CHAPTER VI

PROTECTION OF TRADITIONAL MEDICINE-

A LEGAL ANALYSIS

Traditional Medicine is a complex multi facet issue. Many countries and Organizations world-wide are considering how to address this issue at international, regional and national levels. TRM is thus discussed in a number of forums like WIPO, UNCTAD, UNEP/ CBD which have cooperated with each other to conduct studies in the area of protection of indigenous communities. WIPO and UNEP had undertaken joint studies relating role of IPRS and sharing of benefits with communities for use of TK while on the other hand CBD and FAO had undertaken studies relating to common areas in agriculture. Issue relating to TRM is also discussed in arenas relating to rights of indigenous people and cultural expressions. Of course the role of different organization in framing a policy significantly varies from each other.

1. International Initiatives

International level initiatives for the protection of Traditional Medicine Are;

1.01. Convention on Biological Diversity, 1992

The convention on biological diversity (CBD) was the result of discussion concluded at Rio de Janerio on United nations conference on earth and development (Earth Summit), 1992. The convention provides for protection of environment without compromising with the on-going economic development¹. The convention provides for recognition of knowledge of local and indigenous communities in genetic materials and sharing of benefit derived from it.
Article 8(j) of the convention provides that;

“each contracting party shall as far as possible and as appropriate, subject to its national legislation respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from utilization of such knowledge, innovations and practices”.

Convention on Biodiversity can be regarded as the first international initiative to recognize the contribution of indigenous and local communities in conservation of biodiversity\(^2\). In its preamble CBD recognizes the dependence of many indigenous communities on biological resources and stress on the desirability of benefit sharing. Besides this Article 10 (c) and 18 (4) makes further references to the rights of indigenous communities. Art 10(c) provides that “each contracting party shall protect and encourage customary use of biological resources in accordance with traditional cultural practices which are compatible with conservation”.Art 18(4) defines technology to include ‘indigenous and traditional technologies’.

Art 8(j) is not free from limitations, the said article does not talk about protection of TRM but it vaguely calls on the parties to respect, preserve and maintain it. It does not guarantee indigenous people any rights over their collective knowledge. Besides this the convention leaves the preservation of this knowledge at the discretion of the parties. Phrases “as far as possible” in art 8 (j) indicates that the convention does not makes a mandatory requirement about protection of rights.
of indigenous communities. Though there are flaws, CBD has the most important place as an international instrument which officially recognized the rights of indigenous communities.

1.02. Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)

This agreement also has some provision which can be applied in a limited way for protection of TRM and TK. Article 1 of TRIPS Agreement provides that members may but shall not be obliged to implement in their domestic laws more extensive protection than that is required by the agreement, provided that such protection does not contravene the provisions of this agreement. Many Jurists have opined that this provision can be invoked for protection of TRM and TK. They argue that absence of term TK in the agreement does not prevent any member from enacting any provision for protection of TRM and TK.

But under TRIPS it is not possible to protect TRM and TK under patent law. TRIPS requires member state to grant patent only to that inventions which are new, involving an inventive step and are capable of industrial application. But these attributes cannot be applied in the field of TK, as it is not new and is incapable of industrial application as such. The same provision can be invoked to prevent bio-piracy. Besides this there are authors who argue that obligation to protect geographical indications provided by TRIPS agreement can be used to protect TRM. TRIPS agreement by itself does create any measures for protection of TRM and TK and innovations of indigenous people instead it creates measures for establishing alternative measures for its protection.

Article 27 of the TRIPS agreement states that the members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. The notions of public are not defined in the agreement. However it is clear that those inventions that causes injury to environment as well as plant or animal life can be excluded. It has been argued that states can use this provision for the
protection of biological diversity associated with the indigenous communities. Article 27.3(b) of the TRIPS states that the members shall provide for protection of plant varieties either by way of patents or by an effective *Sui Generis* system.

Besides this there were lots of discussions regarding TRM and TK protection at the TRIPS Council. These initially took place in the context of implementation of Art 27.3(b). The fourth meeting of the WTO Ministerial Conference which took place in Doha in November 2001 a Ministerial Declaration was adopted to which the member states instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and CBD and also the protection of Traditional Knowledge and folklore. TRIPS has left out from its purview the matter of protection of natural assets and associated knowledge which are owned by nation states, communities or individuals. On a whole conventional Intellectual Property laws under the TRIPS does not consider TK as Intellectual Property worth protection though patentability of products or process using Traditional Knowledge poses a number of questions.

1.03. The International Convention for Protection of New Varieties of Plants (UPOV)

The UPOV convention is an international convention exclusively dealing with protection of new plant varieties and is silent on the subject of TRM and TK and genetic resources. However it does not forbid granting or creation of rights in respect of TK. Besides this some provisions of the convention can be used to protect the interest of indigenous persons. Convention vests exclusive exploitation rights in the developers of new varieties of plants as an incentive to pursue innovative activity and to enable breeders to recover their investment in breeding.

Article 7 of the 1991 Act of the UPOV provides that “the variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of filing of the application”. This means that legal protection can be granted to a variety only if it is shown that it is distinct from others including traditional varieties. Thus IP
rights are granted to plant breeders only if they are distinct, novel and stable. These conditions can be considered as similar to the criteria for patenting. These provisions can be invoked as a defensive strategy for the knowledge of indigenous communities relating to plant varieties as to grant IP protection the convention specifically provides it to be distinct and novel⁹.

Besides this it should be noted that the process of applying for plant variety protection is relatively simple and can be done even without legal help. This feature facilitates the applications of small plant breeders. Accordingly UPOV system can be used as a tool for protecting plant varietal innovation of indigenous communities. Under the convention, a farmer who produces a protected variety from saved seeds are guilty of infringement unless national law provides so, these provisions tends to weaken the economic position of indigenous communities.

1.04. WIPO - The Intergovernmental Committee on Intellectual Property

Genetic Resources and Traditional Knowledge In 2000 the WIPO General assembly established the IGC as a forum for discussion of Intellectual Property issues in relation to access to genetic resources, benefit sharing and protection of Traditional Knowledge and expressions of folklore. It acts as an international forum for international policy debate, development of legal mechanisms and for creating practical tools for protection of TRM and TK and traditional cultural expressions against misappropriation and misuse. IGC work has produced large number of discussion papers on the subject of protection of TK. IGC has produced a number of practical outcomes which include, a toolkit for the management of IP in the context of documenting TRM and TK and genetic resources, a practical guide for protection of traditional cultural expressions, proposal for revision of international patent classification to contain categories of TRM and TK¹⁰.

The committee has made substantial progress in addressing the practical linkages between the current Intellectual Property system and the custodians of TRM and TK. Committee is trying to
bring about an international understanding regarding the principles that should guide the protection of TRM and TK.

1.05. United Nations Declaration on Rights of Indigenous Persons

United Nations declaration on Rights of Indigenous persons was adopted by UN general assembly during its 62 session on 13th September 2007. Though a General assembly declaration is not a legally binding instrument, this declaration can be regarded as a dynamic development for setting a standard for protection of rights of indigenous persons. General assembly recognized the urgent need to respect and promote the inherent rights of indigenous peoples which they derived from their social structures.

The declaration emphasizes on the rights of indigenous persons to maintain and strengthen their own institutions, cultures and tradition so as to foster their development. It urges the parties to make mechanism for prevention and redress of any action which has the effect of depriving indigenous people of their integrity or their cultural values or identities. Art 24 recognizes the right to their Traditional Medicines and provides for conservation of their vital medicinal plants animals and minerals.

Article 31 is an important attempt to protect TRM and TK. It asks the states to take all effective measure to recognize and protect the cultural heritage, TRM and TK, traditional cultural expression as well as the manifestations of their sciences, technology and cultures. This declaration is indeed a dynamic measure of international legal norms regarding protection of TRM and TK and also it necessitates the need for an international treaty for protection of TRM and TK.

1.06. Declaration of Belem

In 1988 the First International Congress of Ethnobiology met in Belem, Brazil. Indigenous and traditional peoples (those referred to in the Convention on Biological Diversity as ‘indigenous
and local communities embodying traditional lifestyles’) from various parts of the world met with scientists and environmentalists to discuss a common strategy to stop the rapid decrease in the planet’s biological and cultural diversity. Major concerns included the unique ways in which indigenous and traditional peoples perceive, use, and manage their natural resources and how programs can be developed to guarantee the preservation and strengthening of indigenous communities and their Traditional Knowledge\textsuperscript{12}.

The congress produced The Declaration of Belem, which outlined explicitly the responsibilities of scientists and environmentalists in addressing the needs of local communities and acknowledged the central role of indigenous peoples in all aspects of global planning. Although the language of The Declaration of Belem may seem somewhat antiquated today, it was the first time that an international scientific organization recognized a basic obligation that ‘procedures be developed to compensate native peoples for the utilization of their knowledge and their biological resources’.

\textbf{1.07. Kari-Oca Declaration and Indigenous Peoples Earth Charter}

This is a declaration and a Charter first agreed in May 1992 by indigenous peoples from the Americas, Asia, Africa, Australia, Europe and the Pacific who, at Kari-Oca Villages, united in one voice to collectively express their serious concern at the way the world was exploiting the natural resources upon which indigenous peoples depend. Specific reference is made within the Indigenous Peoples Earth Charter to perceived abuses of indigenous people’s intellectual and cultural properties.\textsuperscript{13} Under a heading, ‘Culture, Science and Intellectual Property’, amongst other matters, it is asserted:

- The usurping of Traditional Medicines and knowledge from Indigenous peoples should be considered a crime against peoples. (99)
➢ As creators and carriers of civilizations which have given and continue to share knowledge, experience, and values with humanity, we require that our right to intellectual and cultural properties be guaranteed and that mechanisms for each be in favour of our peoples. (102)

➢ The protection, norms and mechanism of artistic and artisan creation of our peoples must be established and implemented in order to avoid plunder, plagiarism, undue exposure, and use. (104)

1.08. Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples

On 18 June 1993, 150 delegates from fourteen countries, including indigenous representatives from Japan (Ainu), Australia, Cook Islands, Fiji, India, Panama, Peru, Philippines, Surinam, USA and Aotearoa (New Zealand) meeting at Whakatane (Bay of Plenty region of New Zealand) affirmed indigenous peoples’ knowledge is of benefit to all humanity; recognised indigenous peoples are willing to offer their knowledge to all humanity provided their fundamental rights to define and control this knowledge is protected by the international community; insisted the first beneficiaries of indigenous knowledge must be the direct indigenous descendants of such knowledge; declared all forms of exploitation of Indigenous knowledge must cease.\textsuperscript{14}

Under Section 2 of their Declaration they specifically ask State, National and International Agencies to:
➢ Recognise that Indigenous peoples are the guardians of their customary knowledge and have the right to protect and control dissemination of that knowledge. (2.1)

➢ Recognise that indigenous peoples also have the right to create new knowledge based on cultural tradition. (2.2)

➢ Accept that the cultural and Intellectual Property Rights of Indigenous peoples are vested with those who created them. (2.3)


This declaration arose out of a meeting of indigenous and non-indigenous specialists, who, at Jingarrba, in north-eastern Australia, agreed indigenous Intellectual Property Rights are best determined from within the Customary Laws of the indigenous groups’ themselves. Within the declaration indigenous Customary Laws are (re)named ‘Aboriginal common laws’, and it is insisted these laws must be acknowledged and treated as equal to any other systems of law:

➢ Indigenous Peoples and Nations reaffirm their right to define for themselves their own Intellectual Property, acknowledging ...the uniqueness of their own particular heritage.

➢ Indigenous Peoples and Nations … declare that we …are willing to share (our Intellectual Property) with all humanity provided that our fundamental rights to define and control this property are recognised by the international community.
Aboriginal Intellectual Property, within Aboriginal Common Law, is an inherent, inalienable right which cannot be terminated, extinguished, or taken … Any use of the Intellectual Property of Aboriginal Nations and Peoples may only be done in accordance with Aboriginal Common Law, and any unauthorised use is strictly prohibited.

