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LEGAL FRAMEWORK ON PROTECTION OF TRADITIONAL KNOWLEDGE: A REVIEW

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ABSTRACT: The protection of Traditional Knowledge is important for the conservation and sustainable development of the environment, as much of the world's bio-diversity has been conserved and preserved by indigenous people. Their knowledge is central to the protection and conservation of genetic resources and other bio-resources. Most of these communities live in areas where the vast majority of the world's plant genetic resources (PGRs) are found. There is a danger that the biological resources increasingly subjected to IPRS and patent are likely to be plucked to extinction, which raises concerns over their exhaustibility and loss of habitat besides the loss of lifestyles and livelihoods to indigenous communities that have nurtured and used these resources for generations. This may also ultimately affect food security. International recognition and protection of Traditional Knowledge would help in the protection and conservation of the environment and the management of biodiversity. Thus the present review deals with the international and national perspectives and makes a critical appraisal of CBD, FAO, WIPO, Biodiversity Act, etc. for protection of traditional knowledge.

Keywords- *WIPO, CBD, WHO, Biodiversity Act, Protection of traditional knowledge.*

I. INTRODUCTION

The demand for an effective protection of traditional knowledge has gained momentum, either through the application of the traditional IPR system or by means of a new sui generis system such as traditional community rights or community property rights. There is also a need to enable communities to harness traditional knowledge for their upliftment and growth. Thus the present review deals with legal framework at the international and national perspectives and makes a critical appraisal of CBD, FAO, WIPO, Biodiversity Act, etc. for protection of traditional knowledge.

II. INTERNATIONAL REGIME FOR PROTECTION OF TRADITIONAL KNOWLEDGE

The importance of protecting the knowledge, innovation and practices of indigenous and local communities is increasingly recognized in international forums. The immediate need is to ensure that the benefits of cumulative innovations with traditional knowledge go to their holders while enhancing their socio-economic development. The first effort to protect Traditional Knowledge (TK) under the IP regime was a joint initiative taken by WIPO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1978 which led to the Protection of Expressions of Folklore against Illicit exploitation and other prejudicial Actions in 1982. Since then, the protection of Traditional Knowledge has gained increasing attention with the adoption of the Convention on Biological Diversity (CBD) in 1992. The CBD, through its Article 8 (j) has broadened the scope and mandate of protection

with wider objectives. There has been lot of effort to protect Traditional Knowledge by inter-governmental bodies dealing with IP, environment and even human rights control to the indigenous and local communities over Traditional Knowledge, namely, World Trade Organization (WTO) and its Council for Trips, World intellectual Property Organization (WIPO), Food and Agriculture Organization (FAO), United Nations Conference on Trade and Development (UNCTAD) and World Health Organization (WHO) [1].

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The convention on Biological Diversity (CBD) was concluded on 5 June 1992. It was the result of discussions at the Rio de Janeiro 1992 under the United Nations Environment Programme (UNEP).The CBD administered by UNEP, establishes principles for the protection of the environment while ensuring ongoing economic development, emphasizing conversation of biodiversity, sustainable use, and fair and equitable benefit sharing of the use of genetic resources [2].

CBD is an important re-assertion of the sovereign rights of the States over their biological resource. Article 8 (j), seems to affirm, that the holders have rights over their knowledge, innovations and practices, whether or not they are capable of being protected by IPRs. If they are not capable of being protected by the existing IPR system, still there is an obligation for the governments to safeguard these entitlements either through a new IPR law or by over legal or policy measures. These duties should also extend to uses of TK, innovations and practices [3, 4]. The CBD also recognizes the importance of traditional use of genetic resources in the sustainable preservation of biological diversity. It establishes access to the biological transfer from the industrialized countries, and asserts that IPRs must not conflict with the preservation and sustainable use of biodiversity [5]. Similarly, it also incorporates provisions which provide for the encouragement, development of exchange and use of indigenous and traditional knowledge and technology in the spirit of CBD [6].

FOOD AND AGRICULTURE ORGANIZATION (FAO)

The FAO has wide range of activities relating to access to genetic resources, their sustainable use, promotion, and protection of Traditional Knowledge activities in the Forest Department, including the programs on non-wood forest products and communities foresting deserve special attentions. In the recent years the biggest development was International Treaty on Plants Genetic Resources for Food and Agriculture (ITPGRA), popularly known as International Seed Treaty. It was adopted on 30th Nov 2001 by FAO Conference at its 31st Session in Rome with no country voting against[7].

