

CHAPTER VII

MARCH TO EVOLVE A LEGAL FRAMEWORK FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH MEDICINAL PLANTS

A. ANALYSIS OF TWO PRIVATE DRAFT BILLS OF INDIA FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

PART I

INTRODUCTION

In spite of an urgent need to enact a law exclusively dedicated for protection for traditional knowledge of India, there is such law in India yet. Whatever laws that are in existence in India, offer indirect protection, that is also negative in approach and inappropriate in consequence. Among all other urgencies, the priority should be to have a law exclusively on protection of traditional knowledge. Otherwise India would be losing all its control and right over all its medicinal plants. It is not clear whether the government is contemplating legislation. At the international level there is no such legislative framework that is binding upon all countries. At a preliminary level, WIPO has been struggling to frame something positive. There is pressure from the third world countries on WTO to accommodate this concern. But it is yet to come up with any specific and unanimous international treaty which will be binding on all countries.

In this backdrop, there are two draft bills-first one prepared by National University of Juridical Sciences, Kolkata and the second prepared by National Law School of India University, Bangalore. In addition to their efforts at the international level there are some special laws of some TK of medicinal plants enriched countries such as China, Kyrgyzstan, Peru, Brazil and Thailand etc. These countries are proactive and advanced for traditional knowledge protection, including medicinal values of the biological resources. But the national sentiment to safeguard the century old traditional knowledge of bio-medicine is yet to be honoured.

In this chapter an attempt is made to analyse all the draft bills and the laws of the countries having legal framework for the protection of TK of medicinal plants and assess their legal efficacy.

BIOLOGICAL RESOURCES, TRADITIONAL KNOWLEDGE AND EXPRESSIONS OF FOLKLORE (PROTECTION & REGULATION) BILL, 2003¹-SOME REFLECTIONS

PREAMBLE TO THE BILL

Every enactment has its own preamble. Preamble is the guiding principle or core values over which the law is based. It is an Act to provide for the establishment of an effective regime to prevent the misappropriation of biological resources, traditional knowledge systems that may be found in the country and to secure the rights of the communities in relation to them. As India is rich in biological diversity and traditional knowledge systems, hence, it is recognised that it is considered necessary to reward and respect the contribution of the communities, made over generations, in conserving, improving and making available these resources for the development of nation's bio-diversity. It is said that it is necessary to regulate the access to, and utilisation of the biological resources, traditional knowledge systems. It is also opined that it is considered necessary to provide for the sustainable use of the components of the resources and fair and equitable sharing of the benefits arising out of utilisation of these resources in accordance with CBD and involve maximum community participation in these process.

DEFINITION OF TK AND BIOLOGICAL RESOURCE

“Traditional Knowledge” is a body of knowledge, practice, technology and belief, evolved by adaptive processes and handed down through generations by cultural transmission, within a community and it includes knowledge and belief associated with a biological resource. **“Biological resources”** are plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.

GENERAL PRINCIPLES

In Chapter II there are general principles about the rights relating to biological resources and traditional knowledge. It vests the nation with sovereign rights over its bio-diversity to be known as national heritage rights and the State is to hold these resources in trust for the communities. The community identifiable with a biological resource and traditional knowledge has inalienable right to share benefits arising from biological resource and traditional knowledge and is to be known as community heritage rights. Where the biological resource or traditional knowledge cannot be identified with a specific community, then it would vest in the nation as national heritage rights. As the community has a heritage right over a biological resource and

¹ BIOLOGICAL RESOURCES, TRADITIONAL KNOWLEDGE AND EXPRESSIONS OF FOLKLORE (PROTECTION & REGULATION) BILL, 2003, Anirban Majumder, Published by The W.B. NUJS, Kolkata, 2004.

traditional knowledge, it has the power to commercialise them subject to the condition that benefits of such exploitation is of that community and subject to environmental laws. Moreover, while allowing conditional grant of access to the biological resources and traditional knowledge, prior informed consent of the community and fair and equitable sharing of benefits with them, have to be ensured.

