BIOPROSPECTING OF TRADITIONAL KNOWLEDGE: EFFICACY OF EXISTING LEGISLATIVE FRAMEWORK

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Abstract:

Asian, African and Latin American civilizations are amongst the most ancient ones in the human history, and traditional knowledge systems date from more than 2 million years, when Homo habilis started making his tools and interacting with nature. Countries with ancient cultural traditions are inhabitated by thousands of different traditional (indigenous and local) communities holding traditional knowledge; practiced over a long period of time and constantly evolving. Recognition of the remarkable economic potential of such knowledge has led many multinational corporations of the industrialized nations to "free ride on the genetic resources and traditional knowledge and technologies of the developing countries" (Dutfield, 2006), leading the latter to resent such "biopiracy" or uncompensated exploitation of their natural resources[1]. This has resulted in traditional knowledge being subject to debate and discussion at many international fora[2].

Traditional knowledge, is a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity[3]. Devolution, encroachment, the bio prospecting rush, intellectual arrogance, lack of appropriate legal systems and a clash of systems all make traditional knowledge highly vulnerable to bio piracy, patenting of turmeric and neem offer classical example of alleged misappropriation.

Various environmental, trade, and geographically-specific agreements currently offer incomplete, ambiguous, or conflicting provisions relating to bio prospecting activities. One of the biggest threats to biodiversity and related traditional knowledge is ever increasingly bio-

[1] Biju Paul Abraha, Shamama Afreen, "Biopiracy and Protection of Traditional Knowledge: Intellectual Property Rights and Beyond", (WPS No. 629/ September 2008).
[2] The Convention on Biological Diversity (CBD), the TRIPS Council, the Intergovernmental Committee on Folklore, Traditional Knowledge and Genetic Resources (IGC).
[3]Traditional knowledge, *available at:* http://www.wipo.int/tk/en/tk/ (Visited on Feb 12, 2015)

prospecting activities on behalf of ethnobotanists, pharmaceutical companies and others who wish to profit from the rich biodiversity and traditional knowledge in indigenous territories. One of the key issues involved in prospecting and commercialization of TK-derived technologies and products is the inadequacies in providing protection of TK through appropriate intellectual property laws and policy measures at national and international levels. There is a need 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.

What is required urgently is to develop a national legislation to accord IPR protection to TK-drawn innovations. An efficient and accessible intellectual property system that provides benefits to all must be the common goal of policy makers.

Legal recognition of the rights of the holders of the TK who are mainly the tribal and indigenous people of India is the need of the hour.

1. *Introduction:*

The most serious legal issue is lack of internationally recognised policy that govern the relationship between intellectual property, traditional knowledge, and biodiversity. Various environmental, trade, and geographically-specific agreements currently offer incomplete, ambiguous, or conflicting provisions relating to bioprospecting activities. Consequently, there are no clear rules on ownership, access, benefit-sharing, and environmental responsibility for bioprospecting of the traditional knowledge. Lack of clear rules and guidelines and distinct gaps in the existing laws encourages biopiracy by companies keen to exploit the fragmented legal frameworks and policies for their own commerical benefit.

For the purposes of this paper, I approach the issue of traditional knowledge from an intellectual property perspective, rather than focusing on the ethical and moral issues related to it.

2. *Traditional Knowledge:*

The WIPO IGC struggles to reach a clear definition of traditional knowledge because indigenous peoples, indigenous communities may be holders of traditional knowledge, but not all traditional knowledge holders are necessarily indigenous.

Working definition of Traditional knowledge given by The WIPO[4] Secretariat based on general approach used in other international fora includes:

- tradition-based literary, artistic or scientific works;
- performances;
- inventions;
- scientific discoveries;
- designs;
- marks, names and symbols;
- undisclosed information; and
- all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary, or artistic fields.[5]

Traditional Knowledge (TK) is "the cumulative and dynamic body of knowledge, knowhow and representations possessed by peoples with long histories of interaction with their natural milieu. It is intimately tied to language, social relations, spirituality and worldview, and is generally held collectively". (UNESCO: 2006)[6]

Traditional knowledge includes, a variety of subject matter as: traditional medicinal practices, , traditional farming practices, knowledge relating to the uses of certain biological or chemical resources, and traditional songs, dance, or rituals such as Indian Ayurvedic, Unani medicine system, Yoga, antifungal properties of the Neem, or local remedies as composition of *jamun*, bitter gourd, jaggery and egg plant to treat diabetes.

For centuries indigenous and local communities, have used, transmitted and evolved TK under local laws. But today the wisdom and knowledge accumulated by indigenous communities over thousands of years is under threat of being exploited, lost or plundered by biotechnological, pharmaceutical companies for profit.

The Inter-governmental committee of WIPO has identified specific threats to TK including:

[4] WIPO (World Intellectual Property Organization) is the global forum for intellectual property services, policy, information and cooperation, *available at*: http://www.wipo.int/portal/en/ (Visited on 12 Feb, 2015).
[5] WIPO(2013) Traditional Knowledge, *available at:* http://www.wipo.int/tk/en/tk/ (Visited on 13 Feb, 2015).
[6] UNESCO (2006) Traditional Knowledge, *available at*: http://www.unesco.org/bpi/pdf/memobpi48_tradknowledge_en.pdf (Visited on 13 Feb, 2015).

a) Unauthorised commercial exploitation

b) Insulting, degrading or culturally offensive use of material that is the subject matter of TK

c) False or misleading indications that there is a relationship with the communities wherein the material has originated.

d) Failure to appropriately acknowledge the source of the material.[7]

Few reasons as to why TK should be protected are:

(a) Environment or Biodiversity[8] Conservation

(b) Preventing Misappropriation of TK

(c) Acknowledging the contributions of indigenous and local communities

(d) Improving the livelihood of TK holders.