ITPGRA is a comprehensive international agreement in harmony with CBD which aims at guaranteeing food security through conservation, exchange and sustainable use of the world's plant genetic resources for food and agriculture, as well as the fair and equitable sharing of benefits arising from its use[8].

The treaty recognizes the right of the farmers and local communities, who have been in the centre of origin and diversity, in conserving, improving and making available these resources. The Treaty also emphasizes the need to protect Traditional Knowledge relevant to plant genetic resources for food and agriculture in order to implement farmer's right (Article 9.2). It also makes the national government responsible for bringing about equitable participation in benefit sharing arising from the utilization of plant genetic resources for food and agriculture, amongst farmers. The treaty provides for funding strategy to mobilize funding for priority activities, plans and programmes, in particular in developing countries and countries with economics in transitions, taking into account the Global Plant of Action adopted in Leipzing in 1996 [9, 10].

The Treaty, however, is limited in its scope. It is principally aimed at preventing the loss of agro-biodiversity rather than biodiversity in general, and establishes the principle of farmer's rights and not the rights of local communities in general[11,-14].

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (UNCTAD)

UNCTAD's member states decided to address the protection of Traditional Knowledge as part of UNCTAD's work in the area of trade environment and development. UNCTAD has addressed the issue of protection of Traditional Knowledge from the trade and development perspective. In UNCTAD, the emphasis has been on exchanging national experience on policies and measures to protect Traditional Knowledge for trade and on identifying policies to harness Traditional Knowledge for trade and development. In October 2000, UNCTAD member states convened an Expert Meeting in Geneva. It accepted the importance of Traditional Knowledge in the promoting sustainable development of national and international economics, and therefore it recommended UNCTAD to do further work on its protection [15,16].

WORLD TRADE ORGANIZATION (WTO)

In various communications to the IPRS Council of the WTO during the last few years, it has time and again been emphasized by India that the rights of the holders of TK to share benefits arising out of innovation based on their knowledge and the associated bio-resources should be recognized in the TRIPS Agreement. This, according to them, calls for harmonization of the provisions of TRIPS with those of CB D. It is apprehended by India and others that in the absence of clear provisions in TRIPS Agreement with the member's obligations under CBD, implementation of the TRIPS Agreement may allow facts of bio-piracy and thus result in systemic conflicts with the convention. With a view to avoid such conflicts an amendment of the TRIPS Agreement to accommodate some essential elements of CBD is considered necessary by India and allies [17].

Hence, this group of countries has proposed in the WTO that the TRIPS Agreement should be amended in order to provide that members shall require that an applicant for a patent relating to biological materials or to TK shall provide, as a condition to acquiring patent rights:

a) Disclosure of the source and country of origin of the biological resources and of the traditional knowledge used in invention;
b) Evidence of prior informed consent through approval of authorities under the relevant national regimes; and
c) Evidence of fair and equitable benefit sharing under the national regime of the country of origin.

Even though the recognition of the subject under Doha Ministerial Declaration was initially perceived to be a significant step forward in resolving the issue, the actual chain of development on the matter in the TRIPS Council in the Post-Doha era, has not given much scope for the India and allies to cheer. The principal resistance to the proposal of amendments of TRIPS for incorporating the new patent disclosure requirements to bring TRIPS in line with the CBD has come on behalf of the United States.

The US maintains that while the objectives of TRIPS and CBD are distinct, there is no conflict between them and that these agreements can and should be implemented in a mutually supportive manner. The US clings to the argument that the introduction of the proposed new patent disclosure requirements will not ensure the achievement of the objectives envisaged by CBD and may furthermore have significant negative consequences. For instance, it is argued that the new patent disclosure requirements would add new uncertainties in the patent system. Particularly

where the sanctions for non-compliance include invalidation of a patent, this would create a "cloud" of uncertainty over the patent right over the patent right by opening a new avenue for litigation and other uncertainties. These, according to the US, would undermine the role of the patent system in promoting innovation and technological development.

In light of these concerns, the US is not convinced that the proposed new disclosure requirements in patent applications are an appropriate solution to the problem. Instead, it maintains that the CBD's objectives on access to biological resources and TK, and on benefit sharing, could best be achieved through establishment of separate national legal and other framework (such as contractual arrangements) outside the patent system that can more directly and effectively regulate conduct relevant to these issues.