2. Regional Initiatives

Besides all these international initiatives last decade has witnessed many regional initiatives for laying down measures for protection of TRM and TK. African countries under Organisation of African Union prepared a model law on community rights and access to biological resources. The African Model Legislation for the Protection of Rights of Local Communities, Farmers, Breeders, and for Regulation of Access to Biological Resources aims at establishing a framework of national laws to regulate access to genetic resources and associated TRM and TK. Its provisions on access to biological resources make it clear that the recipients of biological resources or related knowledge cannot apply for any IP rights of exclusive nature. Besides this they provide for community rights over their biological resources and their right to collectively benefit from their use, rights to their innovations, practices, knowledge and technology and the right to collectively benefit from their utilization. Thus in practice this model legislation intend to create a system which allow the community, right to prohibit access to their valuable resources and knowledge.

From the African region itself, the African Regional Intellectual Property Organization (ARIPO) in 2010 has come out with protocol for protection of TK and folklore known as the Swakudump Protocol on the protection of Traditional Knowledge and Expressions of Folklore. This protocol provides for creation of National Authority which is competent to look into the
matters of TK. It also provides for the rights and recognition of holders of TK, concept of equitable benefit sharing, licensing etc.

Other than the African Union there is another group known as the Mega Diverse countries. This group includes seventeen nations including India which are rich in bio diversity. They met in 2002 in Mexico and decided to set up the group as a mechanism for consultation and cooperation so that their interests and priorities related to sustainable use of bio diversity and related TK is protected. The Cusso Declaration on Access to Genetic resources, Traditional Knowledge and Intellectual Property Rights of likeminded mega diverse countries, 2002 stressed on the importance that should be given for protection of bio diversity and associated TRM and TK. It also stressed on the need for an efficient benefit sharing mechanism.

3. National Initiatives

The national level legal initiatives for the protection of Traditional Medicine are;

3.01. Protection of Plant Varieties and Farmers Right Act, 2001

Article 27(3) allows the member countries to make a Sui Generis system for protection of plant varieties. Accordingly India enacted a Sui Generis system in 2001 in the name of The Protection of Plant Varieties and Farmers rights Act. Though the Act is primarily based on International Convention for protection of new varieties of plants, it includes a number of provisions which are not included in the convention. This Act forms an independent Sui Generis form of protection to new varieties of plants.

The objectives of this Act as explicit from its title are IP protection of plant varieties and protection of rights of farmers. The farmer’s rights here arise from their role in conserving, improving and making available plant genetic resources for the development of new plant varieties.
The Act also intends to promote research for development of new plant varieties which in turn will pave way for accelerated agricultural growth.

Breeder’s rights over the varieties developed by him are protected by this legislation. Under the Act a breeder can register his variety and become a PBR holder. Any person can register a community’s claim over a particular breed. This intervention, in practice enables the protection of plant varieties of indigenous communities who is unable to do this by themselves due to illiteracy or lack of awareness. PBR holder has the exclusive right to produce, sell, Market or distribute the seeds of that variety. Another important feature of this Act is the maiden attempt of introduction of benefit sharing between breeders and farming or tribal communities who have contributed to genetic diversity used by the breeder. To make this meaningful, mandatory disclosure of geographical location from where the genetic material has been taken and information relating to the contribution of farming communities have been made. Besides this it is provided that the breeders wanting to use existing varieties for creating new varieties cannot do so without the express permission of the farmers involved in the conservation of such varieties.

The Act is an exclusive legislation regarding protection of plant varieties; it does not have any specific provision for protection of TRM. Yet we can invoke the provision of community rights under section 41 and concept of benefit sharing, for protection of knowledge on indigenous communities at least to the extent of plant varieties.

3.02. Biological Diversity Act, 2002

The CBD recognizes the sovereign rights of states to use their own biological resources. The convention expects the parties to facilitate access to genetic resources by other parties subjected to a national legislation. Convention also asks the state parties to include within its legislation the right of indigenous communities for benefits accruing from the commercial use of their knowledge.
As a signatory to CBD India had committed to make a national legislation which provides for access to biological resources and benefit sharing. In order to fulfil this obligation Indian government has enacted the Biological Diversity Act in 2002. The Act provides for access to biological resources of the country with the purpose of securing equitable benefit sharing arising out of commercial use of those resources. The Act recognizes the Knowledge of local communities and emphasize on the need to protect them. Though the Act was primarily enacted for providing free access to biological resources of the Country by foreign nationals’ institutions and companies, it contains many restrictions regarding the same. A foreign national or a body corporate not registered in India is not allowed to use or obtain any biological resource occurring in India or any knowledge associated thereto for research or commercial utilization without the previous permission of NBA. Section 4 of the Act restricts the transfer of results of any research relating to any biological resources obtained from India to any foreign nationals or corporate. Measures have been taken in the act to prevent instances of bio piracy by restricting any person from applying for Intellectual Property Rights of any nature within or outside India for any invention based on any research or information on a biological resource obtained from India without previous approval of NBA.

As mentioned earlier, the Act recognizes the need for sharing the monetary gain accrued from using biological resources or knowledge associated thereto with persons who have conserved these resources for years. National Biodiversity Authority has been empowered under section 21 to determine the ways and means of benefit sharing. Various means of benefit sharing include grant of joint ownership of IP rights with NBA or If benefit claimer can be identified, then with them, transfer of technology, location of production, research and development units in those areas which will benefit the lives of the benefit claimers or by setting up of venture capitals or monetary compensation to the benefit claimers. Another feature of the Act in relation to protection of TRM and TK is that it makes bio-piracy a cognizable and non-bailable offence with a punishment of
imprisonment up to five years and monetary compensation up to five lacks. The Act also provide for the establishment of a National Biodiversity Authority.

Section 8 of the Act gives power to the Central Government to establish a National Authority to look into the matters provided under the Act. NBA is required to facilitate the access to genetic resources giving due regard to benefit sharing. As provided earlier it shall be the duty of NBA to oppose any application for IP rights in any country for any invention using genetic resources or associated TK obtained from India. The protection, Conservation and Effective Management of TK relating to Biological Diversity Rules, 2009 imposes a duty upon NBA to recognize existing forms of representative organizations of traditional community and when there is no such representative bodies NBA through concerned state authorities make arrangement for formation of representative organizations.

National Biodiversity Authority has to setup a fund known as the Traditional Knowledge Fund, which shall be used for the benefit of traditional communities and for the protection and conservation of TRM and TK by way of various welfare measures. NBA has the discretionary power to give access to both documented and non-documentated TRM and TK. National authority is empowered to develop national strategies, plans and programs for conservation, development and sustainable use of Traditional Knowledge.

The Act can be regarded as a defensive strategy for protection of biopiracy; it is indeed an innovative legislation with adequate measures to safeguard the bio diversity and economic interests of indigenous communities.
3.02.01. Incongruities in Protection of Plant Varieties and Farmers’ Right Act, (PPVFRA), 2001 and Biological Diversity Act, 2002

The Indian Plant Variety Protection Act passed in August 2001, has established that in order to ensure equitable sharing of benefits, the use of farmers’ varieties to breed new varieties will have to be paid for. Revenue is to flow into a NGF. This money is to be collectively, rather than individually, accessed by farming communities (exceptions can be made where individuals are clearly identified as breeders of specific varieties).

Further, Sections 19 and 21 of the Indian Biodiversity Act mandate the approval of the NBA before access to genetic resources takes place. While granting approval, the NBA could impose terms and conditions to secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of IPRSs on research based upon biological resource or knowledge obtained from India, needs to obtain the prior approval of the NBA.

A benefit-sharing regime need not be grounded on the existence and enforcement of IPRSs. It may rather operate according to the model established by the CBD with regard to the access and use of biological resources or to other specific arrangements.

The Biological Diversity Act and PPVFRA present certain apparent and real discrepancies or conflicts in their ABS provisions. According to BD Act, prior approval from NBA is mandatory for accessing Indian plant genetic resources for research or for commercial utilization or for bio-survey and bio-utilization by persons who are non-resident Indians or non-Indian citizens or who work in India for a body corporate, association or organization, which is not incorporated or registered in India or has non-Indian participation in its share capital or management.
Contrary to this, the PPVFR Act allows free access without PIC to any genetic resource, including those varieties protected by plant breeders’ right by any person for conducting experiment or research or breeding.

Unlike the BD Act, the PPVFR Act does not differentiate parties accessing genetic resources as Indian citizens or institutions or otherwise or whether the breeding undertaken is conventional or non-conventional. However, for the purpose of benefit sharing the PPVFR Act discriminates the nationality of beneficiaries as Indian citizens or institutions or otherwise.

From the legal perspective, the access regulation on national resources instituted by the BD Act in consistence with the national sovereignty on biodiversity shall define and limit the researchers’ right available under the PPVFR Act to the non-Indian entities. The NBA takes decisions on benefit sharing under the BD Act while granting permission to establish IPRSs on an innovation based on the biological material or associated knowledge accessed from India. The plant breeder’s right established on a variety under the PPVFR Act is IPRSs of *Sui Generis* class. The BD Act, which requires prior approval from the NBA for establishing any Intellectual Property, by whatever name called, on any product or process derived from Indian biological diversity or associated knowledge, provides exemption from this provision to the grant of plant breeders’ rights under PPVFR Act.

This exemption *inter alia* places the decision on benefit sharing arising out of the plant breeders’ rights outside the purview of NBA. In this context, it is important to underscore that the jurisdiction of PPVFR Act is national, while the liability for benefit sharing arising from the access and use of Indian plant genetic resources for breeding new varieties could be transnational.

Therefore, the establishment of a IPRSs on a plant variety bred outside India using Indian resource requires prior approval from the NBA. In such cases, the decision on benefit sharing falls under the purview of NBA. It also means when a patent or *Sui Generis* protection has to be
established in countries outside India on a variety which is registered in India under PPVFR Act, fresh approval of the NBA with possible liability for fresh determination of benefit sharing becomes necessary. Also notwithstanding the legal position that it is the PPVFR Authority which determines the benefit sharing of varieties registered in India, a non-Indian entity, which is accessing Indian genetic resources is required to make prior commitment on benefit sharing under the BD Act during the access process prescribed under the rules of BD Act or the MTA envisaged thereunder.

These prior commitments on benefit sharing also have the scope to specify the type of benefits, monetary or non-monetary, and other details. The above discussed provisions of these two Acts bring forth two important issues.

First, the inconsistency between the BD Act and PPVFR Act on the eligibility for benefits sharing. BD Act provides *quid pro quo* relationship between ‘commercial utilization’ and benefit sharing\(^\text{27}\). Here, the definition of ‘commercial utilisation’ provided in the BD Act assumes importance.

‘Commercial utilization’ is defined to exclude ‘the conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dry farming, animal husbandry or bee keeping’. According to this definition, the economic gain accrued from IPRS protected crop varieties, which were evolved by selection or conventional breeding is excluded from benefit sharing, despite the fact that the process of breeding could have accessed and used genetic resources and TK including TRM, created and conserved by local communities.

In contrast, the PPVFR Act does not discriminate a variety on the basis of its derivation, whether bred by conventional or non-conventional methods, except in the case of essentially derived variety. PPVFR Act does not prescribe a decision on benefit sharing on an essentially derived variety, while its commercialization is allowed only with prior approval of the party who had provided the initial variety\(^\text{28}\).
The said definition of commercial utilization in BD Act has another implication. Indian citizens’ organizations, public or private, while accessing genetic resources and associated knowledge for use in conventional breeding gain exclusion from the provision, which mandates that such access should be with prior intimation to the concerned SBB\textsuperscript{29}. Interestingly, the BD Act itself is contradicting the above discussed exclusion provided under the definition of ‘commercial utilization’.

