BIO-PIRACY: AN ANALYSIS INTO THE THEFT OF TRADITIONAL KNOWLEDGE

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1. Introduction

Bio-piracy can be described as grant of wrong patents to invention that are neither novel nor inventive having regard to TK already in public domain. Such patents may be granted due to the lack of documentation or recognition of TK as a prior art. Bio piracy may also happen in cases where patents are granted according to the existing national legislations which does not recognize certain form of public disclosure as prior art as in the case of USA[1]. Bio piracy has now emerged as a term to describe the free ride of corporations of developed nations over the genetic resources and TK of developing countries. Bio piracy is thus misappropriation of genetic resources or related TK through the patent system. Bio piracy is not just a matter of law it is one of morality and of fairness. It is more like exploitation of resources of a community which lack development. Bio-piracy can be regarded as double theft because firstly it allows theft of creativity and innovation and secondly it establishes exclusive rights on stolen knowledge and steal economic options of every day survival of indigenous communities on the basis of their common knowledge[2].But we must note that such cases of grant of wrong patents and their subsequent revocation had led to more debate in this area and thereby development of new initiatives like TK digital libraries which provides for documentation of TK .

What makes knowledge "traditional" is not its antiquity, much TK is not ancient or inert, but is a vital, dynamic part of the contemporary lives of many communities today. It is a form of knowledge which has a traditional link with a certain community: it is knowledge which is developed, sustained and passed on within a traditional community, and is passed between

[1] Vandana Shiva ,"Need to change the western IPR system", available at, http://worldinformation.org/wio/readme/992007035/1078487909. Last visited, 23rd January 2018.
[2] Vandana Shiva, "The *US patent system Legalizes Theft and Biopiracy"*, *The Hindu*, Wednesday, July28, 1999.

generations, sometimes through specific customary systems of knowledge transmission. A community might see TK as part of their cultural or spiritual identity. So it is the relationship with the community that makes it "traditional". TK is being created every day, and evolves as individuals and communities respond to the challenges posed by their social environment. This contemporary aspect is further justification for legal protection. It is not only desirable to develop a protection policy that documents and preserves TK created in the past, which may be on the brink of disappearance; it is also important to consider how to respect and sustain the development and dissemination of further TK that arises from continuing use of TK systems. [3]

TK has always been an easily accessible treasure and thus has been susceptible to misappropriation. The traditional knowledge, particularly, related to the treatment of various diseases has provided leads for development of biologically active molecules by the technology rich countries. In other words, TK is being exploited for bio-prospecting. Also TK is often misappropriated, because it is conveniently assumed that since it is in public domain, communities have given up all claims over it. TK includes both the codified (documented) as well as non-codified information. [4]Just a matter of law it is one of morality and of fairness. It is more like exploitation of resources of a community which lack development. But we must note that such cases of grant of wrong patents and their subsequent revocation had led to more debate in this area and thereby development of new initiatives like TK digital libraries which provides for documentation of TK .[5]

While the options and the technicalities of protection systems are diverse, a common thread is that protection should principally benefit the holders of the knowledge, in particular the indigenous and traditional communities and peoples that develop, maintain and identify culturally with TK and seek to pass it on between generations, as well as recognized individuals within these communities and peoples. Representatives of these communities often stress that the approach to protection should take account of their customary laws and practices, rather than imposing an unworkable mechanism that takes no account of their needs and expectations.

[3] Intellectaul Property and Traditional Knowledge, WIPO ,booklet No. 2, available at, http://www.wipo.int/freepublications/en/TK /920/wipo_pub_920.pdf. Last visited, 9th January 2018.
[4] G. Indira Priyadasrshini, 'Traditional Medicinal Knowledge in India - An Appraisal', available at, http://www.indiastat.com/article/25/indira/fulltext.pdf. Last visited, 30th January 2018.
[5] *ibid*

Some TK is closely associated with plants and other biological resources, such as medicinal plants, traditional agricultural crops and animal breeds. TK often provides researchers with a lead to isolate valuable active compounds within biological resources. Such genetic and biological resources are linked to TK and traditional practices through the utilization and conservation of the resource, which has often occurred over generations, and through their common use in modern scientific research. The protection of TK is often closely linked to protection of biodiversity, in particular under the CBD. [6]

The protection of TK is important for communities in all countries, particularly perhaps in developing and least developed countries. On one level, TK plays an important role in the economic and social organization of those countries, and placing value on such knowledge is a viable means of promoting a sense of national cohesion and identity. On another level, developing and least developed countries are engaged in implementing two international agreements, the CBD and TRIPS, that may affect the manner in which knowledge associated with the use of genetic resources is protected and disseminated.[7] Intellectual property, however, is not only about property. It is also about recognition of and respect for the contributions of identifiable, human creators. From this perspective, intellectual property has a very important role to play in protecting the dignity of holders of TK and, by conferring property rights in relation to such knowledge, giving those holders a degree of control of its use by others.

