VULNERABLE POSITION OF TRADITIONAL KNOWLEDGE UNDER IPR: CONCERN FOR SUSTAINABLE DEVELOPMENT

Gargi Chakrabarti
National Law University, Jodhpur, Rajasthan, India.
Corresponding author: 73.gargi@gmail.com

Available at http://www.ssrn.com/link/OIDA-Intl-Journal-Sustainable-Dev.html
 ISSN 1923-6654 (print) ISSN 1923-6662 (online).

Abstract: Asian, African and Latin American civilizations are among the most ancient ones in the human history; inhabitated by thousands of different traditional communities; there is an abundance of traditional knowledge that has been practiced by traditional communities over a considerable period of time and is still constantly evolving. Huge commercial potentiality of traditional knowledge has been evaluated only in recent decades. In recent years, issues related to the importance of traditional knowledge, its role in the economy of the country, its misappropriation by commercial activities and the need of its protection from the misappropriation has been the subject to debate and discussion in international fora. From traditional communities' point of view, traditional knowledge is often not a commercial commodity; instead it is related with their customs, culture, heritage and the way of their daily living. It is important from the sustainable development point of view of the respective country as well, as it can potentially improve the daily problems of food, cloths, medicines, safe drinking water and employment. This is true not only for traditional communities, but also for each and every backward and compromised people in the country or in the region; thus improving the overall growth of the society. That is the reason traditional knowledge needs proper protection in national, regional and international arena. India, Brazil, South Africa, Andean countries, African countries and other developing and least developed countries are concerned about the protection of their traditional knowledge from misappropriation. In the international arena, WIPO (Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore i.e. IGC to be specific) is working since long time to provide a comprehensive guideline for the system of protection of traditional knowledge. The methodology of research adopted for this article is the doctrinal method, and following documents are used for the purpose of research: A) Primary documents - different country's statutory regimes and international conventions (such as CBD), protocol (such as Swakopmund Protocol of ARIPO) and drafts of WIPO IGC model sui generis legislation (specifically the Draft prepared in 16th and 24th session of IGC). This article will discuss the unique nature of traditional knowledge according to its holistic characteristics, will detail the cases of its misappropriation, and will evaluate the available national protection and the gaps therein. This article will also estimate the international attempt to provide the proper guideline for streamlining the protection of traditional knowledge. The issue of inclusion of disclosure of origin in patent application, formulation of sui generis system with introduction of access and benefit sharing regime and WIPO-IGC initiative in preparation of international guideline for traditional knowledge protection will be discussed in depth in this article. This article at the same time will try to get the proper remedy for protection of traditional knowledge in national, regional, inert-regional and international level, so that the effectivity of traditional knowledge can be used for sustainable development of the communities and for the society at large, so that mankind will go towards a better tomorrow using the full potential of the traditional knowledge. This article will also concentrate on creating awareness in every sector of the society, especially among all the stakeholders related with traditional knowledge so that the traditional communities will be empowered to stop the misappropriation of their traditional knowledge and can actively participate in effective use of traditional knowledge, and technology transfer related to it, by taking an essential part in access and benefit sharing mechanism.

Keywords: Bonn guidelines; Disclosure of Origin; Intellectual property rights; Traditional knowledge protection; WIPO IGC.

Introduction

Asian, African and Latin American civilizations are among the most ancient ones in the human history including Chinese civilization, Harappa and Mohenjo-Daro civilization of Indian sub-continent, Arabian civilization of West Asia and Maya, Inca and Aztec civilization of South and Central America. Asian, African and Latin American countries are rich in biodiversity; are inhabitated by thousands of different traditional communities; there is an abundance of traditional knowledge that has been practiced by traditional communities over a considerable period of time and is still constantly evolving. Though this traditional knowledge is practiced since ancient ages, but huge commercial potentiality of them has been evaluated only in recent decades. In recent years, issues related to the importance of traditional knowledge, its role in the economy of the country, its misappropriation by commercial activities and the need of its protection from the misappropriation has been the subject to debate and discussion in international fora. From traditional communities' point of view, traditional knowledge is often not a commercial commodity; instead it is related with their customs, culture, heritage and the way of their daily living. It is important from the public interest point of view as well, as it can potentially improve the daily problems of food, cloths, medicines, safe drinking water and employment. This is true not only for traditional communities, but also for each and every backward and compromised people in the country or in the region; thus improving the overall growth of the society. It is not having a relation with a single aspect of the lives of public; but it is related with the overall facets of their lives, which is discussed herein.

Unique Character of Traditional Knowledge

Holistic Nature of Traditional Knowledge

There is diversity of cultures in all the countries on earth. Local and indigenous knowledge systems are based on those diverse cultures. But certain characteristics are common to the traditional knowledge system of different communities and countries. In particular, biodiversity including agricultural resources, medicinal plants, forest resources; landscapes including mountains and rivers; cultural and spiritual beliefs and customary laws are strongly linked with each other. These are recognized as sacred and interconnected with the whole universe. Traditional knowledge is summation of intangible knowledge and tangible biological resources. Knowledge is generated by the process of utilization of biological resources which are developed, conserved and improved day by day and thus they are inseparable from each other. Landscape affords substantial space to the inhabitants for customary use of biological resource and to acquire and nurture the knowledge which is imperative for sustaining biodiversity and knowledge system. It is evident that particular territory, every physical and geographical features influence traditional knowledge system. Cultural and spiritual values are closely interlinked with customary law which gives shape to the social processes and govern the way knowledge is acquired, used, shared and transmitted. It also ensures the rights and responsibilities attached to traditional community. This forms the basis of existence of the traditional communities and gives them perception of conservation and sustainable use of the resources with utilization and maintenance of related traditional knowledge at the same time.

Challenges for the Protection of Traditional Knowledge

Irrespective of the region, country and community, protection of traditional knowledge is a challenge because of its uniqueness. The challenges are as follows: (i) Holistic nature of the traditional knowledge has to be attributed, (ii) Traditional knowledge is the part and parcel of the daily living and also an identity of the cultural and social structure of traditional people, (iii) Traditional knowledge is the fruit of intellect used by traditional people over ages, so technically it has to be denoted as an intellectual property; but usual intellectual property rights provide individual rights, which is not suitable for traditional knowledge, rather it is helping in misappropriation of traditional knowledge, (iv) Traditional knowledge in most cases are not documented or published, so it is difficult for the search authorities to avoid misappropriation or grant of wrong patent during prior art search, (v) No proper international guidance is available till date for the protection of traditional knowledge, (vi) Several national legal regimes are now coming up with the sui generis regime for protection of traditional knowledge, but none of them are full proof so that it can be used as a model for other domestic and international legislation, (vii) Intellectual property rights, specially patent have been used for indivualisation and monopolization of traditional knowledge, (viii) Traditional community people are not aware of the huge economic potential of commodification of traditional knowledge, nor are they always agreed for it, as some communities want to keep the traditional knowledge secret and sacred, (ix) Serious lack of awareness is also prevailing

Table 1: Traditional Medicinal knowledge of India about usage of some plants resources

Plant Name	**Medicinal use by traditional communities**
Bel (Aegle marmelos)	Treating Diabetes
Ghritakumari (Aloe vera)	Skin disease and hair problems
Guggul (Commifora mukul)	Treating skin disease and lowering body fat
Haldi (Curcuma longa)	Wound healing, skin disease, jaundice, allergy
Kalajira (Nigella sativa)	Oral hygiene, jaundice, skin disorder
Amla (Emblica officinalis)	Skin disease, grey hair, health tonic preparation
Kalimirch (Piper nigrum)	Arthritic disease, skin disease, as a condiment
Chandrabhaga (Rauwolfia serpentina)	Epilepsy, Schizophrenia, high blood pressure
Manjhistha (Rubia Cordifolia)	Paralysis, skin disease
Imli (Tamarindus indica)	Anti-inflammatory, used for dressing boils
Ashwagandha (Withania somnifera)	Heart disease, Rheumatism
Arjuna (Terminalia arjuna)	Cardiac disease, high blood pressure
Behara (Terminalia bellerica)	Germicidal for treating stomach disorder, improving digestion, enlarged spleen

Source: Modified from WPS No. 629/September 2008[1]

[1] Shamama Afreen & Biju Paul Abraham, *Biopiracy and Protection of Traditional Knowledge: Intellectual Property Rights and Beyond*, Working Paper Series of IIM Calcutta, WPS No. 629/September 2008, Table 1.

regarding the legal rights amongst the traditional communities, (x) Access and benefit sharing mechanism with complementary documentation system is proposed as a useful measure for traditional knowledge protection, but proper awareness upto the grass root level among the traditional community along with a proper watch dog arrangement is required.

Treasure of Traditional Knowledge

Traditional Knowledge of India

Traditional communities of India in the every areas of the country use plant resources for treating different diseases, usage started in the Vedic era, most of them are documented in Ayurveda, though there are lot of others in possession of the communities in the nook and corner of the country. Some of them are given in the Table 1.

In Sikkim Himalaya the practice of Cardamom-based agro-forestry[2] is a good example of usage of traditional knowledge for adaptive management system for biodiversity conservation, proper land use, protection of soil quality, increasing and maintaining soil fertility, reducing soil erosion, increasing availability of basic resources and optimum use of land. The cardamom species are adapted to less water and frost, also are appropriate for cultivation in different altitudes. In big plantation areas the shade trees are nitrogen-fixing Himalayan Alder, which helps in maintaining and improving soil fertility. Bari farming technique is another example of adaptive agriculture system practiced in North-East India by a small traditional community named Thengal-Kacharis with the aim of conservation and sustainable use of biological resources.[3] They practice the optimum use of solar energy by the adjustment of different types of plants together in the same space and time by multi-tier canopy configuration and by niche diversification method. Other traditional practices followed by this community are as follows: seeds are selected from the healthy plants with good characteristics; salt is applied to the soil during seed planting to facilitate penetration of roots through the soil and to increase fertility by adding sodium; fallen tree leaves, farm refuse and kitchen wastes and water are applied to the soil to increase moisture and fertility; fish scales and ashes are applied to the soil to increase the phosphorous content of the soil; wood ash is applied on vegetable crops and smoke is produced at the base of the fruit trees to prevent pest manifestation; red tree ant's nest used to introduce in fruit tree orchards to prevent borer infestation and kerosene oil is applied to the fruit tree trunks to prevent shoot stem borer. Seeds of gourd family of plants are collected, sun dried and preserved within the bamboos. This knowledge about sustained conservation and practices usually passed on through generations in the family and community.

This is the one example of community practiced traditional knowledge among lots of other practices.

Traditional Knowledge of China

Traditional Chinese Medicine (TCM) is fully institutionalized and supported by the Chinese government, and very much a part of the contemporary Chinese healthcare system. It delivers almost 40% of total healthcare services, and like western biomedicine, is predominantly based in hospitals.[4] There are almost 3000 dedicated hospitals for TCM, and over 95% of western medical hospitals also have fully-fledged Chinese medicine wards and outpatient departments. TCM is practiced in its own right, integrated with western medicine, or used to enhance the effectiveness of western medical treatments.[5]

Within the realm of the Chinese TMK, there are two major categories: (i) traditional Chinese medicinal knowledge (TCM), mainly developed and accumulated by Han nationality (the majority of Chinese); (ii) second, traditional minority ethnicity medicinal knowledge or traditional indigenous knowledge (TIK), which includes knowledge accumulated by 55 minority ethnicities in China, such as Tibet, Mongolia, Miao, among others. As early as 1100 BC during the West Zhou era, Chinese medicine had developed into different branches, including disease therapy, ulcer therapy, diet therapy and veterinarian medicine (Leung, 1990). Chinese people used to use natural products for medicinal purposes, which include materials from plant, animal and mineral sources, with the majority derived from plants. Some of the well known authoritative

[2] Ghanashyam Sharma, *Traditional knowledge systems in large cardamom farming: biophysical and management diversity in Indian mountainous regions*, Indian Journal of Traditional Knowledge, Vol. 8(1), 2009, pp. 17-22

[3] Madhumita Barooah & Ajit Pathak, *Indigenous knowledge and practices of Thengal Kachari women in sustainable management of bari system of farming*, Indian Journal of Traditional Knowledge, Vol. 8(1), 2009, pp. 35-40

[4] Dr. Mae-Wan Ho, *Traditional medicine in Contemporary China*, available at http://www.i-sis.org.uk/GCM3.php (accessed on 08.08.13).

[5] Id.

Table 2: Traditional Medicinal knowledge of China about usage of some plants resources[6]

Plant Name	**Medicinal use by traditional communities**
Artemisia annua (qinghao)	Treatment of malaria (TCM)
Rhubarb (shengdahuang)	Treatment of ulcers (TCM)
hou pu san wu tang, which is made of da huang (12g), hou pu (24g) and zhishi (15g)	Treatment of constipation (TCM)
Safflowers	Used in Yunnan for wound healing (TIK)
Anisodus luridus (ximalayadongliangdang)	Used in Tibet for plague (TIK)
Type of grass called 'guanyin cao'	Used by Miao ethnic group in southwestern China for cold, cough and pneumonia

documentations on Chinese medicinal plant includes Wu Shi Er Bing Fang (Prescriptions for Fifty-Two Diseases), Shen Nong Ben Cao Jing (Shennong Herbal), Ben Cao Gang Mu (Herbal Systematics) and Shang Han Lun (Typhus Theory).[7] Few examples of TCM and TIK are enlisted in Table 2.

