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Traditional Medicinal Knowledge System and Intellectual Property Rights: Scientific Validation of *Tri-doshas* in Ayurveda

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The role played by Traditional Medicinal Knowledge (TMK) such as, Ayurveda in personalized and preventive healthcare has its foundations in the Humoral Doctrine of *Tri-dosha: Vata, Pitha* and *Kapha*. This encompasses the manifestation of *Panchamahabhutas* within the human body thereby exhibiting unique bodily characteristics. Advanced pharmacogenomics has scientifically been correlated to the traditionally known genetic attributes of *Tri-dosha* and human body – *Prakriti*. Simultaneously the advancement of ethnopharmacology has enabled the extraction of plant-derived chemical compounds and bioactive constituents in drug discovery leading to commercial manufacturing of modern medicine that are a part of global market economy and founded on the western ideals of IPR and monopolistic trade tendencies. This has led to the bypassing of Access and Benefit Sharing (ABS) of the Convention on Biological Diversity (CBD) resulting in rampant misappropriation and bioprospecting of TMK through obtaining of IP rights without prior approval. This has challenged the very subsistence and survival of indigenous and local communities thereby raising a strong necessity for a cooperative model of TMK sharing over the prevailing knowledge commercialization, private rights and monopolistic-capitalistic approaches. The objectives of the research paper is to discuss and understand the scientific validation of *Tri-doshas*, to critically analyze the protection of TMK through IPR, local customary laws & traditions and current national and international policy perspectives. Further, the research explores historical roots of modern western medicine to TMK and also analyses several cases where objections have successfully been raised by TKDL at the global patent offices against the grant of patent to prior art dealing with TMK of India. A detailed case study of the success story of the '*Kani Model*' of Access and Benefit Sharing has been made to emphasis on cooperative knowledge sharing.

Keywords: Intellectual Property Rights, Traditional Medicinal Knowledge, Ayurveda, *Tri-doshas*, Ethnopharmacology, Access and Benefit Sharing, Semi-commons, Cooperative Knowledge Sharing, Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *AyuSoft*

The treatment of diseases originally started as a sacred and spiritual belief and therefore involved a mix of prayers, practices and herbal mixtures thereby forming the basis of traditional medicine knowledge system among the indigenous and local communities in India and at the global level. India has seen the evolution, documentation and practicing of traditional medicinal knowledge such as Ayurveda and yoga as a viable tool of wellness management. Ayurveda is one of the traditional medicinal knowledge system that is widely practiced in India. The evolution of modern medicine too has had its roots in the traditional medicine system until the Renaissance and Industrial Revolution enabled the gradual advancement of technology, understanding of pathology and pharmaceuticalisation procedures in a competitive globalized market as we see today.[1] Notably, there have also been colonial implications in the inter-continental exchange of medicinal plant species and traditional medicinal knowledge at the global level.[2] Therefore, the progress achieved in modern medicine have evolved out of the empirical knowledge from traditional medicinal system such as Ayurveda and Siddha from India.[3]

Ancient civilizations such as China, Egypt, Greece, Mesopotamia, etc. too have roots in traditional medicinal knowledge. Having said that a large chunk of the global population still use medicines that are based on traditional medicinal knowledge systems.[3]

The 1980s saw the role played by biotechnology in the discovery of plant derived pharmaceutical drugs thereby causing greater interest among the scientists and physicians towards ethnopharmacology and traditional medicinal knowledge that were historically and customarily protected and carry forwarded by the indigenous and local communities. The protection of traditional knowledge by deeming it as intellectual property first took shape at the 1992 Rio Summit

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wherein the Convention on Biological Diversity was adopted to ensure access and benefit sharing under the perspective of 'semi-commons' and prevent bio-prospecting of traditional knowledge by third parties.[4] The prospects of Semi-Commons enable the greater benefit of traditional knowledge to its holders and the public through cooperative sharing of knowledge and resources.

Evolution of Traditional Knowledge and Intellectual Property

The historical foundations behind the intellectual property can be traced back to the industrialization era with constant upgradations inorder to suit such nations that were leaders in technology and advanced scientific research post the Industrial Revolution (IR). The First and the Second World Wars proved to the world nations that vital scientific knowledge and cutting edge technological expertise were crucial for the nations to sustain as global and regional superpowers. The disintegration of the USSR was just the beginning of USA's emergence as a monopolistic power with the backing of the European Union. The 'global north' thereafter ensured that the global south unitedly marched behind it practically in all aspects, particularly in trade relationship. This enabled them to have an extra edge over the other nations or societies in ensuring that the legal ledgers played an advantageous role for the 'global north' over the 'global south' in terms of knowledge acquisition under the garb of Liberalization, Privatization and Globalization (LPG).[5] While there existed an established 'selfless culture' of traditional knowledge on the principles of cooperation and togetherness in the countries of the global south, the global north bound the entire world with competition and commercialization through the Trade Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) to bring about a commonality among the world nations and assert that intellectual property is a trade related asset inspite of the diversity prevailing in the intellectual property regimes of the 'global south' that had originally suited their culture, tradition, and indigenous communities. The concern that the indigenous people and their communities are mainly in the developing and underdeveloped countries of the global south have demanded equal protection for traditional knowledge. As a result in the year 2000, the Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the World Intellectual Property Organisation (WIPO) so as to develop a global legal instrument that would render effective protection for traditional knowledge, genetic resources and traditional cultural expression / folklore. The liveliness and richness associated with traditional knowledge is that it has phenomenally been developed, sustained and passed on from one generation to another in a community. The authorship or inventor of any traditional knowledge is mostly unknown and the dynamic nature of traditional knowledge makes its protection difficult using the TRIPS or other legal instrument available.[6]

Intellectual Property and Traditional Medicinal Knowledge in India

A large number of population depend on traditional medicine while several of the modern vaccines and drugs are based on natural resources and associated traditional medicinal knowledge. In India the importance of traditional medicinal knowledge with regards to the indigenous communities also comes with social, cultural and scientific values. As a result it has invited recognition, respect, preservation and protection from undue commercialisation and scientific interest towards traditional medicinal knowledge. TMK are mostly derived from plant and animal varieties and hence fall under genetic resources which are not human creations but occur naturally in the nature and therefore cannot be directly protected as intellectual property. Intellectual Property refers to creation of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. Intellectual Property is protected in law by patents, copyright and trademarks which enable people to earn recognition or financial benefit from what they invent or create. This means that the individual creator or inventor holds the rights over his/her intellectual property – Intellectual Property Rights/IPR.[7]

The World Health Organization (WHO) defines traditional medicine as "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses" wherein 'traditional' means the knowledge that is created in a manner that reflects community traditions that have been created,

preserved and transmitted from generations and held collectively. Though the indigenous community may innovate, the fact which deems their innovation is based on the community's collective heritage that it has held. WIPO, through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, seeks to develop international legal instrument that would provide effective protection of Traditional Cultural Expressions, Folklore and TK – including traditional medicinal knowledge.[8] Though, there are a multitudinal definitions that cover various areas of traditional knowledge, a holistic definition for traditional medicinal knowledge with all its features and aspects concerning indigenous rationale, sustainability and customary self-regulations is required so as to understand the indigenous and local communities in its truest essense.[9] Therefore, a contextual definition for Traditional Medicinal Knowledge is:

"*Traditional Medicinal Knowledge is associated with indigenous communities that are unique and derived through observations from the nature, surrounding environment and then transmitted, originally orally, from one generation to another throughout the world."*

Traditional Medicinal Knowledge with its spirit of local - collective ownership characterizes the continuousness of spiritual belief, diverse culture, dynamic wisdom, collective heritage, sacred values, time tested sustainable practices that are ancestrally inherited within the indigenous & local communities and their social world. This time proven nature of Traditional Medicinal Knowledge system is such that it precisely provides the indigenous and local communities with the required knowledge, wisdom, practices and purpose of their existence by simultaneously enabling the communities to live in harmony with the ecosystem and uncompromisingly adapt themselves to ecological changes. Such holistic interconnectedness between community level activities of humans and various components of mother nature over a prolonged period of time with a scope to adapt to change is what distinguishes Traditional Medicinal Knowledge from that of modern western medicine.