Furthermore, a bio-piracy, it is argued, is a global problem and more often than not, involves the acquisition of material in one country and seeking of a patent in another. This means that relying on national measures alone is not sufficient to address the bio-piracy problem. Hence, to ensure the effectiveness of the contemplated obligations on the applicants, a positive and mandatory obligation needs to be imposed on the member countries of the WTO to require the disclosure by patent applications in their territories of the source and country of origin of the biological resources and/ or TK used in inventions. Such a positive and mandatory obligation, according to them, could be introduced into the TRIPS Agreement either by appropriately amending the existing provisions or by introducing a new article in the Agreement[15,17].

WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

WIPOs work on TK and folklore began in 1978 when WIPO developed a sui generic model for national protection of folklore jointly with UNESCO. In 1998 WIPO launched a new programme, including, interacting fact finding mission to 28 countries in IP and TK, which produced a global report on IP needs and expectation of TK holders. In its 26th session WIPO General Assembly established IGC. The IGC's action so far has focused on trying to understand the needs and expectations of local community ascertaining the adequacy of current methods for protecting Traditional Knowledge and surveying proposals to enhance such protection. It has also done a commendable work of producing impressive number of documents, including the model clauses for genetic resources contracts, a toolkit for documentation of Traditional knowledge protection, and work on elements of a possible sui generis system of protection of traditional knowledge. The WIPO is also taking steps to enhance the coverage of documented traditional knowledge in the minimum documentation of the Patent Cooperating Treaty (PCT), and to expand the International Patent Classification (IPC) for accurate and focused searching for relevant traditional knowledge during the patent examination process [18].

WIPO in its fourth session of IGC, made some notable contributions. It discussed the notion of sui-generis protection of Traditional Knowledge and also some of the factors that might make it difficult to define precisely a legal regime for Traditional Knowledge. It also pointed out to an important fact, that very diversity of conceptions of Traditional Knowledge, embracing technical Traditional Knowledge and expressions of folklore, might dilute the clarity and effectiveness of any sui generic system. At this session, important observations were made regarding the rational for protection. Firstly, IP protection of Traditional Knowledge would enable Traditional Knowledge holders to preserve their identity against any use they do not wish their Traditional Knowledge to be given. The second rationale for protection is the fact that the Traditional Knowledge protection increases legal scrutiny and predictability to the benefit not only of Traditional Knowledge holders, but also of the society as a whole, including firms and research institutions who are potential partners of Traditional Knowledge holders [19].

The third rationale for protection concerns economic development and poverty alleviation, it the communities desire the formalization and recording of traditional communities' intangible asserts then it can transform them into capital, thus facilitating the establishment of commercial venture within traditional communities. The reason being that many traditional communities who live in apparent poverty are actually rich in knowledge, but their knowledge, not being subject of formal property law is prone to commercial misappropriate by others. Furthermore, once recognized through titles, Traditional knowledge can be used as collateral security for giving traditional communities facilitated access to security [2, 19,20].

WORLD HEALTH ORGANIZATION (WHO)

The World Health Organization, the United nations specialized agency for health was established on 7th April 1948. The WHO involvement in Traditional knowledge relates to its work on traditional medicine. The WHO objective as set out in its constitution, is the attainment by all people of the highest level of health, as the economic and trade value of Traditional Knowledge, particularly the knowledge of traditional medicine and medicinal plants, in becoming increasingly recognized, more and more WHO members states have become concerned with the need to protect it and to secure the fair and equitable sharing of any benefit derived from its utilization [2, 19].

WHO's Traditional Medicine Strategy 2002-2005, has four main pillars, namely:

a) Policy- Integrate Traditional and complementary or alternative medicine (TM/CAM) with national healthcare system.
b) Safety, efficiency and quality: provide evaluation, guidance and support for effective regulation.
c) Access: ensure availability and affordability of TM/CAM, including essential herbal medicines.
d) Rational use: promote therapeutically- sound use to TM/CAM by providers and consumers.

At present WTO is supporting clinical studies on anti-malarials in three African countries, the studies are revealing good potential for herbal anti-malarials. In Tanzania, WHO, in collaboration with China, is providing technical support to the government for the production of anti-malarials derived from the Chinese herb *Artemisia annua*. Local production of medicines will bring the price of one dose down from US $6 or US $7 to an affordable US $2 [21].

III. NATIONAL REGIME FOR PROTECTION OF TRADITIONAL KNOWLEDGE

India has not brought out any Traditional Knowledge specific legislations but measures have been adopted by India such as Biodiversity Act, 2002 and Protection of Plant variety and Farmers Right Act, 2001 and the Patent (Amendment) Act, 2005 to give effect to its obligations under the TRIPS agreement, CBD and International Treaty on Plant Genetic Resources for Food and Agriculture 2004. TTPGRFA has reiterated India's stand in different inter-government bodies working on the protection of Traditional Knowledge.