In practice, however, the distinction among the three ways of delivering TCM is blurred. Western biomedical concepts and ideas have been assimilated into Chinese medicine, and western drugs are routinely prescribed in Chinese-medicine wards and outpatients departments. TCM physicians, for their part, face pressure from hospitals to use revenue-generating biomedical diagnostic facilities such as ultrasound and computed tomography. TCM is also used by the China to promote Chinese culture. It is defined as a 'national treasure', which might have further insulated it from debate as a science. Though such a debate should include a thorough critique on the conceptual and practical deficiencies of the mainstream scientific model itself, which is not what the majority who wants a debate has in mind.

Traditional Knowledge of Russia

Russia is one of the most polyethnic countries in the world, about 200 ethnic groups are inhabitant of Russia, and among them the indigenous peoples of North Russia had preserved their distinct lifestyle, culture and customs in traditional way like their ancestors.[8] Indigenous people always connect their cultures with their natural environment and there are traditional cultural ways to maintain ecological balance of the natural environment. For example, the indigenous people of Amur river area used to consider moose, otters, wild hogs, bears, and tigers as totems and used to practice strict regulation regarding hunting of these animals.[9] They also protect the natural habitat as sacred

[6] Id.

[7] Xuan Li & Weiwei Li, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, Journal of World Intellectual Property (2007) 10 (2) 125-148, available at http://www.abifina.org.br/arquivos/encontros/Xuan_Li.pdf accessed on 08.08.12

[8] Anna Naikanchina, *Indigenous Peoples: Development with Culture and Identity Articles 3 and 32 of the United Nations Declaration on the Rights of Indigenous Peoples*, Report submitted to International Expert Group Meeting, Department of Economic and Social Affairs, Division for Social Policy and Development, Secretariat of the Permanent Forum on Indigenous Issues, United Nations, PFII/2010/EGM, New York, 12 - 14 January 2010.

[9] Andrey Laletin & Vladimir Bocharnikov, *Harnessing Indigenous and Traditional Forest Related Knowledge: The Case of North Eurasian Countries*, Case Study Report Prepared for the MGI Workshop on "Applying Sustainable Forest Management to Poverty Reduction: Strengthening the Multi-stakeholder Approach", Ghana, 26-30 July, 2010.

localities and that includes preservation of springs, lakes, forests, rocks, stones, etc. It is the most olden type of the wilderness protection.[10] Indigenous people of Ukraine focused on sustainable production of wood by creating traditional way of monoculture plantation of Norway spruce (Picea abies) in the Carpathians and Scots pine (*Pinus sylvestris*) in Polesye.[11] Tribes of Kazakhstan knows medicinal use of more than 200 wild species of plants for human or animal diseases. Like karakol aconite (Aconitum karakolicum Rapes.), which is found in the spruce forests of Issyk- Kul lakeside in Kyrgyzstan, were used by Kazak tribes as a treatment of rheumatism and pulmonary tuberculosis. They also use unique traditional methods of conservation and drying of fruits and berries.[12] Traditional methods of forest management of peoples of Kyrgyzstan and Tajikistan were exclusive. They used terracing of slopes for tree-planting and also used famous technology of "hanging gardens". This "hanging gardens" technology is useful in conditions like poor soils, scarcity of land and lack of water for irrigation. They used to create a small oasis with fertile soil for planting trees, which will not dry during summer. This technology was extensively used in mountain villages of Tajikistan throughout the pre-Soviet era but mostly disappeared in the Soviet reign.[13]

Misappropriation of Traditional Knowledge

Traditional knowledge has always been an easily available treasure and thus has been vulnerable to misappropriation. The traditional knowledge, particularly, related to the treatment of various diseases has provided leads for development of biologically active molecules by the technology rich countries. In other words, traditional knowledge is being exploited for bio-prospecting. Also Traditional knowledge is often misappropriated, because it is conveniently assumed that since it is in public domain, communities have given up all claims over it. Traditional Knowledge includes both the codified (documented) as well as non-codified information (not documented but only orally transmitted). As Asian countries are very rich in traditional knowledge, the misappropriation of Asian traditional knowledge is also very high; there are several cases of such type, which will be elaborated in the next segment.

Case Studies of Misappropriation of Asian Traditional Knowledge

Apart from the Chinese government, which has widely patented its globally popular traditional medicinal products, most governments of Asia and other developing countries are under threat of misappropriation of their traditional knowledge and busy fighting the cases of biopiracy with foreign countries; which costs them huge time and money to win a single case. Table 3 below is showing cases of misappropriation of Asian traditional knowledge, though this is just the mere tip of a big iceberg.

Continue to next Page

[10] Andrey Laletin & Vladimir Bocharnikov, Harnessing Indigenous and Traditional Forest Related Knowledge: The Case of North Eurasian Countries, Case Study Report Prepared for the MGI Workshop on "Applying Sustainable Forest Management to Poverty Reduction: Strengthening the Multi-stakeholder Approach", Ghana, 26-30 July, 2010.

[11] Synyakevych I. , Soloviy I., Deyneka A. 2009. Forest sector of Ukraine in the 21st century: state of art, scenarios, and policy // Ecological economics and sustainable forest management: developing a transdisciplinary approach for the Carpathian Mountains. Edited by I.P. Soloviy, W.S. Keeton. – Lviv : Ukrainian National Forestry University Press, Liga-Press: 127-150.

[12] S karakol aconite (Aconitum karakolicum Rapes.) – growing in the zone of spruce forests of Issyk- Kul lakeside in Kyrgyzstan – were used by local people from the earliest times as a treatment of rheumatism, pulmonary tuberculosis, etc. Local population used large amount of forest plants for food. Unique methods of conservation and drying of fruits and berries were saved.

[13] Andrey Laletin & Vladimir Bocharnikov, *Harnessing Indigenous and Traditional Forest Related Knowledge: The Case of North Eurasian Countries,* Case Study Report Prepared for the MGI Workshop on "Applying Sustainable Forest Management to Poverty Reduction: Strengthening the Multi-stakeholder Approach", Ghana, 26-30 July, 2010.

Table 3. Misappropriation of Asian Traditional Knowledge[14]

Country providing TK	**Biological Resource**	**Country misappropriating TK**	**Remarks**
China	Bitter Melon (Momordica charantia)	US	US Patent No. 5484889.
China	Xi Shu /Happytrees *(Camptotheca lowreyana)*	US	US Patent No. PP11,959.
Malaysia	Brintangor tree (Calophyllum lanigerum)	US, Singapore	US Patents including No.s 6420571, 6369241, 6160131 and 6277879
Philippines	Nata de coco	Japan, US	US Patent No.s 6280767, 6140105, 5962277 and 5,795,979
Philippines	Bamba (Lagerstroemia sp.)	Japan, US	US Patent No 5980904
Thailand	Plao-noi (Croton sublyratus)	Japan	In 1975 Japanese company Sankyo extracted active ingredient and the patented product 'Kelnac' is produced.
Sri Lanka	Kothala himbutu (Salacia reticulate)	Japan, US	Takama System Ltd. (Yamaguchi JP's) US patent no. 6378682.
India	Turmeric (Curcuma longa)	US	US patent no.5401504, after challenge of CSIR, India the patent had been revoked
India	Neem (Azadirachta indica)	US, EU	EPO patent No.436257, a number of patents were granted, partial revocation had been done so far
India	Jar amla (Phyllanthus niruri)	US	Patent granted in USA and in EPO, India is still fighting for revocation
India	Karela (Momordica charantia) & Jamun (Syzygium cumini)	US	Patent granted in USA, India is still fighting for revocation
India	Kalmegha (Andrographis paniculata) & Pudina (Mentha arvensis)	China	Patent granted in China, but after interference of CSIR, India patent had been revoked

[14] Shamama Afreen & Biju Paul Abraham, *Biopiracy and Protection of Traditional Knowledge: Intellectual Property Rights and Beyond*, Working Paper Series of IIM Calcutta, WPS No. 629/September 2008.

Case Studies of Misappropriation of Latin American Traditional Knowledge

The Natura-Ver-o-Peso Case**:** In 2006, the media in Brazil reported on complaints that the firm Natura[15] had made unauthorized use of TK associated with aromatic herbs and held by a number of merchants of Ver-o-Peso[16] marketplace. According to media reports, five years earlier the cosmetics industry had obtained information about the use of the herbs "pripioca", "breu branco" and "cumaru" traditionally used in scented baths. Allegedly, Natura had interviewed and filmed a documentary on six herb-merchants about methods to prepare aromatic essences from three Brazilian plants and later used developed products for the perfume industry.[17] The concern in the Natura-Ver-o-Peso case is that the associated TK used by the cosmetics firm is widely spread in Brazil as well as in other countries. So much so that the agreement signed establishes the obligation of sharing benefits ensuing from access to and use of "diffuse" traditional knowledge. Knowledge on the aromatic attributes of resources accessed by Natura belongs in the immaterial heritage of the Brazilian people, as does the habit of taking cheiro-baths.[18] Such baths prepared with aromatic herbs and resin is widespread and derives from a fusion of Afro-Brazilian religions and indigenous rituals.[19]

Maca case:[20] Maca plant (Lepidim meyinii) is grown in high altitude of Andean region and well known for enhancing sexual function and human fertility and also for increasing growth hormone level in blood. Andean people used to use it for the same purpose for several years. According to a study on maca produced by the International Plant Genetic Resources Initiative (IPGRI), maca was probably first domesticated in Junin between 1300 and 2000 years ago; and was believed to be widely cultivated in the 16th and 17th centuries. It was used as health drink locally by Andean people for thousand years. Patent was granted to Pure World Botanicals Inc. of USA for treatment of sexual dysfunction with an extract of maca roots, its compositions and methods for their preparation from maca in 2001. This patent is challenged by Peru's National Anti-biopiracy Commission but patent is still valid. Also patent application submitted for food containing extract of maca for its effect of increasing GH level by Towa Corporation of Japan in 2004. Peru's National Anti-biopiracy Commission requested Japan Patent Office (JPO) to consider that the patent application did not meet the requirements of novelty and inventive step criteria and the technical documentation supporting the claim was also sent to the Japan Patent Office. Finally the application was rejected.

Camu Camu Case:[21] Fruit of camu camu (*Myrciaria dubia*) is well known and used traditionally in Andean countries for its preservative properties. T Hasegawa Co. Ltd. of Japan applied for patent on preserves containing whole fruit of camu camu, minerals and peptic substances. Peru's National Anti-biopiracy Commission challenged the patent application on the ground of lack of novelty with the documentation supporting the request. The application is then re-examined and rejected.

Case Studies of Misappropriation of African Traditional Knowledge

Patent on Artemisia judica:[22] Patent is granted to Phytopharm plc.[23] of Cambridge UK for the antidiabetic drug produced from the extract of

[15] Natura is the most successful cosmetics enterprise in Brazil. It has branches in Latin America and France.

[16] Ver-o-Peso market, located in Belém do Pará, is a most renowned street market and commercial exchange site of the Amazon region. Spilotros, D. "As feiticeiras de Belém,". Os Caminhos da Terra, São Paulo, v. 12, n 137, pp. 78-83, Sept. 2003.

[17] O Liberal, "OAB (Order of Lawyers of Brazil) investigates the bio-propection controversy involving Natura". April 2006.

[18] Mauro Souto Maior in his Diccionário de Folclore para estudantes, available online at http://www.soutomaior.eti.br/mario/paginas/dic_b.htm (accessed on 12.11.13) defines the cheiro-bath as a "perfumed bath prepared with herbs, barks of plants, flowers, essences and resins, which has the power to maintain happiness, eliminate caiporismo and recover the favours of good fortune.

[19] Lemos de Arruda Camargo, Maria Thereza, *Sagrado e profano no universo mágico religiosa das plantas rituais afro-brasileiras*. XXIII Cultural Meeting in Laranjeiras, Sergipe, 1999.

[20] See IP/C/W/441/Rev.1 and also Mario Osava, (2006), *South America: Creating a Network Against Biopiracy*, Inter Press Service News Agency

[21] Id.

[22] Liu, C. W. *et al*, *Regeneration of the Egyptian medicinal plant Artemesia judaica*, L. Plant Cell Rep. 2003 Feb. 21(6):525-530.

[23] US patent 6,350,478

Artemisia judica. This plant is found in north African countries and known for its anti diabetic properties for many years in Egypt and other north African countries.