Role of *Panchamahabhuta* and *Tri-dosha* in Ayurveda

Traditional Medicinal Knowledge Systems (TMKS) such as, Ayurveda, uses combinations of physiological exercises, massages, meditation, diet modification, medicines derived from indigenous plants, animal products and minerals for the treatment of ailments.[10] The fundamental aspect of the healing and treatment in TMKS is based on the theoretical understandings of the *Panchamahabhutas* and the *Tri-doshas*. According to Charaka, the famous physician from ancient India, it is the doctrine of tri-doshas that dominates the theory and practice of traditional medicinal knowledge systems such as Ayurveda and are not just theoretical concepts but real substances.[11] The five eternal and base components of nature or the *Panchamahabhutas* are *Prithvi* (Earth), *Apa* (Water), *Agni* (Fire), *Vayu* (Wind) and *Aakasha* (Ether). All the living and non-living beings including the human body are created from the permutations and combinations of different variables or the components of *Panchamahabhutas*thereby making every individual as a unique entity in relation to the external environment from the preview of Ayurveda.[12] This is to precisely say that human body is a 'miniature form of nature' wherein the similar components of the nature are present in our body. The following description of the properties of *Panchamahabhutas* with regards to our body is important:

(i) *Prithvi* or earth is the basic gross element which gives the sense of smell and is characterized with mass, density, opacity and inertia.

(ii) *Apa* or water is the element of aqua or liquids and possesses the characters of fluidity, coldness, viscosity etc

(iii) *Agni* or fire is the thermal element and is related to digestion. Agni also represents the manifestation of anger, passion and courage in the human body.

(iv) *Vayu* or air is the basic gaseous element and possesses the characteristics of lightness.

(v) *Akasha* or Ether is related to space and enables sound and hearing. They form the pores, cavities and channels in the human body.

Panchamahabhutas control various activities of our body through the *Tri-doshas* or body humours which are the three vital energies of our body namely *Vata* (wind), *Pitta* (bile) and *Kapha* (phlegm). Further, each of the doshas are composed of two of the *Panchamahabhutas* and perform anatomical activities as:

1. *Vata*has the primary elements of *Vayu* (air) and *Akasha* (ether) with the functional control over movement and communication.

2. *Pitta* has the elements of *Agni* (fire) and *Apa* (water) to functionally oversee digestion, metabolism and transformation.
3. *Kapha* has the elements of *Apa* (water) and *Prithvi* (earth) to functionally provide cohesiveness, body structure and lubrication.

Each person contain the unique blend of these doshas. So the core and foundational aspect of health and disease as per the principles of Ayurveda is centred in the uniqueness of an individual. However most of them have one of it as a dominating doshas which form the true nature of the body or the *prakriti*.[13] The *Tri-doshas* are present in varying proportions in the human body and tend to form specific body signatures according to the dominant *dosha* of our body to form distinct *prakriti* or the nature of the body. Just like the *Panchabhutas* create atmospheric, climatic and physical changes in the surrounding nature, they also affect our bodily wellbeing through different proportions and combinations in the form of doshas. M. S. Valiathan in his book, "The Legacy of Charaka" writes "*While the homology between the structural materials within the body and outside, in the physical world, is the theme of the pancabhuta doctrine, the functional equilibrium inside the body is explained by tridosa*".[11]

Therefore, the role played by the *Tri-doshas* in our body and mind are crucial for its survival, metabolism, endurance, health, and disease prevention apart from determining of physical and mental characteristics of our body. The ratio of *vata*, *pitta* and *kapha* influence the human body in its individual features, mental and emotional character and traits as well as our unique strengths and vulnerabilities. Every *dosha* has a quality and bodily manifestations of its own. Any deficiency or excessive quantity of the tri-doshas is said to unsettle a condition of health disorders and disturbances. Ayurveda also prescribes several lifestyle oriented remedies and adaptations to ensure the equilibrium of the doshas.[13] Ayurveda not only stresses on the physical nature of the body but also on the psychological aspect of the individual and a holistic approach towards diet and lifestyle inorder to maintain health and prevent disease.[14]

It is also important to understand the specific dosha properties and the detailed results of their balance and imbalances in the human body as shown in Table 1.[15]

The following shloka from the *Susruta Samhita* describes as to what 'health' is according to Ayurveda, a traditional medicinal knowledge system:

Samadosha Samagnischa Samadhatumalakriyaha
Prasannatamenindriyamanaha Swasthya
Ityabhidheeyate

It means "When the doshas are in balance (*samadosha*); when the different forms of *agni* are in balance (*samagni*); when the processes are associated with the creation of dhatus and mala are in balance and working seamlessly; when the atma (soul); the sense organs (*jnanendriya* and *karmendriya*) and the mind (*manaha*) are in a state of happiness and harmony (*prasanna*); this (*iti*) is called (*abhidhiyate*) health (*swasthya*)".[16]

The *vaidyas* or the traditional healer understands the particular *prakriti* that the human body is predominantly associated with for diagnosis of ailments. The treatment is given in accordance with the imbalance of *dosha* in a person. TMKS provide the scope and relevance towards personalized medicine and prevention system through the better understanding of the body type or *prakriti* thereby making Ayurveda a universal concept of traditional medicinal system that can be associated with the concepts of science. Personalised preventive medicine is of greater advantage in the case of Ayurveda wherein other non-traditional systems of medicine have the scope of only personalized medicine.[17] The *prakriti* signature is unique from one person to the other and this has been validated and evidenced by modern science.

Scientific Validation of *Tri-doshas*

The article titled, "*DNA methylation analysis of phenotype specific stratified Indian population"* published in the *Journal of Translational Medicine* has elaborately reported that the respective *doshas* of *vata, pitta* and *kapha* were experimentally correlated with their known characteristics of motion (*vata*), higher metabolism (*pitta*) and structural attributes (*kapha*). The experimental research method involved had been the sampling of whole blood DNA samples of individuals whose ayurvedic *prakriti* specimens of *vata, pitta* and *kapha* was earlier known. The samples were 'subjected to methylated DNA immuno-precipitation (MeDIP) and microarray analysis. After data analysis, *prakriti* specific signatures were validated through bisulfite DNA sequencing'. The research also concluded that the

Table 1 — Specific dosha properties and its result in the human body

State of human body	*Vata*	*Pitta*	*Kapha*
Constitution	• Involved in breathing and eye movement • Motor functioning • Cell functioning • Easily excited, alert without thinking much before constant action • Thin, light and flexible body	• Involved in body metabolism • Involved in appetite, food digestion and absorption, transformation and transportation for assimilation of nutrition into the body and dispelling of waste products • Cell functioning • Neurotransmission and neuropeptides in intelligence • Vitality • Learning and understanding theories and concepts • Seldom gains or loses weight nor has weight fluctuations • Disciplined leaders	• Involved in body structure and the stability of the structure • Involved in water metabolism and fluid distribution throughout the body • Lubricates cells, tissues, joints and organs • Cell functioning • Chubby shape • Retention of knowledge for memory
Balanced	• Personal creativity & accomplishment • Courage	• Intelligence and understanding	• Expression of love and compassion • Faith and devotion • Melodious voice and speech patterns • Longevity in life • Feelings of calmness • Forgiveness and benevolence
Unbalanced	• Fear, worry, and anxiety • Problems with motor functioning, nimbleness, and dexterity • Fear of loneliness • Boredom	• Anger, hatred, and jealousy • Perfectionism • Judgemental and critical • Problems with inflammation leading to chronic disorders and heart diseases	• Addictions and unhealthy attachments to things, substances and people • Calculating greed and ruthlessness • Disorders involving the congestion of fluids trapped in various places within the body. • Slow digestion and weight gain • Cravings for sweet and salty food • Idleness and long periods of sleeping

differential DNA methylation signatures of all three *doshas* showed the genetic basis of traditional human classification system, in accordance with Ayurveda, that provides the scope for personalized medicine.[18]