TK has gained prominence in the contemporary debates regarding intellectual property law and biodiversity law. Each of these regimes has different reasons for valuing traditional knowledge. While intellectual property law values TK for its material value as a commercial product, biodiversity law values TK for its use in conserving biological diversity. Issues relating to protecting, recognizing and rewarding of TK associated with biological resources are very complex. [8] The modalities for protecting TK are still emerging and evolving. The nature of entitlements and share in benefits is also a grey area. Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue. As regards

[6] WIPO, Intellectual Property And Traditional Knowledge Booklet No. 2, p. 6

[7] WIPO International Forum on 'Intellectual Property And Traditional Knowledge: our Identity, our Future' , 22nd January 2002 available at, http://www.wipo.int/arab/en/meetings/2002/muscat_forum_ip/ipTK _mct02_i3.htm. Last visited, 19th January 2018.

[8]Graham Dutfield,'TRIPS-Related Aspects of Traditional Knowledge', available at http://leeds.academia.edu/GrahamDutfield/Papers/890629/TRIPSrelated_Aspects_of_Traditional_Knowledge. Last visited,19th January 2018.

protection of knowledge, innovations and practices associated with biological resources, these do not seem to fall in the conventional legal systems of IPR protection. These conventional forms of IPRs are inadequate to protect indigenous knowledge essentially because they are based on protection of individual property rights, whereas TK is, by and large, collective. [9] Further, the informal knowledge presents other difficulties in being recognized for the purpose of IP protection, such as knowledge is developed over a period of time and may either be codified in texts or retained in oral traditions over generations. Further communities quite often hold knowledge in parallel. Nevertheless, the development of an appropriate form of protection for the knowledge of local communities is of great interest to countries which are rich in biodiversity, and also rich in TK, such as India.

2. Resolving Bio-piracy

Bio-piracy and patenting of indigenous knowledge is a double theft because first it allows theft of creativity and innovation, and secondly, the exclusive rights established by patents on stolen knowledge and steal economic options of everyday survival on the basis of our indigenous biodiversity and indigenous knowledge. Overtime, the patents can be used to create monopolies and make everyday products highly priced.[10]

If there were only one or two cases of such false claims to invention on the basis of biopiracy there could be an error. However biopiracy is an epidemic .the problem was not made out in the case of turmeric by the patent clerk but the problem is deep and systematic and it calls for systematic changes not case by case challenge. Individual challenges will not stop biopiracy. [11]Our IPR system itself has to undergo change. A patent system which is supposed to reward inventiveness and creativity systematically rewards biopiracy, if patent system fails to apply the criteria of novelty and non-obviousness in the granting of patents related to indigenous knowledge, then the system is flawed and needs to change.[12]

[9] 'Protection Of Biodiversity And Traditional Knowledge – The Indian Experience', Report of the Committee On Trade And Environment Council For Trade-Related Aspects Of Intellectual Property Rights 2000, available at, http://www.twnside.org.sg/title/cteindia.htm. Last visited, 13th January 2018.
[10] Calestous Juma,*The Gene Hunters: Biotechnology and the Scramble for Seeds*, Princeton University Press, Princeton New Jersey.
[11]Calestous Juma,*The Gene Hunters: Biotechnology and the Scramble for Seeds*, Princeton University Press, Princeton New Jersey.
[12] Chris Hamilton, "Intellectual property rights, the bio-economy and the challenge of bio-piracy", *Genomics, Society and Policy Journal* ,2008, Vol. 4, No. 3, pp 26-45

3. Legal Perspective at International Level

In last decade of twentieth century, the legalities of obtaining samples of plants, microbes and animals were straightforward. In many instances, a researcher could simply arrive at a field site, collect samples and take them home. There was no applicable law. The majority of the actors estimated that the biodiversity erosion was the lack of the wrong definition of ownership. Before 1992, the living species were regarded as Common Heritage of Mankind. As common resources, private companies and individual scientists could take and use the resource without having justification or giving compensation.