Biovigora patent:[24] Canada's Option Biotech, a Montreal based company, had patented the seeds of *Aframomum stipulatum*, obtained from Congo, for making of anti-impotency drug 'Biovigora'; though A. stipulatum rhizome, a member of ginger family, have documented for its use in Congolese traditional medicine.

Multiple US patent on four African medicinal plant:[25] A researcher obtained multiple US patents on four African medicinal plants, whose extracts are claimed to be useful against different diseases, like breast cancer, leukemia, melanoma, myeloma, diabetes, Parkinson's disease, tuberculosis, viral and fungal infection. All these plants are grown in Ethiopia and known for medicinal uses in many African countries. *Millettia ferruginea* is used for treatment of skin disorders and noted in US Government's own genetic resource database ARS-GRIN and Botanical Dermatology Database of UK. *Glinus lotoide* is known for medicinal uses in Ethiopia, Egypt, Mali and other countries. *Hagenia abyssinica* is known for treatment of tapeworm in Ethiopia, Tanzania and Kenya. *Ruta chalepensis* is known for its medicinal uses in Ethiopia. It is also known in US traditional medicine specially in Texas and New Mexico.[26]

Hoodia patent:[27] Traditional knowledge of San people of South African countries include extracts of cactus as appetite suppressant. South African Council of Scientific and Industrial Research (CSIR) had patent on extract of Hoodia plant. CSIR sold the patents to Phytopharm and they in turn granted a license to pharmaceutical company Pfizer. In 2003 CSIR promised to give a proportion of royalties it receive from Phytopharm to the San community, but in reality San received only 0.003% of total retail sales of the products.

Iboga patent:[28] *Tabernanthe iboga* has been used for long years in Central and West Africa as a stimulant. In larger doses it acts as a hallucinogen. It is traditionally used for these properties by 'shamans'. Now iboga is found to be effective in treatment of drug addiction and quite a few patent application have been made by Myriad Genetics and by Washington University in US and few of them are issued as well.

Patent on Okoume tree resin:[29] In 2004 a French luxury goods maker company, the Dior group was granted US and European patent on Okoume tree resin for its use in cosmetics and pharmaceuticals. This tree is found in Gabon, Congo, Equatorial Guinea and other western-central African countries. Dior group was aware of its traditional uses and even described them in their application. The companies obtaining the resin may be covered by a benefit sharing agreement under Biodivalor project, which is a co-operative agreement set up in 2001, funded by a French group GEF and led by Pro Natura. However no detailed information is available regarding

[24] J Ethnopharmacol. 2002 Feb, 79(2):213-20 and Citation in the Prelude Medicinal Plants Database, available at http://www.metafro.be/prelude/view_symptom?si=H(152 (accessed on 12.11.13).

[25] See Minja, M. M. J. The Maasai Wonder Plants. Paper presented at the People and Plants training workshop, Tropical Pesticides Training Institute, Arusha, Tanzania, 15-18 March 1999, available online at http://www.tanzaniagateway.org/ik/docs/PEOPLEANDPLANTSWKSHP.pdf and Githiori J. Evaluation of Anthelmintic Properties of Ethnoveterinary Plant Preparations Used as Livestock Dewormers by Pastoralists and Small Holder Farmers in Kenya, Doctoral thesis, Swedish University of Agricultural Sciences, Uppsala 2004, available at http://diss-epsilon.slu.se/archive/00000514/01/John_Githiori_Thesis.pdf (accessed on 12.11.13).

[26] Woldedmichael, Worku Abebe., *Some Aspects of Traditional Ethiopian Medicine*, Addis Tribune, 28 Jan 2005.

[27] Wynberg, R., *Sharing the Crumbs with the San*, 2003, BioWatch South Africa, available online at http://www.biowatch.org.za/main.asp?include=docs/clippings/csir-san.htm (accessed on 12.11.13).

[28] US patent 5,616,575; 5,958,919; 6,211,360; Aina Hunter, *Current goings-on with Iboga in the US*, and *The Drug to End All Drugs*, 18 Feb 2005, available at http://www.villagevoice.com/news/0508,hunter1,61311,6.html and *Busted for Iboga*, 20 Dec 2005, URL: http://www.villagevoice.com/people/0551,hunter,71171,24.html (accessed on 12.11.13).

[29] Mapangou, M.P. "Illegal exploitation of Gaboon resin in Gabon", pp. 62-65 in Forest Management Transparency, Governance and the Law, Prepared for the Ministerial Conference on Africa Forest Law Enforcement and Governance (AFLEG), Yaoundé, Cameroon, 13-16 October 2003; IPHAMETRA's website available at http://www.refer.ga/cenarest/recherche/labo/iphametra.htm (accessed on 12.11.13).

distribution of benefits among indigenous communities from Biodivalor's fund.

Brazzein case:[30] Brazzein is a protein derived from West African berry (*Pentadiplandra brazzeana*); it is used as a replacement of natural, low-calorie sweetner as it is many times sweeter than sugar. Researchers of University of Wisconsin have isolated the protein, brazzein, discovered the genetic sequence coding for it and also made the transgenic organisms that produce brazzein in the laboratory. For that they have been granted US patents,[31] and European Patent.[32] West African native communities known this property since ages and used to collect and/or grow this particular type of berry for commercial purpose.

Take Home Message From Case Studies

Here a brief analysis of only few cases has been done because the purview of this article will not permit the detailed analysis of all the existing and past cases of misappropriation of traditional knowledge. In this brief analysis some painful facts have become evident, which are as follows: (1) Patent has been used vastly for misappropriation of traditional knowledge; (2) Offender countries are mostly the industry based developed countries, like USA, European countries, Japan etc; (3) Countries of same region are also doing misappropriation of each other's traditional knowledge. Example is available in Asian countries where Japan misappropriating TK of Philippines, Thailand and Sri Lanka; Singapore misappropriating TK of Malaysia; and China misappropriating TK of India (refer to Table 3.); (4) Even some business house of a country sometimes try to misappropriate domestic TK, the recent case of Natura-Ver-o-Peso of Amazon region (see Section 3.2) is the example of such a circumstances.

These are the factors which have to be taken care of during legislating protection regime for traditional knowledge, especially in the regional or international set up.

Access and Benefit sharing Regime: Proposed Line of Protection for TK

Proposed ABS Regime by CBD

Bonn Guideline, provided by Working Group on Access and Benefit Sharing (Decision VI/24), is intended to provide the access and benefit sharing regime for genetic resource; but this mechanism can be wisely utilized for traditional knowledge and associated GR. According to the CBD, access related activities start with obtaining of prior informed consent. Article 15 of CBD recognised the sovereign rights of States over their natural resources. To facilitate the access each contracting party need to create conditions for this facilitation. CBD's intention is to give guideline or to assist parties to establish a mechanism of PIC.[33] There are some basic principles of PIC[34] which are as follows: (a) legal certainty and clarity have to be there, (b) facilitation is to make possible at minimum cost, (c) any restriction on access should be transparent based on legal grounds and (d) not to be contrary to the objectives of the Convention.

For proper legal regulation of the ABS mechanism, one competent national body should be there as a central regulatory body and should supervise the whole process. According to Bonn Guideline a Competent National Authority should be established "in accordance with applicable national legislative, administrative or policy measures" to grant of access permit, to negotiate between stakeholders and users, to provide PIC and to advise on mutual agreed terms (MAT), to evaluate and enforce ABS agreement, to monitor conservation and sustainable use of GR and TK and to ensure effective participation of different stakeholders particularly traditional and indigenous communities in ABS process.[35] This Competent National Authority would have the legal power to grant PIC after proper assessment of every access application.[36] If relevant traditional community provides the PIC, that will be supervised and approved by the competent national authority.

ABS Regime given by FAO

Commission on Genetic Resources for Food and Agriculture in its twelfth session in 2009 has provided the Policies for Access and Benefit Sharing for GR for Food and Agriculture. Part IV of this document deals specifically with the provisions of access and benefit sharing which is termed as the 'Multilateral System' (MLS). It follows closely the CBD objectives and provisions. Article 10.1 calls for

[30] ETC Group, "Biopiracy - RAFI's Sixth Annual Update" May 11, 2000, at http://www.etcgroup.org/article.asp?newsid=174 (accessed on 12.11.13).

[31] US Patent Nos.5,362,580, 5,346,998. 5,362,580, 5,346,998 and 5,741,537.

[32] European Patent No. 648995.

[33] Paragraph 24 of Decision VI/24

[34] Paragraph 26 of Decision VI/24

[35] Paragraph 14 of Decision VI/24

[36] Paragraph 15 of Decision VI/24

the contracting parties to recognize the sovereign rights of the State on their plant genetic resources (PGR). Importance of facilitated access to the PGR is established.[37]

ABS Regime proposed by WIPO

WIPO IGC group is also working on the principle of 'easy access and fair and equitable benefit sharing'; Policy Objective of Document prepared in Sixteenth Session clearly mentioned that PIC should be obtained before access to GR and TK in accordance with the existing national and international regime. PIC here is undertaken as an enforcement mechanism for the development of effective legal measure against misappropriation. According to Article 1.3 (ii), PIC is to be regarded as a condition of access to the traditional knowledge and that will be helpful in organizing regulatory instrument for prevention of misappropriation of traditional knowledge. Article 7 further elaborate that objective and PIC is recognized as a central legal principle to policy debate and measures concerning TK protection. Article 7 gives importance on providing prior information to the TK holders about potential exploitation of TK and for the proposed use TK holders need to give consent. The mechanism should be implemented properly, with the legal certainty; at the same time it should be flexible to adapt the principle to the national legal system.

ABS provision in National Legal Regime

Brazilian Provision

Brazilian law facilitates the access to and transfer of knowledge and technology and it is intended for preservation of knowledge. In Brazilian law with access they include transfer of technology also. Here the purpose of access has been emphasized, to promote the scientific research and technological development Brazilian law introduced incentive policy in their legislation. In regards to benefit sharing mechanism Brazilian law provides regulations and relevant legislation (Chapter VII) which could support fair and equitable benefit sharing arising from economic exploitation of a product a process developed from genetic heritage and associated TK. This law emphasis on some other points in relation with derived benefits, like: (a) Division of profits (b) Payments of royalties (c) Technology access and transfer (d) Unrestricted licensing of products or services (e) Training of human resource

If terms and conditions are not fulfilled accordingly, this law has provisional measures to levi the payment of an indemnity equivalent to a minimum of 20% of the gross invoiced amount; obtained through the marketing of the product or of royalties obtained from third parties as a result of the licensing of the product or the process or the use of technology, whether or not protected by IPR. Parties of the contract for use of the genetic heritage and benefit sharing are owner of the public or private area or the representative of the indigenous community and official indigenous body and the national institution authorised to have access. This law has following essential clauses in the contract use of genetic heritage and benefit sharing: (a) Purpose, elements, quantification of samples and intended use (b) Duration (c) Method of fair and equitable benefit sharing and access to and transfer of technology (d) Rights and responsibilities of the parties (e) IP rights (f) Cancellation (g) Penalties (h) Jurisdiction in Brazil

These contracts are needed to be submitted to the management Council for registration and it can effective after approval. If terms and conditions are not fulfilled in accordance with law, said contracts can be null and void as legal effect.

Provision by African Union (OAU)

In OAU model law 2000, African union elaborately framed the criteria for application of access to TK. To set the criteria of access OAU model starts with necessary consent and written permit to access any biological resource, community knowledge or technology directed by the national competent authority. This access application is concerned about the potential risk arise from access to GR and also about the nature of benefit i.e. economic, social, technical, biotechnological, scientific environmental. They also put emphasis on environmental and socio-economic impact assessment for at least coming three generations, and this is nothing but a part of risk assessment. OAU model totally contemplate on the involvement of local community for PIC with national competent authority. Without local community involvement this access deemed to be invalid and subject to the penalty. So, for any grant of access their principle requirement is the decision of the local community. After completion of the application, the national competent authority used to publish the said application in the public registry or gazette or newspaper. So, any person may consult with the public registry and comment on the application. It is denoted as an effective dissemination of the relevant information on

[37] Article 12 of CRGFA says about facilitated access to plant genetic resources for food and agriculture within the Multilateral System.

traditional knowledge associated genetic resources. They grant access permit after PIC for specified time period.

According to Section 12 of African Model law, after grant of access permit and before starting of collection activities, the user is to make payment of a sum; the amount of the sum will be dependent on the purpose of access (whether commercial or non-commercial), number of samples collected, area of collection, duration of collection and the rights provided to the collector (whether exclusive right is provided or not) (Section 12.1). The payment collected will then be shared between the community or communities and the State (Section 12.2).