Rule 14 of BD Act, which sets out procedures for accessing bio-resource and TK and Form I prescribed under this Rule require flow of benefits to the communities out of the ‘use of accessed bio-resource and TK’. Further, under Section 18 of the BD Act, it is asserted that the NBA ‘has authority to advise the Central Government on the equitable sharing of benefits arising out of the utilization of biological resources’. These variations in the expressions like ‘commercial utilization’ and ‘use’ and ‘utilization’ for determination of eligibility for benefit sharing are inconsistent and confusing, particularly in the absence of definition for ‘use’ and ‘utilization’ either in the Act or in the Rules.

According to Rule 14 and Section 18, anything done with the genetic resource or TK accessed entitles flow of benefit share. Thus, the BD Act links the eligibility for benefit sharing with ‘commercial utilization’, ‘utilization’ and ‘use’ of genetic resources and despite a clear exclusion provided under commercial utilization, considerable inconsistency and lack of clarity persist in the Act and its Rules on the eligibility for benefit sharing.

The definition of ‘commercial utilization’ is also causing a major legal infirmity to one of the pivotal provisions of the BD Act, which mandates prior approval of NBA for accessing Indian bio-resource or associated knowledge by non-Indian entities. According to this provision, such an entity can undertake commercial utilization, bio-survey and bio-utilization only after such prior approval\textsuperscript{30}. Bio-survey and bio-utilization are essentially defined as research activities for exploring
the commercial utilization potential of a bio-resource or associated knowledge. Conventional breeding or other practices used in agriculture are not included under bio-utilization. Commercial utilization is defined essentially as an activity, which can generate economic gain, but excluding the conventional breeding and traditional practices in agriculture.

Therefore, access to genetic resources and associated knowledge for conventional breeding by non-Indian entity *de jure* does not warrant prior approval from NBA. Once these resources are accessed under this exclusion provision, there is no way to regulate their use in bio-survey or bio-utilization or non-conventional method of breeding. This virtually pre-empts the cause for entering into an access or MTA in exercise of national sovereignty rights over these resources, particularly the agro-biodiversity, and for ensuring benefit sharing to the local communities who have been creating and conserving these resources\textsuperscript{31}.

This virtually underwrites the national sovereignty that the BD Act seeks to protect. The above major infirmity on the national sovereignty over plant genetic resources in conjunction with Section 40 of this Act opens a wide corridor for legitimised free outflow of Indian plant genetic resources.

According to Section 40 of the BD Act, ‘the Central Government may in consultation with the NBA, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities’. Seeds or other propagating material of plant varieties are tradable commodities. The current national trade policy allows unrestricted trade of seeds and other propagating plant material\textsuperscript{32}. This allows export of virtually any seed in any quantity, including small quantities. In the absence of a credible system at the customs port of exit to verify what is exported and what is purported to be exported, there exists a wide-opened corridor for unrestricted free outflow of seeds of any national plant genetic resource, including improved varieties, farmers’ varieties, land races and pre-bred material. This is a corridor
now being increasingly used by multinational seed companies to legitimately transfer all valuable Indian plant genetic resources. The law established to protect Indian plant genetic resources, which is in fact legitimising their piracy.

According to Rule 41 of this PPVFR Act, a person or group of persons or a firm or a non-governmental organization is entitled to make a claim for benefit sharing from a variety registered under this Act within a period of six months from the date of publication of its registration. It further states that such applicants shall provide information on the commercial viability or the actual market performance of the variety in question, apart from other specified information. In the case of a plant variety, irrespective of its possible commercial superiority, its propagation system and the multiplication rate of its planting material may demand duration much longer than six months for making a realistic assessment of its potential commercial market size. In India, most of the varieties require at least three to five planting seasons to attain their potential commercial market. Therefore, a determination of benefit share made on commercial market size achieved within six months will be highly disadvantageous to the benefit claimants.

Another implied aspect of benefit sharing under this Act and its Rules is that the benefit sharing awarded on a breeder for using a given genetic resource contributed by a community for breeding a specific variety is apparently a one-time event. In other words, when the same breeder, institution or seed company repeatedly uses the same genetic resource in the form of certain variety, for which benefit sharing was once awarded, or its derivatives for developing increasingly superior varieties, the liability to share benefit with the community for every such variety remains nebulous. This apparent limitation denies perpetual entitlement of communities or other parties for benefit sharing, whenever a genetic resource or its derivative is used for evolving newer commercial varieties.
3.03. The Patent (Amendment) Act, 2005

The TRIPS agreement signed along with WTO agreement in 1995 provides for making certain changes in domestic patent laws, for reaching a uniform system of legislations relating to patent throughout the world. In order to fulfil this obligation under TRIPS patent act was duly amended in 2005. This amendment introduced into Indian IP system certain new measures for protection of TK. The new amended Act in the area of specification of inventions which are not patentable made an addition that ‘an invention which is mere new use for a known substance’ and ‘an invention which, in effect, is Traditional Knowledge or which is an aggregation or duplication or known properties of traditionally known substances’ will not be an invention.

Another provision is inclusion of new provision for opposition of patent, on specific grounds under section 25(1) of the Act. It provides after publication of patent application any person can in writing make an opposition to the controller of patents on the ground of lack of novelty or inventive step, or non-disclosure or wrongful disclosure of source or geographical origin used in the invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous groups in the complete specification. Also now we can oppose a complete patent specification which was publicly known or publicly used in India before the date of claim.

All the above provisions are defensive in nature which can help to oppose any patent granted to an invention which is based on the knowledge available within the indigenous groups of this nation. But these provisions are also not capable of covering the entire area of TRM.

3.04. The Geographical Indications Goods (Registration and Protection) Act, 1999

The Act primarily intends to protect the valuable ‘geographical indications’ of our country. The protection is available only to the ‘registered geographical indications’ under the Act and to
the ‘authorised users’. The Act permits any association of persons or producers or any organisation of authority established by law representing the interests of the producers of the goods to register a geographical indication. Registration confers upon the authorised users the right to use the indication in relation to the goods with regard to which the indication is registered.

It also allows registered users to obtain relief against use by a person who is not an authorised user and uses the indication to suggest that the goods originate in a geographical area other than the true place of origin or that uses the indication in a manner that constitutes unfair competition.

When considering the protection of TK and TRM, it is possible for the holders of TK in goods produced or sold using geographical indication, can register and protect their TK under this Act. All the above mentioned provisions are well suited for the protection of TK including TRM in goods produced or sold using geographical indication.

3.05. Documentation of Knowledge/Traditional Knowledge Digital Library (TKDL)

Since time immemorial, India has possessed a rich TK 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 TK 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\textsuperscript{43}.

Traditional Knowledge Digital Library provides information on TK 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 TK information existing in local languages and the patent examiners at IPOs. Traditional Knowledge Digital Library 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\textsuperscript{44}.

The project TKDL involves documentation of the TK 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\textsuperscript{45}.

Presentation on TK Resource Classification (TKRC) at IPC Union led to the creation of WIPO-TK Task Force consisting of USPTO, EPO, JPO, China and India by (IPC) Union for enhancing the sub-groups in IPC for classifying the TK related subject matter and considering the linking of TKRC with IPC.
Though this type of defensive strategy is capable to prevent misappropriation of TRM, it is not able to address all issues faced by TRM. Besides this it is to be accepted that it is very difficult to compile all those data which was transmitted through generations over the years. TRM is widespread, besides this old texts are vast and difficult to translate, also being a country with linguistic varieties, a particular process or a thing will be known in different names in different parts of the country. All these add to the difficulty of documenting TRM. Another limitation of concept of documentation is that the traditional words which are often used generally cannot be equated with present terminology. For e.g. Indian traditional text books use the word Liver complaint and suggest certain medicines for that, but modern medical terminology have given different name for this, like Hepatitis A, Hepatitis B etc. So when a plant is used by Indian for centuries for liver complaints western world may refuse it as a prior use by stating that the exact medical terminology is not found anywhere in Indian medical texts.

4. Efforts at Sub-National Level

The main and important development at sub national level is the Intellectual Property Rights Policy of Kerala

4.01. Intellectual Property Rights Policy of Kerala

The government of Kerala released an Intellectual Property Rights (IPRS) policy document on 27 June 2008. Kerala thus became the first state to come out with a policy on Intellectual Property Rights. The scope of the document is limited. It simply gives the state government’s approach on certain selected issues of practical importance for Kerala in the context of the new IPRS regime<sup>46</sup>.
4.01.01. The Main Objectives

The main objectives of this policy are;

- To Institute a legal arrangement for the protection of TK and biodiversity associated with such knowledge, given the fact that TK forms the basis of livelihoods of many TK practitioners and the absence of any legal property rights on such knowledge may render an opportunity for the private appropriation of the TK by multinational corporates.

- State proposes to commit all TK, including TRM, the practice of which sustains livelihoods of many, to the realm of ‘Knowledge Commons’ and not to the ‘Public Domain’. While the Policy envisages creating property rights on Traditional Knowledge, all the right holders will be deemed to be holding their rights under an obligation that they shall permit others the use of the knowledge in their possession for non-commercial purposes.

- Setting up of a Supervisory Council on Intellectual Property (SCIP) to provide overall supervision in matters relating to IPRSs with Chief Minister as its Chairman and Law Minister as its Vice-Chairman.

- SCIP will help any potential patent applicant who asks for its assistance to prepare proper patent applications. It will disseminate knowledge in the state about Intellectual Property Rights.
➢ To declare the stand of the Government with regard to the ownership of IPRSs over the outcome of research in state Government-funded and State Government-aided institutions, especially given the current trend of outsourcing from the west.

➢ While such outsourcing, giving rise to collaborative research can be academically productive for the states’ research institutions, it is important to ensure that our public research institutions do not simply become providers of cheap labour to multinational corporations.

4.01.02. ‘Knowledge’ Under IPRSs Policy

There are three basic practical issues that the IPRS policy addresses. The first, and by far the most important, relates to the protection of TK, especially Ayurveda. The ‘traditional’ nature of ‘TK’ is expressed not just in its being insufficiently codified, or in the non-formality of its mode of transmission, or in its not being subject to any legally-defined property rights; it is expressed also in the fact that it remains largely outside the domain of capitalist, especially corporate, operations. While it yields livelihoods to many, or forms the basis for practice for many, the absence of legal property rights over such knowledge creates scope for its private misappropriation. The IPRS policy suggests a legal arrangement for preventing this. Such knowledge obviously cannot be transformed into private property of any sort. At the same time it cannot simply be put in the public domain, since, this, while preventing direct private patenting of existing knowledge and practices, would not prevent their indirect private appropriation, through what will be claimed as ‘improvements’ but constitute mere repackaging or minor modifications.

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The Kerala Government’s approach therefore is to put all such knowledge and practices in the domain of ‘knowledge commons’\(^5\), which have two main characteristics:

- while such knowledge is available for non-commercial use by anybody, its commercial use can be made only through negotiations with the existing right-holder; and
- any improvement made on the basis of this knowledge will have to be put back into the ‘commons’.

4.01.03. Elements of Legal Arrangement

The basic elements of the legal arrangement suggested for the protection of TK are the following\(^5\):

- all TK, including TRM, the practice of which sustains livelihoods, must belong to the domain of ‘knowledge commons’, and not to the ‘public domain’;
- in the case of knowledge of the first category which has a community or family custodian, this custodian will be deemed to have rights over the knowledge, while in the case of the second category, the Kerala State will be deemed to have rights over the knowledge;
- no entity that is registered as a medium or large enterprise may be deemed to have any rights over TK.
- the right-holders will have two kinds of rights: first, the right, where applicable, to a ‘brand name’ or a name associated with the unique practice of an institution or community or
family, such as ‘Kotakkal massage’; and secondly, the right to the use of the knowledge;

- everybody else, other than the right-holder to the Traditional Knowledge, who wishes to use this knowledge will have to do so under a ‘commons license’;

- any use of Traditional Knowledge or practice in violation of the ‘commons license’ within or outside the State of Kerala will be considered a violation of the rights of the right-holders and will invite prosecution.