Today, there are three main ways, through which bio-piracy is regulated: International regulations, national laws and professional self-regulation. In this paper firstly the international regulations will be explored. The two conventions that are most relevant when speaking of bio-piracy and protection of Indigenous Knowledge are, as mentioned above, the CBD and TRIPS. Let's start with an examination of the CBD.

3.1. The Convention on Biological Diversity.

A big step was made in 1994 when the CBD came into force. This convention gave sovereign national rights over biological resources.[13]. One of the advantages of it is that it enables developing countries to better benefit from their result of traditional knowledge. Under these rules, one might expect that Bio-prospecting implies a prior informed consent and that it must result in a shared benefit between the biodiversity-rich country and the prospecting firm. Some critics say that the CBD must establish appropriate regulations to prevent bio-piracy. Some critics even go as far as saying that the CBD along with GATT are a prescription for a monoculture of knowledge since "these instruments are being used to universalize the U.S. Patent regime worldwide, which inevitably lead to an intellectual and cultural impoverishment by displacing other ways of knowing, other objectives for knowledge creation, and other modes of knowledge sharing."[14] The view can be interpreted to be radical, but a conflict can be seen within the CBD. On the one hand, the CBD protects biodiversity and gives legal space for the

[13] Article 3 Convention on Biological Diversity---States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

[14]Calestous Juma,*The Gene Hunters: Biotechnology and the Scramble for Seeds*, Princeton University Press, Princeton New Jersey.

recognition and enforcement of indigenous rights. On the other hand, in assuring a market of shared benefits emanating from natural resources, the Convention legitimizes a market for owned genes and thereby diminishes biodiversity.[15]

Any biodiversity legislation which is aimed at implementing the CBD needs to have a principle of sovereignty as a starting point and as a working principle. This is a topic for the national legislation. The sovereign biodiversity property rights, embodying both biological and intellectual heritage have to be formalized and protected as existing prior to intellectual property rights. These rights can only exist where they do not infringe on the former, otherwise it becomes an infringement and violation of sovereignty.[16]A possible solution, as suggested by Vandana Shiva, is that ownership of biodiversity needs to be based on a combination of rights and responsibility and a co-ownership of the state and local communities.

3.2. The Agreement on Trade-Related Aspects of Intellectual Property Rights - TRIPS

The adoption of the TRIPS Agreement in 1994 has represented a historical change in intellectual property, with profound implications in the area of pharmaceutical patents. It seems clear that it is in developing countries where the patenting of pharmaceuticals has undergone dramatic changes. About 50 countries did not confer protection for pharmaceutical products, which TRIPS obliged all WTO Member countries to do. TRIPS sets forth minimum standards to be provided for. TRIPS establishes a general framework for the interpretation of its provisions and aim at balancing the interests of innovators and users of technology in the protection of intellectual property, in a manner that enhances social and economic welfare. [17] TRIPS leaves considerable room in certain areas to legislate at the national level and, in particular, to adopt measures that may mitigate eventual negative effects of the introduction of pharmaceutical product patents.[18]Article 8.1 is of significant interest:

[15] Beth Burrows "Biopiracy, Patenting and International Trade Agreements." ,*Synthesis/Regeneration 15*,Winter 1998.
[16] 'The Scientist', 24th April , 2002. Available at, www.biomedcentral.com/news/20020424/04/. Last visited, 22nd February, 2018.
[17] TRIPS Article 7 The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.
[18] Carlos M. Corea, "Implementinug the TRIPS agreement in the patents field. Options for developing countries", *Journal of World Intellectual Property*, Vol. 1,2009

"*Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement*."

3.3. Loopholes within TRIPs

Although, TRIPs essentially favors the expansion of current IPR regimes, there are some provisions in TRIPs that can be exploited by parties having greater money power.

Article 8 provides for legal measures to protect public health and nutrition in public interest. Environmental protection has not been explicitly built into this provision. Although, "Public Interest" would be interpreted to include environmental protection, however, this provision gives a wide scope to interpretation of the term "Public Interest".