Indian Provision

In Indian Biological Diversity Act 2002 no definition is provided for the terms 'access' and 'prior informed consent' which is a loose end of the knot. The term 'prior informed consent' never expressly mentioned even anywhere in the Act, which is recognised as a core component of the access mechanism. Whether the term 'access approval' can be understood as synonymous to 'PIC' is left for the individual discretion, which may create some confusion and ambiguity. Under Indian Biological Diversity Rules 2004, approval for access to GR and associated knowledge for research and for commercial utilization is granted by the national authority. According to the merit of the application, the authority may grant the approval for access to GR and associated knowledge with relevant terms and conditions, and this approval is a written agreement. Ingredients of the agreement are as follows: (a) General objective, purpose of application, description of biological resource, and intended use of biological resource; (b) In case of any question of intellectual property rights, conditions need to be mentioned explicitly; (c) Nature of benefit need to be mentioned, fresh agreement is needed for any change in intended use; (d) Third party transfer without approval of the traditional community is restricted; (e) Regarding genetic resources (which is associated with traditional knowledge) if accessed the quantity and quality of that material have to be specified and quantity will be limited to a certain extent. Reference sample of the genetic resource have to be deposited as well; (f) Regular status report of research is to be submitted to the national authority; (g) Minimization of environmental risk and measures for conservation and sustainable use of the related genetic resource is another important point; (h) Provisions for specific duration of the agreement, notice regarding termination of agreement and provision of benefit sharing obligations are the other requisites; (i) Application if rejected by the national authority, has to accompany proper reasons and before rejection applicant must get opportunity of being heard;

Revocation of approval is to be based on specific ground like violations of the provisions of the Act or failure of the applicant to comply with the terms and conditions of the agreement or activity against public interest or against environmental protection. Separate approval is needed for transferring of results of research to a third party or before application of intellectual property rights for the said research.

Section 21 of Biological Diversity Act India 2002, deals with the provisions of benefit sharing. According to this section, equitable sharing of benefits arising from use of the biological resources, their by-product, innovations, practices and application of related knowledge, is to be included in the 'mutually agreed terms' (MAT); the terms and conditions will be approved by the National Biodiversity Authority (NBA), concerned local bodies and the stakeholders (Section 21.1). But in Section 21 of the Act though the issue of benefit sharing is addressed but lots of clarification is needed. Benefit sharing arrangement in its capacity may include all or some of the matters where benefit claimers are identified. In Section 21(2)(d) the phrase 'benefit claimers and the local people' is mentioned; but when protection of traditional knowledge is in concern the actual benefit claimers are the traditional communities, which is not specified by the phrase 'benefit claimers and the local people'. NBA is flexible to 'grant joint ownership of intellectual property rights to NBA or ..... such benefit claimers'; but it is to be decided definitively whether this provision is relevant for protection of traditional knowledge associated with genetic resources. There is some confusion regarding type of benefits to be shared; in Section 21(2)(f) it is mentioned as 'monetary compensation' and 'other non-monetary benefits' but needs to be more specified in the national legal regime to provide legal certainty. Biological Diversity Rule 2004 mentioned about 'benefit sharing formula'[38] which is also not defined and clarified; actual meaning and scope of the term has to be specified in the statute for its proper utilization for development of traditional community. The benefit sharing formula has to be determined as a case-by-case basis[39], as per the requirement of the

[38] Rule 20(1) of Biological Diversity Rule 2004 of India

[39] Rule 20(3) of Biological Diversity Rule 2004 of India

situation, but some general provisions would be better as a guideline which can minimize the controversy and confusion. It is specified in the Rule that '5% of the assessed profit has to be given to the Authority or Board' as 'administrative or service charges'[40] but there is no specific percentage mentioned for the traditional community people who are the actual benefit claimers in case of access of traditional knowledge associated with genetic resources. Transfer of result is included within the ambit of benefit sharing; for which the approval is needed from the National Biodiversity Authority. Benefit sharing arrangement can facilitate the better living standard to benefit claimer specifically in such areas where research and development unit or production unit is established; Indian scientists can evaluate BS arrangement through bio-survey with benefit claimers and association of Indian scientists can assess different level of R&D in bio-resources and bio-utilization. Adequate valuation process can protect best interest of benefit claimers. NBA is the deciding authority to determine monetary and/or non-monetary benefit to benefit claimer (Section21.2). NBA has the authority to direct the amount of money out of benefit sharing to be deposited in the NBA fund and dissemination of fund also done by NBA. To regulate this benefit sharing fund NBA is needed to consult Central Government with required regulations and guidelines (Section 21.3). According to Biological Diversity Rules of India, 2004 there are some criteria for equitable benefit sharing complementary to Biodiversity Act 2002 (Rule 20). This guideline provide monetary and other benefits such as royalty, joint ventures, technology transfer, product development, institutional capacity building which includes education awareness raising activities and valuation system. On case by case basis, formula for benefit sharing shall be determined and stipulated time frame for assessing benefit sharing also determined by the authority; authority may impose terms and conditions for any applicant to transfer the result of the research relating to biological resources. Authority may impose the terms and condition for ensuring equitable benefit sharing which includes third party transfer of accessed biological resource and associated knowledge. Benefit sharing rose out of used biological material and associated knowledge on the basis of mutually agreed terms between applicant and the authority in consultation with local bodies and benefit claimers. Terms are decided in due regards to defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels which will consider conservation and sustainable use of biological diversity. Authority may reject an application for considerable reason.

The traditional Knowledge (Protection and Regulation to Access) Draft Bill 2009 mentioned that to restrict misuse and misappropriation of traditional knowledge there is a need to adopt benefit sharing mechanism.

Gap analysis of national legislations and comparison with Indian regime

After analysing important national legislation on protection of TK and associated GR, it is evident that traditional community involvement is the most expected criteria, mentioned explicitly in African and Indian law, but it is not there in Brazilian law. African law talks about traditional community involvement at a larger level because they invalidate the access permit and put penalties if access is taken place without consent of traditional communities. The uniqueness of Brazilian law in this context is the provision for incentive to promote research and development. In terms of access permit or access approval stakeholders should negotiate for access to TK and associated GR with license agreement. In case of Brazilian law the terms and conditions of the access application and detailed procedure is not discussed in their legal regime. Regarding the criteria and procedure of access mechanism, African Union Model law and Indian Biodiversity Rule is very close to each other. The only difference is the degree of engagement or attachment of traditional community. African Union is much more concerned about this for decision making on access to TK and associated GR. Both the countries' legislation elaborately described the procedure of access mechanism and terms and conditions for each and every step. Both the country has rejection and revocation provision for access application when the access activities are contrary to the national interest. There is another difference between African law and Indian law, i.e. African law is strictly prohibiting the IPR on TK and associated GR, but Indian law is having provision for assessment the merit of the application of IPR.

Biodiversity Act 2002 and Biodiversity Rules 2004 of India and Brazilian Law No 2.186-16, 2001 provides elaborate guideline of benefit sharing mechanism with all required criteria of mutually agreed terms (contract as per Brazilian law). Still some limitations are there, which may create some form of legal ambiguity and uncertainty. IP rights on inventions related to traditional knowledge and

[40] Rule 20(9) of Biological Diversity Rule 2004 of India

associated genetic resource is acceptable in both Indian and Brazilian law, though the party has to take the special approval from the representative of traditional community and relevant competent national authority. Grant of existing IPR in relation to traditional knowledge is still a controversial aspect, so acceptance of IPR for invention based on TK might create another debate and might make the whole system unacceptable for the traditional or indigenous communities. Whether a certain specific percentage of the shared benefit is to be channelized directly to the traditional community is not specified in Indian or Brazilian law, though it is specially mentioned in the Peruvian law. African Model law and Peruvian law is surprisingly brief in its statutory provisions regarding benefit sharing, only few points have been mentioned in both of them regarding benefit sharing. TK Draft Bill India 2009, on the other hand hardly mention about requirement of benefit sharing, no specific mention is there about the process and procedure of the benefit sharing mechanism. It is better if the minimum standard amount of monetary benefit sharing is mentioned in the legislation; the upper limit will vary according to the other specification and can be settled as per case by case basis. To become a model legislation for protection of traditional knowledge associated genetic resources, Indian legal regime has to incorporate all the necessary changes suggested in this chapter taking relevant important points mentioned in the other national regimes and ensure a legally implementable and transparent benefit sharing system to protect India's vast traditional knowledge and at the same time to help Indian traditional communities get proper recognition and remuneration for their age-old effort.

Regional Approach of TK Protection

Traditional knowledge is often shared by the communities of the neighbouring countries. So regional regime is a better option for protection of traditional knowledge as that will ensure the better protection of the rights and interests of different communities residing in different countries in the same region having same or similar traditional knowledge.

ASEAN

South East Asian Countries have joined together for formation of Association of South Asian Nations (ASEAN)[41] and this Association has made a Framework Agreement on Access to Biological and Genetic Resources in 2000,[42] with the aim of ensuring the uniform and consistent access regulation throughout ASEAN region with maintenance of minimum standards which has to be followed by all the Member Countries (Article 2). It recognizes the potential of traditional knowledge of indigenous and local communities and want to facilitate fair and equitable benefit sharing if the TK is used (Article 2). Scope of this Agreement is to cover the traditional knowledge related to genetic resources only (Article 4). It is specifically mentioned that if access is permitted for genetic resources that does not mean access is also permitted for related TK as well – explicit mention for access to TK has to be mentioned (Article 4). It does not allow the application for IPR, nor the patenting of plant or animal genetic resources or associated knowledge (Article 4). Regional clearing house mechanism has been proposed for coordination between users and relevant competent national authorities and it is aimed to serve as an information node for all the Member States (Article 7). Main components of access and benefit sharing mechanism is incorporated well in this Agreement; PIC has to be taken through competent national authorities with active involvement of indigenous and local communities, though procedure of availing PIC will be determined by the individual Member States in compliance with customary law and practice (Article 10). Member States are suppose to provide proper legal instrument to ensure fair and equitable benefit sharing after use of TK (Article 11); benefit sharing may be in the form of monetary or non-monetary as per the minimum standard of the Framework (Article 12). Other relevant factors like Biosafety, environmental risk and social impact as well as dispute resolution between two Member States have been properly addressed (Article 13 and Article 9 respectively).

SAARC

Other than ASEAN community, South Asian Association for Regional Cooperation (SAARC)[43] is

[41] ASEAN community is formed by following Asian countries: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam; official website is http://www.aseansec.org/index2008.html (accessed on 12.03.13).

[42] Full text of the Agreement is available online at http://ictsd.org/i/ip/legal-instruments/3598 (accessed on 12.03.13).

[43] SAARC is formed by association of 8 south Asian countries, namely, Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka; its official website is http://www.saarc-sec.org

also working in South Asia with the aim of developing a regional consensus on the legal system for protection and conservation of traditional knowledge. SAARC forum for IP Cooperation is formed in Thimpu in October 2002 which is now giving emphasis on formulating a model legal mechanism for protection of TK from misappropriation. Sui generis system of protection is suggested with creation of a distinct IP right for TK to exclude unauthorised users from certain specified acts. Access and benefit sharing mechanism is suggested to be the part of the sui generis model to stop unfair competition and it has to be developed using the references from the customary law and protocols as far as possible.[44]

ANDEAN

ANDEAN treaty is a regional economic, social and political integration treaty of Latin America, signed in 1969; Member states are Bolivia, Colombia, Ecuador, Peru, Venezuela (originally Chile was a member state, now an associate state with Panama). This region is one of the most biodiversity rich areas in the world, with high concentration of indigenous peoples. Treaty originally focused on lowering trade barriers and harmonizing phyto-sanitary measures. Decisions and Resolutions are the main legal instruments approved by the Community; Decisions prevail over national legislation and they usually approve "common legal regimes" applicable to all member states. Decision 391, a Common Regimen on Access to Genetic Resources passed in 1996, where TK has been recognized as critically important for indigenous people's livelihood and ultimate survival. Indigenous people have been provided with the right to determine how and under what conditions TK is accessed and use; contracts are chosen as the main tool to establish obligations and rights between indigenous people and interested users; defensive protection is recognized. The mandate to develop a specific sub-regional regime is also proposed on TK protection. Decision 486 (2001) established the defensive protection mechanism of TK. As per Decision 524 of 2002, Indigenous Peoples Working Group started making the draft elements for a common regime for TK protection. Important factors chosen are as follows: (i) Need for time and bottom up approaches to ensure inputs and effective participation from indigenous peoples; (ii) Need to involve IP authorities and a wide range of stakeholders; (iii) Need for strong capacity building for key actors, including indigenous people; (iv) Importance of clear scope for TK protection policies and laws like, What is to be protected? From what is protection needed? How will rights be assigned? etc.[45]

ARIPO

African Regional Intellectual Property Organization (ARIPO) is an organization formed with the aim of promoting harmonization of intellectual property law and development of IP related activities among the member states[46] and thus to strengthen the IP law in the region. In 2000, the Council of Ministers of ARIPO had began their initiative of formulating the legal regime for protection of traditional knowledge and expression of folklore.[47] On August 9, 2010 Swakopmund Protocol on the Protection of Traditional Knowledge and Knowledge and Expressions of Folklore is adopted within the framework of the African Regional Intellectual Property Organization (ARIPO) by the Diplomatic Conference of ARIPO at Swakopmund (Namibia). The Protocol recognizes the *"the intrinsic value of traditional knowledge, traditional cultures and folklore, including their social, cultural, spiritual, economic, intellectual, scientific, ecological, agricultural, medical, technological, commercial and educational value;"*[48] and put forward the concern for

[44] See Summary of Discussions and Consultations, *WIPO/SAARC Expert Workshop on Intellectual Property and Genetic Resources*, New Delhi, November 2003 (WIPO-SAARC/GRTK/DEL/03/xx)

[45] Manuel Ruiz Muller, *A Regional Approach to the Protection of Traditional Knowledge: the Case of the Andean Community*, (2008) at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtk_kin_08/wipo_grtk_kin_08_presentation08_3.pdf

[46] According to Article IV of the Lusaka Agreement that created ARIPO, membership to the Organization is open to states members of the United Nations Economic Commission for Africa or the African Union (AU). There are currently sixteen states which are party to the Lusaka Agreement and therefore members of ARIPO. These are: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe (Total: 18 Member States).