(e) Benefiting national economies in a knowledge driven era

(f) Preventing rampant exploitation of biological resources i.e. Biopiracy

The traditional knowledge dialogue has advanced to a stage where there is growing recognition of the need to value and acknowledge the contributions of indigenous and local communities. There is an attempt to maximize the benefits of traditional knowledge for these communities while minimizing the harmful effects of misappropriation.[9]In India, after the neem patent controversy[10], the need to protect the traditional knowledge of India has gained importance.

3. Bioprospecting

3.1 Definition of Bioprospecting

Bio-prospecting, which usually precedes biopiracy, is the systemic search for, and the development of, new sources of chemical compounds, genes, micro and macro-organisms and

[7] Overview of the Activities and Outcomes of the Committee, Intergovernmental Committee, WIPO/GRTKF/IC/5/12-2003, *available at:* http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_12.pdf (Visited on 15 Feb, 2015).

[8] Biodiversity is defined as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." See Article 2, Convention on Biological Diversity, 1992.

[9] J. Janewa Osei Tutu, "Emerging Scholars Series: A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law", 15 *IPLR* 147 (2011).

[10] US patent No 4946681 and US patent No 5124349 were granted by the US Patent Office to W.R. Grace for extraction and storage processes of *Neem*, which is traditionally used in India since ages for its medicinal properties. US Patent Office counts only published work on inventions as prior art. However, there was a lot of hue and cry against these grants and US Patent Office Policies. India claimed that US is stealing their knowledge.

other valuable bio-products. One of the biggest threats to biodiversity and related traditional knowledge is ever increasingly bio-prospecting activities on behalf of ethnobotanists, pharmaceutical companies and others who wish to profit from the rich biodiversity and traditional knowledge in indigenous territories[11],[12].

Bioprospecting is the exploration for useful organic compounds occurring in nature, commonly involving the collection and examination of plants, animals, microorganisms for sources of genetic or biochemical resources of social and economic value.

Bioprospecting, defined as the systematic search for valuable, molecules, genes and organisms in nature, has the potential to provide developing countries a means:

- to use biodiversity without disrupting nature;
- to add value to their natural resources;
- to ensure that such resources are protected and used in a sustainable manner; and
- to build the necessary skills to apply biotechnology in improving quality of life (Sittenfeld and Villers 1993; Sittenfeld and Lovejoy, 1999).

TK based bio-prospecting may significantly cut costs of pharmaceutical R&D, as compared to the conventional system of screening millions of synthesized chemical formulations. Hence the Pharma and Biotech-industry is looking increasingly at medicines and products that have been developed by local communities in older cultures like India, Africa and China where the centuries-old traditions of indigenous healing are still viable and in use[13].

Large pharmaceutical companies generate close to USD 250 billion annually from drugs directly derived from biodiversity. In 2010, the natural products mix in the pharmaceutical industry was estimated to be 40%. Currently, 62% of cancer drugs approved by the US Food and Drug Administration come from, or are modeled based on, natural products. In 2010, more than 40% of all the new chemical entities were obtained from natural sources. Nearly 48% of drugs in the clinical phase are derived from plants[14].

[11] S. Sahay, P. Pavithran, I. Barpujari, "Biopiracy: Imitations Not Innovations", Gene Campaign Publication (2007).
[12] V. K. Chouhan, "Protection of Traditional Knowledge in India by Patent: Legal Aspect", 3 IOSRJHSS (2012).

[13] R. D. Singh, S.K. Mody, and et al, "Pharmaceutical Bio-piracy And Protection Of Traditional Knowledge", 3 *IJRDPLS* (2014).
[14] K Kurien, A Das. "Nagoya Protocol and Its Implications on Pharmaceutical Industry", Beroe Inc. Publication (2011).

3.2 Process of Bioprospecting

Generally Bioprospecting process[15] consists of four phases:

- Phase 1: On-site collection of samples;
- Phase 2: Isolation, characterisation and culture of specific compounds;
- Phase 3: Screening for potential uses, such as pharmaceutical or other uses; and,
- Phase 4: Product development and commercialisation, including patenting, trials, sales and marketing.

Being biotech companies a major entity in deriving benefits from tk, it is important to know the steps involved in Biotechprospecting of biodiversity for new medicines which are:

1. *Discovery,* identification and collection of material by random, bio-rational and traditional (medicinal) approaches, followed by screening for particular bio-activites, and elucidation of novel molecular form.

2. *Intellectual property rights*: Protection of intellectual property through patenting of new genes and/or bioactive[16] principles with novel antibiotic, insecticidal or anti-tumour properties.

3. *Process technology*: Isolation, synthesis and purification of new bioactive chemicals for laboratory, clinical and field trials to demonstrate and compare the effectiveness and biosafety of the newly discovered product with contemporary market products.

4. *Manufacturing* and *Marketing Strategies:* Development of techniques for larger scale industrial production of the final bioactive product and its market availability and accessibility to the public.[17]

Though the bioprospecting principle may be simple, the interaction between biotechnology use and biodiversity conservation and its sustainable does require a careful designed strategy to complement other aspects of biodiversity protection and socio-economic development.

3.3 Biopiracy

[15] Lydia Slobodian, Rémy Kinna, Alphonse Kambu and Lara Ogniben, "Bioprospecting In The Global Commons: Legal Issues Brief", *available at*: http://www.unep.org/delc/Portals/119/Biosprecting-Issuepaper.pdf (Visited on Feb 13, 2015).

[16] A natural product that has biological activity can also be called a "bioactive" or "bioactive compound".

[17] Ana Sittenfeld, Jorge Cabrera Medaglia, and Marielos Mora, "Bioprospecting and Biotechnology: some policy issue", *available at*: http://www.geneconserve.pro.br/siteantigo/artigo022.pdf (Visited on Feb 12, 2015).