Article 27 (2) provides for exclusion from patentability of inventions, whose commercial use needs to be prevented to safeguard against "serious prejudice to environment". This phrase is rather vague. A country would be required to first define "what is serious prejudice ?", justify the prevention of commercial use and only then justify non-granting of patents.

Article 27 (3) provides the countries to exclude plants and animals from patentability by providing an effective means or *sui generis* system of protection of IPRs related to these, which will be interpreted differently by various countries.

3.4. Loopholes within CBD

Although conservation of biological resources has been considered as important in CBD, exploitation of biological resources can run counter to conservation and sustainable use as clear cut standards for sustainable use have not been defined. Moreover, CBD is subject to national and international legislations, which raises the issue that between TRIPs and CBD which holds legal priority. Legal opinion, would perhaps be that between the two, TRIPs being the later treaty would supersede CBD in case of conflicts. However, given that CBD deals much more with the protection of public interest and morality, which TRIPs acknowledges as valid grounds for any measures that a country would take, it could be argued that CBD's provision should supersede those of TRIPs. This interface between TRIPs and CBD is yet to be tested in

international legal arena. The CBD unfortunately is at a serious disadvantage, as it does not have a dispute resolution mechanism of its own, unlike WTO as in TRIPs. Besides, CBD in Article 8j requires the countries to respect and protect indigenous and local community knowledge and ensure its equitable sharing of benefits arising out of use of such resources. Various parties involved in the sharing mechanism can interpret this provision differently.

4. Attempts at Protection of TK in India

Recently amended patent law of India contains provisions for mandatory disclosure of source and geographical origin of the biological material used in the invention while applying for patents in India. Provisions have also been incorporated to include non- disclosure or wrongful disclosure of the same as grounds for opposition and for revocation of the patents, if granted. To protect TK from being patented, provisions have also been incorporated in the law to include anticipation of invention by available local knowledge, including oral knowledge, as one of the grounds for opposition as also for revocation of patent. In order to further strengthen these provisions, a new provision has been added to exclude innovations which are basically TK or aggregation or duplication of known properties of traditionally known component or components from being patented.

India is a party to the Convention on Biological Diversity (CBD), which came into force in December 1993. The CBD offers opportunities to India to realize the benefit of these resources. India has already enacted an Act to provide for protection of biological diversity, sustainable use of its components and equitable benefit sharing arising out of the use of the biological resources. It addresses the basic concerns of access to, collection and utilization of biological resources and knowledge by foreigners and sharing of benefits arising out of such access. The legislation also provides for a National Authority, which will grant approvals for access, subject to conditions, which ensure equitable sharing of benefits. The main intent of this legislation is to protect India's biodiversity and associated knowledge against their use by individuals/ organization without sharing the benefits arising out of such use and also to check bio-piracy. The legislation provides for a federal management structure with the National Biodiversity Authority (NBA) at the apex and Biodiversity Management Committees (BMCs) at local community level. The BMC and the NBA is required to consult BMC in decisions relating to the use of biological resources/ related knowledge within their jurisdiction. The legislation also provides for promotion of conservation, sustainable use and documentation of biodiversity.

Prior approval of NBA would be required for applying for any form of IPR within or outside India for an invention based on research or information on biological resource obtained from India.

The Indian legislation for the **Protection of Plant Varieties and Farmer's Right Act 2001** also acknowledge that the conservation, exploration, collection, characterization. Evaluation of plant genetic resources for food and agriculture are essential to meet the goals of nation food and nutritional security as also for sustainable development of agriculture for the present and future generations. It also acknowledges that the plant genetic resources for food and agriculture are the raw material indispensable for crop genetic improvement. The concept of effective benefit sharing arrangement between the provider and the recipient of the plant genetic resources forms an integral part of our Act. The amount of benefit sharing will be based on the extent and nature of the use of genetic material of the claimant in the development of the variety and also the commercial use and sale in the market of the variety. To make this meaningful, mandatory disclosure of the geographical location from where the genetic material has been taken and information relating to the contribution, if any, of the farming community involving such variety, has been made. The protection provided to a plant variety bred by a breeder can be cancelled if there is an omission or wrongful disclosure of such information.