[47] See ARIPO website, at http://www.aripo.org/index.php/services/traditional-knowledge (accessed on 01.11.13).

[48] Clause 4 of Preamble of Swakopmund Protocol, at http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf (accessed on 01.11.13).

"gradual disappearance, erosion, misuse, unlawful exploitation and misappropriation of traditional knowledge and expressions of folklore".[49] The Protocol aims to *"encourage and reward authentic creativity and innovation resulting from traditional knowledge systems and expressions of folklore, and to promote innovation, creativity and the transfer of technology to the mutual benefit of society, holders and users of traditional knowledge,"*[50] at the same time provide suitable protection for traditional knowledge in such a way that " *protection must reflect the need to maintain an equitable balance between the rights and interests of those who develop, preserve and maintain traditional knowledge and expressions of folklore, and those who use and benefit from such knowledge."*[51] This Protocol provides a guideline for access (s 15) and equitable benefit sharing (s 9), the definition of traditional knowledge (s 2.1), and also rights conferred to the holders of traditional knowledge (s 7). The Protocol provides a model for national legislative development. ARIPO wants to assess the African position for the framework provided by IGC and also wants to address trans-boundary traditional knowledge protection in an user friendly way.

Inter-regional Approach

NAASP

Now there is a need for co-operation between different regional bodies to reach in a global consensus for the protection of TK. This kind of approach is initiated by the formation of New Asian African Strategic Partnership (NAASP)[52] which is adopted in Bandung, Philippines in 2005. It is adopted specially for the protection of TK, GR and TCE by proper access regulation to get maximum benefit sharing for the holder community and country. It specifies the urgency of establishment of internationally accepted legally binding sui generis mechanism of protection for TK, GR and TCE.

BRICS

Idea of BRIC[53] formation has been conceived by Goldman Sachs in 2001 including Brazil, Russia, India and China for economic betterment of these countries. In 2010 South Africa invited to join the group to form BRICS. This group is formed with the aim of discussing the current situation of global economy and to do betterment in terms of development by strengthening the collaboration and joint activities in the field of financial and economic reform. Poverty alleviation, debt relief, market access, technology transfer, food security, increment of energy efficiency, environment protection, reduction of risk of natural disaster are the key issues for BRICS. Protection and proper utilization of traditional knowledge would be a good agenda to achieve some of these goals, specifically for poverty management, food security, environment protection and reduction of risk of natural disaster.

International Efforts for Traditional Knowledge Protection

Convention on Biological Diversity (CBD) is the first international body to provide the access and benefit sharing regime (ABS regime)[54] but that was for the protection of genetic resources, not for traditional knowledge. ABS regime is again consolidated in Nagoya Protocol which is adopted in Nagoya, Japan on October 2010.[55] TRIPS Agreement is silent about protection of traditional knowledge though it suggested about the sui generis system of protection for plant varieties.[56] In the international community, a long term debate is undergoing regarding compatibility of provisions of TRIPS Agreement and objectives of CBD. The core element of this discussion is lack of recognition of the objectives of CBD and the need to incorporate those objectives

[49] Clause 8 of Preamble of Swakopmund Protocol, at http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf (accessed on 01.11.13).

[50] Clause 15 of Preamble of Swakopmund Protocol, at http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf (accessed on 01.11.13).

[51] Clause 13 of Preamble of Swakopmund Protocol, at http://www.cbd.int/doc/measures/abs/msr-abs-aripo-en.pdf (accessed on 01.11.13).

[52] See "Bandung Declaration on the Protection of Traditional Cultural Expressions, Traditional Knowledge, and Genetic Resources" submitted in Eleventh Session of WIPO IGC in Geneva in July 2007 (WIPO/GRTKF/IC/11/12)

[53] See http://www.bricsindia.in/index.html (accessed on 08.08.13)

[54] CBD COP6 Decision VI/24, Bonn Guideline, Chapter IV available http://www.cbd.int/decision/cop/?id=7198 (accessed on 14.03.13)

[55] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, available at* http://www.cbd.int/abs (accessed on 14.03.13).

[56] Article 27.3(b) of TRIPS Agreement, available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (accessed on 14.03.13).

into the text of the TRIPS Agreement. According to Article 16(5) of CBD *"the Contracting Parties, recognizing that patents and other IP rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives"*. In the view of TRIPS binding nature it is well understood that the essence of non-compliance between TRIPS and CBD objective is included in this way in the text of Article 16(5). As recognition of CBD objective is important for TK protection, so there is a need to highlight this debate here. The implementation of TRIPS Agreement is affecting the fulfilment of CBD objectives in different areas like, dominance of private rights over public rights; recognition of patent and other IP rights using TK and associated GR without prior informed consent (PIC) and benefit sharing arrangements; and lack of acknowledgement over alternative knowledge and innovation system (of which TK is a part) and no respect for the holders of that knowledge. Views regarding compatibility between CBD & TRIPS can be divided into four broad categories: (a) There is no conflict between these two instruments and they can be implemented in a mutually supportive way. This is the view of most developed countries like USA,[57] Australia,[58] Japan,[59] Canada;[60] and according to this view the scope and subject matter of these two Agreements are different; implementation of both can be pursued in separate frameworks; no reference of specific clash has been cited; sovereignty of States over biodiversity and GR, and ABS mechanism is not influenced by patent system; and existing patentability criteria is foolproof even for grant of patents on invention related to biodiversity and GR. It has been suggested that conservation of biodiversity and implementation of benefit sharing mechanism can be done by voluntary contractual basis and protection of undisclosed information will help in this.[61] (c) There is no conflict and they can be used in mutually supportive way in national regime but further discussion is needed to decide whether any international action is required for patent system. This view is coming up also from some developed countries like USA, Japan, Korea, Australia, Canada[62] and as per their communication to WTO, minimal material evidence have been put forward from national level to prove that ABS system is not providing proper protection from misappropriation of GR[63] and if really there is any problem that can be sorted out by administrative measures other than IP rules like information sharing between patent offices and establishment of database.[64]

(a) Third view suggests there is no inherent conflict between these two instruments but during their implementation international action is needed for increasing mutual supportiveness and to reduce chances of potential conflict between them. This view is expressed by a number of developing countries and few developed countries, including Andean Community,[65] Brazil,[66] China,[67] Colombia,[68] Ecuador,[69] EC,[70] Egypt,[71] India,[72] Indonesia,[73]

[57] IP/C/W/209, IP/C/W/162, IP/C/W/434, IP/C/W/257, IP/C/M/43, IP/C/M/42, IP/C/M/46, IP/C/M/25,

[58] IP/C/W/310, IP/C/M/47, IP/C/M/46, IP/C/M/40, IP/C/M/38, IP/C/M/36/Add.1

[59] IP/C/W/236, IP/C/M/47, IP/C/M/39, IP/C/M/26, IP/C/M/25,

[60] IP/C/M/47, IP/C/M/40, IP/C/M/37/Add.1, IP/C/M/36/Add.1,

[61] United States, IP/C/W/434, IP/C/W/257, IP/C/M/30,

[62] IP/C/W/209, IP/C/W/162, IP/C/W/434, IP/C/W/257, IP/C/M/43, IP/C/M/42, IP/C/M/46, IP/C/M/25, IP/C/W/310, IP/C/M/47, IP/C/M/46, IP/C/M/40, IP/C/M/38, IP/C/M/36/Add.1, IP/C/W/236, IP/C/M/47, IP/C/M/39, IP/C/M/26, IP/C/M/25, IP/C/M/47, IP/C/M/40, IP/C/M/37/Add.1, IP/C/M/36/Add.1

[63] Australia, IP/C/M/46, para. 65, IP/C/M/40, para. 101; Canada, IP/C/M/47, para. 66, IP/C/M46, para. 55, IP/C/M/40, para. 115; New Zealand, IP/C/M/47, para. 54, IP/C/M/46, para. 61.

[64] Australia, IP/C/M/40, para.101; Canada, IP/C/M/40, para. 115.

[65] IP/C/M/37/Add.1, para. 231;

[66] IP/C/W/228, IP/C/M/48, para. 35, IP/C/M/32, para. 128, IP/C/M/29, paras. 146, 148 and 234, IP/C/M/28, para. 135, IP/C/M/27, para. 122;

[67] IP/C/M/47, para. 57, IP/C/M/42, para. 119, IP/C/M/39, para. 132, IP/C/M/38, para. 239, IP/C/M/37/Add.1, para. 229, IP/C/M/36/Add.1, paras. 227-228;

[68] IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209;

[69] IP/C/M/47, para. 49, IP/C/M/25, para. 87;

[70] IP/C/W/383, IP/C/W/254, IP/C/M/48, para. 62, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 226, IP/C/M/35, para. 233;

[71] IP/C/M/37/Add.1, paras. 203-204, IP/C/M/36/Add.1, para. 215;

[72] IP/C/W/198, IP/C/W/195, IP/C/M/48, para. 53, IP/C/M/38, para. 232, IP/C/M/36/Add.1, para. 212, IP/C/M/30, para. 169, IP/C/M/24, para. 81;

[73] IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217, IP/C/M/32, para. 135;

Kenya,[74] Norway,[75] Pakistan,[76] Peru,[77] Philippines,[78] Switzerland,[79] Thailand,[80] Turkey,[81] and Venezuela.[82] These countries' suggestion is to include disclosure of origin in the patent application especially when invention is related to TK or associated GR and they called for international action on that. They also suggested that in clear language that if any inventions include genetic resource or traditional knowledge, the source and country of origin is to be disclosed and it is to be furnished that PIC from competent national authority has been taken from the country of origin and there is fair and equitable benefit sharing arrangements.[83] Switzerland's opinion is to include the 'disclosure of origin' criteria into international patent application for invention on TK or GR in PCT of WIPO[84] at the earliest possible time. EC suggested that origin or source of the genetic material has to be made mandatory for all patent applications at national, regional and international level and there has to provision of penalties for non-compliance to the legal provisions.[85] In case of international applications, if patent application has to have the disclosure of source of origin, regulations of the PCT is to be amended to incorporate that requirement; moreover in that case it is necessary that declaration of source is to be made publicly available at earliest possible time.[86] It can be implemented only by co-operation of CBD, WIPO, FAO and WTO.