Biopiracy is an act of unminedful, unchecked and unethical bioprospecting. One can say, that biopiracy is an untamed child of bioprospecting.

Biopiracy can be defined as, "the misappropriation and commercialization of genetic resources and traditional knowledge of rural and indigenous people".[18] *Pharmaceutical biopiracy* is a term used generally to describe the legal practice by pharmaceutical companies exploiting the indigenous people's traditional knowledge of medicine.

India covers only 2.4 per cent of the world's land area, but accounts for 7.3 per cent of the global fauna. It is considered the origin of 30,000 to 50,000 varieties of crops and is home to two "hotspots" — the Western Ghats and eastern Himalayas. It has five world heritage sites, 12 biosphere reserves and six wetlands.[19] Thus, India and other developing countries rich in bio-resources and TK are favourite targets and victims of biopiracy, turmeric, neem and basmati rice are some of the well known examples.

Renowned economist and Nobel Prize winner *Joseph E. Stiglitz* comments on the World Trade Organization's Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) highlights the dangers posed by the biopiracy - What we were not fully aware of was another danger, what has come to be termed *bio-piracy*, international companies patenting traditional medicines and foods. It is not only that they seek to make money from 'resources' and knowledge that rightfully belongs to the developing countries, but in so doing, they squelch domestic firms that have long provided the products[20].

Pharmaceutical, biotechnological, cosmetic and agrifood firms are the main biopirates, they exploit biodiversity hotspots in order to create supposedly "innovative" products and guarantee their monopoly on them through the patent system, not giving any profit or proper benefit to local communities and TK holders.

Following acts can said to assist biopiracy:

- Grant of wrong patents to invention that are neither novel nor inventive having regard to traditional knowledge already in public domain.

[18] Understanding, resisting and acting against biopiracy, *available at:* http://www.france-libertes.org/IMG/pdf/understanding_resisting_and_acting_against_biopiracy.pdf (Visited on Feb 23, 2015).
[19] India's Fourth National Report to the Convention on Biological Diversity, *available at:* http://nbaindia.org/uploaded/Biodiversityindia/4th_report.pdf (Visited on Feb 16, 2015).
[20] Abstract given under a book on Globalization written by J E Stiglitz: "Globalization and its discontents", W.W. Norton & Company, New York, 2002.

- Lack of documentation or recognition of traditional knowledge as a prior art.
- Patents granted according to the national legislations which does not recognise certain form of public disclosure as prior art.

Biopiracy is misappropriation of genetic resources or related traditional knowledge through patent system. It is the exploitation of resources of a community which lack development. It can be regarded as a double theft because:

(a) it allows theft of creativity and innovation and

(b) it establishes exclusive rights on stolen knowledge and steal economic options of everyday survival of indigenous communities on the basis of their common knowledge[21].

Another widely cited definition is by Daniel F. Robinson. He adds the element of lacking authorization and benefit-sharing and distinguishes between three different categories of biopiracy:

- Patent-based biopiracy: The patenting of inventions which are based on biological resources and/or traditional knowledge, extracted without adequate authorization and benefit-sharing from biodiversity rich countries, indigenous or local communities.
- Non-patent biopiracy: Extraction of biological resources and/or traditional knowledge that have been extracted without adequate authorization and benefit-sharing from other (usually developing) countries, indigenous or local communities through plant-variety protection or deceptive trademarks.
- Misappropriation: The unauthorized extraction of biological resources and/or traditional knowledge from developing countries, indigenous or local communities, without adequate benefit-sharing and prior consent[22].

3.4 Impact of Biopiracy

Natural populations of around 12% of the 6000 species of potentially medicinal plants are currently estimated to be under threat due to degradation and loss of habitats alongside unsustainable ways of harvesting and lack of cultivation.

[21] Nithin V. Kumar, "Protection of Traditional Knowledge: International and National Initiatives and Posssible Ways Ahead", *available at:* SSRN: http://ssrn.com/abstract=2012724 (Visited on Feb 15, 2015).

[22]Abstract given under a book on Biopiracy written by D. F. Robinson, *Confronting biopiracy: challenges, cases and international debates*, (Earthscan, London/Washington, 2010).

The main threats to biodiversity include:

- habitat fragmentation, degradation and loss;
- over-exploitation of resources;
- shrinking genetic diversity;
- invasive alien species;
- declining forest resource base;
- climate change and desertification;
- impact of development projects;
- pollution of environment.

In the backdrop of the varying socio-cultural milieu and often conflicting demands of various stakeholders(indigenous communities, companies, ngos), there is an urgent need for augmenting and accelerating the efforts for conservation and sustainable use of biodiversity, and for the fair and equitable sharing of benefits arising from the utilisation of genetic resources[23].The Earth's biological resources are vital for the economic and social development of mankind. As a result, there is a growing recognition that biological diversity is a global asset of tremendous value to present and future generations.

Pharmaceutical biopiracy is sharply criticized for patenting traditional knowledge of medicinal plants without recognizing the fact that it is not new, or invented, and depriving the indigenous community to the rights to commercial exploitation of the technology that they themselves had developed. Thus, profits have accrued solely to the pharmaceutical companies and indigenous peoples received little or nothing in return[24].These practices create inequality between developing countries rich in biodiversity, and developed countries hosting companies that engage in 'biopiracy'.

[23]Biodiversity Facts, Status and trends of biodiversity, including benefits from biodiversity and ecosystem services, *available at:* http://www.cbd.int/countries/profile/?country=in (Visited on Feb 17, 2015).
[24] Abstract given under a book on Commercialization of indigenous knowledge written by IKECHI MGBEOJI, *Global Biopiracy: Patents, Plants, And Indigenous Knowledge* (University of British Columbia Press, 2006).

The Maya ICBG case was among the first to draw attention to the problems of distinguishing between benign forms of bioprospecting and unethical biopiracy, and to the difficulties of securing community participation and prior informed consent for would-be bioprospectors[25].