In India, preparation of village-wise Community biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices has been undertaken in a few States.An exercise has been initiated to prepare to easily navigate computerized database of documentation Traditional Knowledge relating to use of medicinal and other plants, known as Traditional knowledge Digital Library (TKDL). Such digital database would enable Patent Office's all over the world to search and examine any prevalent use or prior art, and thereby prevent grant of patents and bio-piracy. In India provisions have been made for protecting Traditional knowledge in Biodiversity Act 2002, Protection of Plant varieties and Farmer's rights (PPVFR) Act, 2001 and Patent (Amendment) Act, 2005 [22-25].

THE BIOLOGICAL DIVERSITY ACT, 2002

The Biodiversity Act 2002 primarily addresses access to genetic resources and associated knowledge by foreign individuals, institutions or companies, to ensure equitable sharing of benefits using out of the use of these resources

and knowledge to the country and the people. The Act stipulated norms for the access to biological resources and Traditional knowledge based in three ways [22-26]:

1. Access to biological resources and Traditional Knowledge to foreign citizen, companies and NRI based on "Prior approval of National Biodiversity Authority,"
2. Access to Indian Citizens, companies, Associations and Organizations registered in India on the basis of "Prior intimation to the State Biodiversity Board", concerned, and
3. Exemption of prior approval or intimation for local people and communities, including growers and cultivations of biodiversity, vaids and hakims, who have been practicing, indigenous medicines.

There is no requirement under the legislation for seeking permission of the National Biodiversity Authority for Carrying out research, if it is carried out in India by Indians, as well as under the collaborative research projects that have been drawn within the overall policy guidelines formulated by the Central government. The only situation that would require permission of the NBA are (i) when the results of any research which has made use of the country's biodiversity is sought to be commercialized (ii) when the results of the research are shared with a foreign institution or individual wants access to the country's biodiversity for under taking research.

The Act, subject to Section 21 and Rule 20 of the Biodiversity Rules, insists up on including appropriate benefit sharing provisions in the access agreement and mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The Authority shall develop guidelines and shall notify the specific details of benefit sharing formula in an official gazette on a case-to-case basis. The time frame and quantum of benefits to be shared shall be decided on case-to-case based on mutually agreed terms between the applicant, authority, local bodies, and other relevant stakeholders, including local and indigenous communities. One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge was accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits shall be paid to the National Biodiversity Fund. Five percent of the benefits shall be earmarked for the Authority or State Biodiversity Board towards the administrative service charges [25,26].

THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS (PPVFR) ACT, 2001

The PPVFR Act 2001 and the PPVFR Rules 2003, deal primarily with the protection of plant breeder's rights over the new varieties developed by them and the entitlement of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties, which the latter have developed, improved, and maintained over many generations. The Act is a deviation from the 1991 UPOV Model and can regarded as an alternative *'sui generis'* system that accord protection of the rights of the formal innovations of a plant breeder and informal knowledge system and traditional plant varieties of the farmers as well. The important provisions contained in this Act relevant to ABS are those on the protection of farmer's rights and the mechanisms suggests for compensation or benefit-sharing for the contributions of local communities or farmers in the development of a new variety.

The Indian legislation on PPVFR is the singular attempt made by a developing country to give effect to the concept of Farmers' Rights as provided for in the International Treaty. Although this act has several limitations, it nonetheless provides a model of an effective sui generis system for protection of plant varieties that WTO members are expected to put in place in fulfilment of their commitment to the Agreement on TRIPS [22,23].

THE PATENT (AMENDMENT) ACT, 2005

India has utilized the flexibility of TRIPS in the Patent (Amendment) Act, 2002. This Amendment has introduced a new obligation (in Section 10 (4) of the principle (1970) Act, which stipulates the requirements of a patent

application) on the patent application, when used in an invention. Such a provision is perfectly compatible with TRIPS, since, it is not violating other provisions of this Agreement.

The Patents (Amendment) Act 2005, passed by the parliament recently has also introduced some important provisions. Dealing with the post-grant opposition further stipulates that at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of patent, any person interested may give notice of opposition to the Controller in the prescribed manner on certain specified grounds. The eleven grounds stipulated for such post-grant opposition include the following two grounds, That the complete specification does not disclose or wrongfully mentions the source and geographical origin of biological material used for the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere. These two provisions ensure protection of the rights of the source country of a biological material or traditional knowledge of local or indigenous community, and thereby enabling recognition and reward of source countries and traditional knowledge holders through appropriate benefit sharing mechanisms [27,28].