(b) There is inherent conflict between the two and TRIPS Agreement need to be amended to minimize the conflict; this view is reflected in some communications by developing countries; among the developed countries European Community is supportive for this view.[87] To hold up this view they referred that according to TRIPS Agreement patenting of certain genetic resources are possible and that is very much contrary to the CBD principle of States' sovereignty over genetic resources and traditional knowledge and the access and benefit sharing mechanism proposed by CBD.[88] Two proposals are put forward to sort out this ambiguity; TRIPS Article 27.3(b) be amended to make all the life forms or their parts non-patentable,[89] but this proposal is not very much accommodative for the TK protection. Other proposal is directly beneficial for TK. That is amendment of TRIPS Agreement in such a way that invention based on traditional knowledge or its products or processes related to its derivatives should be excluded from patenting and any application inconsistent to Article 15 of CBD should not be granted.[90] Concern has been raised about erroneously granted patents and it has been justifiedly stated that post-grant opposition and re-examination is a necessarily lengthy and costly procedure which could possibly be avoided by provisions of stricter

[74] IP/C/M/47, para. 68, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144;
[75] IP/C/W/293, IP/C/M/38, paras. 241-242, IP/C/M/32, para. 125;
[76] IP/C/M/36/Add.1, para. 211;
[77] IP/C/M/48, paras. 92-93, IP/C/M/36/Add.1, para. 203;
[78] IP/C/M/47, paras. 79-80;
[79] IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/48, para.16;
[80] IP/C/M/48, para. 61, IP/C/M/42, para. 105, IP/C/M/25, para. 78;
[81] IP/C/M/47, para. 63, IP/C/M/27, para. 132;
[82] IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165
[83] IP/C/W/368/Rev.1 para 14
[84] IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115, IP/C/M/46, para. 22, IP/C/M/45, paras. 47-48, IP/C/M/44, para. 25, IP/C/M/42, paras. 97 and 99, IP/C/M/40 para. 71.
[85] IP/C/W/383, IP/C/W/254, IP/C/M/35, para. 234, IP/C/M/30, paras. 144 and 146
[86] Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115, IP/C/M/46, para. 22, IP/C/M/45, paras. 47-48, IP/C/M/44, para. 25, IP/C/M/42, paras. 97 and 99, IP/C/M/40 para. 71.
[87] IP/C/W/383, IP/C/W/254, IP/C/M/48
[88] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163; Brazil, IP/C/W/228, IP/C/M/48, para. 37, IP/C/M/29, paras. 146 and 148; IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/356; Colombia, IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; EC, IP/C/W/383, IP/C/W/254, IP/C/M/48, para 63, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 226, IP/C/M/35, para. 233; India, IP/C/W/198, IP/C/W/195, IP/C/M/48, para.52, IP/C/M/36/Add.1, para. 212, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Peru, IP/C/W/447, IP/C/M/48, paras. 18-19; Thailand, IP/C/M/48, para. 61, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.
[89] African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76 and 107, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Bangladesh, IP/C/M/42, para. 103; Zambia, IP/C/M/28, para. 147.
[90] India, IP/C/W/196, IP/C/M/37/Add.1, para. 224, IP/C/M/25, para. 70.

patentability criteria[91] and by *"searchable database of knowledge, innovation and practices of local and indigenous community"*.[92]

Two approaches have been taken about the solution of the conflict issue: one is the national based approach and the other is to include the 'disclosure' requirement in patent application. USA is the main voice behind 'National Based Approach' and they suggested for use of contract system in national legislation for authorised access by PIC and access permit and imposition of civil or criminal penalties. Contract system, as per USA, can also be effectively used for establishment of rights and obligations of both parties, imposition of transfer and sharing of benefits and monitoring of the same; and inclusion of mandatory disclosure of source or origin to competent authority.[93] According to this view the advantages would be, it is easily accustomed in country's national legal regime as every country has its contract law therein; valuable time and cost will be saved if new legal regime is not enforced and access and benefit sharing system can be started for protection of TK and related GR with an immediate effect; it can provide the criminal or civil remedies for non-compliance with the legal obligations. Contract system can provide necessary flexibility ensuring benefit sharing arising out of commercialization of TK and associated GR.[94]

Second approach as a solution is the 'Disclosure Approach; three different proposals have been given.
a) The TRIPS disclosure proposal – Amendment of TRIPS Agreement to include source and country of origin of TK and associated GR, evidence of PIC from the competent national authority of the source or origin country and evidence of fair and equitable benefit sharing arrangement according to available in the patent application.[95] Member countries need to make it mandatory[96] in their national legal regime, and implementation of the same by providing evidence. If no national legal regime is available then also applicant should have at least consent from the community or the capable authority. Documents have to be handed over within stipulated time period and non-disclosure or wrong disclosure will be associated with the penalties.[97] For legal effect of this amendment the suggestions of developing countries suggested:
1. Amendment of Article 27 of TRIPS Agreement to include another exception of patentability [98] by the following wording:
"[Members may also exclude from patentability]:
(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.
Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity."
2. Another proposal is amendment of Article 29,[99] alternative text is also proposed:
"Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."[100] or

[91] Switzerland, IP/C/M/30
[92] Switzerland
[93] United States, IP/C/W/434, IP/C/M/46, para.31, IP/C/M/37/Add.1, para. 235
[94] United States, IP/C/W/434, IP/C/M/46, para. 31, IP/C/M/37/Add.1, para. 235
[95] African Group, IP/C/W/404, IP/C/M/40, para. 76; Andean Community, IP/C/M/37/Add.1, para. 231; Brazil, IP/C/W/228, IP/C/M/46, para. 81, IP/C/M/42, para.101, IP/C/M/39, para. 126, IP/C/M/38, para. 230, IP/C/M/37/Add.1, para. 237, IP/C/M/36/Add.1, para. 219, IP/C/M/33, para. 121, IP/C/M/32, para. 128, IP/C/M/29, paras. 146 and 148; IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/403, IP/C/W/429/Rev.1, IP/C/W/356; India, IP/C/W/198, IP/C/W/195, IP/C/M/45, para. 25, IP/C/M/42, para. 113, IP/C/M/40, paras. 81-82, IP/C/M/36/Add.1, paras. 212 and 214, IP/C/M/30, para. 169, IP/C/M/24, para. 81;
[96] Brazil, IP/C/M/47, para. 25.
[97] Brazil et al, IP/C/W/438, IP/C/W/429/Rev.1, IP/C/W/403; India, IP/C/M/46, para. 40, IP/C/M/45,paras. 22-23.
[98] Brazil, IP/C/W/228, IP/C/M/33, para. 121, IP/C/M/32, para. 128; Peru, IP/C/W/447, IP/C/M/48,para. 20
[99] African Group, IP/C/W/404, IP/C/M/40, para. 76; China, IP/C/M/40, para. 121; Colombia, IP/C/M/40, para. 127; Cuba, IP/C/M/40, para. 117; India, IP/C/W/195, IP/C/M/24, para. 81; Peru, IP/C/W/447, IP/C/M/48, para. 20; Zimbabwe, IP/C/M/40, para. 76.
[100] African Group, IP/C/W/404.

"Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted."[101]

3. Introduction of a new Article in TRIPS Agreement.[102]

4. Proper interpretation of Article 29.[103]

b) PCT disclosure proposal: Patent Co-operation Treaty (PCT) of WIPO regulates the international patent applications and Switzerland proposed the requirement of disclosure of origin and source of GR and TK to be included in PCT applications related to that TK and GR.[104] The declaration of source of origin is to be incorporated in the international patent application, according to Swiss suggestion it will not be mandatory but it will depend upon the discretion of the Member Country's Government to incorporate it into the national legal regime. Once undertaken in the national regime, then it will be compulsory for patent applications applied for that country for inventions based on TK and GR to provide declaration of source of used TK and GR. The voluntary nature of this proposal is helpful to achieve experience on the implementation of this new requirement without problem for further international discussion and obligation. Once it is submitted, within stipulated time period it is to be finalised, provided that it is reasonably without a doubt in its wording. Post grant level if it is found that no disclosure document is there or more importantly, some wrong information has been submitted, then validity of that patent can be reviewed by the Member country and can be revoked.[105] Patent offices, on receiving patent application having declaration of source, will in turn inform relevant competent national authority, so that national authorities need no to keep an eye on patent applications worldwide.[106] The advantages claimed are formation of a legal base at international level to converge to the ABS system, provision of flexible and effective national law and mutual supportiveness between related international agreements, like TRIPS Agreement, Bonn Guideline by CBD and International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA) of FAO.

c) Mandatory disclosure approach: EC suggested[107] this proposal in WIPO IGC, which calls for all national governments to include requirement of disclosure of country of origin or source of TK and/or GR in all patent application, if such TK or GR is used in that invention. Special mention about the following: TK has to be defined properly; this requirement should be have binding nature and should be applied to all national, regional and international application, disclosure of origin and source is to be done as early as possible in the procedure of patent application. Submission of wrong information is to be associated with civil or administrative remedies as available in that national legal set up. PIC and other BS measures is to be followed strictly in the application, patent office will notify a central body about the receipt of application, regarding dissemination of information either that central body will work in co-ordination with relevant competent national authorities (list of such authorities would be maintained in WIPO and CBD) or clearing house mechanism can be started by the central body.[108]

WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in taking care of the preparation of a sui generis legal regime for protection of traditional knowledge; this is still under process and debate and discussion is still going on. In the 24th Session of IGC it has submitted its most recent document "The Protection of Traditional Knowledge – Draft Articles" on April 2013.[109] This is going to be discussed by the participating members. WIPO IGC group was working on the principle of 'easy access and fair and equitable benefit sharing'; Policy Objective of Document prepared in Sixteenth Session clearly mentioned that PIC should be obtained before access to GR and TK[110] in

[101] Peru, IP/C/W/447, IP/C/M/48

[102] Brazil et al, IP/C/W/403.

[103] Cuba, IP/C/M/40, para. 117.

[104] Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115.

[105] Article 10 of Patent Law Treaty of WIPO

[106] Switzerland, IP/C/M/49, para 115, IP/C/M/46, para. 76.

[107] EC, IP/C/M/48, para. 62, IP/C/M/47, para. 58.

[108] EC, IP/C/W/383, IP/C/M/47, para. 59, IP/C/M/46, para. 47, IP/C/M/42, paras. 107-108, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 228, EC, IP/C/M/47, para. 58, IP/C/M/49, para. 124

[109] See "The Protection of Traditional Knowledge – Draft Articles" submitted in 21st session of WIPO IGC at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_21/wipo_grtkf_ic_21_4.pdf ((WIPO/GRTKF/IC/21/4)) accessed on 15.03.12.

[110] Policy objective (ix) of WIPO/GRTKF/IC/16/5: *Respect for and cooperation with relevant international agreements and processes* – take account of, and operate consistently

accordance with the existing national and international regime. PIC here is undertaken as an enforcement mechanism for the development of effective legal measure against misappropriation.[111] According to Article 1.3 (ii), PIC is to be regarded as a condition of access to the traditional knowledge and that will be helpful in organizing regulatory instrument for prevention of misappropriation of traditional knowledge. Article 7[112] further elaborate that objective and PIC is recognized as a central legal principle to policy debate and measures concerning TK protection. It gives importance on providing prior information to the TK holders about potential exploitation of TK and for the proposed use TK holders need to give consent. The mechanism should be implemented properly, with the legal certainty; at the same time it should be flexible to adapt the principle to the national legal system. Due to commercial or industrial use of TK, fair and equitable sharing of benefit is important; for non-commercial purposes non-monetary benefit sharing is suggested by WIPO. Users of TK are needed to respect cultural values of its holders and recognise the origin of source. Customary law is also vital deciding factor for benefit sharing arrangement. If above said facilitation is not available to TK holders, legal measures provides remedies to TK holders. In WIPO documents no specific mechanism for benefit sharing is provided; neither the principle given; nor the characteristics of benefits suggested; even judging factors and terms and conditions for MAT and MTA are not recommended. Recently in International Symposium "discussion was held on how the decisions would be made to access TK and to share benefits……" and "concern was expressed about how States, if receiving benefits arising from access to TK, would distribute those benefits to the community. Some support was expressed for the idea that the State should establish a legislative framework for distribution of national benefits wherever benefits might occur. The funds generated from utilization of TK and TCEs should be used for preserving and developing cultural heritage of the indigenous peoples." From legislative point of view this is a remarkable concern as in most of the national and international legislation and guideline it is not ascertained how to channelize the shared benefits towards the development of holder traditional community.

Chapter III of IGC document provides "*Substantive Provisions*" which is elaborating different practical points and that is the actual guidance for governments to frame national sui generis TK protection regime. Article 1 is on misappropriation of TK and its prevention. Act of misappropriation is defined in Article 1.2. Importance of obtaining PIC before access, stoppage of granting of false IPR claims, disclosure of origin in patent application and respect of customary practices to stop misappropriation is discussed in other in Article 1.3, 1.4 and 1.5. Other above mentioned elements of sui generis system like scope of subject matter and eligibility of protection,[113] fair and equitable benefit sharing mechanism,[114] Obtaining of PIC before access,[115] duration of protection,[116] and supervision by

with, other international and regional instruments and processes, in particular regimes that regulate access to and benefit-sharing from genetic resources which are associated with that traditional knowledge;

[111] Commentary on General Guiding Principles (c) of WIPO/GRTKF/IC/16/5: *Principle of effectiveness and accessibility of protection* – Measures for protecting traditional knowledge should be effective in achieving the objectives of protection, and should be understandable, affordable, accessible and not burdensome for their intended beneficiaries, taking account of the cultural, social and economic context of traditional knowledge holders. Where measures for the protection of traditional knowledge are adopted, appropriate enforcement mechanisms should be developed permitting effective action against misappropriation of traditional knowledge and supporting the broader principle of prior informed consent.

[112] WIPO/GRTKF/IC/16/5 Annex, Page 41, Article 7 Principle of Prior Informed Consent – 1. The principle of prior informed consent should govern any access of traditional knowledge from its traditional holders, subject to these principles and relevant applicable national laws; 2. The holder of traditional knowledge shall be entitled to grant prior informed consent for access to traditional knowledge, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation; 3. Measures and mechanisms for implementing the principle of prior informed consent should be understandable, appropriate, and not burdensome for all relevant stakeholders, in particular for traditional knowledge holders; should ensure clarity and legal certainty; and should provide for mutually agreed terms for the equitable sharing of benefits arising from any agreed use of that knowledge.