4.01.04. Operation of Legal Arrangement

For operationalising this legal arrangement a body called the Kerala Traditional Knowledge Authority (KTKA) is proposed, with which all practitioners of Traditional Knowledge of the first category will have to be registered. They have to specify what is unique about their actual traditional-knowledge-practice, the details of the nature of their practice, and the details of the nature of the community/group/individual that constitutes the custodian of this practice. The KTKA will give general notice to the public, regarding all applications being made to it by practitioners, so that any contestations of applicants’ claims, or challenges to claims of uniqueness, or prevalence of similar practices in more than one location or community, can be brought to its attention. It is only after scrutinising all such cases of dispute that the KTKA can finally register a community/group/individual as knowledge-practitioners of the first category pursuing a unique set of practices.

4.01.05. Enforcement of the Rights

In addition to creating and maintaining such a register of traditional practitioners, the KTKA will also be in charge of enforcing the rights created under the legal arrangement mentioned above, recommending legal action against the violators of these rights and of the ‘commons license’,
helping the right-holders, both the State and the private communities/individuals, to negotiate terms with other possible commercial users of TK, and undertaking promotional activities like forming TK Users’ Co-operatives, in order to enable such users to access larger markets for their practices and products. Its activities will be financed from a fund created by the Government of Kerala and it will be administered by a Board consisting of a Chairman and four members, of whom at least one each must be from the TK community and the scientific community.

All right-holders of TK will be deemed to be holding their rights under a ‘commons license’. Under this license the right-holder permits others the use of the knowledge over which the right is held for non-commercial purposes. If any development is made using this knowledge, then under the conditions of this license this development will have to be put back into the TK ‘commons’ and cannot be patented anywhere. If any commercial use of TK is to be made by any entity other than the right-holder, then the terms and conditions under which this can be done will have to be negotiated between the right-holder and the other potential user. In the case of TK of the second category, where there is no specific knowledge-custodian and the Kerala State is deemed to be the right-holder, it will be presumed that all actual practitioners of this category of knowledge in Kerala, provided they are not classifiable as medium or large enterprises, have an automatic license for right of commercial use given by the Kerala State which is the original right-holder, but are not empowered to transfer this right of commercial use to anybody else. Only the Kerala State, the original right-holder enjoys that right.

The operationalisation of this policy will throw up major challenges, arising inter alia from the Constitutional limits upon state government powers. But before these legal possibilities are even explored, there has to be clarity about the approach of the State Government. Such clarity will also help in the attempt to create a national consensus on these important issues. The policy document of the government of Kerala therefore is only the first step in a rather protracted journey.
4.01.06. Constitutional Sanctity of the Policy

The arguments regarding the Constitutional sanctity of the proposed legislation are;

- The words like ‘TK’, ‘Intellectual Property’, ‘Biodiversity’ etc. did not find specific mention anywhere under Union List and the Entry 49 is limited to ‘patents, inventions and designs, copyright, trade-marks and merchandise marks’.

- The ownership of TK may be attributed to the State, given the fact that TK is an accumulated traditional wealth and the long kept preserve of its practitioners, tribal communities and families, wherein all of them act as deemed ‘trustees’ of the State. So TK is very well a ‘treasure trove’. Item No. 44 of State List), where the State has power to legislate.

- Item No. 26 of State List can be used to regulate trading of ‘knowledge’. Item No. 64 provides for enforcement of punitive mechanisms.

- Item No. 7 (Contracts) of Concurrent list and Item No. 6 (Transfer of Property) also is relevant.

- Article 300A covers Intellectual Property also. Article 304(b) and Article 19(6) gives added advantage to treat TK as a property and hence regulate its trading

- The proposed legislation does not intend to touch the Patent Act at all, it being a union subject. But a few provisions in Biodiversity Act (made using the residual powers of Central Government) needs to be supplemented with additional
provisions, but employing the provisions of Articles 258A and 258 (2).

➢ There is support of State directives under Article 38, 39 (b) and 39(c).

While there is no bar on Kerala State in having a policy on IPRSs (IPRS) to proclaim its stand with respect to its culture, geography, people, and biodiversity etc., constitutional sanctity of a legislation based on the Policy is debatable as IPRS is a Union Subject.

5. Non-Governmental Efforts

The main Non-Governmental level efforts are;

5.01. Efforts by Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI)

Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), which means creation in Sanskrit, was born in 1993 as a result of the felt need for an institutional support to the activities of the Honey Bee Network. Based in Ahmedabad, Gujarat, SRISTI is a registered charitable organization under Bombay Public Trust Act, 1950. The organization is also registered under Sec. 80 of Income Tax Act, 1961 and Foreign Contribution Regulation Act, 1976. SRISTI was set up to provide organizational, intellectual and logistics support to the Honey Bee Network54.

The primary objectives of the organisation are55:

Systematic documenting, disseminating and developing grassroots green innovations, providing IPRSs protection to grassroots innovators, working on the in situ and ex situ conservation of local biodiversity, and providing venture support to grassroots innovators. SRISTI manages the
Honey Bee database of innovations, and supports the publication of the Network’s newsletter in three languages, English, Hindi and Gujarati.

Lately SRISTI has being focusing on more concerted ways of hitherto neglected domains like women’s knowledge systems, value addition through a natural product laboratory, using ICT to establish knowledge network, connecting innovators, Traditional Knowledge holders with the centres of formal excellence, entrepreneurs etc and innovations in education.

5.02. Efforts by Centre for Ecological Sciences (CES), Indian Institute of Science

An effort by CES is worth notable in the field of TK. In mid-1998 they established 75 Peoples’ Bio-Diversity Registers in ten states. Another experience is the Gene Campaign that has been undertaken work on documentation of bio-diversity and knowledge relating to this population. Medicinal plants and knowledge thereto was documented with the help of tribal youth, while the elders, medical practitioners and traditional healers were consulted in the collection and understanding of the information.

5.03. Efforts by Research Foundations of Science, Technology and Ecology (RFSTE)

In 1999, RFSTE initiated a movement called ‘jaiv panchayath’ (living democracy), whose aim was to establish definitive sovereignty of local communities regarding their biodiversity resources. The members of these institutions are interested with the task of inquiring and recording information on biological resources and various uses of the same in the form of Community Biodiversity Registers. It is estimated by RFSTE that efforts towards ‘jaiv panchayaths’ were under way in above 300 sites in country.

5.04. Efforts by Kalpavriksh and Beej Bachao Andolan

In Uttar Pradesh, the efforts of Kalpavriksh and ‘Beej Bachao Andolan’ (save the seed campaign) in collaboration with the villagers of Jardar, initiated an exercise in 1995 to document
the various bio-resources uses by the community and conservation practices\textsuperscript{62}. There was an agreement between this network of farmers and Kalpavriksh that one copy of the register would be kept with them while the one with Kalpavrisksh, and that all information can be distributed and used only with the consent and knowledge of the villagers\textsuperscript{63}.

6. Intellectual Property Rights Protection of Traditional Medicine

Intellectual Property is a term referring to a number of distinct types of creations of the mind for which a set of exclusive rights are recognized and the corresponding fields of law. Under Intellectual Property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works, discoveries and inventions, and words, phrases, symbols, and designs. Common types of IPRS include copyrights, trademarks, patents, industrial design rights and trade secrets in some jurisdictions\textsuperscript{64}.

Although many of the legal principles governing Intellectual Property have evolved over centuries, it was not until the 19\textsuperscript{th} century that the term ‘Intellectual Property’ began to be used, and not until the late 20\textsuperscript{th} century that it became commonplace in the majority of the world\textsuperscript{65}. The British Statute of Anne 1710 and the Statute of Monopolies 1623 are now seen as the origins of copyright and patent law respectively\textsuperscript{66}.

6.01. The Main Objectives of Intellectual Property Rights

The main objectives of IPRS are\textsuperscript{67};

- Financial incentive

(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.)

- Economic growth
- Morality

(The protection of Intellectual Property is essentially a moral issue. The belief is that the human mind itself is the source of wealth and survival and that all property at its base is Intellectual Property. To violate Intellectual Property is therefore no different morally than violating other property rights which compromises the very processes of survival and therefore constitutes an immoral act.)

6.02. Intellectual Property Rights and Traditional Medicine

Intellectual Property protection, in the form of copyrights, trademarks, designs and patents usually applies to an identifiable author, inventor or other originator, who will be individually rewarded or an identifiable work, invention or other object and defined restricted acts. TRM does not fit well within these three characteristics of IPRS. There are rarely well-identified authors or inventors of creations, inventions and knowledge passed on and improved from one generation to the next. The knowledge is sometimes amorphous and hard to circumscribe for the purposes of a patent application or to identify as one or more copyrighted works. Finally, the types of acts that indigenous communities want to prevent are not necessarily those that propertisation provides. For instance, benefit-sharing obligations, which can be based on ethical standards, or national or international legal norms, or a combination thereof, resemble more a liability-type regime, or perhaps a compulsory license, than a full Intellectual Property right, in large part because they do not include a right to exclude or prohibit.
6.02.01. Patent Protection of Traditional Medicine

According to TRIPS Agreement, countries are obliged to provide patent protection for any inventions, whether products or processes, in all fields of technology, provided that they are ‘new’, ‘involve an inventive’ and are ‘capable of industrial application’. However, there is variation at the national level among WTO members as to what they consider to be an inventive that is ‘new’ or that involves an ‘inventive step’ for the purpose of granting patent protection.

A patent is granted by a national office upon filing and a formalities check or substantive examination. There is no international patent; rather, patent protection must be sought in each country or region where patent protection is desired. The substantive requirements for patent protection, as indicated above are that an invention be ‘new’, and ‘involves an inventive step’ a comparison is made between that invention and the ‘prior art’.

Thus three major constraints in filing for patent protection are:

- First, most TK including traditional medical knowledge is ancient and does not meet the requirements of novelty and inventive step.
- Second, TK is held collectively, there is not a single individual or discrete group of individuals that can be identified as an ‘inventor’ in whose name the application may be filed.
- Third, the complexity and cost of drafting and prosecuting patent applications is outside that which holders of TK can manage and afford.
Each of these constraints was identified by WIPO in fact-finding missions conducted in 1998 and 1999 on the Intellectual Property needs and expectations of holders of TK\textsuperscript{72}.

Prior art being technical disclosure that predate the patent application or invention. Such technical disclosures may include patent literature-patent applications or patents published by national patent offices or non-patent literature, including scientific and technical journals or periodicals. Because a patent application must disclose the invention so that others skilled in the relevant technical area may practice it and because it must claim the invention with specificity, it must be drafted with great care\textsuperscript{73}.

A patent grant is a ‘negative right’, it allows the patent holder to prevent others from making, using, selling, offering for sale, or importing the patented invention. Other laws including those for the protection of human or animal health or the environment must be complied with. The protection is granted for a limited period generally for 20 years from the date of the patent application is filed. After that time, the invention disclosed and claimed in the patent becomes part of the public domain for all to use.

6.02.01.01. Novelty

The novelty requirement will generally impede the patenting of TRM knowledge that has been published or openly used before the filing date of the patent application. National and regional patent systems can be unforgiving if the requirement of novelty or inventive step is not met, a patent shall not be granted\textsuperscript{74}. Thus, if the invention for which protection is sought has been previously disclosed, the invention lacks ‘novelty’ and a patent shall not be granted. Concerns in this respect have been raised about the publication of results of academic research in respect of traditional phyto-medicines and the effect of such publication on the ability of holders of TK to seek and obtain patent protection.
Hence, a large portion of TRM held by local or indigenous communities, and codified TRM, is likely to be deemed not to be novel and therefore not patentable. As mentioned above, the definition of ‘novelty’ for patent purposes depends on the national or regional law under which a patent is granted. Thus, some National Laws define oral disclosures as part of the ‘prior art’ which will defeat ‘novelty’ only if they are made within their national borders.