Another study determined the genetic basis of doshas, in varying proportions of dominance, which were as described in the *Charaka Samhita* by performing SNP (single nucleotide polymorphism) analysis of the three *prakritis*. The results were also independently confirmed by '*AyuSoft*' which is a software developed on the basis of classical ayurvedic literature.[19] The scientific and genetic basis for body's *prakriti* have been distinguished and differentiated with individuals of *pitta-prakriti* having faster metabolism and those of *kapha-prakriti* having slower metabolism thereby enabling drug discovery, pharmacogenomics and personalized medicine.[20] A better understanding of *dosha* theory as abided in Traditional Medicinal Knowledge system such as Ayurveda from the perspective of genetic and biotechnological research have opened the scope for pharmacogenomics which is but the study of genetic response with regards to variations and responses to a drug thereby utilizing the genetic information in preventing an adverse reaction.[14] Simultaneously, genomic research have shown correlations between genetic patterns and *doshas* thereby impacting physiological and psychological applications.[21] The *Prakriti* of human body has genetic connotation that are totally based on the *dosha* cluster thereby making every individual as a unique entity in terms of physical, physiological and psychological characteristics.[22, 23, 24]

TMK and IPR: Cases of Modern Medicines Derived from Traditional Medicine

The therapeutic use of traditional medicinal plants for the treatment of human diseases has been in practice in many of the cultures and societies across the globe. This has also, over the period of time, led to the development of various independent and organised medicinal systems in accordance with the geographic availability of various species of medicinal plants until they were finally institutionalized from the modern perspective. A large population of the developing countries depend on Traditional Medicinal Knowledge as it is an available and affordable source of treatment for various ailments. With the aid of modern sciences and technological tools it has become possible to extract active drug compounds from the medicinal plants and this has become possible because the medicinal plants are naturally capable of amalgamating thousands of such individual bioactive constituents from the soil and environment that are rooted to it. Plant derived chemical compounds have thereby enabled the manufacturing of modern medicine and it has been scientifically correlated that the diagnosis based on traditional medicinal plant and that of chemical compounds derived from the active compounds of the plant happen through similar process and mechanism. Therefore, traditional plant based medicines are as effective as the modern - conventional medicines while Traditional Medicinal Knowledge continue to be the foundational base for the development of modern drugs as they are the best source for obtaining a variety of drugs.[25] Since the plant – derived drugs continue to be an inevitable source of new drug discoveries and opportunities they are also the simultaneous interjecting points of global platform for pharmaceutical market economy, determining factor for the stability of pharmaceutical markets worldwide, intellectual property rights and bio-prospecting of Traditional Medicinal Knowledge, habitat degradation and sustainable exploitation of natural resources, tropical forest-biodiversity conservation and rights of indigenous & local communities.[26]

The *Materia Medica* of *Ayurveda* contain 8000 known medicinal recipes made of herbs, metals, minerals, animal products and their ash in right proportions and a systemic therapy.[25] Further, the detailed study of ethnopharmacology and traditional medicine have led to several natural products, drug discoveries and several pharmaceutical companies have altered their strategies accordingly to differing guidelines of standardization, manufacture and quality control. Importantly, the process of reverse engineering towards traditional knowledge driven drug development by adopting reverse pharmacology path with much faster and cheaper cost with the help of modern technologies have found scope too. [27]

In this regard, Traditional Medicinal Knowledge involves themedicinal use of plants and herbs that form the integral part of genetic resources and are therefore not the original creation of the human intellect and hence does not qualify for protection as an intellectual property. Moreover, the Traditional Medicinal Knowledge have been guarded, preserved and held as collective heritage by the indigenous and local communities as a part of their cultural traditions that have been continuing for several generations. Such time-proven knowledge have also been a source of subsistence and survival for the indigenous and local communities and therefore any intention to commercialiseTraditional Medicinal Knowledge should happen in accordance with the Access and Benefit Sharing (ABS) mechanism of the Convention on Biological Diversity (CBD). Instances of patents granted to plant based genetic resources involving Traditional Medicinal Knowledge such as, turmeric and neem had invited criticism thereby resulting in subsequent revoking of the patents that were awarded to them. Prevention of misuse and misappropriation of Traditional Medicinal Knowledge is therefore crucial. Inspite of this the global attraction garnered by Traditional Medicinal Knowledge has been immense due to the growing side-effects of allopathic medicines and therefore, the systems of traditional medicinal knowledge has become subject to biopiracy and patenting. The development of the Traditional Knowledge Digital Library (TKDL) by Council of Scientific and Industrial Research (CSIR) to prevent the misappropriation of traditional medicinal knowledge from awarding of patent at the International Patent Offices by scientifically classifying India's Traditional Medicinal Knowledge systems such as Ayurveda, Siddha, Unani and Yoga into a multi-language searchable database is therefore important in this regard. [28]

While this is the case, patents for products, formulation, compositions and processes for traditional ayurvedic medicine, medicinal plants and herbal based formulations have well been granted to several of Indian and foreign entities. Table 2 shows some of the patents that have been granted in India.[29]

Table 2 — Patents granted for traditional ayurvedic medicine, medicinal plants and herbal formulation in India

Sl. No.	Application number	Date of patent grant	Patent number	Patent grant title	Main herbs described in the patent
1.	155/MUM/2008	20/04/2011	247558	Herbal extract and ayurvedic composition for the treatment of diabetes	*Momordica charantia*
2.	1734/KOL/2007	17/08/2011	248741	A process for preparing an ayurvedic medicament effective against leukaemia and carcinoma of lung and intestine	Lime, Asafoetida and Black jeera
3.	1938/DEL/2006	29/03/2010	239637	A process for preparation of ayurvedic composition for treatment of hepatic disorder	*Kaghzinimbu* (Lemon) *Citrus medica (aurantifolia)*; Sarjika *Salsola kali* Linn., *Fagoni acretica* Linn., Barilla and Varat (Kapard) *Cyprae amoneta*
4.	1623/MUM/2006	03/072008	221770	An ayurvedic composition for oral consumption in treatment of heart diseases and hypertension	Arjuna - *Terminalia arjuna*, *Ajamoda*– *Apium graveolens*,Punarnava–*Boerhavia diffusa*, Rasona - *Allium sativum*, Shigru–*Moringa oleifera*, Draksha–*Vitis vinifera*, Pippali - *Piper longum*, Guduchi–*Tinospora cordifolia*, and Triphala
5.	228/CHE/2006	30/07/2010	241922	A process for the preparation of ayurvedic tooth powder/paste	*Azadirachta indica*, menthol, thymol, camphor and gall nut
6.	3207/DEL/2005	28/09/2007	210329	An ayurvedic composition for joining fractured bone & as anti-inflammatory and process for preparation thereof	*Cissus quadrangularis, Pterocarpus marsupium* heartwood, Buffalo/Cow Milk and *Chenopodium murale* (kurund)
7.	313/CHE/2005	05/02/2009	228654	A unique combination of ayurvedic compounds for correcting a rare form of *Mullerian dysgenesis*	*Asoka, Asana* and Bilwa, *Shorea robusta* Gaertn, *Pinus roxburghii* Sargent, *Cyperus rotundus* Linn., *Sidar hombifolia, Gmelina asiatica* Linn., *Nardostachys jatamansi* DC, *Randia dumetorum* Linn., *Kaemferia galangal* Linn., *Teramnus labialis* Spreng., *Phaseolus trilobus* Ait., *Inula racemosa* Hook F, *Cinnamomum zeylanicum*, *Syzygium aromaticum* Merr., *Parmelia* (Sangejaranath), *Crocus sativus* Linn., *Cinnamomum camphora* T. Nees and Ebem
8.	146/MUM/2005	09/01/2009	227476	An ayurvedic herbal hair oil composition and preparation thereof	Jatamasi (*Nardostachys jatamansi* (D. Don) DC.), Amla Bramhi (*Gratiola*), Bhrungaraj (*Eclipta alba)* thistles, Nagamothra (*Cyperus rotundus*), Kapurkachari (*Hedychium spicatum*) and Kavath (*Feronia elephantum*)
9.	2352/DEL/2004	01/11/2007	211481	An ayurvedic composition useful for the treatment of migraine	*Psidium guava* and Eucalyptus *Camel dulensis*
10.	1145/MUM/2004	13/11/2009	236637	A process for preparation of ayurvedic anti-snake venom capable of administering orally or intravenous	*Jasminum sambac, Erythina indica*, *Eugenia jambolana* and *Mangifera indica*