[113] Vide WIPO/GRTKF/IC/16/5, Article 3 (Annex page 27) and Article 4 (Annex page 31)

[114] Vide WIPO/GRTKF/IC/16/5, Article 6 (Annex page 38)

[115] Vide WIPO/GRTKF/IC/16/5, Article 7 (Annex page 41)

[116] Vide WIPO/GRTKF/IC/16/5, Article 9 (Annex page 46)

competent national or regional competent authority[117] is ascertained in relevant articles. 'Sui generis' nature of this proposed legal regime is explained in Article2;[118] it is stated that this legal regime "*... shall be implemented through a range of legal measures....*;" a list of suggested "*range*" of legal regime is also included therein; and it is ensured that being a newly introduced legal regime, TK protection system needs proper transition period of time[119] for accurate implementation. Respect for TK holders and also for their customary rules and practices, has been emphasised in several Articles, especially in Article 4 and Article 5.[120] WIPO IGC sui generis model gives importance on some relevant and significant points, viz. legal remedies for TK holders in cases of inequitable and unfair kind of benefit sharing by users;[121] during implementation of principles of ABS systems it should be ascertained that there is legal certainty and clarity in the system and moreover the procedure should not be a burden for the TK holders;[122] exceptions and limitations of this law is specifically mentioned in relation to TK, based on customary law and practice and for public health purposes, but not at the cost of rights of TK holders;[123] there should not be any 'formalities' for protection of TK, there is a provision left open for maintenance of 'register' of TK but that "*should not compromise the status of hitherto undisclosed traditional knowledge or interests of TK holders"*.[124] But on the other hand some important points are missing like, the details of information to be included in PIC; what are the points to be given importance during MAT and basic requirements for MAT; suggested elements of material transfer agreement; structural format and duties of competent national authority, provision of separate approval during new use of same TK or associated GR, monetary and non-monetary forms of benefits etc; which might create ambiguity and confusion during national implementation.

In the recent document submitted by WIPO IGC in April 2013 in their 24th Session,[125] some additional changes have been done to make the provisions more useful for the traditional communities. After submission of draft of 16th Session there was a prolonged discussion and criticism regarding the gaps and lacunae in that draft. In the draft of 24th Session necessary addition and changes of the previous draft have been made. For example, modified definition of traditional knowledge and traditional knowledge associated with genetic resources are provided;[126] criteria of traditional knowledge to be eligible for protection are also modified;[127] scope of protection of traditional knowledge and traditional knowledge associated with genetic resources are elaborated;[128] disclosure requirement, with mention of country of origin, is included as an essential component while applying for the patent or plant variety protection for the process or product involving traditional knowledge;[129] it is mentioned that Member States should establish the appropriate national or regional competent authority to administer the rights of the traditional knowledge holders 'according to their customary protocols, understandings, laws and practices';[130] and involvement of traditional knowledge holders is further reinforced. Additionally Article 4 for 'Sanction, remedies and exercise of rights', Article 5BIS for 'Application of collective rights', Article 11 for 'National treatment and other means of recognizing foreign and interests' and Article 12 for 'Trans-boundary Cooperation' is added. The effort given to make this draft is really exhaustive and appreciable. This Draft document is now open for debate and discussion and the shortfalls will be discussed by the Member countries in near

[117] Vide WIPO/GRTKF/IC/16/5, Article 13 (Annex page 56)

[118] Vide WIPO/GRTKF/IC/16/5, Annex page 23

[119] Vide WIPO/GRTKF/IC/16/5, Article 10 (Annex page 49)

[120] Vide WIPO/GRTKF/IC/16/5, Article 4 (Annex page 31)and Article 5 (Annex page 35)

[121] Vide WIPO/GRTKF/IC/16/5, Article 6.4 (Annex page 38)

[122] Vide WIPO/GRTKF/IC/16/5, Article 7.3 (Annex page 41)

[123] Vide WIPO/GRTKF/IC/16/5, Article 8 (Annex page 44)

[124] Vide WIPO/GRTKF/IC/16/5, Article 11 (Annex page 51)

[125] Vide The Protection of Traditional Knowledge: Draft Articles Rev. 2 (Draft submitted by WIPO-IGC in their 24th Session on April 26, 2013), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_21/wipo_grtkf_ic_21_4.pdf (last accessed on 20.11.13).

[126] Article 1.1 & 1.2 of The Protection of Traditional Knowledge: Draft Articles Rev. 2, p. 10.

[127] Article 1.3 & 1.4 of The Protection of Traditional Knowledge: Draft Articles Rev. 2, p. 10.

[128] Article 3 of The Protection of Traditional Knowledge: Draft Articles Rev. 2, pp. 12-13.

[129] Article 4 BIS of The Protection of Traditional Knowledge: Draft Articles Rev. 2, p. 16.

[130] Article 5 of The Protection of Traditional Knowledge: Draft Articles Rev. 2, pp. 17-18.

future. But still the question remains that if the holder countries implement the protection regime for TK according to these suggestions but the complementary changes are not made in the user countries' legal regime, then the usefulness will not be worthy. Because the misappropriation used to happen from the user countries. According to previous experience different 'Free Trade Agreements' always affect the national legal regime in terms of protection of TK and TK associated to GR. Conventional intellectual property rights like patent is having room in this proposition. So there will be a question of proper guideline of examination of the applications of patent for invention related to TK and TK associated to GR. Research and development (R&D) activities are necessary for the improvement of TK; but the fact is research activities are done usually with the genetic resources having known traditional knowledge. For example, active ingredients of Brahmi have got patent, but Brahmi is chosen for the R&D because the memory enhancement capacity of Brahmi was known for over 1000 years and used thereby.[131] So, the potentialities of this type of genetic resources are already judged by traditional communities earlier. That is why it is utilized for further innovation. No one can deny when access to medicine is a question worldwide, the alternative sources of traditional medicinal knowledge to resolve the access to medicine issue can be a pathfinder. There is a strong need of research regarding traditional knowledge and also there is a need of application of modern technology to enhance the efficacy of known properties of traditional medicinal knowledge. The current scenario is looking forward for a combination of patent and access & benefit sharing mechanism for inventions related to TK and TK associated with GR. Draft of 24th Session of IGC has given that indication as well. Now it is a question of implementation and execution of this model by holder and user countries.

Many initiatives are taken in the international arena to give proper protection to the traditional knowledge and associated genetic resources. Still a comprehensive legislation which will provide protection for all forms of traditional knowledge is yet to come. In the view of incompetence of the existing intellectual property regime to protect the traditional knowledge increases the requirement of a sui generis system for protection of traditional knowledge Proper international negotiation of binding nature with a minimum standard of protection incorporating the national legal regime is the urgent need to resolve this issue and to prevent misappropriation of traditional knowledge and associated genetic resource.

Awareness and Capacity building

Sui generis model of protection, following the rule of ABS system in its fullest possible way, is the best procurement system for TK protection. That should include terms of positive as well as defensive protection. Still that system of protection will be ineffective if not complemented by the capacity building and awareness activities among the actual holder community. Capacity building should incorporate manifold of activities.

Traditional and indigenous community people should be empowered by the knowledge of various things, like their stipulated rights on the TK; legal protection provided by the national governments; different ways of involvement by them during implementation of ABS system; their critical role in registration of TK and TK holders; what are the international discussion and policy debates undergoing in this relevant topic etc. The indigenous and local community representatives have participated in some international meetings, including three expert meetings dealing respectively with "concepts, terms, functional definitions and sectoral approaches;" "compliance;" and "traditional knowledge associated to genetic resources." In the process of development of an international regime on ABS, some Parties and regional groups come in collaboration with the Secretariat to guarantee the involvement of indigenous peoples, such as the European Union sponsored Vienna workshop on matters related to traditional knowledge associated with genetic resources and the international access and benefit-sharing regime, which was held in December 2008;[132] Vilm workshop on issues related to traditional knowledge associated with genetic resources and the drafting of international regime on access and benefit-sharing, was sponsored by the Government of Germany. This workshop was held on the Isle of Vilm in June 2009.[133] In 2008 just prior to the 9th and

[131] Jagath Gunawardena, *Memory enhancing herbs: proven and patented, but not pirated*, Midweek review, available online at http://www.infolanka.com/org/srilanka/food/12.htm (accessed on 12.03.13)

[132] Ahmed Djoghlaf, (2010), *Recognizing the Crucial Role of indigenous People and Local Communities*, Pachamama, A Traditional Knowledge Newsletter on the Convention on Biodiversity, 4(4)1.

[133] Id.

final meeting of the Working Group on ABS the Government of Spain has arranged a meeting of indigenous negotiators, in collaboration with the Secretariat in Cali, Colombia.[134] The Secretariat, with the initiative of the Government of Spain, signed a long term capacity-building strategy in early 2009 and entered into a three-year memorandum of understanding with the Fundación para la Promoción del Conocimiento Indígena, acting on behalf of the Latin American and Caribbean Indigenous Women's Biodiversity Network.[135] This will ensure capacity-building for indigenous women and men, will assist them in effective participation in meetings held under the Convention and will assist their active co-operation in the ABS negotiation for COP 10. These workshops are important way forward to the development of indigenous and local community participation and help enhancement of their understanding regarding international activities under the Convention. There are some other innovative initiative undertaken by the convention, which include: a short film on traditional knowledge in the South Pacific on coral gardening, traditional fish traps and reef restoration; a photography exhibition launched at the Ninth Session of the United Nations Permanent Forum on Indigenous Issues at UN Headquarters in April 2010 to highlight the crucial role of indigenous and local communities as custodians of the World's biological and cultural diversity; Secretariat and United Nations Educational, Scientific and Cultural Organization (UNESCO) preparing and distributing posters on the importance of traditional knowledge in various indigenous languages; indigenous and local community radio broadcast in the Amazonia and Andean regions to produce news stories by indigenous experts on topics related to those communities and to the goals of conservation and sustainable use.[136]

Historically traditional and indigenous community work in coherence with the environmental protection and the innovation and practices are necessarily way forward to conservation and sustainable use of TK and GR. But due to commercialisation and industrialisation of recent years they are losing that insight. Now is the time to develop know how on environmental protection. For the commercial need if the exploitation of GR is higher then it can cause two fold problems; firstly the quality of the genetic resources can be decreased, may be by use of chemical and semi-bio manures; and secondly nature allows the growth of GR according to its own rule, exceeding that rule may be contrary to the environment and hamper ecological balance. So, at the time of capacity building there is a need of awareness and proper education to handle the important issue like restoration of environment to have ecological stability for our better future. Some NGOs are taking initiative towards this approach, like SRISTI (The Society for Research & Initiatives for Sustainable Technologies & Institutions)[137] in Ahmedabad, Honeybee network[138] and the Biodiversity Conservation Prioritization Program (BCPP) are important among them.

There is accelerating loss of TK and biodiversity based learning system. Traditional knowledge is lost by the erosion of vernacular language, lack of interest to preserve traditional culture, so in totality general degradation of biodiversity resources. If we incorporate the traditional knowledge with formal educational knowledge and there is a need to structure of interactive education by which traditional knowledge can be conserved and maintained. In this context there is a good example happened by the initiative of The Society for Research and Initiatives for Sustainable Technologies (SRISTI)and Institutions and National Innovations Foundation (NIF).[139] They together organised a contest with involvement of college, school children, parents and school teachers. They developed the chain of learning and knowledge network in the society based on traditional knowledge system which helps to conserve and integrate the local wisdom of biodiversity for the sustainable development. This programme held in various villages and schools of Seoni district of Madhya Pradesh with students of B.Sc agriculture. The aim of the contest was to introduce the traditional knowledge and associated GR among students of rural schools and to facilitate rural wisdom to recollect traditional knowledge associated with GR. It is an innovative step taken by those NGOs to regain valuable knowledge.[140] Technology based society somehow losing interest to conserve traditional

[134] Ibid.

[135] Ibid supra FN 132.

[136] Ibid supra FN 132.

[137] http://www.sristi.org/cms/ (available on 13.10.13)

[138] http://www.sristi.org/cms/en/our_network (available on 13.10.13)

[139] Ranjay K. Singh, *Learning the indigenous knowledge and biodiversity through contest: A participatory methodological tool of ecoliteracy*, Indian Journal of Traditional Knowledge, 2010, 9(2)355-360

[140] Id.

knowledge and younger generation also feeling reluctant to ignite this knowledge among them. The truth is, traditional knowledge is intricately deep rooted in our society and it is inexpensive. So, for our socio economic reason the grooming of this traditional knowledge is vastly needed; on the contrary we need to focus on the issue of commercialization of this knowledge can be expensive or can raised high in price as per market value and can be out of reach of the local livelihood. Same thing can happen for the raw material also. It can be the grey areas of the ABS system, so we need to look after this area in the early stage.

Capacity building is needed for both provider and user country. Already the needs of capacity building for holder community have been discussed, now the discussion will be on the requirement of it in the user country and institutions. Proper understanding should be there for legalities of ABS regime, how to obtain PIC, how to negotiate MAT, and how to follow the user country's obligations regarding research, transfer of knowledge and applying for IPR. This will help to minimize the future litigation and will create a healthy environment of facilitated access among the countries. In 2005 Germany organized an international workshop to identify the German users and to give them awareness on access and benefit sharing system under the CBD[141]. More of that kind of workshops is needed for all the user countries for effective implementation of ABS regime.