AUTHORITIES UNDER THE ACT

Chapter III deals with the establishment of National Heritage Authority which shall consist of various committees along with Committee on Biological Resources and Traditional Knowledge. It has different functions to discharge the responsibilities of protection and regulation of biological resources and traditional knowledge: (a) to create, consolidate and maintain a database, which is to be a public document, by way of documentation of the available biological resources and traditional knowledge systems in the country and attempt to trace their origin to individual communities or geographical territories. (b) to create and maintain a website, which is to contain the database and the consolidated report of licenses and certificates granted for the biological resource and traditional knowledge. (c) to initiate proceedings against wrongful intellectual property rights obtained by violating the national or community heritage in India.

The functions of the Committee on Biological Resources and Traditional Knowledge are to process the application for accessing biological resources and traditional knowledge; to enter into licence agreement for access and utilisation and to coordinate between the applicant and the communities if they are more.

In this chapter, there is provision for the establishment of the State Heritage Authority and Local Heritage Authority. These authorities have various functions under this Act. The functions of the SHA are (a) to notify the local authorities of the publication of the periodical reports and supplying them with the reports; (c) to monitor and supervise the functions of the local authorities.

Functions of the LHA are more important because it has to perform some primary functions. These are: (a) to determine the communities identifiable with the biological resources and traditional knowledge; (b) to oversee the procedure and aid such community in the process of formulating the licence agreement for access to the biological resource and traditional knowledge; (c) to ensure the proper implementation and enforcement of access and benefit sharing agreement; (d) to locate, acknowledge and document information of biological resources and traditional knowledge etc.

Another important provision of this Act is the creation of National Heritage Fund. This fund shall be credited all charges and royalties received by NHA from the licensing of national heritage rights, compensation, fines and damages accrued from the infringement proceedings relating to national heritage rights. The fund is to be applied for the conservation and promotion of biodiversity, biological resources and

traditional knowledge. The fund is to be applied also for the development of incentive models to support the communities applying for commercial development of biological resources.

REGULATION OF ACCESS TO BIOLOGICAL RESOURCE AND TRADITIONAL KNOWLEDGE

Chapter IV deals with many things about procedural matters. Its subject matters are (a) application to NHA; (b) information to be provided in the application; (c) procedure on receipt of application; (d) procedure in cases of National Heritage Applications; (e) procedure in case of community heritage; (f) procedure after grant of certificate of permission; (g) right to deny access; (h) licence agreement; (j) conflict of rights; (k) exception to public sector research; (l) standard licensing terms ; (m) void license agreements etc. Among other subject matters of this chapter 'information to be provided in the application' and 'standard licensing terms' need some special attention.

The former would require the informations: (1) type and quantity of biological resources, traditional knowledge to which access is sought; (2) identification of place of origin of biological resource and source of traditional knowledge; (3) evaluation of the possible impact of the access activity on conservation and sustainable use of the resource; (4) accurate information for the purpose of collection, research, expected results and nature and extent of intended use; (5) information on how and where the research and development is to be carried out; (6) types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from commercial and other utilisation of the resource and (7) indication of benefit sharing arrangements etc.

The latter shall compulsorily include (1) description of biological resource, traditional knowledge including accompanying information; (2) permitted uses and any limitation on it including its potential uses and related products and derivatives; (3) the licence must make a disclosure of the source of the origin of the biological resource, traditional knowledge; (4) terms of benefit sharing agreements, including commitment to share monetary and non-monitory benefits.

INFRINGEMENT

This Chapter V deals with acts which constitute infringement. Infringement is of two types- civil penalties for infringement and criminal penalties in certain cases. Infringement occurs when there is breach of procedure established under this Act for gaining access to or for the utilisation of a biological resource, traditional knowledge or the breach of any term of the license agreement by the licensee or non-inclusion of any standard licensing terms. Civil penalties for the infringement are: (a) no certificate u/s 23 and no license u/s 24 will be issued for a minimum period of twenty or more years; (b) imposing of liability to pay damages to the community whose community heritage right has been infringed in addition to damages to NHA. The

amount of compensation will be determined on the basis of profits or value of biological resource, traditional knowledge; (c) for breach of procedure or breach of term of license agreement, there is a provision of injunction prohibiting the sale of such product; (d) no intellectual property rights in India shall be conferred on any product owing to its origin to the biological resource, traditional knowledge it has been obtained or utilised by infringement and if any such right was conferred, it is subject to immediate revocation.