In 2000, the Council of Scientific and Industrial Research (CSIR), India, found that almost 80 per cent of the 4,896 references to individual plant-based medicinal patents in the United States Patents Office (USPTO) that year related to just 7 medicinal plants of Indian origin. Three years later, there were almost 15,000 patents on such medicines spread over the US, UK and other patent office registers. In 2005, this number had grown to 35,000, which clearly demonstrates the interest of the developed world in the knowledge base of the developing countries[26].

3.5 Famous cases of Biopiracy of Indian Traditional Knowledge

A few examples of bio-piracy of traditional knowledge are:

Name of plant	Biological name	Patent granted
Neem	*Azadirachta indica*	European Patent
Basmati Rice	*Oryza sativa*	US patent 5663484
Amla	*Phyllanthus emblica*	USPTO has granted five patents Four patents filed by Japanese Patent Office
Kala Jeera	*Cuminum cyminum*	US 5653981
Kumari	*Aloe barbadensis*	US 5652265
Amaltas	*Cassia fistula*	US 5411733
Pomegranate	*Punica granatum*	US 5411733

[25] Maya ICBG bioprospecting controversy, *available at:* http://www.snipview.com/q/Maya%20ICBG%20bioprospecting%20controversy (Visited on Feb 19, 2015).
[26] Tripathi, S.K. "Traditional knowledge-its significance", 2 *IJTK*, 2003.

Harad	*Terminalia chebula*	US 5529778
Aswagandha	*Withania somnifera*	US 5466452
Turmeric	*Curcuma longa*	US patent 5,401,504
Wheat	*Triticum aestivum*	EP 0445929 B1

A survey conducted by the Indian Drug Manufactures' Association (IDMA) found 668 pharmaceutical patents filed during 1997. Most of the patents are based on the traditional medicinal system of India i.e. Ayurveda. Many of these claims with minor modifications in methods of extraction and processing- could amount to bio-piracy of the centuries old traditional knowledge[27].

3.5 Issues related to Biopiracy

- National criterion of novelty: Different interpretation of patentability criterion of novelty according to national legal system gives rise to a number of conflicts, as in the basmati case[28]. Hence, in determining whether an invention is new, patent authorities only review national prior art and foreign prior art that is patented or documented easily accessible which is absent in case of tk.
- Disclosure of origin: There is a strong conflict between country of origin and benefittor over disclosure of origin of genetic resources and traditional knowledge. The mandatory disclosure of origin would have ensured compliance with mutually agreed ABS-terms and prior informed consent in patent applications.
- Patent authorities capacity: An efficient mechanism to tackle lack of sufficient resources, trained personnel, time and expertise for scrutiny of application which is a major obstacle needs to be implemented.

[27] BD associated TK IP Protection in India with special reference to ABS Experience of the Kani Tribe in Kerala, *available at*: http://shodhganga.inflibnet.ac.in/bitstream/10603/27083/12/12_chapter6.pdf (Visited on Feb 19, 2015).

[28] Utsav Mukherjee, "A Study of the Basmati Case (India-US Basmati Rice Dispute): The Geographical Indication Perspective", *available at*: SSRN: http://ssrn.com/abstract=1143209 (Visited on Feb 17, 2015).

- Obstacles to trade: Local producers from developing countries are prevented from exporting and selling their products in the name of patents, trademarks or plant-breeders' rights. Threat of litigation, as was the case with the yellow enola bean or rooibos[29] looms over their heads.
- Cultural perceptions: Indigenous peoples consider traditional knowledge sacred thus they may perceive extraction of plants, research methods and the idea of intellectual property as an affront to their values which many a times create a clash of opinions over economic benefit and cultural values.
- Over-harvesting: Biopiracy of biological resources leads to exploitation and consequently threat to existence, as was the case with hoodia[30]. Sustainable exploitation must be encouraged and emphasized upon which can be guaranteed by Access and benefit-sharing mechanisms.

4. *Legal Framework*

The new rules for biodiversity prospecting and natural products research derive from three sources: international treaties, national laws, and professional self-regulation.

4.1 International Instruments

Traditional Knowledge is a complex multi facet issue. Many countries and Organizations worldwide are considering how to address this issue at international, regional and national levels. Issues relating to TK as also discussed in arenas relating to rights of indigenous people and cultural expressions, access to resources, benefit sharing and protection at different forums like WIPO, UNCTAD,UNEP/ CBD.

[29] Gillian N. Rattray, The Enola Bean Patent Controversy: Biopiracy, Novelty and Fish-And-Chips, 1 *DLTR* (2002).

[30] This concerns a dispute and subsequent partnership between the San people in South Africa and pharmaceutical companies in developed countries over the ownership and the right to commercially exploit as well as benefit sharing of the use of Hoodia plant which contains traditional medicinal knowledge and patentable active components. An appetite-suppressant drug developed by pharmaceutical companies are faced with counterfeiting drugs, *available at:* http://www.wipo.int/export/sites/www/academy/en/about/global_network/educational_materials/cs1_hoodia.pdf (Visited on Feb 15, 2015).

Table 2 lists core instruments forming part of the international legal framework working for the protection of TK in direct or indirect manner.

ORGANISATION	MAIN OBJECTIVE
1. *WIPO -The IGC on Intellectual Property Genetic Resources and Traditional Knowledge, 2014*[31].	International forum for discussion of intellectual property issues in relation to access to genetic resources, benefit sharing and protection of traditional knowledge and expressions of folklore.
2. *Convention on Biological Diversity, 1993*[32].	First international initiative to recognize: (a) conservation of biological diversity, (b) the sustainable use of its components, and (c) the fair and equitable sharing of benefits derived from its utilization
3. *The Nagoya Protocol, 2010*[33].	To ensure fair and equitable sharing of benefits arising out of genetic resources and to provide for appropriate access to genetic resources and transfer of technology for protection of biodiversity.