In order to destroy novelty, however, the prior use must generally be such that access to the information would have allowed a third party to execute the invention, without significant further research. Thus, there may be situations in which novelty may not be lost, despite the relevant TRM knowledge having been previously used, even for long periods. Other patent laws define oral disclosures made anywhere in the world as forming part of the prior art. National and regional patent systems can be made less unforgiving. For example, some national systems provide for a so-called ‘grace period’ during which disclosures—in particular disclosures by the applicant—will not be taken into considerations for the purpose of determining if the novelty of an invention has been defeated. The introduction of a ‘grace period’ would adjust the definition of prior art to exclude from consideration any premature disclosure whether made as part of a documentation project or made for the purpose of seeking to commercialize the invention— if that disclosure was made within a specified period before the filing of the application. But it would be incorrect to assume that all TRM, because it may be old and previously used, has necessarily lost its novelty for the purposes of patent law.

An important issue is whether novelty should be deemed to exist in cases where the chemical structure of the active substance responsible for the therapeutic effect of an openly used product was not known. According to Koon, it is not necessary for an active substance to be identifiable or reproducible for it to have been made available to the public. Applied in the context of TRM, this doctrine would mean that the fact that local or indigenous communities were unable to
scientifically describe the structure of a useful compound, would not prevent it from entering the public domain.

Further, disclosure in a non-written form may not be an obstacle to obtain patents on TRM in countries where a relative novelty standard is applied. In the US, for instance, according to Article 102 of the Patent Law,

“A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...”

This means that TRM knowledge that has been published in a written form in the US or in any other country is not patentable. However, if such knowledge was publicly used but not documented in a foreign country, novelty is not lost and patenting remains a possibility. As a result of the relative novelty requirement of the U.S., as mentioned above, several patents relating to or consisting of genetic materials or TK acquired in developing countries, have been granted to researchers or firms by the US PTO.

6.02.01.02. Inventive Step

One of the characteristic of TK is that it is typically developed and held collectively. When certain TRM knowledge has remained undisclosed and, thus, the novelty of the information preserved, an additional standard of patentability must be met in order to acquire patent rights that is ‘inventive-step’ or ‘non-obviousness’. This standard requires that the claimed invention be non-
obvious for a person with ordinary skills in a given technical field. Even if novel, knowledge will not be patentable if it is proven obvious or lacking an inventive step. ‘A person with ordinary skills’ is a legal fiction. Patent offices and Courts may apply different standards, according to the technical field concerned\textsuperscript{78}.

Thus, something that may be obvious to a healer or professional trained in TRM may not be so for somebody trained in the western medical tradition (or the reverse), thereby allowing for the granting of a patent.

The loose application of the inventive step or non-obviousness standard allows for the patenting of minor advancements, if any, in relation to previously available information\textsuperscript{79}. This is clearly undesirable from the point of view of public policy and the preservation of the freedom to use knowledge within the public domain. There is little society may gain by extending legal monopolies to holders of TRM, or to those that obtained knowledge from them, where no genuine invention can be claimed.

\textbf{6.02.01.03. Inventorship}

Inventions for which patent protection is sought are made by one or a small, discrete number of inventors. First, the concept of inventorship may be broad enough such that for a given claimed invention, inventorship should include not only those working in a lab who isolate and purify an active ingredient from a plant, but the traditional healer who identified that ingredient in the first place. A determination of inventorship is very fact-intensive and must be determined in accordance with the relevant national or regional law\textsuperscript{80}.

Traditional medical practitioners have identified the high costs of filing patent applications as the biggest obstacle to the acquisition of patents by practitioners of TRM. Concerns about costs, are not unique to holders of TK\textsuperscript{81}. Suggestions have been made that are specific to holders of TK,
including requests for financial and legal assistance to traditional healers’ organizations for the filing of patent applications and suggestions of collective filing of patent applications by traditional healers’ associations on behalf of individuals or groups of informal innovators. This would allow holders of TK to share transaction costs for acquiring and exercising patent rights.

Some organizations are systematically disclosing the innovations compiled in their TK databases in order to prevent possible future patents based on the innovations. An example of an institution that engages in systematic, intentional disclosure is the Farm Rights Information System (FRIS) maintained by the M.S. Swaminathan Foundation in India. An example of an organization in the process of compiling a data base was given by the Government of India the ‘Honey Bee Data Base’ established by SRISTI which explained it in the following terms:

“…the Honey Bee database, established ten years ago in India, is a facility for registration of innovations by innovators. The database can be accessed for adding value to these innovations and sharing benefits with the knowledge providers and innovators. Thus, the Honey Bee Network involves documentation, experimentation and dissemination of indigenous knowledge. The network has probably the world’s largest database on grass root innovations, having now about 10,000 innovations, with names and addresses of the innovators, individuals or communities”.

Holders of TK have identified patents that had been granted for inventions that did not satisfy the test of ‘novelty’ because of prior TK-related disclosures. Some of the patents were later invalidated due to the TK related disclosures that were cited against the patent. The most efficient use of such TK related disclosures and the patent system is to make such disclosures available to
patent examiners so as to prevent such patents from issuing in the first place. Indeed, as the GOI has said\textsuperscript{84},

“…documentation has one clear benefit. It would check patents based on Traditional Knowledge in the public domains that are today difficult to prevent due to lack of availability of information with patent examiners”.

The need to improve documentation of TK for use by patent offices as part of the ‘prior art’ upon which their examination of patent applications is based is widely accepted. Indeed, the Government of Brazil stated that\textsuperscript{85};

“…it considers that documentation of TK would have the clear benefit of providing documentation for patent offices to determine prior art and check against patent claims that are filed without the consent of the holders of TK. It should be noted that different Members of the WTO -such as Switzerland (IP/C/M/25, paragraph 81), India (IP/C/W/198, paragraphs 16 to 23) and the United States (IP/C/W/209, paragraph 3 of item 4) -have already agreed on the usefulness of documenting TK”.

According to Government of India\textsuperscript{86},

“..In the recent past, there have been several cases of bio piracy of TK from India. For preventing such instances in the future there is a need for developing digital databases of prior art related to herbs already in the public domain. Following
patents on brinjal, etc., in India, an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as TKDL. Such digital databases would enable Patent Offices all over the world to search and examine any prevalent use or prior art. And thereby prevent grant of such patents and bio piracy.”

The documentation of TK, in the view of the Indian government, fosters not only the prevention of ‘bio-piracy’. It may also provide a basis for the sharing of benefits arising from the use of such knowledge, though documentation per se will not ensure benefit sharing with the holders of such knowledge. A clear effect of such libraries is that both local or indigenous communities and third parties will be prevented from obtaining patents over documented knowledge.

The issue of TKDL has also been addressed by WIPO with the aim of not only detailing in writing TK already in the public domain, but of improving the WIPO International Patent Classification (IPC) so that the data is easily accessible to patent examiners. Ideally, as these TKDL come into being, they will be incorporated in the minimum search documentation list of the Patent Cooperation Treaty (PCT), therefore ensuring that the data in these libraries will be considered during the processing of patent applications filed under the PCT system. It has also been suggested that search and examination guidelines in patent examining authorities be updated to ensure that TKDLs are consulted.

Concerns have been expressed about the extent to which documentation programs may expedite ‘bio-piracy’, rather than preventing it, by facilitating the work of those who wish to appropriate the benefits of the knowledge which is being documented. Since this may occur, the
development of TKDL does not exclude the need for regulations to prevent misappropriation. A related issue which is beyond the remit of this study is the protection conferred to the data bases containing that information\textsuperscript{88}. If the policy goal is to facilitate the patentability of TRM, rather than to limit it, a possible option would be to establish an extended grace period for inventions pertaining to this field whenever claimed by the communities or individuals that legitimately developed or hold them. This would certainly expand the scope of patentability in cases where it would have been excluded by loss of novelty.

Consistent with this approach, WIPO is taking steps to facilitate improved availability of TRM documentation data for patent examiners at patent-granting authorities. For example, the Committee of Experts of the International Patent Classification Union has just created a Task Force to study the relation and possible integration into the IPC of a TKRC. The Committee established a TK Task Force comprising representatives of Intellectual Property offices of China, India, The United States of America, and the EPO.

6.02.02. Trade Secrets Protection

Trade secret protection is another mechanism for the protection of IPRSs in TRM. Trade secrets may be applied for the protection of some components of TRM, if the information is kept secret and is of actual or potential commercial value\textsuperscript{89}.

Trade secrets are commonly protected under the doctrine of unfair competition, which provides legal protection against commercially dishonest practices, provided that the knowledge holder takes reasonable steps, under the circumstances, to keep the knowledge secret. In some cases, TK including healing practices and materials are deliberately kept secret by the few individuals in the community privy to the knowledge. Often the knowledge is kept secret because of the place it holds in cultural concepts and practices such as rituals and magic.
The requirements for the protection of confidential information or trade secrets at the international level are summarized in Article 39.2 of the TRIPS Agreement. This says that,

➢ “…natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information;

➢ is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

➢ has commercial value because it is secret, and

➢ has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret”.

Trade secrets law may be suitable for the protection of TRM knowledge, due to a number of its characteristics⁹⁰;

➢ First, conceptually, the protection of trade secrets does not presuppose the granting of property rights, but simply the right to take actions against whoever has acquired commercially valuable secret knowledge through unfair commercial practices. This approach may be compatible with
the view prevailing in many communities, that any form of appropriation of their members’ knowledge is inappropriate.

- Second, registration is not needed in order to acquire the rights conferred under trade secrets law. This is particularly important for TRM holders, since in many cases they are neither equipped for, nor inclined to comply with registration formalities, and/or unable to bear the ensuing costs.

- Third, though the protected knowledge should be commercially valuable, trade secrets law does not require establishment that the knowledge is ‘new’ or involves an ‘inventive step’ as required under patent law. In some jurisdictions\(^{91}\), trade secrets protection may be extended to knowledge of potential commercial value\(^{92}\). This extension may permit the protection of TRM which currently has no commercial application, but which may become used for such purposes in the future.

- Fourth, unlike other forms of IPRs, trade secrets protection lasts as long as the protected knowledge is not divulged. This feature is especially appropriate to the nature of TRM that has remained secret and must remain so if cultural norms are not to be violated.

- Finally, in the case of TRM, the possession of knowledge is often collective in nature. While communities do not generally fall under the category of ‘legal persons’, nothing would prevent a Member country from extending trade secrets protection to information held by such communities.
As noted by Grulac⁹³,

“…acknowledgement of the fact that secret TK may be protected by means of unfair competition law will make it possible for access to that knowledge, its exploitation and its communication to third parties to be monitored. Control over the knowledge, and regulation of the manner in which it may be acquired, used and passed on, will in turn make possible to arrange contracts for the licensing of secret TK and derive pro from its commercial exploitation”

As in the case of other IPRSs, trade secret holders need the capacity, including financial, to enforce their rights through generally costly and lengthy court procedures. This is not, a minor point when considering not only the availability of protection but its possible efficacy in protecting the interests of TRM holders.

There are two important differences between patent and trade secret protection.

➢ First, there is no requirement that a trade secret be new or involve an inventive step as required for patent protection.

Certainly, if a trade secret is not ‘new’ it may not be a secret and, therefore, not protectable. But a trade secret need not meet the more formal, rigorous standards for patent protection of novelty and inventive step.

➢ Second, a trade secret can, if kept secret, last in perpetuity.

In contrast, as noted above, patent protection generally lasts for only 20 years after the filing date of the patent application.
Here it is worth mentioning that trade secret protection is of greatest applicability to non-medicinal including ceremonies, methods or processes practiced by traditional healers. This is because information that certain plants, animals or minerals have medicinal value may be more difficult to retain in confidence than ceremonies practiced by a traditional healer. Moreover, if TRM knowledge is ancient, the prospect of its being secret and, therefore, protectable as the trade secret is diminished. That is because over the years, a particular item of traditional medical knowledge may have become generally known. In cases where TK is known among only a small, closed circle of traditional healers, however, or is passed down generation to generation within a family, the knowledge may not be generally known and may, therefore, be protectable as a trade secret.