(Contd.)

Table 2 — Patents granted for traditional ayurvedic medicine, medicinal plants and herbal formulation in India*(Contd.)*

Sl. No.	Application number	Date of patent grant	Patent number	Patent grant title	Main herbs described in the patent
11.	611/MUM/2004	10/01/2008	213692	A process to prepare a novel ayurvedic composition and the composition resulting there from	*Terminalia arjuna* bark, *Hemidesmus indicus* root, *Mangifera indica* bark, *Moringa oelifera* bark, *Murraya koenigii* leaf, *Piper longum* fruit, *Boerhavia diffusa* root, *Achyranthes aspera* root, *Rauwolfia serpentine* root, coconut oil, sunflower oil, cashewnut oil, groundnut oil, linseed oil (refined) and sesame oil
12.	1048/MUM/2003	17/04/2007	206091	Ayurvedic immuno modulator composition for treatment of acquired immuno deficiency syndrome	Guduchi or Giloe *(Tinospora cordifolia)*, Panash or Kathal (Jack fruit), Tulsi or Krishna Tulsi (Holy Basil), Kuda or Kutaja (Kurchi) Bhui Amla or Bahu Patra (Gooseberry), *Gingko biloba* Shilajeet or Silaras (Asphaltam), Karavella or Karela (Bitter gourd)
13.	553/KOL/2003	20/11/2007	212143	A process for preparing nutrient fortified ayurvedic sweets like Sandesh and Rosogolla containing at least one herb	Tulsi *(Osimum sanctum)* leaves Pudina *(Menthaaervensis)* leaves, Coriander *(Coriandrum sativum)* leaves Tender mango *(Mangifera indica)* leaves, Stone apple *(Bael - Aegle marmelos)* leaves, Spinach *(Spinacia oleracea)*, Carrot *(Daucus carota)* Beet root, Cucumber, Kulekhara *(Asteracantha longifolia)*, Shushni *(Marselia quadrifolia)* Karipata, Ashawagandha *(Withania somnifera)*, Guduchi *(Tinospora cordifolia)*, Amla *(Embica officinalis)*, Shilajeet (Black bitumen or mineral pitch), Suvambhasm (incinerated gold), Mandookparni *(Bacopa monnieri)*, Mulethi *(Glycirrhiza glabra)*, Shankkapushpi *(Convolvulus alsinoides)*, Vijaysara *(Pterocaspus marsupium)*, Katuka (*Picrosshiza kurroa*), Vidang *(Abies webiana)*, Bakuchi *(Psoralia corylifolia)*, Bhallatak *(Semecarpurs anacardium)* Brahmi *(Centella asiatica)*, Arjun bark *(Terminalia arjuna)*, Ashok bark *(Saraca indica)*, Bael leaf *(Aegle marmelos)*, Clove fruit *(Myrtus caryophyllus)*, Dalchinibark *(Cinnamomum zeylanicum)*, Elaichi fruit *(Elettaria cardamomum)*, Ginger rhizome *(Zingber officinale)*, Grapeseeds *(Citrus paradisi)*, Gorgon nuts, Walnuts, Almonds, Cashew nuts, Ground nuts, Hing *(Ferula asafoetida)*, Orange peel, Jatamanshi *(Nardostchyas jatamansi)* – Extracts from skin of Lemon & Grape fruit, Jayphal fruit *(Myristica fragrans)*, Liquorice *(Glycyrrhiza glabra)*, Cucumber seeds, Tea leaves Spirulina, Dates, lemon grass, mango, papaya, lichi, pineapple, guava, banana, apple, fig, coconut milk cream, roseberry, etc.
14.	1048/MUM/2003	17/04/2007	206091	Ayurvedic immuno modulator composition for treatment of acquired immuno deficiency syndrome	Guduchi or Giloe *(Tinospora cordifolia)*, Panash or Kathal (Jack fruit), Tulsi or Krishna Tulsi (Holy Basil), Kuda or Kutaja (Kurchi) BhuiAmla or Bahu Patra (Gooseberry), *Gingko biloba* Shilajeet or Silaras (Asphaltam), Karavella or Karela (Bitter gourd)
15.	1049/MUM/2003	14/02/2007	203986	Ayurvedic anti retro viral composition for treatment of acquired immune-deficiency syndrome	Guduchi *(Tinospora cordifolia)*, Panash *(Artrocarpus integrifolia)*, Tulsi *(Ocimum sanctum)*, Kuda *(Holarrhena antidy scentrica)* and Bhumi Amla *(Phylanthus niruri)*

(Contd.)

Table 2 — Patents granted for traditional ayurvedic medicine, medicinal plants and herbal formulation in India

Sl. No.	Application number	Date of patent grant	Patent number	Patent grant title	Main herbs described in the patent
16.	717/DEL/2003	19/11/2010	244133	A process of preparing said synergistic herbal ayurvedic ointment for the treatment of analgesic, rheumatoid arthritis, backache, spondilitis, sprains, joint pains, headache, cold, inflammations and muscular pain	*Cinnamom camphora, Mentha arvensis, Commiphora mukul* (Gulggulu) and *Syzygiu*
17.	459/MUM/2003	24/05/2007	207188	Process for preparation of skin care composition by combining micro nutrients with ayurvedic substances	Haridra, Raktachandana, Manjistha, Kumari, Almond Oil and Coconut Oil
18.	22/MUM/2003	20/07/2007	208269	A process of preparing an ayurvedic composition for treatment of cold, pain, cough, etc.	Poppy, Cowith, *Hycosxix orsiodiasis, Salvia plebia*, Nutmeg, Mace, Clove and Cardamom
19.	56/BOM/1998	24/08/2001	183805	A process for the preparation of an immuno modulator from the ayurvedic medicinal plant, gulvel (*Tinospora sp*.)	Gulvel *(Tinospora sp)*
20.	667/BOM/1997	27/07/2007	208438	Oral herbal ayurvedic composition for treatment of psoriasis	*Matricaria chamomilla* and *Piper nigrum* (only seeds)
21.	668/BOM/1997	27/07/2007	208437	Herbal ayurvedic composition for treatment of psoriasis	*Psoralia corylifolia* (only seeds), *Santalum album* Linn., *Cassia occidentalis* (roots), *Matricaria chamomilla* (whole plant)
22.	423/BOM/1997	01/01/2000	183487	An improved process for manufacture of the extract obtained from ayurvedic medicinal plant, Guduchi	Guduchi *(Tinospora cordifolia)*
23.	1471/DEL/1996	17/01/2008	213809	An ayurvedic eye drop composition for treatment of various eye diseases particularly in improvingeye-sight by the flatting of the cornea and interior surface of the lens	Apamarg *(Achyranthu saspera)*, Punarnava *(Boerrhavia diffusa)*, Plash *(Butea monosperma)*, Fitkari (Alum), Tuth (Copper Sulphate), Peppermint *(Mentha piperata)*, Taknamal (Borax), Yashad (Zinc Sulphate)