[31] Established in September 2000, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) serves as a forum where WIPO member states can discuss the intellectual property issues that arise in the context of access to genetic resources and benefit sharing as well as the protection of traditional knowledge and traditional cultural expressions, *available at:* http://www.wipo.int/tk/en/igc/ (Visited on Feb 15, 2015).

[32]The Convention was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). It remained open for signature until 4 June 1993, by which time it had received 168 signatures. The Convention entered into force on 29 December 1993, a*vailable at:* http://www.cbd.int/convention/ (Visited on Feb 15, 2015).

[33] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,2010, The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components, *available at*: www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (Visited on Feb 17, 2015).

4. *ITPGRFA, 2004*[34].	Recognizes the right of farmers to save, use, exchange and sell farm-saved seed through creation of a multilateral system.
5. *Doha Ministerial Declaration, 2001*[35].	To examine the relationship between the TRIPS Agreement and CBD and also the protection of traditional knowledge and folklore.
6. *The UPOV Convention*[36].	Protection of new plant varieties by conferring monopoly rights on production, sale and trading.
7. *UN Declaration on Rights of Indigenous persons, 2007*[37].	Emphasizes on the rights of indigenous persons to maintain and strengthen their own institutions, cultures and tradition so as to foster their development.
8. *Regional Initiatives* a) Swakudump Protocol[38].	Provides for the rights and recognition of holders of TK, concept of equitable benefit sharing, licensing.

[34] The International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA) is a crucial legal instrument in the fight against hunger and poverty, particularly in an era of climate change that also affects food production, *available at*: http://www.planttreaty.org/ (Visited on Feb 15, 2015).

[35] The November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines, a*vailable at:* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Visited on Feb 17, 2015).

[36] UPOV (International Union for the Protection of New Varieties of Plants) was established by the International Convention for the Protection of New Varieties of Plants. The Convention was adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991. UPOV's mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society, a*vailable at:* http://www.upov.int/portal/index.html.en (Visited on Feb 17, 2015).

[37] On September 13, 2007, the Declaration on the Rights of Indigenous Peoples was adopted by the General Assembly, *available at*: http://undesadspd.org/indigenouspeoples/declarationontherightsofindigenouspeoples.aspx (Visited on Feb 18, 2015)

[38] Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization (ARIPO), *available at:* http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=201022 (Visited on Feb 18, 2015)

b) Cusco Declaration, 2002[39].	Stressed on the importance that should be given for protection of bio diversity and associated TK.

4.2 Law's in India

Despite the challenges it still faces, India has made considerable progress in a short period of time when it comes to the protection of its biodiversity and traditional knowledge.

As a member of the Convention on Biological Diversity (CBD), India identified the following as some of its main goals in its National Policy and Macrolevel Action Strategy on Biodiversity (1999):

1. Securing the participation of State Governments, local communities and people, NGOs, industry and other interested parties;
2. Realizing the value of biodiversity through research and development;
3. Ensuring that India gets the benefits as being the country of origin of biological resources, and
4. Indian indigenous communities and people get the benefits as being the conservers of biodiversity, creators and holders of traditional knowledge systems, innovations, and practices.

1. Plant Varieties Protection and Farmers' Rights Rules, 2003[40]

India passed the Plant Varieties Protection and Farmers' Rights Act (PVPFR) 2001[41], followed by the PVPFR Rules 2003. These two pieces of legislation ensure the protection of plant breeders' rights over new varieties they develop and give farmers the entitlement to register

[39] Cusco Declaration on Access to Genetic resources, Traditional Knowledge and intellectual property rights of like minded mega diverse countries, 2002, a*vailable at*: https://www.environment.gov.za/sites/default/files/docs/cuscodeclaration_traditionalknowledge_intellectualpropertyrights.pdf (Visited on Feb 18, 2015)

[40] Vide G.5.R. 738(E), published in the Gazette of India, Extra., Pt. ll, See. 3(i), dated 12th September, 2003.

[41] *The Protection of Plant Varieties and Farmers' Rights Act,* 2001 (Act 53 of 2001)

new varieties and also to save, breed, use, exchange, share or sell the plant varieties that farmers have developed, improved and maintained over many generations[42].

2. Patent Act, 2005[43]

India also ratified the Patent Second Amendment Act 2002[44] and Patent Third Amendment Act 2005, amending its Patents Act 1970[45]. These amendments prohibit the granting of patents for plants, animals, and traditional knowledge. Furthermore, India's patent laws now require "mandatory disclosure of source and geographical origin of the biological material in the specification when used in an invention." Should a party fail to disclose this information, or participate in wrongful-disclosure, then the amendments permit opposition to, or revocation of, the patent.

3. Biological Diversity Act, 2002[46]

In 2002, India enacted the Biological Diversity Act of 2002, it covers conservation, use of biological resources and associated knowledge occurring in India for commercial or research purposes or for the purposes of bio-survey and bio-utilisation. As per Article 15 of the CBD, the Act regulates access to biological resources and associated traditional knowledge to ensure equitable sharing of benefits arising out of their use[47]. The Act mandated the implementation of its provisions through the formation of a three tier structure promote conservation, sustainable use, and documentation of biodiversity. In order to achieve its objectives, the drafters of the *Biological Diversity Bill* 2000[48] have envisaged a three tier institutional structure:

1. A National Biodiversity Authority[49] (NBA);

[42] Francisco A. Laguna & Priya Lamba, "India – Efforts Taken to Protect Against the Bio-Piracy", *available at:* https://translegalllc.wordpress.com/2013/03/08/india-efforts-taken-to-protect-against-the-bio-piracy/ (Visited on Feb 16, 2015)
[43] *The Patents (Amendment) Act, 2005* (Act 15 of 2005)
[44] *The Patents (Amendment) Act, 2002* (Act 38 of 2002)
[45] The *Patents Act, 1970* (Act 39 of 1970)
[46] *The Biological Diversity Act, 2002* (Act 18 of 2003)
[47] Law Commission of India, 171th Report on Biodiversity Bill (January, 2000)
[48] *Biological Diversity Bill 2000* (Bill no. 93 of 2000)
[49] The National Biodiversity Authority (NBA) was established in 2003 to implement India's Biological Diversity Act (2002). The NBA is Autonomous body and that performs facilitative, regulatory and advisory function for Government of India on issue of Conservation, sustainable use of biological resource and fair equitable sharing of benefits of use. *Available at:* http://nbaindia.org/content/16/14/1/introduction.html (Visited on Feb 18, 2015).