Criminal penalties in certain cases are imprisonment from one to three years and fine of Rs five lac to twenty lac for knowing infringement or abetment for infringement.

PROVISIONS RELATING TO THE CONSERVATION OF BIODIVERSITY

This chapter is about conservation of biodiversity—a widened measure of protection of biological resources, traditional knowledge. Central government is empowered to develop national strategies, plans and programmes for the conservation, promotion and sustainable use of biological diversity which includes measures for the identification and monitoring of areas rich in biological resources, promotion of in situ and ex situ conservation, incentives for research etc. There are some duties of the local authorities i.e. to anticipate, prevent any activity that can cause the loss or cause a threat to biodiversity. If the local authority thinks that any area rich in biological diversity is being threatened by overuse, abuse or neglect, it can issue directives. Any person who wants to import, export, experiment, mobilise, release in to the environment, multiply, commercialise or use for research genetically modified organisms, can do so with the previous permission. Apart from these, the authority can regulate the use of pesticides and fertilizers used for agricultural purposes and causing danger to biological diversity.

ANALYSIS OF THE BILL

This bill is a welcome step to explore a model law of India for the protection of traditional knowledge. This bill has many positives for the traditional knowledge protection—name of the right—community heritage right and national heritage right, protection of existing knowledge, prior informed consent, benefit sharing formula, regulation of access and utilisation, conservation of biodiversity etc. But much water has flown down the rivers since its proposal and new situations have arisen which needs new strategy and new approach. Moreover, from the point of view of the present research work, there is further opportunity of improvement for a better model law to offer better protections, as indicated below.

A. Traditional knowledge and biological resources are not two different subject matters and so need not be treated differently. Traditional knowledge associated with biological resources is an intangible component of the resource itself. Traditional knowledge and biological resources i.e. medicinal plants have a unifying subject rather than two distinct categories. It also may be that traditional knowledge has many categories deserving legal protection and ‘medicinal products’ is one such category.

The main object of the law is to protect the medicinal plants or all biological resources over which there exists traditional knowledge of the medicinal, aromatic and agricultural values. If this is the object of the law, the nomenclature of the bill is overlapping and not specific.

B. Traditional knowledge enjoys dual ownership, one by the specific community and the other by the nation. This is the basic premise of the present research work. The distinction is important to understand. Some traditional knowledge of medicinal plants are identified with some indigenous communities where the members of those communities know the knowledge and apply it for their purposes and pass down the knowledge from one generation to the next or a few persons in these communities possess the knowledge and pass down to a few others of the next generation. There is also a TK which belongs and is of the whole society, either documented or non-documented. For example, haladi, neem etc. Hence these are to be considered as the intellectual property of India and Indians. These distinctions are narrow and negatively worded in this bill and not properly recognised. Such recognition is important for enforcement of the right on one hand and benefit sharing on the other.

C. Though the Bill makes provision for both civil and criminal liability, it does not deal with the refund of the profits. Mere compensation or stopping of grant of licence are insufficient if a person or company does not refund the profits arising out of wrongful use of TK.

D. Present national and international legal frameworks of intellectual property rights protect only new and novel knowledge. There is no protection of the existing knowledge so far. In the name of public domain, existing knowledge is researched, experimented and utilised to build and derive something new or novel. When something new or novel is found out of existing knowledge, this non-original invention gets IPR protection and very strangely holders of the existing traditional or individual knowledge do not get anything. This is exploitation in nature. The bill does not address these concerns adequately. This bill, if becomes an Act, does not have retrospective effect. Moreover, there is small and large-scale legal and illegal business in India for selling of medicinal plants, raw materials and the end products. As this manufacturing and selling business is the use of intellectual property right, there is no such royalty given to the holders of the knowledge. This present bill is silent on this. Moreover, there is a tendency to appropriate the medicinal plants associated with TK and using the resources in the name of individuals and groups of individuals as if they are new inventions by them for obtaining patents. This how the knowledge in the public domain becomes individual property. The present bill is silent regarding this. Hence the protection contemplated under the Bill is not adequate or comprehensive.