Conclusion

Traditional knowledge is different from non-indigenous knowledge and the difference lies in the fact in what way it has been used. The way traditional community defines traditional knowledge is the best way to understand the insight of traditional knowledge, which is not mere romanticism for them. It is result of practical common sense which is based on experiences and teachings and propagated to future generations. This knowledge is derived from the resources of the environment and relationship between each and every components of it. TK is holistic in nature; it cannot be interpreted in a constricted way and cannot be detached from the people who hold it. It is rooted in the way of life, like spirituality, health, culture and language of the specific territory. TK is dynamic, cumulative and stable. It is an integration of emotion and intellect. So, it is the survival for the existence for evolution. TK doesn't fit into the norms of conventional intellectual property due to its diverse and mesmerizing quality. When on the basis of this knowledge and following the footstep of traditional people, others try to 'create', or 'innovate' something, that should be taken as 'misappropriation' as the inventor willfully appropriate the traditional knowledge to skip the basic background work. Potentiality of translation of traditional knowledge into commercially useful and costly products, especially using modern techniques, makes TK much more vulnerable of misappropriation. Role of proper legal awareness and capacity building is to be considered very seriously, which will empower traditional people to protect their knowledge from misappropriation and they will be encouraged to participate in the ABS system. Processes included in traditional knowledge for agriculture, conservation of varieties of plant genetic resources, soil and water conservation, genetic resource conservation, treatment of many diseases by traditional healers or by using traditional medicines etc are still practiced in different parts of the world and very useful for socio-economic development of the country and region. Proper legal protection of traditional knowledge will ensure the maintenance of dynamics of traditional knowledge and will lead the mankind to the sustainable development.

Acknowledgement

I would like to thank a few people who have helped and inspired me, who have been instrumental in the completion of my dissertation. My deepest gratitude goes to library staff and other staff members of National Law University Jodhpur for their help and cooperation. I am deeply thankful to my friends and colleagues for their support and inspiration to name a few and to everybody who has been part of my life and has been there for any help and support in this endeavor.

References

Reports

[1] Communication from India, Committee on Trade and Environment, Council for TRIPS, *Protection of Biodiversity and Traditional Knowledge – the Indian Experience* (WT/CTE/W/156, July14, 2000).

[2] Communication from India, Committee on Trade and the Environment, Council for TRIPS, WTO Document WT/CTE/W/65 (September 29, 1997).

[141] Report of international workshop in Bonn, Germany on 8-10 November 2005 on, *Access and Benefit Sharing of Genetic Resources: ways and means for facilitating biodiversity research and conservation while safeguarding ABS provisions*, Convened by the German Federal Agency for Nature Conservation

[3] Communication from different countries at WTO: IP/C/W/246, IP/C/W/356, IP/C/W/383, IP/C/W/403, IP/C/W/404, IP/C/W/420, IP/C/W/429, IP/C/W/438, IP/C/W/441/Rev1, IP/C/W/442, IP/C/W/447, IP/C/W/458, IP/C/W/459, IP/C/W/469, IP/C/W/470, IP/C/W/474; IP/C/M/37, IP/C/M/42, IP/C/M/43, IP/C/M/48.

[4] Communication at WIPO: WIPO/GRTKF/IC/6/8, WIPO/GRTKF/IC/5/6.

[5] Conference of the Parties to the CBD, CBD Document *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use* UNEP/CBD/COP/3/22 (September 22, 1996).

[6] Doha Ministerial Declaration, WT/MIN(01)/DEC/W/1 (November 14, 2001).

[7] IPDEV Work Package 6, Literature Review and Commentary on Legal Regime and Model for Protecting Plant Varieties, *Assessing the economic implications of different models for implementing the requirement to protect plant varieties* (Queen Mary, University of London, 2006) available online at: http://www.ecologic.de/download/projekte/1800-1849/1802/wp6_turkey_case_study.pdf

[8] Report of Sub-Regional Meeting in Asia on Intangible Cultural Heritage: Safeguarding and Inventory-Making Methodologies; held in Bangkok, Thailand, on 13 -16 December 2005.

[9] WIPO General Assembly, WIPO document, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* WIPO/GA/26/6 (August 25, 2000).

[10] WTO Panel Report, *Canada--Patent Protection of Pharmaceutical Products*, WT/DS/114/R, (March 17, 2000.)

[11] The report of joint E.U./U.S. Biotechnology Consultative Forum (launched at the Quelez Summit in May 2000 and delivered its report to the following E.U./U.S. Summit in Washington in December, 2000). The text of the report found online at: www.europa.eu.int/comm/external_relations/us/biotech/report.pdf.

Journal Articles

[12] Aerts, R. J. "The industrial applicability and utility requirements for the patenting of genomic inventions: a comparison between European and US law" (2004) *E.I.P.R.*, 26(8), 349-360.

[13] Ang , S. "Patent term extensions in Singapore for pharmaceutical products" (2005) *E.I.P.R.*, 27(10), 349-358.

[14] Antons, C. "Sui generis protection for plant varieties and traditional agricultural knowledge: the example of India" (2007) *E.I.P.R.*, 29(12), 480-485.

[15] Badami, S. " In-vitro antioxidant properties of Indian traditional Paan and its ingradients" (2004) *Indian Journal of Traditional Knowledge* 3(2)187-191

[16] Bonadio, E."Crop breeding and intellectual property in the global village" (2007) *E.I.P.R.*, 29(5), 167-171.

[17] Campolini, M. "Protection of innovative medicinal products and registration of generic products in the European Union: Is the borderline shifting? State of play and the proposed European medicine legislation" (2003) *E.I.P.R.*, 25(2), 91-97.

[18] Carson, J. & Mekjian, K. "United States: patents - written description requirement to biotechnology inventions" (2005) *E.I.P.R.*, 27(4), N86-87.

[19] Cullet, P. "Property Rights over Biological Resources: India's Proposed Legislative Framework" (2001) *Journal of World Intellectual Property* 8(3)219

[20] Curley, D. & Sharples, A. "Patenting biotechnology in Europe: the ethical debate moves on" (2002) *E.I.P.R.*, 24(12), 565-570.

[21] Feldman, R. C., "The Open Source Biotechnology Movement: Is it Patent Misuse?". *Minnesota Journal of Law, Science & Technology*, Vol. 6, 2004 Available at SSRN: http://ssrn.com/abstract=545082

[22] Gopalakrishnan, N. S. "TRIPs and protection of traditional knowledge of genetic resources: new challenges to the patents system" (2005) *E.I.P.R.*, 27(1), 11-18.

[23] Hayhurst, W. "Canada: patents - patent claiming a gene and genetically modified cell" (2005) *E.I.P.R.*, 27(4), N83-84.

[24] Hayhurst, W. "Case Comment: Canada: patents - patentability of non-human life forms - the Harvard mouse" (2001) *E.I.P.R.*, 23(7), N103-105.

[25] Kariyawasam, K. "Access to biological resources and benefit-sharing: exploring a regional mechanism to implement the Convention on Biological Diversity (CBD) in SAARC countries" (2007) *E.I.P.R.*, 29(8), 325-335.

[26] Keating, D. "Access to Genetic Resources and Equitable Benefit Sharing through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum" (2005) 87 *Journal of the Patent and Trademark Office Society (JPTOS)* 525.

[27] Khan, A. "EPO: patents: biotechnological inventions" (2004) *E.I.P.R.*, 26(4), N48-49.

[28] Kiruba, S. "Traditional pest management practices in Kanyakumari District, southern peninsular India" (2006) *Indian Journal of Traditional Knowledge* 5(1)71-74

[29] Kongolo, T. "Biodiversity and African countries" (2002) *E.I.P.R.*, 24(12), 579-584.

[30] Krist, L. V. *et al* "Identification and evaluation of Peruvian plants used to treat Malaria and

Leishmaniasis" (2006) *Journal of Ethnopharmacology* 106(3)390-402.

[31] Kumar, S. and Wilson, N. "Biotechnology in the limelight" (2006) *Managing Intellectual Property*, Supplement Life Sciences 46.

[32] Laurie, G. "Patenting stem cells of human origin" (2004) *E.I.P.R.*, 26(2), 59-66.

[33] Lawson, C. "Patents and biological diversity conservation, destruction and decline? Exploiting genetic resources in Queensland under the Biodiscovery Act 2004" (2006) *E.I.P.R.*, 28(8), 418-428.

[34] Li, X. "Novelty and inventive step: obstacles to traditional knowledge protection under patent regimes: a case study in China"(2007) *E.I.P.R.*, 29(4), 134-139.

[35] Matthews, D. "TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements" (2005) *E.I.P.R.*, 27(11), 420-427.

[36] Monotti, A. L. "Australia: patents - exclusion from patentability - human beings and the biological processes for their generation" (2004) *E.I.P.R.*, 26(12), N205-206.

[37] Monotti, A. L. "Australia: patents - the concept of obviousness in combination patents under the Patents Act 1952" (2003) *E.I.P.R.*, 25(6), N85-86.

[38] Moore, S. "Challenge to the Biotechnology Directive" (2002) *E.I.P.R.*, 24(3), 149-154.

[39] Mueller, J. M. "The Evolving Application of the Written Description Requirement to Biotechnological Inventions" (1998) *Berkeley Tech. L. J.*, 13, 615 – 621

[40] Mutter, K. "Traditional knowledge related to genetic resources and its intellectual property protection in Colombia"(2005) *E.I.P.R.*, 27(9), 327-333.

[41] Nielsen, J. & Nicol, D. "Australian medical biotechnology: navigating a complex patent landscape" (2005) *E.I.P.R.*, 27(9), 313-318.

[42] Overwalle, G. V. & Jacobs, P. "Gene patents: a different approach" (2001) *E.I.P.R.*, 23(11), 505-506.

[43] Purkaystha, J. *et al* "Ethnomedicinal plants from Dibru-Saikhowa reserve, Assam" (2007) *Indian Journal of Traditional Knowledge* 6(3)477-480.

[44] Richards, G. A. & Thomas, D. "The importance of the morality exception under the European Patent Convention: the Oncomouse case continues ...." (2004) *E.I.P.R.*, 26(3), 97-104.

[45] Roberts, T. "Intellectual property: 9th meeting of the Intergovernmental Committee on genetic resources, traditional knowledge and folklore, Geneva, April 24-28, 2006" (2006) *E.I.P.R.*, 28(8), N155.

[46] Sagar, R. "Intellectual Property, Benefit-Sharing and Traditional Knowledge: How Effective is the Indian Biological Diversity Act, 2002?" (2005) *Journal of World Intellectual Property* 8(3)387-388

[47] Sampson, T "Achieving ethically acceptable biotechnology patents: a lesson from the Clinical Trials Directive?" (2003) *E.I.P.R.*, 25(9), 419-425.

[48] Sampson, T. "Rewriting the genetic code: the impact of novel nucleotides on biotechnology patents" (2002) *E.I.P.R.*, 24(8), 409-414.

[49] Santamauro, J. "Reducing the rhetoric: reconsidering the relationship of the TRIPs Agreement, CBD and proposed new patent disclosure requirements relating to genetic resources and traditional knowledge" (2007) *E.I.P.R.*, 29(3), 91-99.

[50] Schertenleib, D. "The patentability and protection of DNA based inventions in the EPO and the European Union" (2003) *E.I.P.R.*, 25(3), 125-138.

[51] Schertenleib, D. "The patentability and protection of living organisms in the European Union" (2004) *E.I.P.R.*, 26(5), 203-213.

[52] Shillito, M. "Patenting genetically engineered plants" (2002) *E.I.P.R.*, 24(6), 333-336.

[53] Stenton, G. "Biopiracy within the pharmaceutical industry: a stark illustration of how abusive, manipulative and perverse the patenting process can be towards countries of the South" (2004) *E.I.P.R.*, 26(1), 17-26.

[54] Straus, J. *et al* "HUGO Statement on the patenting of DNA sequences", (1995), *Human Genome Organization* [online]. Available at *www. gene.ucl.ac.uk/hugo/patent.htm*.

[55] Tanziani, D. "Case Comment: South Africa: patents - Government use of patented pharmaceuticals" (2001) *E.I.P.R.*, 23(10), N153-154.

[56] Thomson, G. & Kempton, L. "Construction issues in pharmaceutical and biotech cases" (2002) *E.I.P.R.*, 24(12), 591-596.

[57] Toumi, E. "EC: patents - biotech patents - question of morality" (2004) *E.I.P.R.*, 26(2), N15-16.

[58] Tuosto, C. "The TRIPs Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licenses" (2004) *E.I.P.R.*, 26(12), 542-547.

[59] Vivas Eugui, D. "Issues linked to Convention on Biological Diversity in the WTO negotiations: implementing DOHA mandates" (2002) *Center for International Environmental Law (CIEL).*