD in Johannesburg this past August, their group was established as a permanent negotiating body to address these issues.

It has also been suggested that a requirement on patent applications to disclose in their applications any traditional knowledge used in the invention in question could help in the assessment of novelty and also assist countries with possible claims to examine the application and oppose the patent in time.

The Geographical Indication of Goods (Registration and Protection) Act, 1999 passed by Parliament is another step taken by India. The Act primarily intends to protect the valuable geographical indications of our country. The protection under the Act is available only to the geographical indication registered under the Act and to the authorized users. The Act permits any association of persons or producers or any organization or authority established by law representing the interest of the producers of goods to register a geographical indication. It may be possible to argue 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.

¹ The Cancun Declaration & Cusco Declaration on Access to Genetic Resources. Traditional Knowledge and Intellectual Property Rights

Suggestion to Improve Indian Patent act for Protection Traditional Knowledge:

In response it has been said that, even if the national laws applicable do not allow patents on invention based on traditional knowledge, patents in other regimes that allow such patents reduce the economic value of the knowledge of local community and may constrain the development and use of their knowledge in the market-place or may facilitate otherwise of exploitation of their knowledge with out any rewards to them. It has been suggest that the development of database on traditional knowledge would help patent examiners discover relevant prior art so as to improve examination of patent application and prevent the grant of patents for subject matter that should not be patentable. Database would also help potential licensees in terms of searching for knowledge, innovations and parties’.

Various suggestions have been advanced in India to extend protection to knowledge, innovations and practices. These include:

- (i) Documentation of TK;
- (ii) Registration and innovation patent system; and
- (iii) Development of a sui generis system.

It is sometimes believed that proper documentation of associated TK could help in checking bio-piracy. Documentation could be a double-edged sword. It is assumed that if the material/ knowledge are documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such materials/knowledge are/is readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom benefits of commercialization of such materials/knowledge has to be shared.

Suggestions:

1. Access to these databases for patent authorities and relevant judicial authorities could be facilitated through the establishment of an international gateway for traditional knowledge, which would electronically link this data based.

2. At least minimum harmonization of the structure and content for these data based should be achieve

3. Data based should be reachable over the Internet.

4. To the extent that traditional knowledge which already recorded in databased and print media, it is important to insure that patent examiners are made familiar with this resources.

5. Database should only disclose traditional knowledge already in the public domain or traditional knowledge for which prior inform consent has been obtained.

6. Access these data based should not involve costly or burdensome procedures.

In this regard, concerns have been expressed about the following:

1. In this responsibilities for bearing cost of maintaining these database.

2. While serving as repository of information, database cannot be completely exhaustive as they may not contain knowledge held by local communities in oral form or knowledge that is continuously evolving through informal innovation within a community.

3. While database may help forestall the grant of inappropriate patents, they cannot address the problem of the non-accrual to the holders of traditional knowledge of economic benefits resulting from the use of knowledge.

4. Reference to database by patent examiner would be voluntary and patent examiners in member countries would have no obligation to consider this information in their prior art searches. Obligations, guidelines or recommendations should be established to

improve and substantial tighten up search systems in respect of information that is relevant to traditional knowledge so as to evaluate novelty and inventiveness.

Documentation of traditional knowledge is also acknowledge as a means of giving due recognition to the traditional knowledge holders. This particular aspect of documenting formulations in the Ayurvedic system of medicine in India in the shape of traditional knowledge Digital Library (TKDL) is already on and we appreciate the efforts of WIPO to arrange for a presentation in this regard as also on the topic of Health Heritage Data Base for the benefit of the members attending the last Intergovernmental Committee meeting in Geneva in June 2002. The scope of the TKDL work relates to the transcription of 35,000 formulations used in Ayurvedic system of medicines. These details are being converted into Patent Application Format and will include description, method of preparation, claim and the usage of the bibliography.