E. The concept of protection is manifold. It includes creating rights, preventing misuse, regulation, management, conservation, augmentation of the resources, sustainable use, commercialisation etc. From this perspective, protection of traditional knowledge of biological resources is limited in this Bill and is positive only to a

certain extent. In this Bill, though there are provisions for the commercialisation of traditional knowledge related biological resources, it is to be done by the others. There is no such advice to establish government company-autonomous and professionally managed, to commercialise the vast potentiality of the traditional knowledge related biological resources i.e. medicinal plants, on its own, without depending others, either by producing medicines independently or making an offer to start a joint venture with others. This would benefit the national economy either by creating new jobs and earning foreign currency and generating income from within the country itself. There is no advice to establish research institutes exclusively dedicated for the invention of new, novel or innovative products and processes out of the existing knowledge. It can do on its own or can finance the research activities or can initiate to enter into agreement with other research institutes and individuals to pursue research activities and as such this Bill does not create a holistic positive intellectual property right on traditional knowledge.

E. Inter-relationship between this proposed law and national and international patent laws is not clear.

F. There are various ways to commercialise the bio-medicine related traditional knowledge. This is most important to create job opportunities. Additionally, it can be a good source to earn foreign exchange. It also can be done by setting up hospitals under the management and control of Traditional Knowledge Authority in India and abroad. This novel approach has not been explored in this Bill.

The concern for umbrella protection traditional knowledge is not adequately reflected in the preamble or statement of the reasons.

PART II

TRADITIONAL KNOWLEDGE (PROTECTION AND MANAGEMENT) BILL 2010²-SOME REFLECTIONS

PRELIMINARY

It is to provide for protection, conservation and effective management of traditional knowledge and related matters.

PREAMBLE

Preamble sets the tone and tune of the entire of legal framework. In this preamble, recognising India as rich in traditional knowledge which is also an important part of India's living heritage, it is admitted that the forms of traditional knowledge have the potentiality of wealth creation for these communities and the nation. So the traditional

² Available at http://www.brainleague.com/files/NLSIU_TK_Bill_Draft.pdf. Visited on 11th June, 2011 at 2.35 PM.

knowledge needs to be conserved, protected and promoted for the cultural enjoyment and commercial gain for the knowledge holders. It is also emphasised that for the protection of traditional knowledge and the rights of the traditional communities to practice, use, share and sell the products of the use of traditional knowledge as per their customary practice. It is also accepted that there exists a need to protect the integrity and sentiments of the communities against distortions and disrespectful representations of traditional knowledge and to prevent improper commercial exploitation of traditional knowledge. It is in a way prejudicial to the interests of the nation and the communities. Moreover, it is also recognised that there is need to ensure that traditional knowledge is accessed only with the consent of the traditional communities and to regulate third parties wishes to research, access or utilisation of TK.

DEFINITION OF TRADITIONAL KNOWLEDGE

TK means the collective knowledge of a traditional community of a family related to a particular subject or a skill passed down from generation to generation and includes (a) medicinal products and processes developed from indigenous or traditional material, custom and knowledge by traditional communities; (b) all other products or processes not made by person which was discovered through a community process or when the person making the innovation does not claim the knowledge as his own or when the person has discovered it to be used openly for common purposes; (c) discoveries, innovations and technologies made by communities that are usually not recorded in written form and are transmitted orally from generation to generation.

RIGHTS AND DUTIES OF TRADITIONAL COMMUNITIES

Here it is found that not only rights are recognised. Together with rights, duties are also enforced. These are: (a) every member of a traditional community shall have right to practice their own traditional knowledge; (b) every member of a traditional community shall have right to use, modify and derive benefits from their own traditional knowledge for their livelihood, provided the use modified or carried out in a sustainable manners; (c) collective traditional knowledge forming part of cultural heritage of traditional community shall be inalienable; (d) where the traditional community as a whole or a member of a traditional community has provided an informed consent to an Accessor and/or entered into a Licence to use agreement with the Accessor, the traditional community or a member thereof has duty to inform the TKA along with the details of the agreement; (e) every member of the community shall ensure the continuum of the practice of TK and the conservation of associated resources from undue exploitation and its possible extinction.