Source: *IPR issues related to medicinal and aromatic plants (herbs &their allied products), Journal of Traditional Folk Practices*

Apart from these patents for drugs and cosmetics, chemical compound extracts and compositions that are derived from Indian plants and herbs have also been granted to several allopathic pharmaceuticals. The TKDL enlists several such patent applications at various international patent offices on the likes of United States Patent and Trademark Office (USPTO), European Patent Offices (EPO), Canadian Intellectual Property Office (CIPO), German Patent and Trademark Office (DPMA), United Kingdom Patent & Trademark Office (UKPTO), IP Australia and Controller General of Patents Designs and Trademarks (CGPDTM India) on objections raised by the TKDL with respect to the grant of patent for 'Prior art' concerning India's Traditional Medicinal Knowledge and systems. There exist a total of 239 cases wherein objections have been submitted by the TKDL in the above international patent offices at the pre-grant stage of patent thereby resulting either in the withdrawal, cancelling, nullifying, termination or leading to necessary amendments over the claim to patent by the

patent examiners. As a result, TKDL's submissions and reference to prior art has made definite contributions in preventing misappropriation and preventing attempts towards patenting existing Traditional Medicinal Knowledge or in preventing biopiracy. [30]

Table 3 enlists some of the patents applications at various international patent offices over the period of time that were rejected, withdrawn or amended due to TKDL's objection and providing prior art evidences regarding Traditional Medicinal Knowledge and Indian medicine system.

Roots of Modern Western Medicine in TMK

The roots of western medicine too is founded on the basis of traditional humour based medicine that are similar to those of the *Tri-doshas* and had plant based herbal medicines as its medicinal materials.[3] Before the 20thcentury, European Medicine depended on the indigenous medicine system wherein the components of drugs were availed from natural products such as plants and their parts that were available from the mediterrane an region and with the Middle East, Asia, and the Americas contributing knowledge and materials in the medieval and early modern periods and therefore a large number of Traditional European Pharmaceutical writings that can be located to the mediterranean region that were compiled by the physicians of Greece, Rome, Byzantine and medieval Islamic with the earliest dating back to 500 BC uptill the 19th century AD that reveal the earliest tradition and imprints of Western - European Ethnopharmacology by providing plant, animal and mineral based medicinal informations and therapeutic formulations that cured diseases from time to time.[1]As multi-disciplinary studies on pharmacology from the historical perspective reveal European herbal medicines were used for the treatment of rheumatic disorders in the 16th and 17th century.[31] Instances of medicinal plant species introduced from other continents during European colonization show the importance accorded to Traditional Medicinal Knowledge.[2]

Inspite of having such a tradition in the history of European medicine which forms the foundation of modern western medicine, the effectiveness of TMK and herbal medicine is termed as unscientific and therefore brushed off as invalid and ineffective.[4] Importantly we have already discussed the widespread urge and exhaustive efforts by pharmaceutical companies to discover new drugs and develop modern allopathic medicines from Traditional Medicinal Knowledge by obtaining Intellectual Property Rights that emphasise on knowledge commercialization and bioprospecting.[29]

The role played by renaissance and industrial revolution with regards to advancing science and technology played a role in altering the history of pharmacy and medical chemistry thereby causing the gradual diminishing of traditional medicinal use and rise of pharmaceutical companies with economical motives. The change of attitude from traditional medicine towards medical science in Europe was seen in 19th century and to study the ancient sciences was considered waste as against scientific experimentation. In 20th century the scientific discovery of life saving antibiotics like Penicillin further declined the study of traditional medicine.[32]

Success Stories of 'Access and Benefit Sharing' and Protection of TMK

Amidst past instances of unauthorized use and misappropriation of traditional medicinal knowledge by third parties, there are also success story models that have taken prior consent from the indigenous and local communities who are the holders of Traditional Medicinal Knowledge by sharing the benefits of access and commercialisation by patenting chemical compounds that are derived from plant based Traditional Medicinal Knowledge.

From *Arogyapacha* plant to 'Jeevani': The Traditional Medicinal Knowledge of the *Kani* Tribe

The indigenous *Kani tribe* inhibit the wind-ward side of Agasthyamalai hills in the tropical forests of Western Ghats in the state of Kerala.[33] The *Plathi* who are the tribal physicians of the *Kani* tribe 'customarily' hold the exclusive Traditional Medicinal Knowledge belonging to the community and they alone have the right to transfer and disseminate their Traditional Medicinal Knowledge which includes the use of wild plants as medicines. It was in December 1987 that an ethnobotanical expedition team from the All India Coordinated Research Project on Ethnobiology (AICRPE) led by Dr. Palpu Pushpangadan who was then the director of the Jawaharlal Nehru Tropical Botanical Garden and Research Institute (JNTBGRI) in Kerala noticed the 'untiring' *Kani* guides while the expedition team

Table 3 — Patents applications at various international Patent Offices

S. No	Patent publication number and date	Name of Patent Office and application title	Date of objection by TKDL for patent grant	Traditional Medicinal Knowledge - prior art evidence given by TKDL	Remarks
1.	EP1747786, 26 July 2006	EPO; *Natural product in cream with anti-vitiligo therapeutic properties*	8 July 2009	*Cucumismelo* or Snake Cucumber; *Urvaru/ Kakri/ Vellarikkai*	Intention to grant Patent refused on 27 July 2009 leading to closing of application on 11 October 2011
2.	109/DELNP/2007; 4 January 2007	CGPDTM, India; *Composition comprising Neel oil and oil extract of Hypericum perforatum*	7 February 2013	*Azadirachta indica A Juss* or Neem; *Nimba/ Neem/ Vembu/*	Patent application refused on 14 September 2018
3.	3387/DELNP/2004; 1 November 2004	CGPDTM, India; *Formulations useful in the treatment of male and female impotence*	7 November 2012	*Tribulus terrestris* or Bullhead *Gokshura/ Nerunjil/ Thirikandam. Turnera diffusa* or *Damiana Cinnamomum cassia* or Cinnamon; *Tvak/ Daarchini/ Lavangapattai*	Patent application refused on 17 October 2013
4.	EP1660007, 11 August 2004	EPO; *Compositions for diabetic treatment and prophylaxis*		*Gymnema sylvestre* or Miracle Fruit; *Madhunashini / Sirukurinjan/ Athingam/ GurmarButi*	Decision to refuse patent on 27 June 2012 leading to closing of application on 10 October 2012
5.	1962/MUM/2008, 16 September 2008	CGPDTM, India; *A herbal formulation for treating sickle cell disease*	1 June 2012	*Phyllanthus emblica*or Indian Gooseberry; *Amlak/ Aamla/ Nelli* *Myristica fragrans Houtt* or*;* Nutmeg*; Jatiphala/ Bisbasa/ Jathikai/ Kulakkai*. *Zingiber officinal Roscoe* or Ginger*; Ardraka/ Sunthi/ Inji/ Chukku* *Leptadenia reticulata – Jivanti/ Palaikodi/ Pala. Terminalia chebulaor*Myrobalan*; Haritaki/ Halelah/ Kadukkaai* *Tinospora cordifolia or* Tinospora; *Guguchi/ Gilo/ Seendhil/ Amirdhavalli* *Asparagus racemosus* or Indian Asparagus; *Shatavari/ Satawar/ Seemai Sathaveri/ Kilavari* *Punica granatum Linn* or Pomegranate; *Dadim.* *Piper longum Linn.* or Long Pepper; *Pippali/ Filifil Moya/ Thippili* *Plumbago zeylanica* or Leadwort; *Chitrak/ Sheetraj/ Chithiramooam/ Venkodiveli* *Aloe barbadensis Mil l* or Aloe Vera*; Kumari/ Gheekawaar/ Sibr/ Katrazhai*	Patent application refused on 12 December 2013

(Contd.)