2. State Biodiversity Boards[50] (SBBs); and
3. Biodiversity Management Committees[51] (BMCs) at village and municipal levels[52].

National Biodiversity Authority (NBA), an autonomous body advises the Central Government of India on conservation matters, sustainable use of biological resources, and fair and equitable sharing of benefits arising out of the use of such resources.

In December 2012, the First National Biodiversity Congress 2012 (Congress) was held in Kerala, India. It was organized by the Ministry of Environment and Forest, the NBA, and SBBs to address several biodiversity issues, including the management of traditional knowledge and access and benefit sharing of genetic resources.

4. Traditional Knowledge Digital Library (TKDL)[53]

Collaboration between many groups, including the Council of Scientific and Industrial Research, has led to the development of the Traditional Knowledge Digital Library (TKDL), a valuable resource. The TKDL is a database that documents existing traditional knowledge and makes it available in the public domain. The vast database created by India has 34 million pages of information in five international languages in formats easily accessible by patent examiners at International Patent Offices.[54] Thus, patent examiners worldwide now have the

[50] State Biodiversity Boards (SBBs) are to be established under Section 22(2) of the Act, So far 25 States have established the SBBs. *Available at*: http://nbaindia.org/text/13/StateBiodiversityBoards.html ((Visited on Feb 18, 2015).

[51] As per the Biological Diversity Act, the local bodies constitute the BMC in accordance with Section 41, within their area of jurisdiction for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals, micro-organisms and chronicling of knowledge relating to biological diversity. *Available at:* http://nbaindia.org/text/14/BiodiversityManagementCommittees.html (Visited on Feb 18, 2015).

[52] *Available at:* Chapter X (Section s.41 (1) to s.41 (3) of the *Biological Diversity Act*,2002 and s.22 of the *Biological Diversity Rules*, 2002.

[53] TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented at CSIR. An inter-disciplinary team of Traditional Medicine (Ayurveda, Unani, Siddha and Yoga) experts, patent examiners, IT experts, scientists and technical officers are involved in creation of TKDL for Indian Systems of Medicine. Available at: http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng (Visited on Feb 17, 2015).

[54] Editorial, "India may win patent claims due to Traditional Knowledge Digital Library: Manmohan Singh" The Economic Times, Oct 16, 2012.

ability to check patent applications against the TKDL before issuing a patent that could be later-challenged, even revoked, on the grounds of bio-piracy.

4.3 Professional Self Regulation

Although trade in medicinal plants from developing countries has increased in the past few decades with more drugs developed, few if any benefits accrue to the source countries and the traditional communities. There are, however, a few exceptions.

These include Shaman Pharmaceuticals and the Body Shop[55]. Shaman develops new therapeutics by working with indigenous peoples of tropical forests. The Body Shop is bioprospecting in the Kayapo[56] area of Brazil extensively drawing on traditional knowledge of the Kayapo Indians. It has invested in ethnobotanical research for the development of new ingredients for its body-care products. In 1991, the Body Shop had at least 300 products with annual sales of US$90 million. By 1995, its annual sales stood at least at US$ 200 million[57].

Both Shaman and the Body Shop have developed mechanisms for returning some of the benefits from the commercialization of medicinal plants and traditional knowledge to the traditional people. The Body Shop also sponsors projects to assist local people to establish enterprises for processing crude products. One logical place to look for guidance in resolving the issues related to biopiracy of traditional knowlege would be any agreements between developing nations (or their private sectors) and industrialized nations (or their private sectors) which relate to the preservation of and access to genetic resources. One such agreement that

[55] These are pharmaceutical companies whose product development activities are largely based on traditional knowledge. They have established systems to recognize the value of traditional knowledge and to provide a certain measure of compensation to local people for the knowledge.
[56] The Kayapo are a powerful and well-known Brazilian tribe who inhabit a vast area of the Amazon across the Central Brazilian Plateau.
[57] Dr. John Mugabe, "Intellectual property protection, and traditional knowledge : an exploration in international policy discourse", WIPO (1998), available at: http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_4.pdf (Visited on Feb 17, 2015)

has been widely hailed was struck between the U.S. pharmaceutical firm, Merck, and the government of Costa Rica, in late 1991[58].

Merck-INBio agreement in Costa Rica signed in 1991 is an ideal example of professional self regulation which work for the benefit of pharmaceutical companies and traditional knowledge holders simultaneously.

An agreement between Merck & Company, the world's largest pharmaceutical company, and the Instituto Nacional de Biodiversidad, a two-year "collaborative research agreement" under which Merck agreed to pay INBio a sum of $1 million for all of the plant, insect, and soil samples the institute could collect in addition to a percentage of the royalties from any drugs that Merck develops from samples provided by INBio. This kind of bilateral contractual arrangements between ecologically-rich states or communities and private corporations are based on the principles of "prior informed consent" and "equitable sharing of the benefits". In such case, bioprospecting is regulated through "Access and Benefit-Sharing Agreements". The agreement is a win-win situation as it protects the proprietary rights of the industry, while at the same time recognizing that it is to the advantage of industrial nations to help with the custodianship of natural resources[59].