ESTABLISHMENT OF TRADITIONAL KNOWLEDGE AUTHORITY

The important functions of TKA are: (a) to prepare a national policy, strategy and action plan for ensuring the protection, continuum of use and practice of traditional

knowledge and to ensure the sustainability of the resources including the human resources on which the TK is dependent, prevent biopiracy and other misuse of traditional knowledge and take preventive and/or punitive action if required (b) to ensure that any access to traditional knowledge is brought under the purview of the Authority and is fair by way of non-exclusive informed consent of the traditional communities; (c) to ensure through required instruments and proceedings that no Traditional Knowledge in the country is the subject to any IPR application; (d) to provide the informed consent or prior informed consent as the case may be, to the Accessor, in case where a traditional community is not identifiable; (e) to help and facilitate the traditional communities to negotiate the terms and conditions of benefit sharing upon access to use the traditional knowledge; (f) to set up a watch cell to monitor the applications and/or use of traditional knowledge, both in the country or any part of the world, and to take appropriate corrective action if there is a violation of any provision under this Act, including taking measure on behalf of the Central Government for the opposition/revocation of grant of IPR on traditional knowledge in any part of the world; (g) to administer the traditional knowledge fund for protection of traditional communities and ensuring the continuum and sustainable use of traditional knowledge by traditional communities etc.

REGULATION OF ACCESS TO TRADITIONAL KNOWLEDGE AND INFORMED CONSENT

In this chapter, there are two separate systems and procedures for the regulation of access i.e. acquisition of information pertaining to traditional knowledge for commercial gain or purposes of scientific research, technological development or biological prospection with a view to commercial gain, to traditional knowledge. The first one is for the traditional knowledge owned by traditional community and another is for the traditional knowledge which is not owned by any traditional community or communities and which is in the public domain. These systems include 'informed consent', 'prior informed consent', 'consultation process,' 'negotiation process', 'assessment on sustainability of the resources-social and environmental', 'potential value of traditional knowledge', 'terms and conditions of access to traditional knowledge', 'benefit sharing formula' and 'license for use' etc. Here there is provision to oppose the move for giving access to and revocation of the grant. About the sharing of benefits, it says that sharing of all benefits arising out of the access to traditional knowledge and/or its consequential commercial use shall be as negotiated between the traditional community and the applicant and facilitated by STKB through TKMC and all benefit shares shall directly be paid to the traditional community. In case of benefits that arise from an agreement between Traditional Knowledge Authority and the applicant shall accrue to the Traditional Knowledge Fund.

As there is provision for the establishment of TKF, its functions are also decided. The fund shall be used for the protection, conservation and development of traditional knowledge and the traditional communities which includes (a) conservation and sustainability of traditional resources, welfare and livelihood support for traditional communities and traditional practitioners; (b) ecological and cultural restoration

programmes related to traditional knowledge practices; (c) socio-economic and cultural development and promoting the use and practice of common public domain traditional knowledge etc.

In this chapter the functions of TKA has also been assigned. These include (a) to develop national strategies, plans and programmes for the conservation, development and sustainable use of traditional knowledge including measures for identification and monitoring of areas rich in traditional knowledge, incentives in support systems for traditional communities and traditional practitioners and incentives for training and public education to increase awareness about TK; (b) to issue directives to state governments to take immediate measures and offer for assistance where TKA thinks that any area or traditional community rich in traditional knowledge and resources is being threatened by overuse, abuse or neglect; (c) to recommend in appropriate circumstances the integration, conservation, and to sectoral plans, programmes and policies; (d) to undertake measures for assessment of socio-cultural, economic and environmental impact of that project which is likely to impact or has adverse effect on TK and traditional practices with a view to avoiding or minimising such effects etc. and to prevent the risks associated with the use of any technology or process that is likely to impact the conservation and continuum of the use and practice of traditional knowledge. Excluding this, there are also special provision for traditional knowledge and resource which are on the verge of extinction and establishment of Traditional Knowledge Heritage Zones.

DUTIES OF THE GOVERNMENTS

In Chapter 7, there are duties to be performed by the Central and State governments. They are to develop national strategies, plans etc., for conservation etc., of traditional knowledge and resources likely to TKA.