Trade secret protection must be made on a case by case basis because the question of the applicability is very much fact dependent. Thus, the holder of traditional medical knowledge will have to consider and be advised on the elements identified above for the protection of trade secrets. A decision will have to be made, then, whether the elements for protection have been satisfied in a particular case. In addition, questions of ownership individual or collective in reference to patent protection will also have to be resolved.

6. 02.03. Trade Mark Protection

Trademarks are signs or combinations of signs used to identify the origin or source of a good or service. Trademarks come in a variety of shapes, two and three dimensional, and forms. A trademark may be a simple word or phrase, a company’s name, a number, letters, combinations of colours, or an image. In some countries, sounds and smells are afforded protection as trademarks.

In addition to general trademarks for goods or services, some national or regional systems provide for specialized trademarks called certification or classification marks. Because of their relevance to the protection of TK, certification and classification marks will be explained in some
Trademark protection is, generally, accorded only after an application is filed, which is examined and granted by a competent national authority.\textsuperscript{94}

Certification marks are trademarks used to identify a product which meets certain standards established, managed and enforced by an organization ‘competent to certify’ the products concerned. The organization applies for the registration of the mark and if successful, becomes the trademark owner. Only manufacturers who offer products for sale made in accordance with the standards established by the relevant organization are licensed by the organization to use the mark. Consumers thus benefit from knowing that the products concerned meet the required standards. Collective marks are trademarks which serve to distinguish the geographical origin or other common characteristics of goods or services of different enterprises which use the collective mark under the control of the owner. Collective marks are usually owned by associations of enterprises which offer the goods or services offered under the mark.

The regulations governing the use of the collective mark have to be included in the application for registration of the mark. In general terms, the difference between collective marks and certification marks is that the former may only be used by members of the organization, while certification marks may be used by anyone who complies with the relevant standards. Thus, the use of a collective mark may not in and of itself be considered as a guarantee of quality, but merely an indication of association.\textsuperscript{95}

Trademarks do not protect the knowledge or technology incorporated in a trademarked product and, hence, do not impede the commercialization by a third party of an imitative product under a different trademark, or without a trademark. In addition, since the basic function of a trademark is to distinguish the products or services of one enterprise from those of other enterprises, the protected sign must be different from the generic denomination of the product.
Local or indigenous communities could acquire trademarks subject to compliance with national rules on ownership and representation. Given the collective nature of TRM knowledge, ‘collective marks’ or ‘certification’ marks may be particularly suitable. Such marks are used by a group of producers generally the members of an association and may serve to distinguish the geographical origin or other common characteristics or quality of certain products. The acquisition of a collective or certification mark normally requires the submission of approval of regulations for the use of the mark.  

Trade marks may be as important for the marketing of TRM based products as for any other medicine, depending on the strength of the mark, the particular conditions of the relevant market and the prevailing prescription practices of healers and physicians. Domestic companies may benefit from trademarks identifying medicines derived from TRM systems. Trademarks can also be useful to local or indigenous communities if they decide to commercialize themselves certain products, provided that they are able to monitor its use and enforce their rights in cases of violation. The use of collective marks or certification may have the benefit of providing a specific badge of approval of a local or indigenous community, in addition to give an indication of geographically dependent qualities of products.  

With other IPRSs, the effectiveness of trademarks as a means of promoting the commercialization of TRM will depend on the title-holders’ capacity to exercise their rights, so as to deter the commercialization of infringing products. Moreover, the value of trademarks, as well as of geographical indications, depends on the capacity to establish and preserve product homogeneity and quality standards, and on investments, sometimes substantial, in promotion and marketing. In other words, protection by such signs does not automatically guarantee that they would generate added value for the right holders.
Trademarks in particular certification and collective marks and geographical indications may have some relevance to the protection of traditional medical knowledge. Certification marks may be useful in the protection of TRM in the event an organization is established to ‘certify’ that medicinal products are made in accordance with established standards.

This may be useful, for example, where botanicals are gathered, processed, or purified in accordance with defined standards prior to shipping to foreign markets. Buyers in those foreign markets would be inclined to purchase products that are so certified to ensure the botanicals they purchase meet consistent high standards or quality or potency.

6.02.04. Protection of Geographical Indications

A Geographical Indication\textsuperscript{99} is a sign used on goods that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin\textsuperscript{100}. Most commonly, a geographical indication consists of the name of the place of origin of the goods. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil\textsuperscript{101}.

A geographical indication points to a specific place or region of production that determines the characteristic qualities of the product that originates therein. It is important that the product derives its qualities and reputation from that place. Since those qualities depend on the place of production, a specific ‘link’ exists between the products and their original place of production\textsuperscript{102}.

Geographical indications are understood by consumers to denote the origin and the quality of products. False use of geographical indications by unauthorized parties is detrimental to consumers and legitimate producers. The former are deceived and led into believing to buy a genuine product with specific qualities and characteristics, while they in fact get a worthless
imitation. The latter suffer damage because valuable business is taken away from them and the established reputation for their products is damaged\textsuperscript{103}.

Thus, such indications may provide a competitive advantage, both domestically and in foreign markets, when a TRM product is associated by the public with its geographical origin. An essential condition for the recognition of a geographical indication is that specific characteristics of a product must be attributable to its geographical origin.

According to Grulac\textsuperscript{104},

“Geographical indications, especially appellations of origin, may be used to enhance the commercial value of natural, traditional and craft products of all kinds in so far as their particular characteristics may be attributed to their geographical origin. A number of products that come from various regions are the result of traditional processes and knowledge implemented by one or more communities in a given region. The special characteristics of those products are appreciated by the public, and may be symbolized by the indication of source used to identify the products. Better exploitation and promotion of traditional geographical indications would make it possible to afford better protection to the economic interests of the communities and regions of origin of the products”.

Like in the case of trademarks, geographical indications may be useful to enhance the commercial value of TRM, whenever the consumer can establish an association between the geographical origin and the characteristics or quality of certain products. While such indications
cannot be legally used in the country of registration by parties not belonging to the relevant region or locality, procedures for the international recognition of such indications are still under negotiation in the framework of WTO\textsuperscript{105}. Several developing countries have strongly advocated the strengthening of protection of geographical indications for products other than wines and spirits, which already receive an enhanced protection under the TRIPS Agreement. There are some examples of geographical indications linked to TK used in the Andean Group countries, which illustrate the potential use of such indications to protect TRM\textsuperscript{106}.

Thus the commercial value of geographical indications depends on adequate management practices and quality controls and marketing capabilities. Hence legitimate users of a geographical indication must establish the standards to be applied, and the monitoring mechanisms to ensure that the characteristics and quality of products conform to such standards. They must also enforce their rights domestically and internationally. All this may not be possible for TRM holders, in most cases, without significant State or other support.

7. *Sui Generis* Protection

Through their association with nature for centuries indigenous communities have acquired immense knowledge, which when properly modified is having large commercial value. Current IP system has proved to be inefficient to deal with the issues relating to protection of TRM, this was reason for a proposal of development of a *Sui Generis* system for protection of TRM and TK. *Sui Generis* systems are alternate models created outside the prevailing Intellectual Property regime. Article 27.3 of the TRIPS agreement asks the states to provide for a *Sui Generis* system for protection of plant varieties and TK. Developing countries are looking at *Sui Generis* clause as a window, an opening, to enact legislations that goes beyond IPRS for protecting rights of farmers, indigenous and local communities who apply creative intellectual efforts and develop useful technologies with bio diversity and their knowledge of the same.
The International Seminar on *Sui Generis* rights\(^{107}\) records that:

“…developing and least developed countries are looking at *Sui Generis* clause as a window, an opening, to enact legislation that goes beyond IPRS for protecting rights of vast majority of their citizens -farmers, healers, indigenous and local communities -who apply creative intellectual efforts and develop useful technologies with bio diversity and their knowledge of the same. Going beyond IPRS is not prohibited by TRIPS. What is unknown is how *Sui Generis* laws that go beyond IPRS, providing rights that are different from IPRS, will function in a world increasingly dominated by IPRS - and how WTO will react to it. It is important to note that in many countries the discussion on rights related to biodiversity for grassroots communities is not linked to TRIPS and therefore many Latin American countries that has notified WTO of their plant variety protection laws to comply with the *Sui Generis* option, are working towards a legislation with broader rights to deal with plant varieties as part of bio diversity.”\(^{108}\)

In a report\(^{109}\), the International Bureau of WIPO proposed a *Sui Generis* right that is both systematic and ‘comprehensive’, in that it does not separate the components of the knowledge and thus reserves its ‘holistic’ nature. The *Sui Generis* right(s) would include;
- A right to prevent unauthorized use (making, using, offering for sale, selling or importing) of Traditional Knowledge;

- A right to prevent any reproduction of a fixation of Traditional Knowledge that is unauthorized or distorting;

- A strong moral right;

- A right in respect of databases similar to the right (of preventing unfair commercial use and preventing disclosure) contained in Article 39.3 of TRIPS;

- A right to assign or transfer, notably in respect of benefit-sharing under the Convention on Biological Diversity.\(^{110}\)

A *Sui Generis* legislation in TRM which recognizes the autonomous character of TRM is able to ensure a more objective valuation of TRM. A system that views TRM as a composite resource having, both economic and cultural features have a better prospect of ensuring protection of TRM. National measures of a *Sui Generis* system backed by international regulation can definitely help in preserving the knowledge of communities from misappropriation.

### 7.01. Status of *Sui Generis* in Various Countries

Some countries have already enacted or are in the process of enacting a *Sui Generis* system of protection of TRM. Philippines is one among those nations who has enacted a legislation giving indigenous communities right over their TK\(^{111}\). These rights extend to controlling access to ancestral lands and access to biological and genetic resources and to indigenous knowledge relating to these
resources. Access by other parties under this legislation is based on the concept of ‘Prior Informed Consent’ of the community. The Act provides that any benefit arising from genetic resources of associated indigenous knowledge will be equitably shared. The law seeks to ensure that indigenous communities are able to participate in all levels of decision making. The Guatemalan law also seeks to preserve and promote the wider use of its TK by placing expressions of national culture including medicinal and music under the protection of the state. India also by Biological diversity Act has made an attempt to make a separate system of law for protection of genetic resources and associated Knowledge.

8. Customary Law Protection of Traditional Medicine

The success of a Customary Law approach would depend on the formal recognition, accompanied by adequate legal arrangements concerning matters such as self-determination, land rights and biodiversity protection. The recognition of communities’ Customary Law, hence, raises delicate political issues in the framework of the modern nation state, the relationship between indigenous peoples and national governments being problematic in many countries. An important limitation of the Customary Law approach is that, if adopted at the National Level, it would not encompass very much like in the case of Sui Generis regimes recognition of the rights conferred in foreign countries, unless specific agreements on the matter are put in practice under International Agreements or unilaterally under national laws.

9. Conclusion

In spite of all these efforts in different levels the future of TRM is at the verge of unauthorized exploration. Even now it is getting commercialized and exploited without the consent of the original holders. The present globalized world is an easy medium for trans-national exploitation. Hence there is a need to protect the TRM in the international level. The modalities for protecting TRM are still emerging and evolving. Even at the international level clarity has not
yet emerged and countries are grappling to understand the issue. Work on TK including TRM is undertaken by various inter-governmental bodies like WIPO, FAO and UNCTD etc. But the efforts of these bodies are in stage of discussion and a comprehensive framework has yet to evolve.

In most of the cases, patents are granted outside country that holds knowledge. In such a situation the interests of the nations’ cannot be protected unless presence of international framework that recognizes and respects national laws. Besides international action, there is a need for nations to protect their communities by making national laws and addressing relevant issues like documentation of knowledge, access benefit sharing and PIC.