Table 3 — Patents applications at various international Patent Offices (*Contd*.)

S. No	Patent publication number and date	Name of Patent Office and Application title	Date of objection by TKDL for patent grant	Traditional Medicinal Knowledge - prior art evidence given by TKDL	Remarks
6.	201001732022, 22 March 2010	USPTO ; *Composition for treatment of Diabetes mellitus and metabolic syndrome*	3 August 2010	*(a) Momordica charantia* or Bitter gourd; *Karbellam/ Karela/ Pavakkai* *(b) Emblica officinalis* or Indian gooseberry; *Aamlak/ Amla/ Nelli/* (c)*Trigonella foenum-gracum* or Fenugreek; *Methi/ Vendhayam/ Uluva* *(d) Curcuma longa* or Turmeric; *Haldi/ Manjal*	Patent claims rejected on 19 September 2012 leading to abandonment of application
7.	EP2464363, 11August 2010	EPO; *Natural extract from whole banana fruit*	23 May 2014	*Musa paradisiacal Linn*. or Edible Banana/ Plantain; *Kadali/ Kela/ Vazhai*	Decision to refuse grant of patent on 20 March 2015 leading to closing of application on 7 July2015
8.	EP2435057, 28 May 2010	EPO*;Compositions and methods for modulating lipid composition*	20 March 2013	*Origanum vulgare Linn* or Common or Wild marjoram, Oregano; *Maruvaka/ Ban tulsi, Mirzanjosh Rosmarinus officinalis* or Rosemary; *Rujamari/ Gulmehendi/ Thalisabatri*	Decision to refuse grant of patent on 17 June 2015 leading to closing of application on 28 August 2015
9.	CA 2572031; 29 June 2005	CIPO; *Fat combustion accelerator*	24September 2010	*Pinus roxburghii Sarg*or Himalayan long leaved pine; Sarala/ Kilima/ SeemaiDevadaru	Patent application declared as dead on 29 June 2011
10.	2011257388; 23 May 2011	IP Australia; *Tamarind seed polysaccharide for use in the treatment of inflammatory diseases*	6 February 2016	*Tamarindus indica Linn* or Tamarind; Imali/ Tamar Hindi/ Imli/ Puli/ Amilam/ Sinduram	Patent claims amended on 23September 2016
11.	20120231032, 3 May 2012	USPTO; *Agent for expelling parasites in humans, animals or birds*	25 February 2013	*Ferula asafoetida regel or Asafetida; Hingu/ Heeng/ Perungayam/ Ingu*	Rejection of Patent claims on 24 June 2013 on the basis of India's Traditional Knowledge
12.	20140106002, 15 March 2013	USPTO; *Homeopathic composition and method for the treatment of skin irritations and other skin diseases*	17 October 2013	*Aloe barbadensis Mill* or Aloe Vera*; Kumari/ Gheekawaar/ Sibr/ Katrazhai*	Patent claims rejected on 6 January 2015
13.	20150174185, 15 January 2015	USPTO; *Viral trappers*	12 November 2015	*Tephrosia purpurea or Wild indigo; Sarphuka/ Kolinji/ Paavali/ Mullukai*	Patent claims rejected on 29 August 2018

Source: *TKDL outcomes against bio-piracy, Traditional Knowledge Digital Library*

experienced constant fatigue and tiredness throughout the expedition across the rough terrain. The expedition team was curious in knowing the reason and had observed that the *Kani* guides intermediately ate certain black berry fruits of some plants. These fruits were also offered totheexhausted expedition team by the *Kani* guidesandthe team instantlyexperienced unusual increased level of energy and vitality in them. Due to the traditional tribal culture and customary laws that are practiced among indigenous communities for the protection and preservation of traditional knowledge the Kani guides had also initially refused to share the details of the plant that bore these edible 'fruits of energy' as this

particular traditional knowledge has enabled the *Kani* tribals to survive for generations altogether in travelling large distances in search of food and other forest resources. After constant persuasion the *Kani* guides finally led the expedition team and identified the plants that are locally known as *Arogyapacha* and scientifically as *Trichopus zeylanicusTravancoricus*. Though *Trichopus zeylanicus* is also found in Sri Lanka and Thailand, only the Indian sub-specie is found to possess medicinal properties.[34,35]

Dr. Palpu Pushpangadan and his team of scientists took the *Arogyapacha* plant to JNTBGRI so as to study it scientifically and to look into the possibility of commercializing. After undergoing over an eight year research constituting several chemical and pharmacological tests it was discovered that the fruit and the leaves of the plant exhibited properties of anti-stress, immune-stimulating, stamina boosting, fatigue relieving, controlling tumor growth, activating body's natural defenses and cellular immune system. This followed the isolation of twelve active chemical compounds from the *Arogyapacha* plant that was responsible for the effects that the team had experienced during their expedition. While the *Kani* tribals traditionally practiced eating the berry fruits of the *Arogyapacha* plant to directly obtain these compounds and the benefits associated with them, the JNTBGRI team discovered that crushing of the *Arogyapacha* plant leaves was the most effective way to obtain the twelve compounds. The JNTBGRI team, through a standard research and development program successfully conducted clinical trials and scientifically demonstrated the critical medicinal benefits of the *Arogyapacha* plant. The JNTBGRI team had in 1994 decided to file process patent application with the IP office in India for the manufacturing of polyherbal sports medicine named 'Jeevani' based on the isolated chemical compounds from the *Arogyapacha* plant for protection and effective commercialisation of the accessed traditional medicinal knowledge for which the benefit incurred was intended to be shared with the Kani community.[36] Notably 'Jeevani' was a standardized medicinal formulation obtained as an end product of the research and development using the *Arogyapacha* plant, its isolated chemical compounds and other herbal plants. The intellectual property protection for 'Jeevani' was crucial for preventing third party misuse and misappropriation and for the sharing of benefits by JNTBGRI with the indigenous and local communities as per the benefit-sharing agreement signed with the Kani people, which is in accordance with the Access and Benefit Sharing (ABS) mechanism of the United Nations Convention on Biological Diversity (CBD).[35]