OFFENCES AND PUNISHMENTS

Chapter 8 is about offences, penalties and procedures. Whoever contravenes or attempts to contravene any of the provisions of the Act is offence. Punishment for the offence is of two types either one or both-imprisonment upto five years or fine upto Rs ten lacs and where the damage caused exceeds Rs ten lacs such fine may commensurate with the damage caused. Apart from these there are offences by companies. If the decision or the activity of the company constitutes offence, as a legal person, company is to be accountable and under certain situations also there would be individual liability to face punishment, for those persons who took the decisions.

ANALYSIS OF THE DRAFT BILL

There are many good provisions for the protection of traditional knowledge in this Bill drafted by NLSUI. Take for example, medicinal products related TK, recognition of rights and emphasis of duties of the indigenous communities, establishment of Traditional Knowledge Authority and assigning on it some important functions,

widened concept of protection of TK, regulation of access mandating prior informed consent and benefit sharing scheme, duties of the governments and punishment for contraventions etc. In spite of all these good things in this draft Bill, there are still further scopes of improvement from the perspective of some fundamental premises over which this research work seeks to explore a model law. The NUJS draft Bill and NLSUI draft Bill have same view in some areas and on some other areas have divergent view. The TRADITIONAL KNOWLEDGE (PROTECTION AND MANAGEMENT) BILL 2010 has to theoretically improve in some of the areas. These are (1) admission and recognition of two types of traditional knowledge-traditional community and traditional knowledge of the society in general; (2) apart from negative rights to protect TK associated medicinal plants, perfectly positive traditional knowledge rights-including power to offer proposal to enter into contract within the country and abroad for the purpose of commercialisation in different ways medicinal plants associated TK, rather than relying on others to come forward to do that; (3) power has also to be given to TKA or a professional managed government company (fully autonomous) to start commercialising TK by setting factories or manufacturing units on its own to produce medicines and establishment of research institutes for various purposes; (4) legal protection of existing knowledge of the public domain by making some provisions to deal with non-original inventions; (5) appropriate legal framework for punishment-including refund of profit and moratorium of all future grant of licenses; (6) making the application of the law with extra-territorial operations; (7) its relationship with national and international patent laws; (8) utilisation of TK Fund money not only for the life standard improvement of the traditional communities but also for the life standard improvement of BPL families out of the proceeds of royalties etc., from the commercialisation of traditional knowledge of the society; (9) it also would be a very good idea to start hospitals in India and in foreign countries where this type of medicine and Indian treatment method would be applied under the aegis of TKA.

These concerns for the positive and overall traditional knowledge protection are not adequately reflected in the preamble or statement of the reasons. Even then whatever ii there for these above mentioned reasons the bill cannot fulfil the statement of the objects and not in consonance with its preamble.

PROTECTION OF TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS THROUGH BIODIVERSITY PROTECTION ROUTE IN INDIA-SOME REFLECTIONS

India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th June, 1992. The Convention came into force on 29th December, 1993. In the backdrop of India being exceptionally rich in biological diversity and associated traditional and contemporary knowledge system and reaffirmation of the sovereign rights of the States over their biological resources by the Convention with the main objective of conservation of biological diversity,

sustainable use of its components and fair and equitable sharing of the benefits arising out of utilization of genetic resources. Biological Diversity Act was passed in 2002 to give effect to the objects of CBD i.e., to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and related matters.

ANALYSIS OF BIODIVERSITY ACT OF INDIA REGARDING PROTECTION OF TK

1. There is no definition of traditional knowledge associated with biological diversity or categories of it.
2. In general, as sovereign right over the biological diversity is given to the State, there might be possibility of conflict between State exercising sovereign rights over biological resources and the exercise of ownership right of the traditional knowledge associated biological diversity holders.
3. The TK protection is one component of whole biological diversity protection. It is not a special law wholly for the purpose of TK associated with medicinal plants protection.
4. One provision of the biological diversity regulation says that no person shall apply for any intellectual property right, in any form in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making the application. This poses a serious challenge to the traditional knowledge associated with medicinal plants protection. It means that invention based on any information from the traditional knowledge can get intellectual property protection and NBA also can approve it. As a result, the inventors of non-original invention and non-original innovation can claim intellectual property right. This provision is tacitly legalising biopiracy. Though while granting IP protection NBA can impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights, it is totally a different issue and should not be mixed up with the granting of TK protection to the non-original innovators and non-original inventors.
5. There is no comprehensive positive and negative protection as well.
6. There is no sufficient and appropriate civil and criminal liability for the violation.