Thus, provisions included in the Indian Patents Act in conjunction with the PIC and benefit sharing requirements incorporated in the Biological Diversity Act 2002 create sufficient room for combating the biopiracy threats at the national level in India. Nevertheless, the problem remains that existence of a similar protective shield for Indian bio-resources Traditional Knowledge cannot be guaranteed under the national patent laws of other countries. The Agreement does not make it obligatory for the member countries to include in their respective patent laws provisions aimed at protecting the bio-resources and Traditional Knowledge of the country of origin against biopiracy. However, the protection of these precious assets cannot be guaranteed until and less certain compulsory provisions are included in TRIPS in this regard, which all the Member countries would be obliged to comply with [29,30].

IV. CURRENT STATUS OF IPR PROTECTION WORLDWIDE

As of 1988, 53 countries statutorily excluded plants and 54 excluded animals from patent protection (WIPO, 1990, Annex II). These include the members of the European Patent Convention (EPC) which in Article 53(b) excludes patents for "plant or animal varieties and the essentially biological processes for the production of plants and animals". Written in the pre-biotechnology days, the interpretation of that phrase has proven complex over the years. Several patents have been granted bases on an interpretation that "variety" refers to a variety in a "fixed form" so that a development which was applicable across multiple varieties could be patented. Most recently, the European Patent Office appeals ruling on a Plant Genetics System patent rejected coverage for the plant and seeds (EPO, 1995). The significance of that decision will not become clear for some time. The bulk of the other countries are developing nations, many of which have language similar to the EPC.As noted, there are presently 30 members of UPOV, with all but Argentina, Chili, Uruguay, and South Africa being developed countries. A number of additional countries have national PBR laws, including Colombia, Taiwan, Kenya, and Chile, among others. Details on the operation of those laws are limited.

Membership in a national convention standardizes the conditions of protection to a large degree. Standardization of patent and trademark laws is assured in part by the Paris Convention of 1883 with its 100 plus members. Among the key provisions are *national treatment* which stipulates that foreigners must be granted the same rights as nationals. Additionally, the right of priority stipulates that an application filed in any member country establishes that filing date for all other countries for a period of one year. The filing date is critical for the bulk of countries which follow the *first-to-file* system. The major difference is the USA which uses the first-to-*invent procedure* (Lesser, 1987b). The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, which oversees administrative and harmonization responsibilities administer the Paris Convention. The Paris Convention also sets

limits on conditions for compulsory licenses; rules which allow rights to third parties to license patented technologies.

The final major difference in worldwide patent laws is the form and duration of the *grace period*, the time between the publicizing of an invention and the initial filing of a patent application. These range from none in the EPC member countries to one year in the USA (Lesser, 1987b). Recent efforts for further patent harmonization broke down, but GATT imposes some standardization, such as setting the patent duration at 20 years from the first filing [29,30].

V. CONCLUSION

To conclude, so far, no international regime for the protection of Traditional Knowledge has emerged, although an incremental progress has been registered through piecemeal efforts, namely the FAO's ITPGRFA and the CBD's Bonn guidelines on access to genetic resources and benefit sharing. Their scope, however, is limited to access to GRs and benefit-sharing and they thus relate to the physical aspects of these resources rather than their intellectual or intangible aspects, which are mainly related to Traditional Knowledge and are the subject-matter of intellectual property protection. Developing countries would like to see faster progress towards an international regime of some kind, and the sui-generis mode, according to them, would be most appropriate to protect the holistic character of Traditional Knowledge and to tackle the problem of illegal acquisition of GRs.

In India, in order to check bio-piracy an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants, known as Traditional Knowledge Digital Library (TKDL). However, documentation of TK is only one of the means of giving recognition to knowledge holders. Mere documentation may not enabler sharing of benefits out of the use of such knowledge unless it is backed by some kind of mechanism for protecting knowledge. Documentation of TK may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form of which it exists.

National level mechanisms and legal provisions to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to TK holders should also be given international recognition for their effective implementation and for their enforcement in other countries. Thus, there is a need for development of an international mechanism for protecting TK. Positive and defensive protection measures along with development of *sui generis* law may perhaps be the best and immediate options for countries like India to provide IP rights to Traditional Knowledge holders.

VI. CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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