The product technology licensing for the effective commercialisation of 'Jeevani' was granted to *Arya Vaidya Pharmacy Ltd* of Coimbatore for primary commercial manufacturing of 'Jeevani' in 1995. The initial licensing agreement between JNTBGRI and *Arya Vaidya Pharmacy Ltd*was for a period of seven years and a license fee of $ 50,000 USD. However large scale commercial cultivation of *Arogyapacha* plant at the land inhibited by the Kani people, which belonged to the Indian Forest Department, caused environmental concerns pertaining to land and forest degradation, and therefore necessitated prior approval and significant challenges. It is here that JNTBGRI pointed out the usage of only the leaf part of the *Arogyapacha* plant need to be harvested without actually destroying the plant as a whole. It was only after JNTBGRI gave assurances to the Forest Department and 'Integrated Tribal Development Program' of the Directorate for Tribal Welfare, Govt. of Kerala, that it would pay *Kani* people for the seeds as well as the leaf-harvests which in turn would fetch a stable source of income for the *Kani* cultivators, that the cultivation of *Arogyapacha* plant was permitted by the Forest Department. This followed the training and skilling of selected Kani cultivators in cultivation and harvesting that enabled JNTBGRI to supply *Arogyapacha* plant leaves to the *Arya Vaidya Pharmacy Ltd.* The formation of Kerala Kani Samudaya Kshema Trust in 1997 with people of the Kani tribe as its members has the objective to promote welfare and development activities amongst the members of the Kani community. In March 1999, the first royalty payment of US $ 12,500 was received in accordance with the benefit sharing agreement that have been simultaneously used for various welfare projects of the Kani people. Further in 2006, JNTBGRI formed a Business Management Committee with the Kani people in setting minimum conditions for Access and Benefit Sharing (ABS) such as extending license and royalty benefits.[35]

The role played by traditional medicinal knowledge in customarily protecting and preserving the medicinal secrets of *Arogyapacha* plant within the indigenous *Kani* tribe is notable. The access to the traditional medicinal properties of *Arogyapacha* plant by JNTBGRI, the subsequent commercial

development and licensing of 'Jeevani' sports drug, the ultimate benefit sharing and financial impact on the lives of *Kani* people is but a unique global model that signifies the pivotal importance and the need for the recognition of traditional medicinal knowledge holders and their intellectual property towards 'cooperative' R&D induced drug discovery in the modern times. *Kani model* is also a epitome of an idea of semi-commons that calls for the rights of indigenous and local communities.

Protection of Traditional Medicinal Knowledge

The WIPO postulates the preservation of the indigenous community as the best possible way for the protection of Traditional Medicinal Knowledge as they are linked to the subsistence of the community just as seen in the case of the Kani tribe. By protecting the indigenous and local communities in accordance with their customary laws, practices and protocols enables them to pass on from one generation to another as a part of their traditional obligatory duties. Customary laws and protocols are the traditional rules abided by the indigenous communities so as to enable the elderly members to govern their community. This has been seen as important because the customary laws define as to how the resources and knowledge of the community are shared, utilized and inherited within the community so as to prevent inappropriate and unauthorized use by those outside the community.

Apart from the customary laws, there are several international instruments that provide Intellectual Property Protection of Traditional Medicinal Knowledge. The Convention on Biological Diversity, 1992 recognizes the value of TK of the indigenous and local communities. The CBD in Article 8 (j) requires the party countries to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity; promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices; and encourage equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2010, objectivizes "the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components."

In India, The Biological Diversity Act, 2002, mandates an individual or a body to obtain approval from the National Biodiversity Authority to access biological resources or Traditional Knowledge associated with it for the purposes of research, bio-survey, bio-utilization or commercial utilization, to make any application for obtaining any IPR and transfer of any results of research pertaining to genetic resources. However, the act has proven to be too stringent in enabling the securing of patents so as to enable the sharing of knowledge and benefit to the traditional knowledge holders.

Conclusion

The role played by indigenous and local communities in the preservation, protection and proliferation of traditional knowledge including traditional medicinal systems through the respective customary and cooperative mechanism as an effective tool for wellness management is well evident. However the growing concern of biopiracy, bioprospecting and misappropriation of Traditional Medicinal Knowledge on one side and inappropriate claims over the genetic resources through the various instruments of intellectual property rights by third parties without prior approval has already posed as a challenge to the subsistence and survival of the indigenous and local communities.[37] The advent of biotechnology and related disciplines such as, Ethnopharmacology and Pharmacogenomics has scientifically validated traditional medicinals concepts such as the humoural theories into factual entities thereby attracting greater interest of the modern medicine and pharmaceuticals to look into the expertise of wellness management and health related solution held by traditional medicinal systems. Particularly the validation of *Tri-dosha* as the foundational entity of Ayurveda has been attractive enough for pharmaceutical companies to commercialise herbal medicines and drugs that are derived from plant/animal sources. However, the traditional medicinal systems are also deep rooted as cultural entities that hold multitudinal character and immense value among the practitioners of such

systems.[38] This has importantly been a definite outcome of inter-generational interaction of the indigenous communities over a greater period of time resulting in the carving of substantial necessities and economic needs on traditional lines.

The evolving of an alternative global economic regime post the second-world war and the disintegration of the USSR on the lines of liberalization, privatisation and globalization with emphasis on intellectual property rights has increased the scope for knowledge as a private entity through commercialisation which is in contradictory with the perception of knowledge as a common entity for the benefit of the social constituents.[39] This is irrespective of the fact that Traditional Medicinal Knowledge has historically been a cooperative phenomenon at the global stage. The 'Kani Model' of access and benefit sharing provides a greater scope for furthering the true nature of indigenous and local communities with regards to the protection of traditional medicinal knowledge on the lines of cooperative knowledge sharing and equitable benefit mechanism that can be made possible through a *sui generis* instrument.[40] With this the scope of intellectual property as a semi-commons finds greater emphasis wherein every stakeholder is benefitted through cooperative knowledge sharing.[41]

References

1 De Vos P, European materia medica in historical texts: Longevity of a tradition and implications for future use, *Journal of Ethnopharmacology*, 132 (1) (2010) 28, doi:10.1016/j.jep.2010.05.035.

2 Brandão M G L, Zanetti N N S, Oliveira P, Grael CFF, Santos A C P & Monte-Mór R L M, Brazilian medicinal plants described by 19th century European naturalists and in the Official Pharmacopoeia, *Journal of Ethnopharmacology*, 120 (2) (2008) 141,doi:10.1016/j.jep.2008.08.004.

3 Lemonnier N, Zhou G-B, Prasher B, *et al*., Traditional Knowledge-based Medicine: A Review of history, principles, and relevance in the present context of p4 systems medicine, *Progress in Preventive Medicine*, 2 (7) (2017), doi:10.1097/pp9.0000000000000011.

4 Gertsch J, How scientific is the science in ethnopharmacology? Historical perspectives and epistemological problems, *Journal of Ethnopharmacology*, 122 (2) (2009) 177, doi:10.1016/j.jep.2009.01.010.

5 Drahos P& Braithwaite, *Journal of Information Feudalism : Who Owns the Knowledge Economy?* Earths can Publications Ltd, 2002, doi:10.4324/9781315092683.

6 Traditional Knowledge and Intellectual Property – Background Brief, https://www.wipo.int/pressroom/en/briefs/tk_ip.html (accessed on 16 November 2018).

7 About IP, https://www.wipo.int/about-ip/en/index.html (accessed on 26 November 2018).

8 World Intellectual Property Organisation. Intellectual Property and Traditional Medical Knowledge - Background Brief No 6 (2015), https://www.wipo.int/publications/en/details.jsp?id=3871 (accessedon18 November 2020).

9 Traditional Knowledge, http://www.wipo.int/tk/en/tk/index.html (accessed on 24 November 2018).

10 Mehta D D, Positive Sciences in the Vedas, Arnold Heinemann Publishers, India, 1974.

11 Valiathan M S, The Legacy of Caraka, Orient Blackswan, 2003, https://books.google.co.in/books?hl=en&lr=&id=ocOktxn-u28C&oi=fnd&pg=PP17&ots=IlxTXrD92L&sig=3-QlgdIvvVT4r5nl-n3DMyLoZoc&redir_esc=y#v=onepage&q&f=false.