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

Various suggestions have been advanced in India to extend protection to knowledge, innovations and practices. These include: (i) documentation of TK ; (ii) registration and innovations patent system; and (iii) development of a sui generis system. It is sometimes believed that proper documentation of associated TK could help in checking bio-piracy. Documentation could be a double- edged sword. It is assumed that if the material/ knowledge is documented, it can be made available to patent examiners the world over so that prior art in

the case of inventions based on such materials/knowledge are readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom benefits of commercialization of such materials/ knowledge has to be shared.

In 1999, following the ultimately successful, but expensive, Indian challenge of the turmeric and basmati patents granted by USPTO, it was agreed that the Indian National Institute of Science Communication (NISCOM) and the Department of Indian System of Medicine and Homoeopathy (ISM&H) would collaborate to establish a Traditional Knowledge Digital Library (TKDL). The TKDL project is initially targeting Ayurveda (a traditional Indian system of medicine), and proposes to document the knowledge available in public domain (the existing Ayurveda literature) in digitized format. Information from about 35,000 Slokas (Versus & Prose) and formulations will be inputted on a database, and it is expected that the web site will have approximately 140,000 Ayurveda pages. The data will be made available in several international languages. The TKRC is an innovative, structured classification system that has been designed to facilitate the systematic arrangement, dissemination and retrieval of the information in the traditional knowledge DL. The TKRC is based on the International Patent Classification system (IPC), with the information classified under section, class, subclass, group and subgroup for the convenience of its use by the international patent examiners. But it provides greater definition of traditional knowledge information by expanding one IPC group into about 5000 subgroups. The TKDL will give legitimacy to existing traditional knowledge, and by ensuring ease of retrieval of traditional knowledge-related information by patent examiners will hopefully prevent the granting of patents, such as the turmeric and neem cases discussed above which claim subject matter already in the public domain. Work on such libraries is also being pursued in WIPO where a specialized Task Force including representatives from China, India, the USPTO, and the EPO are examining how such libraries can be integrated into the existing search tools used by patent offices.[19]

Documentation has one clear benefit. It would check patent based on TK in the public domain that is today difficult to prevent due to lack of availability on information with patent examiners. In pursuance thereof, we have documented TK in the form of a digital library.

[19] Report prepared by IPR commission, "Traditional Knowledge and geographical indication", http://www.iprcommission.org/papers/pdfs/final_report/ch4final.pdf. Last visited, 8th March 2018.

Documentation of TK is also acknowledged as a means of giving due recognition to the TK holders. This particular aspect of documenting formulations in the Ayurvedic system of medicine in India in the shape of TK DL is already on. The scope of the TK DL work relates to the transcription of 35,000 formulations used in Ayurvedic system of medicines. These details are being converted into Patent Application Format and will include description, method on the preparation, claim and the usage of the bibliography. The retrieval will be based on the TK RC and IPC. The original Sanskrit text is translated and presented in French, German, English, Japanese, Spanish and Hindi through unit code technology that is language independent. The total number of pages in each language will be 1, 40,000. The local names of plants are converted into botanical names and Ayurvedic descriptions of diseases into modern medical terminology. The TK DL will eventually cover other indigenous system like Unani, Siddha, Naturopathy, folklore etc. The documentation of such TK in a digitized format would, it is hoped prevent patenting of knowledge which is already in the public domain. Work on such libraries is also being pursued in WIPO where a specialized Task Force including representatives from China, India, the USPTO, and the EPO are examining how such libraries can be integrated into the existing search tools used by patent offices.

Also in India, preparation of village- wise CBRs for documenting all knowledge, innovations and practices has been undertaken in a few States. With all these efforts some experts still suggest that a sui generis system separate from the existing IPR system should be designed to protect the TK of the local and indigenous communities of India. However, the parameters, elements and modalities of a sui generis system are still being worked out.

5. Conclusion

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

The call for protection of TK against misuse or misappropriation raises deep policy questions and practical challenges alike. The changing social environment, and the sense of historical dislocation, that currently affect many communities may actually strengthen resolve to safeguard traditional knowledge for the benefit of future generations. Just as the technological value of traditional knowledge is increasingly recognized and its potential realized, the challenge is to ensure that the intellectual and cultural contribution of traditional communities is appropriately recognized. This means taking greater account of the needs and expectations of traditional knowledge holding communities. Its traditional qualities and frequent close linkage with the natural environment mean that traditional knowledge can form the basis of a sustainable and appropriate tool for locally based development. It also provides a potential avenue for developing countries, particularly least-developed countries, to benefit from the knowledge economy.