Such kind of agreements will help in many ways:

1. Using natural resources in a sustainable way, keeping the resources intact.
2. Strengthening the economy of biodiversity rich countries.
3. Ceating more jobs, profits, and a better-educated constituency.
4. Reducing time and effort on part of companies.

All this can be achieved by cataloging and selling rights to the country's natural resources than by destroying its resources, thus legalizing bioprospecting benefitting both companies and biological diverse countries.

[58] M. D. Coughlin Jr., "Using the Merck-INBio agreement to clarify the Convention on Biological Diversity", 2 CJTL 31 (1993), *available at:* http://www.ciesin.org/docs/008-129/008-129.html (Visited on Feb 17, 2015).
[59] E Blum, "Making biodiversity profitable: A case study of the Merck/INBio agreement", 4 *Environment* 35 (1993), *available at*: http://www.ciesin.org/docs/002-270/002-270.html (Visited on Feb 17, 2015).

5. *Protection of traditional knowledge:*

Protection of TK is important for communities in of developing and least developed countries with their diverse stores of traditional knowledge. Broadly, a two fold approach has been floated for the protection of TK in the present Intellectual Property Rights regime- positive and defensive approaches[60].

(*a*) *Positive Protection*: Empowering communities through granting of rights to promote their traditional knowledge, control its uses and benefit from its commercial exploitation. Existing intellectual property system can protect only few kinds or types of traditional knowledge, and specific legislation developed by a number of countries can provide protection to tk. However, specific protection enforced under national law may not hold for other countries, one reason why many indigenous and local communities as well as governments are pressing for an international legal instrument. South African Traditional Knowledge Bill, which seeks to provide recognition for expressions of indigenous knowledge as an aspect of intellectual property is a classical example.

The basic modalities through which positive protection can be provided to TK:

(*i*) The existing Intellectual Property Rules: Such as, copyright, patents, plant varieties, industrial designs, trademarks, trade names, and geographical indications. Geographical Indications and Trade Secrets are the two most suitable forms of IP for TK protection.

(*ii*) Sui Generis[61] protection to match identified needs of TK holders: A distinct *sui generis* system specifically for protection of TK that consists of a set of nationally recognised laws differing from country to country. It is a system that can create legal rights associated with traditional knowledge and promote its access and benefit sharing.

[60] Vera Shrivastav, Protection of Traditional Knowledge within the Existing Framework of Intellectual Property Rights: Defensive and Positive Approach, SSRN (July 7, 2014). Available at: http://ssrn.com/abstract=2463017 (Visited on Feb 18, 2015)

[61] *Sui generis* literally means 'of its own kind' or 'unique'.

(*iii*) Contracts (the most flexible way to protect TK): Contracts with biotech or other companies for commercialisation, transfer of technology, benefit sharing, etc such as Merck-InBio Agreement.

(iv) *Registration:* It deals with creating a system for registration of innovations by the inventor Traditional knowledge holders.

(*b*) *Defensive Protection*: aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge. The safeguards in defensive protection with respect to patents include:

a) Requirement of disclosure of origin of genetic resources and traditional knowledge relevant to the invention in the patent application.

b) Preparing a database containing complete information about traditional knowledge in a scientific and technical manner and accessible to patent examiners. Such a database will be helpful in determining the novelty of the invention in question.

India, for example, has compiled a searchable database of traditional medicine (TKDL) that can be used as evidence of prior art by patent examiners when assessing patent applications. This followed a well-known case in which the US Patent and Trademark Office granted a patent (later revoked) for the use of turmeric[62] to treat wounds, a property well known to traditional communities in India and documented in ancient Sanskrit texts. People's Bio-diversity Register, the Honey Bee Network are among various initiatives for TK documentation in India.

Preventive patent applications and defensive trademark registration come within the ambit of this definition[63].

[62] In Turmeric case, the US patent and Trademark office granted a patent on the 'use of wound healing' which was successfully challenged by India on the grounds of 'prior art' and that this use of turmeric was well known and nothing new had been invented. The document relating to this traditional knowledge of India were unknown to the US patent and Trademark Office. When they came to know about this, patent was revoked.

[63] Traditional Knowledge and Intellectual Property – Background Brief, available at: http://www.wipo.int/pressroom/en/briefs/tk_ip.html (Visited on Feb 18, 2015).

6. A model to fight biopiracy- Case of Kani Tribe

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements concerning the "Jeevani" drug[64], which was developed by scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe in Kerala, South India. Within the Kani tribe the tribal healers, known as Plathis hold customary rights to transfer and practice certain traditional medicinal knowledge. The three Kani tribal members divulged the knowledge about arogyapaacha to the Indian scientists who isolated 12 active compounds from it, developed the drug "Jevaani", and filed two patent applications on the drug. The technology was then licensed to an Indian pharmaceutical manufacturer the Arya Vaidya Pharmacy, Ltd., pursuing the commercialization of Ayurvedic herbal formulations[65].

In 1996 the pharmaceutical company agreed to pay $50,000 as license and a royalty of 2% on the sale price. Kanis and TBGRI were to share it 1:1. The Kerala Kani Samudaya Kshema Trust has been formed to channelise the returns among the 16,000 widely dispersed Kanis. The Trust has an elected governing council and the funds are utilized for primary education, basic health services and other community development programme. Kerala's Forest Department has now leased forest lands to the Kanis where they will sustainably cultivate Arogyapacha for medicinal purposes[66].

This model of equitable benefit sharing can help resolve many problems related with biopiracy activities carried on by multinational companies. But there is a strong need to include PIC and ABS in the prevailing arrangements and mechanisms.

With its entire demerits Kanis benefits model is the first successful benefit sharing model of the world to protect indigenous people and their traditional knowledge.