12 Patwardhan B, Mutalik G &Tillu G, Chapter 11 - Personalized Approaches for Health, In: Patwardhan B, Mutalik G, Tillu G, eds, *Integrative Approaches for Health*, Academic Press,(2015) 293, doi:10.1016/B978-0-12-801282-6.00011-5.

13 Whitehouse T, Ayurveda: the knowledge of life, *British Medical Journal*, 331 (2005) (Suppl S5), doi:10.1136/sbmj.0511402.

14 Lurie D I, Ayurveda and Pharmacogenomics, *Annals ofAyurvedic Medicine*, 1 (4) (2012) 126, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.301.9694&rep=rep1&type=pdf.

15 Al-Shura AN, Chapter 1 - The science of personal autonomy. In: Al-Shura AN, ed. *Perspectives of Ayurveda in Integrative Cardiovascular Chinese Medicine for Patient Compliance*, Academic Press, 4 (2020) 3, doi:10.1016/B978-0-12-817570-5.00001-3.

16 Sharma A K, ed. *History of Science in India: Medicine and Pharmacology*, The National Academy of Sciences, New Delhi & The Ramakrishna Mission Institute of Culture, Kolkata, 2 (2014).

17 Dey S &Pahwa P, Prakriti and its associations with metabolism, chronic diseases, and genotypes: Possibilities of new born screening and a lifetime of personalized prevention, *Journal of Ayurveda and Integrative Medicine*, 5 (1) (2014) 15, doi:10.4103/0975-9476.128848.

18 Rotti H, Mallya S, Kabekkodu S P, *et al.*, DNA methylation analysis of phenotype specific stratified Indian population, *Journal of Translational Medicine*, 13 (1) (2015) 151, doi:10.1186/s12967-015-0506-0.

19 Govindaraj P, Nizamuddin S, Sharath A, *et al*., Genome-wide analysis correlates Ayurveda Prakriti, *Science Report*, 5 (1) (2015) 15786, doi:10.1038/srep15786.

20 Ghodke Y, Joshi K &Patwardhan B, Traditional Medicine to Modern Pharmacogenomics: Ayurveda Prakriti Type and CYP2C19 Gene Polymorphism Associated with the Metabolic Variability, *Evid Based Complement Alternative Medicine*, (2011) 5 doi:https://doi.org/10.1093/ecam/nep206.

21 Rhoda D, Ayurvedic Psychology: Ancient wisdom meets modern science, *International Journal of Transpersonal Studies*, 33 (1) (2014) 158, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.686.7124&rep=rep1&type=pdf.

22 Patwardhan B, Joshi K &Ghodke Y, Genetic basis to concept of prakriti, *Current Science*, 90 (7) (2006), https://www.researchgate.net/profile/Bhushan_Patwardhan/publication/230607181_Genetic_basis_to_concept_of_prakriti

/links/0f317539f151049b81000000/Genetic-basis-to-concept-of-prakriti.pdf.

23 Mukerji M &Sagner M, Genomics and Big Data Analytics in Ayurvedic Medicine, *Progressive in Preventive Medicine*, 4 (1) (2019), e0021. doi:10.1097/pp9.0000000000000021.

24 Pradeep T, Rintum K, Tavpritesh S, *et al*., Recapitulation of Ayurveda constitution types by machine learning of phenotypic traits, *Plos One*, 12 (10) (2017), :e0185380-e0185380doi:10.1371/journal.pone.0185380.

25 Alamgir A N M, Medicinal, Non-medicinal, Biopesticides, Color- and Dye-Yielding Plants; Secondary Metabolites and Drug Principles; Significance of Medicinal Plants; Use of Medicinal Plants in the Systems of Traditional and Complementary and Alternative Medicines (CAMs). In: Alamgir ANM, ed. *Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy*, Progress in Drug Research, Springer International Publishing, (2017) 61, doi:10.1007/978-3-319-63862-1_3.

26 Alamgir A N M, Introduction. In: Alamgir ANM, ed. *Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy*, Progress in Drug Research. Springer International Publishing; (2017) 1, doi:10.1007/978-3-319-63862-1_1.

27 Patwardhan B, Vaidya A D B &Chorghade M, Ayurveda and natural products drug discovery,*Current Science*, 86 (6) (2004) 789, https://www.jstor.org/stable/24109136 (accessed on 26 August 2020).

28 Alamgir A N M, Intellectual Property (IP) and Intellectual Property Right (IPR), Traditional Knowledge (TK) and Protection of Traditional Medical Knowledge (TMK), In: Alamgir ANM, ed. *Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1: Pharmacognosy*. Progress in Drug Research. Springer International Publishing,(2017)515, doi:10.1007/978-3-319-63862-1_12

29 James T C, IPR Issues related to Medicinal and Aromatic Plants (Herbs & Their Allied Products), *Journal of Traditional and Folk Practices*, 02 03 4 (1) (2016) 7, https://www.academia.edu/38700293/IPR_Issues_related_to_Medicinal_and_Aromatic_Plants_Herbs_and_Their_Allied_Products (accessed on 19 October 2020).

30 TKDL Outcomes against Bio-Piracy, Traditional Knowledge Digital Library, http://www.tkdl.res.in/tkdl/LangDefault/Common/outcomemain.asp?GL=Eng (accessed on 20 October 2020).

31 Adams M, Berset C, Kessler M & Hamburger M, Medicinal herbs for the treatment of rheumatic disorders--a survey of European herbals from the 16th and 17th century, *Journal of Ethnopharmacology*, 121 (3) (2009) 343, doi:10.1016/j.jep.2008.11.010.

32 Touwaide A, De Santo N G &Aliotta G, The Origins of Western Herbal Medicines for Kidney Diseases, *Advanced Chronic Kidney Disease*,12 (3) (2005) 251, doi:10.1016/j.ackd.2005.03.005.

33 Boorstin D J,Intellectual property as a lever for economic growth: The Asian and Pacific region experience (Part II), *WIPO Magazine*, 6 (2004) 8, https://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2004/wipo_pub_121_2004_11-12.pdf#page=11 (accessed on18 October 2020).

34 Suchitra M,The Kani learning: How benefit-sharing between a research institute and the Kani tribe went awry, *Earth*, Published online 28 June 2015, https://www.downtoearth.org.in/coverage/the-kani-learning-39208 (accessed on 18 October2020).

35 WIPO, Using traditional knowledge to revive the body and a community, World Intellectual Property Organisation, published on 31 August 2010, https://www.wipo.int/ipadvantage/en/details.jsp?id=2599 (accessed on 18 October2020).

36 Wynberg R, Schroeder D &Chennells R, *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science & Business Media, 2009.

37 Pierotti R, World Views and the Concept of "Traditional" *Ethnobiology Letters*, 9 (2) (2018) 299, https://www.jstor.org/stable/26607704 (accessed on 5 October 2019).

38 Mazzocchi F, Western science and traditional knowledge: Despite their variations, different forms of knowledge can learn from each other, *EMBO Reports*, 7 (5) (2006) 463, doi:10.1038/sj.embor.7400693.

39 Pierotti R, Indigenous Concepts of 'Living Systems': Aristotelian 'Soul' Meets Constructal Theory, *Ethnobiology Letters*, 6 (1) (2015) 80, https://www.jstor.org/stable/26423607 (accessed on 7 October 2019).

40 Stoianoff N P& Wright E, Fair Use and Traditional Cultural Expressions, In: CORBETT S, LAI JC, eds., *Making Copyright Work for the Asian Pacific*, Juxtaposing Harmonisation with Flexibility,ANU Press, (2018) 75, https://www.jstor.org/stable/j.ctv8bt2xn.8 (accessed on 17 September 2019).

41 Damle S, Science and human welfare,*Contemporary Clinical Dentistry*, 1 (4) (2010) 207, doi:10.4103/0976-237X.76383.