In the national level he existing legal provisions relating to the protection of Traditional Knowledge is not enough and adequate to prevent the misappropriation of that knowledge and it has been proved that it clearly needed an assessment to evaluate some of the problems and gaps in policies and laws which are causing stress and tensions. Any solution to the problems associated to the protection of TK requires a holistic approach. In the light of public health priorities, Governments may adopt several measures to promote the use of TK for the affordable treatment of national and regional priority diseases, such as encouraging the validation, registration and quality control of TK-based products. The laws should not run counter to but should support public health.

The efforts at governmental level result in the documentation of TK of medicine. It will help in the future protection of this knowledge against misappropriation. But there must be crystal clear guidance for access to this database. Otherwise it will result in frequent bio-piracy. The efforts at non-governmental organization level mainly focus on the registration of knowledge. And the effort by SRISTI and NIF in registering and rewarding innovations in the informal sector is another significant movement for the protection of knowledge of medicine. Hence there is the need for a mechanism for the preservation, promotion and protection of the reservoir of TRM because in India as the invasion of multinational corporations pose a big threat to this knowledge in this neo-capitalist world.
Traditional Medicine which is orally transferred and preserved by generations may not be available in a systematic and organized document. Besides this even if it is recorded it may be recorded in the local language which the foreign patent offices may find difficult to access. Current IP system considers only documented knowledge as prior art. This paves way for granting of erroneous patents for commercial products based on knowledge of indigenous communities. Current IP system is inadequate to protect TRM is that it is based on individual private property rights and TRM on the other hand rests on collective creation and ownership. Besides this the term ‘protection’ under present IP system indicates the owner of that IP has a legal right to exclude others from using or reproducing it. This aspect is contrary to the concept of TRM and TK. Indigenous Knowledge are not exclusive rights of a particular individual they are often shared between the social group, thus there is an inherent difference between current IP protection and TRM. The current patent system provides for economic interests of only those who have slightly altered TRM and left out the entire community which developed this knowledge to the present stage. Besides this the current IP system does not provide for community patent which can be used to protect collective knowledge of the society. This lacking of provisions for community patent has led to the question of who can be the owner of patents, based on TRM and how benefits incurring from such patents can be distributed among the society who are in fact the 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 TRM. TRM is something evolved through generations so it lacks the principle of novelty. TRM is developed by trial and errors. Also TRM as such may not be having any commercial application, it indeed requires certain changes. So the existing patent system is incapable of giving protection to TRM as there is an essential difference between both the concepts.


3 See G. Dutfield, “Can the TRIPS Agreement Protect Biological and Cultural Diversity?” Available at www.wipo.int/cgi-bin/koha/opac-detail.pl?bib=24572 Accessed on 23 October (2011)


6 See Art 24(3) (b) of TRIPS agreement “Members shall provide for the protection of plant varieties either by patents or by an Sui Generis or by any combinations thereof”.

7 See www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm Accessed 12 October (2011)


10 See WIPO/GRTKF/IC/5/12, 13 April (2003)

11 See Art 8(2) (a) of UN Declaration on Rights of Indigenous Persons


14 Ibid

15 Ibid


18 See Section 28(1) of PPFR Act 2001

19 See Section 26 of PPFR Act 2001

20 See Section 3(1) of Biological Diversity Act 2002

21 See Section 5 of Biological Diversity Act 2002

22 P. Pushpangadan, “Traditional Knowledge and Folklore – A Benefit Sharing Model Experimental in India” Based on the presentation made during the Conference organized by the Commission on Intellectual Property Rights at London on 21-22 February (2002)

23 It should be noted, however that, in principle, benefits under the CBD accrue to the States supplying genetic resources, not communities.
Section 3 of the Biological Diversity Act. It states “No person, who is not a citizen of India, who is a non-resident Indian as defined under Income Tax Act, 1961, a body corporate, association or organization, which is not incorporated or registered in India or incorporated or registered in India under relevant law in force and having non-Indian participation in its share capital or management, shall without prior approval of the NBA obtain any biological resource occurring in India or knowledge associated thereto for commercial utilization, or for bio-survey or for bio-utilization”

Section 26(2) of the PPVFR Act limits the eligibility for benefit claim to a person or group of persons, who are citizens of India or to a firm or governmental or nongovernmental organization established in India.

Section 6(3) of Biological Diversity Act states that provisions of Section 6(1) (vide ref. 14 above) shall not apply to any person making an application for any right under any law relating to protection of plant varieties.

Section 6(2) of the BD Act: This subsection states “The NBA may, while granting the approval (for establishing any Intellectual Property Rights) impose benefit sharing fee or royalty or both or impose conditions, including the sharing of financial benefits arising out of the commercial utilization of such rights”.

Section 23(6) of PPVFR Act: “A breeder will become eligible to enjoy plant breeder’s right granted on an essentially derived variety only on authorization of the breeder/conserver (vide Section 43) of the initial variety, which was used for the derivation”.

Section 7 of the BD Act. This section states: “No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization except after giving prior information to the State Biodiversity Board concerned. Each SSB is required to define the administrative procedure for providing prior information”.

Section 3 of the BD Act, 2002


Ibid

Rule 41 of PPVFR Act, 2001

See Section 3(d) and 3(p) of Patent (Amendment Act), 2005

See Section 25(3) (d) of Patent (Amendment Act), 2005

Section 2 (e) of the GI Act defines, ‘Geographical Indication’ in relation to goods means an indication in which identifies such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of the country, or a region or a locality in that country, where a given quality, reputation or other characteristics of such goods is essentially attributable to its geographical origin and in case where such goods are of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality, as the case may be.

Explanation- For the purposes of this clause, any name which is not the name of the country, region or locality of that country shall also be considered as the geographical indication if it relates to a specific geographical area and is used upon or in relation to particular goods originating from that country, region or locality, as the case may be.

Section 20 of the GI Act provides that there shall be no action for infringement or unregistered GI.

Section 20 (1) of the GI Act reads: “No person shall be entitled to institute any proceedings to prevent or to recover damages for, the infringement of an unregistered GI”.

Section 17 of the GI Act provides for the application for registration as an authorized user.
Section 17 (1) of the GI Act reads: “Any person claiming to be the producer of the goods in respect of which a GI has been registered may apply in writing to the Registrar in the prescribed manner for registering him as an authorized user of such GI”.

Section 11 (1) of the GI Act reads: “…any association of persons or producers or any organization or authority established by or under any law for the time being in force representing the interest of producers of the concerned goods, who are desirous of registering a GI in relation to, such goods shall apply in writing to the Registrar in such form and in such manner and accompanied by such fees as may be prescribed for the discretion of GI”.

Section 21 of the GI Act provides for the rights conferred by registration.

Section 21 (1) of the GI Act reads: “Subject to the other provisions of this Act, the registration of a GI shall, if valid, give, -

b) to the authorised user thereof the exclusive right to the use of GI in relation to the goods in respect of which the GI is registered”.

Section 21 of the GI Act provides for the rights conferred by registration.

Section 21 (1) of the GI Act reads: “Subject to the other provisions of this Act, the registration of a GI shall, if valid, give, -

a) the registered proprietor of the GI and the authorised user or users thereof to obtain relief in respect of infringement of the GI in the manner provided in the Act”.

Section 22 of the GI Act provides for the infringement of the registered indication.

Section 22 (1) of the GI Act reads: “A registered geographical indication is infringed by a person who, not being an authorised user thereof,-

a) uses such geographical indication by any means in the designations or presentation of the goods that indicates or suggests that such goods originate in a geographical area other than the true place of origin of such goods in a manner which misleads the persons as to the geographical origin of such goods; or

b) uses any such geographical indication in such manner which constitutes an act of unfair competition including passing off in respect of registered geographical indication”.


See Ibid


See http://spicyipindia.blogspot.com/2008/06/keralas-IPRS-policy.html

Paragraph 3 of the Kerala IPRS Policy reads: “Within the corpus of Traditional Knowledge, a distinction is drawn between two components, one component refers to knowledge which is the preserve of particular communities, especially tribal communities or particular institutions or particular families, often located in specific regions, and passed down from generation one to the next in a variety of traditional ways. The other refers to knowledge whose practice sustains the livelihoods of many persons scattered across the state, which does not have any specific community or family custodian, thus while Kottackal massage clearly belongs to the first category, the knowledge that sustains the daily practice of ayurvedic medicine by numerous practitioners strewn across the state belongs to the second”.

See supra n. 46
Paragraph 16 of the Kerala IPRS Policy reads: “In the first set of projects, it should be a condition that the patents taken out on the research output should be in the domain of commons, so that anyone can use these for what purpose, and all useful modifications derived from or based on whose will be put back into commons available for anyone to use. That means Knowledge Commons refers to the knowledge, which is the collectively produced sphere of ideas and which is left unencumbered for the greater benefit of all.

Paragraph 4 of the Kerala IPRS Policy

Paragraph 5 of the Kerala IPRS Policy reads: “For operationalizing this legal arrangement a body called the Kerala Traditional Knowledge Authority has to be set up, with which all practitioners of Traditional Knowledge holders of the first category will have to be registered. They have to specify what is unique about their actual Traditional Knowledge practice, the details of the nature of their practice, and the details of the nature of the community or group or individual that constitutes the custodian of the practice. The KTKA will give general notice to the public, regarding all applications being made to it by practitioners, so that any contestations of applicants’ claims or challenges to claims of uniqueness or prevalence of similar practice in more than one location or community, can be brought to its attention, it is only after scrutinizing all such cases of dispute that the KTKA can finally register a community or group or individual as knowledge-practitioners of the first category pursuing a unique set of practices”.

Paragraph 6 of the Kerala IPRS Policy reads: “In addition to creating and maintaining such register of traditional practitioners, the KTKA will also be in charge of the rights created under the legal arrangement mentioned earlier, recommending legal action against the violators of these rights and of the common license, helping the right-holders, both the private communities or individuals to negotiate with other possible commercial users of Traditional Knowledge and understanding promotional activities like forming Traditional Knowledge Users Cooperatives, in order to enable such users to access larger markets for their practices and products. Its activities will be financed from a fund created by the government of Kerala and it will be administered by Board consisting of a chairman and four members, of whom at least one each must from the Traditional Knowledge community and the scientific community”.

Paragraph 9 of the Kerala IPRS Policy reads: “In the case of Traditional Knowledge associate with the use of biological resources, which of course is the most important source of livelihood, there is way of providing additional safeguards by using the Biological Diversity Act, 2002. Section 3 of the Act provides that all foreigners must get previous approval of the National Biodiversity authority to “obtain any biological resource occurring in India or knowledge associated with thereto, for research or for commercial utilization or for bio-survey or bio-utilization”. The term foreigners refers to a person who is not an Indian citizen (or is no-resident citizen as defined on clause 30 of section 2 of the Income Tax Act of 1961), or a body corporate, association or organization that is not incorporated or registered in India (or even registered in India or incorporated in India, has any non-Indian participation in its share capital or management). The State will make it obligatory, whether by asking the NBA to refer all applications by foreigners pertaining to Kerala to the State Biodiversity Board, or by enacting legislation asking foreigners to obtain the additional approval of the SBB, that any innovation based on Traditional Knowledge associated with the biological resources of the state is put into the realm on knowledge commons”.

Paragraph 10 of the Kerala IPRS Policy reads: “For prevention of misappropriation of Traditional Knowledge associated with biological resources by Indian corporates the provision of Section 7 of the Biological Diversity Act will be extended, through appropriate legislation if necessary, to cover the acquisition of knowledge as well, for which prior approval of the State Biodiversity Board will be made obligatory for Indians other than the local users. The State Biodiversity Board will ensure in this case too, as in the case of foreigners that Traditional Knowledge remains within
the realm of knowledge commons. As regards the commercial use of biological resources of the State, where the reference to the SBB is obligatory under the Act for Indian non-traditional users, the SBB will give the permission only after consultation with the KTKA, which can go into the question of possible damage to Traditional Knowledge users and possible compensation for such damage”.