[64] "Jeevani" is a restorative, immunoenhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant arogyapaacha, used by the Kani tribals in their traditional medicine.
[65] K Gupta, Value addition to local Kani tribal knowledge: patenting, licensing and benefit-sharing (2002), Available at: http://www.iimahd.ernet.in/publications/data/2002-08-02AnilKGupta.pdf (Visited on Feb 15, 2015).
[66] Editorial, "A model to fight bio-piracy", GoodNewsIndia, Sep 15, 2002

7. Limitations of the Intellectual Property Rights Regime in Protecting Traditional Knowledge

The Patent Act considers knowledge available (oral or otherwise) within local/indigenous communities 'to be anticipated', a 'prior art', and hence not patentable. Traditional knowledge does not meet the required conditions of novelty, inventiveness and industrial applicability as required of the legally defined IPR. Another issue is that IPR regimes are based on individual rights where as TK is by and large collective right[67].The indigenous peoples experience difficulty in protection of their traditional knowledge handed down from generation to generation through IP mainly from its failure to satisfy the requirements for protection under existing IP law.

Benefit sharing in the emerging IPR regime, it is argued, requires documenting TK to identify both the knowledge and knowledge holders. But there is a fear that documentation and registration, would establish the knowledge in the public domain and therefore prevent granting of patent. Another key concern shared by indigenous peoples worldwide is that the present intellectual property rights regime favours multinationals and promotes monopoly. Where IP protection may apply, high registration costs and huge expenses in defending a patent or other intellectual property right effectively limit its availability to the vast majority of indigenous communities, who are poor primarily in developing countries. In this way, the existing intellectual property rights regime is seen to help corporate interests and entrepreneurs lay claim to indigenous knowledge without appropriate acknowledgement or compensation for the communities who have developed that knowledge[68].

Patent law in India needs a haul in order to be protected from being plagiarized by multinational profit making giants who are stealing the age-old Indian traditional knowledge.

8. Conclusion and Suggestions

[67] C.R Bijo, "Access And Benefit Sharing From The Indigenous Peoples Perspective: The TBGRI-Kani Model, 3/1 *LEDJ (2007)*

[68] Tonina Simeone, "Indigenous Traditional Knowledge and Intellectual Property Rights", *available at:* http://www.parl.gc.ca/content/lop/researchpublications/prb0338-e.htm (Visited on Feb 18, 2015).

There is a need to develop a two pronged (legal and economical) approach in dealing with the issues of traditional knowledge use and protection. It is desirable following points must be taken into account:

1. Strengthening national legislation for efficient use and better protection of traditional knowledge.
2. Efforts for promotion of traditional knowledge.
3. Creating awareness among the indigenous communities regarding their rights.
4. Resolving the issue of benefit sharing which is tantamount.

Firstly, it is evident that India is on the right path when it comes to protecting its national interest in its biodiversity and traditional knowledge, while granting access on a case-by-case basis. India must now adopt a balanced approach to safeguard its genetic resources while promoting much needed growth in the biotechnology sector.

In the last few years, developing countries have become more vocal in the international arena. However to fight the problem of biopiracy, it is important for biodiversity rich countries to come together and work cooperatively with each other so they can have strong bargaining position with industrialized countries.

Efforts must be made to restrict biotech and pharmaceutical companies from converting the world's natural genetic resources into private monopolies. Privatizing what ought to be public must be strongly opposed and counter measures must be taken to stop bioprivateering.

Treaty obligations and policies are widely discussed but the implementation is overlooked, The key issue is the setting up of regulatory structures.

Secondly, efforts should also be taken for the promotion of TK. The focus must not be just on harnessing of TK for trade and development but measures must be taken to ensure strengthening and development traditional knowledge base. It will facilitate the movement of holders of tk along a path of development and betterment.

The focus must not be restriction on access to tk because if kept secret TK will continue to be a non economic entity. One cannot justify stalling economic development of the society in the

name of protection of moral rights of indigenous community. Thus main concern of protection of traditional knowledge should be regarding sustainable use of indigenous knowledge and benefit sharing of the profits incurred from its use.

Thirdly, some mechanism must be developed to make tribes legally aware about the issues concerning the knowledge they hold and which needs to be protected. Tribal communities do not have access to legal information that would protect their plants and cultural knowledge nor do they have the finances to obtain them. The biopirate companies often overexploit the beneficial traditional knowledge for commercial use, which ultimately result in the loss of forests and genetic material, crisis of land, plants and cultural knowledge of the indigenous communities.

The issue of erosion of traditional knowledge is tantamount, and creating awareness among the indigenous communities is need of the hour.

Fourthly, people from the developing parts of the world really need, for their agriculture and medicine is exemption from monopolies of biotech and pharmaceutical companies. They need to secure legal recognition and rights of governance:

- To be free to grow and breed all sorts of plants and animals for agriculture;
- To use genetic engineering, to commission the genetic modifications that suit their needs.
- To collectively decide over development project/programmes by recognising the free, prior and informed consent of tribes through the use of local customary laws;
- To collectively benefit from the use of their biological resources;
- To their innovations, practices, knowledge and technologies acquired through generations;
- To collectively benefit from the utilisation of their innovations, practices, knowledge and technologies;
- To use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity; and
- To the exercise of collective rights as legitimate custodians and users of their biological resources

Lastly, biologically rich countries must aim at establishing a framework of national laws for traditional communities to:

- Have their voice heard on issues that are important to them.
- Defend and safeguard their rights.
- Have their views and wishes genuinely considered when decisions are being made about their lives.

There is a need to take concrete steps in the right direction to develop model law based on rights and clear recognition of the access to biological resources which provide for community rights over their biological resources and their right to collectively benefit from their use, rights to their innovations, practices, knowledge and technology and the right to collectively benefit from their utilization, so that the treasure trove of traditional knowledge could be used for the benefit of all humankind rather than for private profit.

Brief Profile

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