Documentation of TK is one means of giving recognition to knowledge holders. But mere documentation may not enable sharing of benefits arising out of the use of such knowledge, unless it is backed by some kind of mechanisms for protecting the knowledge. This necessitates the need for extending some kind of protection to TK. Documentation of TK may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form in which it exists. Documentation per se, however, will not facilitate benefit sharing with the holders of TK.

ABBREVIATIONS

ABS	---	Access and Benefit-sharing
ANDES	---	Association for Nature and Sustainable Development
APEDA	---	Agricultural and Processed Food Exports Development Authority
IARI	---	Indian Agricultural Research Institute
CBD	---	Convention on Biological Diversity
CFTRI	---	Central Food Technological Research Institute
CSIR	---	Council for Scientific and Industrial Research
EPO	---	European Patent Office
FAO	---	Food and Agriculture Organization
GATS	---	General Agreement on Trade Services
GATT	---	General Agreement on Trade and Tariff
GNP	---	Gross National Product
ICAR	---	Indian Council of Agricultural Research
ICBG	---	International Cooperative Biodiversity Group
ICMR	---	Indian Council of Medical Research
IGC-GRTKF	---	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
ILO	---	International Labor Organization
IP	---	Intellectual Property
IPC	---	International Patent Classification
IPR	---	Intellectual Property Rights
ITPGRFA	---	International Treaty for Plant Genetic Resources for Food and Agriculture
LDC	---	Least Developed Countries
NAFTA	---	North American Free Trade Agreement
NIC	---	National Informatics Center
NWFPs	---	Non-Wood Forest Productions
PCT	---	Patent Co-operation Treaty
PIC	---	Prior Informed Consent
RAFI	---	Rural Advancement Foundation International
RFSTE	---	Research Foundation for Science, Technology and Ecology

SACSIR	---	South African Council of Scientific & Industrial Research
SADC	---	Southern Africa Development Community
TK	---	Traditional Knowledge
TKDL	---	Traditional Knowledge Digital Library
TKRC	---	Traditional Knowledge Resource Classification
TPOs	---	Third Party Observations
TRIPS	---	Agreement on Trade Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods.
UNBC	---	UN Biodiversity Congress
UNDD	---	UN Draft Declaration
UNDP	---	United Nations Development Program
UNEP	---	United Nations Environment Program
USDA	---	US Department of Agriculture
USPTO	---	US Patent & Trademark Office
WIPO	---	World Intellectual Property Organization
WTO	---	World Trade Organization

Legislative Texts on the Protection of Traditional Knowledge¹:

This compilation includes some examples of (i) special laws and measures which specifically protect traditional knowledge, sometimes referred to as "sui generis" laws, (ii) patent laws which provide protection of a sui generis nature for traditional knowledge, and (iii) laws and measures which establish regulatory frameworks for traditional knowledge that have an effect on, or relate to, intellectual property-type protection.

Constitutional Law

Special/Specific Laws and Legislative Measures

Patent Laws

Regulatory Frameworks for TK

Other Resources

Constitutional Law

Bolivia:

- Constitucion Politica de Bolivia, 2009 (Particularly see: Article 30.II.9 Article 30.II.11, Article 42.II, Article 100, Article 304.II.3, Article 381, Article 382)

Ecuador:

- Constitution of Ecuador, 2008 (Particularly see: Article 57(12), 385(2), 387(2), 387(4), 388, 402)

Special/Specific Laws and Legislative Measures

ARIPO

- Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, 2010

¹ Source: <http://www.wipo.int/tk/en/laws/tk.html>

Bhutan:

- Biodiversity Act of Bhutan, 2003 (Particularly see Chapter 4)

Costa Rica:

- Biodiversity Law No. 7788 (Particularly see: Chapter V)
- Executive Decree No. 31514, General Rules for the Access of Genetic and Biochemical Elements and Resources of Biodiversity (2003) (Particularly see: Article 19, 25, 28)

Ethiopia:

- Access to Genetic Resources and Community Knowledge and Community Rights Proclamation 2006

Kyrgyz Republic:

- Law of the Kyrgyz Republic on the Protection of Traditional Knowledge

Organization of African Unity:

- African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources of 2000 [PDF]

Panama:

- Law No. 20 of 26 June 2000 on the Special Intellectual Property Regime with Respect to the Collective Rights of Indigenous Peoples to the Protection and Defense of their Cultural Identity and Traditional Knowledge
- Executive Decree No. 12 of March 20, 2001 establishing regulations under Law No. 20 of June 26, 2000 about a Special Regime of Collective Rights of Intellectual Property of Indigenous People for Protection of their Cultural Identity and their Traditional Knowledge
- Decreto Ejecutivo No. 257 que reglamenta el artículo 71 de la ley 41 de 1 Julio de 1998, General de Ambiente

Peru:

- Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources, N° 27811

Related database/register: CTPI

- Law for the Protection of Access to Peruvian Biological Diversity and Collective Knowledge, N° 28216

- Decreto Legislativo N° 1075: Decreto Legislativo que aprueba Disposiciones Complementarias a la Decisión 486 de la Comisión de la Comunidad Andina que establece el Régimen Común sobre Propiedad Industrial

- Ley N° 29316 que modifica, incorpora y regula diversas disposiciones a fin de implementar el Acuerdo de Promoción Comercial suscrito entre el Perú y los Estados Unidos de América

Philippines:

- Indigenous Peoples Rights Act of 1997

Portugal:

- Decree Law No. 118/2002 Establishing a Legal Regime for the Registration, Conservation, Legal Safeguarding and Transfer of Autochthonous Plant Material as well as Associated Knowledge

Thailand:

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United Nations

- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

Patent Laws

Andean Countries:

- Decision 486 of 2000 on a Common Intellectual Property Regime

China:

- Patent Law of 2000

Related database/register: Traditional Chinese Medicine Patent Database

India:

- The Patent Amendments Act of 2005 (Particularly see: Article 23 (1)(k) and Article 23(2)(k))

Related database/register: Traditional Knowledge Digital Library

Switzerland:

- Patent Law (2008) (Particularly see: Article 49a, 81a, 138)

Regulatory Frameworks for TK

Brazil:

- Provisional Measure No. 2,186-16 of 2001 Regulating Access to the Genetic Heritage
- Decree N° 5.459 of 2005 Regulating Art. 30 of the Provisional Measures N° 2.186-16 (Particularly see: Article 23)

China:

- Regulations on Protection of Traditional Chinese Medicines, 1992

EC:

- European Directive 2004/24 as Regards Traditional Herbal Medicinal Products
- European Directive 2006/509 on Traditional Specialities Guaranteed

Related database/register: Register on Traditional Knowledge in Agricultural Products and Food - Austria

Ecuador:

- Law on Intellectual Property of Ecuador, 1998 (Particularly see: Article 377)

India:

- Drugs and Cosmetics Act, 1940

Italy:

- Attuazione della direttiva 92/73/CEE in materia di medicinali omeopatici

Philippines:

- Traditional and Alternative Medicine Act of 1997

Other Resources (WIPO)

- Information of the National Commission for the protection of Peruvian biological diversity and traditional knowledge of indigenous communities: CNB
- India: Traditional Knowledge Digital Library
- China: Traditional Chinese Medicine Patent Database
- Austria: Register on Traditional Knowledge in Agricultural Products and Food
- Comparative Table on Existing Sui Generis Laws and Measures [PDF]
- Comparative Summary of Existing National Sui Generis Measures and Laws for the Protection of Traditional Knowledge (WIPO/GRTKF/IC/5/INF/4)
- The Protection of Traditional Knowledge: Revised Outline of Policy Options and Legal Mechanisms (WIPO/GRTKF/IC/9/INF/5)
- Consolidated Survey of Intellectual Property Protection of Traditional Knowledge (WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/7 Corr.)
- Composite Study on the Protection of Traditional Knowledge (WIPO/GRTKF/IC/5/8)