55 Ibid
56 Ibid
57 Three populations are:- the Munnars in South Bihar; the Bhils of Madhya Pradesh; and the Tharus of the Terai region. The documented knowledge has been made into manuals for the tribal people who now use it as a practical healing guide. During the data collection exercise, Gene Campaign also conducted a public education program, telling the community about the new national and international developments and the growing bio-piracy which steals their knowledge and their materials. Gene Campaign has made them aware of their rights so that the people are now fully aware that this knowledge belongs to them and cannot be used without their permission, even by the Government of India.

Gene Campaign has also been working to conserve Traditional Knowledge by its field projects which include:

i. Collection of local medicinal flora and establishing a herbal garden in Jharkhand

ii. Establishment of a medicinal plant project in Jhabua, M.P

iii. Developing a Genetic Diversity Centre in Kishanpuri, M.P

iv. Collection of landraces and traditional varieties of rice, millets and pulses and setting up of medium term gene banks in UP and Bihar.

v. Survey and mapping of wild relatives of important crop plants in the Upper Western Ghats

vi. Study on Agro-Biodiversity and farmer perceptions about genetic diversity in the states of U.P and Bihar.

vii. Inventorisation of genetic diversity in Indian trees and their known characteristics.

58 See Sini, Un Published LL.M. Dissertation on Traditional Knowledge, Dept. of Law, University of Kerala
59 Ibid
60 See http://beejbachaoandolan.org/ Accessed on 23 October (2011)
61 Beej Bachao Andolan is a network of local farmers who have been involved for a number of years in reviving and spreading indigenous crop diversity. See Ibid
62 Ibid
63 Supra n. 58
66 Ibid
Duration is not a factor. While the Constitutional text seems to prescribe a limited duration for copyrights and patents, other IPRS, in particular confidential information and trademarks, can be protected indefinitely.

V. Venkateswara, “Traditional Knowledge Commercialization-Benefit Sharing” Presentation at the International Seminar on systems for the Protection of Traditional Knowledge, UNCTAD, New Delhi, 3-5 April (2002)


In 1998 and 1999, WIPO conducted nine fact-finding missions to the South Pacific, Southern and Eastern Africa, South Asia, North America, Central America, West Africa, the Arab Countries, South America and the Caribbean on the on the Intellectual Property needs and expectations of holders of TK. The report on these fact-finding missions may be found at the WIPO web site: www.wipo.int/TK, Accessed on 23 January (2011). Moreover, UNCTAD also identified these three constraints and described them in the following terms; While individual TK holders could in theory acquire a patent, it is generally the case that TK is passed on orally from generation to generation and evolves incrementally. Thus, it would be difficult to meet the criteria of novelty and inventive step. Second, TK tends to be generated collectively to the extent that no inventors are identifiable. Indeed the source of much TK cannot be traced to a specific community or even to a geographical region. Even if these obstacles were somehow overcome, most traditional communities do not have the resources to file patent applications or to take legal action to prevent patent infringement. See TD/B/COM.1/EM.13/2, 35, 22 August (2000)


It has been suggested that holders of traditional medical knowledge could seek protection through petty patent systems. (For novel and useful innovations, some kind of petty patent giving protection for a limited duration may be worked out.) In some countries, protection may be obtained for ‘utility models’ or ‘petty patents’ which refer to titles of protection distinct from patent protection. Utility models generally protect the external configuration of mechanical devices and are generally subject to lower novelty and inventive step criteria. There are exceptions, however, to the limited subject matter for which ‘utility model’ protection is typically available. For example, Kenya’s Industrial Property Act of 1989 is reported to provide utility model protection for traditional medicinal knowledge in the form of ‘herbal as well as nutritional formulations which give new effects. See UNCTAD Background Note 36. Moreover, the term of protection is generally shorter than for patents. Utility models are not discussed further, however, as the discussion on patents raises the necessary issues regarding the protection of inventions in the field of TRM. ‘Petty patents’ may be available for all subject matter or a limited range - but typically more than just the external configuration of mechanical devices as in the case of ‘utility models’. ‘Petty patents’ may have different standards for protection than patents (narrower novelty and inventive step requirements) and, typically have a shorter term. Moreover, while a regular patent may be subject to a substantive examination prior to grant, ‘petty patents’ typically are not. Neither ‘petty patents’ or ‘utility model’ protection is referred to in the TRIPS Agreement, nor are standards regarding requirements for such protection or its scope established in the Paris Convention for the Protection of
Industrial Property. Because of the lack of international standards for utility models and the great variation at the national level, they are not discussed further. See Supra n. 6

54(1) An invention shall be considered to be new if it does not form part of the state of the art.

54(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

Some national patent systems already provide for a ‘grace period’ for such disclosures. For example, U.S. patent law provides for a one-year grace period (35 U.S.C. § 102). In Japan a six-month grace period for certain limited types of disclosures may be claimed pursuant to Article 30 of the Japanese Patent Law. From 1984 to 1991, negotiations proceeded under the auspices of WIPO towards completing a treaty on the harmonization of certain substantive provisions in laws for the protection of inventions. Those negotiations culminated in the Draft Treaty Supplementing the Paris Convention for the Protection of Industrial Property as Far as Patents are Concerned (Patent Law Treaty) which was considered at the first part of a Diplomatic Conference 12 to 30 July (1991). The second part of the Diplomatic Conference was never convened. Hence the Draft Treaty was never concluded. Article 12 of the Draft Treaty would have provided for a 12 month grace period in respect of disclosures by the inventor. Negotiations to revive the substantive patent harmonization effort have begun under the auspices of WIPO. See Suggestions for the Further Development of International Patent Law, SCP/4/2, 13, 25 September (2000) (Among the issues proposed for discussion is the definition of ‘prior art’ including a general grace period)


80 See Huft and J. Michael, “Indigenous Peoples and Drug Discovery Research: A Question of IPRs” 89 Nw. U.L. Rev. 1678 (1995) (“The cases dealing with joint inventions (in the United States) teach that the requirements for joint inventorship, although specific, are quite broadly stated. Joint inventors must have collaborated, but their collaboration need not be contemporaneous and may be minimal. Although they cannot have worked completely independently of each other, so that neither knew of the other's work (case law) suggests that it is sufficient that only one knew of, and relied upon, the work of the other. Joint inventors must each have contributed to the final conception, but each need not be responsible for the entire conception. The cases suggest that any contribution, however small, that is essential in distinguishing the invention from the prior art, that is, in making it a patentable item, will be sufficient for joint inventorship. Any contribution, however large, that does not provide an essential element of the conception, but merely aids the inventive process of another, will be insufficient for joint inventorship.”)

81 The high costs associated with Intellectual Property protection has is not just a concern of holders of TK. The WIPO Industry Advisory Commission at its meeting 4 and 5 May (2000) adopted the following resolution:

Recognizing that the effectiveness of Intellectual Property as a stimulant to social and economic development is dependent upon the availability of protection at reasonable cost, the Industry Advisory Commission of the World Intellectual Property Organization (WIPO)
Urges the Member States of WIPO to adopt a work program for the development of a more comprehensive approach to the reduction of the costs of obtaining and maintaining Intellectual Property protection in multiple countries. (See WO/GA/26/4, Annex II, page 2, 18 August (2000)

Further, the prohibitive costs involved in registering and maintaining patent protection has been identified as a potential violation Article 15 (1) (c) of the International Convention on Economic, Social, and Cultural Rights. See Doris Estelle Long, “Traditional Knowledge and the Fight for the Public Domain” 5 The John Marshall Review of Intellectual Property Law 320 (2006)

82 “Protection of Biodiversity and Traditional Knowledge: The Indian Experience” Committee on Trade and Environment and Council for Trade-Related Aspects of IPRs, WT/CTE/W/156, IP/C/W/198 No. 25 14 July (2000)

83 On March 28, 1995, the U.S. Patent and Trademark Office granted U.S. Patent No. 5,401,504 entitled ‘Use of Turmeric in Wound Healing’ to Suman Das and Hari Har Cohly. The patent was assigned to the University of Mississippi Medical Center. A reexamination of the 504 patent was requested by the Government of India, acting through the Council of Scientific & Industrial Research, India (CSIR). The 504 patent, on the basis of ‘prior art’ documents submitted by CSIR, all claims in the patent were rejected, in essence invalidating the patent.

84 See Indian Government WTO Submission, No. 17 (Further, the WIPO Standing Committee on Information Technology has agreed to incorporate TK in a digital form in the Intellectual Property digital library. Merely making such information available in a digital form is not sufficient to ensure that it is regularly used by patent-examining authorities. Technical standards will have to be agreed upon regarding international exchange of TRM documentation within existing international Intellectual Property information systems for the search of prior art. Moreover, thought will have to be given to inclusion into the International Patent Classification of classes, subclasses, groups or subgroups for TRM, so that TRM-based patents can be systematically searched. Classification is indispensable for the retrieval of patent documents in the search for prior art. Such retrieval is needed by the patent-issuing authorities, potential inventors, research and development institutions, and potentially by association of holders of TK.)

85 See Review of Article 27.3(b) Submission by Brazil, IP/C/W/228 (40) 24 November (2000)


88 Article 10.2 of the TRIPS Agreement establishes that, compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself”. Specific legislation introducing a Sui Generis type of protection (including an ‘extraction right’) has been adopted in Europe, but in most countries original data bases are protected under the general rules of copyright law.


91 See Article 1771 (1) of The North-Americn Free Trade Agreement (NAFTA)

92 See Article 1771 (1) (b) of The North-Americn Free Trade Agreement (NAFTA)
A 'collective' mark is generally owned by an association that does not use it. Use is done by the members of the association. The owner should ensure that the relevant standards are complied with by the authorized users. The main difference between ‘collective’ and ‘certification’ marks is that the former can only be used by the members of the association, while the latter can be used by any undertaking, even if not belonging to a particular association that complies with specified standards. See WIPO (1997) 18


The TRIPS Agreement, in Article 22.1 defines a geographical indication to be indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

Dei J. George, Budd L. Hall and Dorothy Goldin Rosenberg, Indigenous Knowledge In Global Contexts Toronto: University of Toronto Press (2000)

Ibid

Ibid

See Supra n. 94 at. 3

See The WTO Doha Ministerial Declaration, para 18 (WT/MIN(01)/DEC/1)

The “Chuao Cacao” (from the native cacao varieties found in the Chuao locality of the Venezuelan coastal region) is produced under particular climate conditions and using the traditional drying and fermentation procedures of the Afro-American communities living within this area. The Chuao Cacao is highly aromatic and has an excellent lasting favour. It is exported to the high quality chocolate producers of Switzerland, Belgium, France and the United Kingdom. ‘Cocuy Pecayero’ is a spirited drink produced with green agaves from the State of Lara (Venezuela), similar to the Mexican tequila. The Cocuy, which is basically a product consumed domestically, is currently produced by the region’s local communities, based on traditional procedures inherited from the indigenous communities. See D. Vivas Eugui and M. Ruiz Muller, “Handbook on Mechanisms to Protect the Traditional Knowledge of The Andean Region Indigenous Communities” Prepared for the UNCTAD BIOTRADE initiative, UNCTAD, Geneva (2001)

Sign posts to Sui Generic Rights (December 6, 1997) <http://www.grain.org/publications/signposts.htm>. (This was also used as a resource material for the international seminar on Sui Generis rights.)


Id. at p. 27-28


“Some indigenous peoples understand themselves to be a nation within a nation or a nation whose peoples cross the borders of two or more nations. Some governments consider themselves to be the sole and entirely sufficient voice of all the peoples within their sovereign territory. See The Crucible Group, Seeding Solutions Rome: IDRCIPGRI (2000)