FOREIGN LAWS FOR TK PROTECTION

PART I

SALIENT FEATURES OF THE LAWS FOR TRADITIONAL KNOWLEDGE PROTECTION-EXAMPLES OF SOME COUNTRIES

LAW OF THAILAND FOR THE TRADITIONAL KNOWLEDGE PROTECTION--SOME REFLECTIONS³

BASIC OBJECT

There is an expediency to have a law on protection and promotion of traditional Thai medicinal intelligence. Basically this law contains certain provisions that restrict the rights and liberties of the people, which are permissible under section 29, along with section 35, section 48 and section 50 of the Constitution of Thailand.

DEFINITIONS OF SOME KEY CONCEPTS

It is important to understand the nature and scope of the traditional knowledge protection in Thailand's legal framework. The definitions of some of the concepts serve that purpose preliminarily. Here some of the definitions are quoted from the Act with that objective. "**Traditional Thai medicinal Intelligence**" means the basic knowledge and capability concerned with traditional Thai medicine. "**Traditional Thai medicine**" means the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention of, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production of traditional Thai drugs and the invention of medical devices on the basis of knowledge on text that has been passed on generation to generation. "**Text on traditional Thai medicine**" means technical knowledge concerned with traditional Thai medicine which has been written or recorded in Thai books, palm leaf, stone inscription or other materials or that have not been recorded but passed on from generation to generation. "**Thai traditional drugs**" means medicines obtained directly from herbs or derived from mixture, blended or transformed herbs and also includes Thai traditional drugs under laws on drugs. "**Formula on traditional Thai drugs**" means a formula stated as the production process and ingredients which contain Thai traditional drugs, no matter what form the ingredients are. "**Herbs**" means plants, animals, bacteria, minerals, extracts of plants or animals used, or transformed or mixed or blended as drugs or food for diagnosis, therapy, treatment or prevention of diseases, or for promotion of the health of humans or animals. The meaning also includes the origin or the areas in which the products exist.

COMMITTEE ON PROTECTION AND PROMOTION OF TRADITION THAI MEDICINAL INTELLIGENCE

For the stated objects of this Act, it has constituted a committee to take care the all matters of traditional knowledge protection. According to section 6, this committee

³ ACT ON PROTECTION AND PROMOTION OF TRADITIONAL THAI MEDICINAL INTELLIGENCE, H.E. 2542. Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=179713. Visited on 15th June 2011 at 6 PM.

shall have some important power and duties to carry forward its functions. These are (1) to provide consultation or advice to the Minister in issuing the Ministerial Regulations, Rules or Notifications under this Act; (2) to promote and develop the use of intellectual traditional Thai medicine and herbs; (3) outline measures to strengthen stability and coordination between government agencies, state enterprises, communities and non government organisations on issues concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs; (4) to approve the withdrawal of registration on intellectual property rights on traditional Thai medicine; (5) to consider the appeal against the order or decision of the registrar or the licensing authority under this Act; (6) to lay down rules about the standards and procedures on lodging an appeal and consideration of appeal, registration of intellectual property rights on traditional Thai medicine, the administration and arrangement of benefits and expenses of the fund and works concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs etc.

PROTECTION AND PROMOTION OF INTELLIGENCE ON TRADITIONAL THAI

MEDICINE

Section 14 lays down that the intellectual property rights on traditional Thai medicine which is to be protected, shall be the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine. According to section 15, the Institute for Traditional Thai Medicine shall be responsible for compiling information on traditional Thai medical intelligence concerned with formulas of traditional Thai drugs and text on traditional Thai medicine from throughout the country for registration. Section 16 distinguishes traditional Thai medicinal intellectual property rights into three categories: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine; (2) the general formula of traditional Thai drugs or general traditional Thai medicine document; and (3) the personal formula of traditional Thai drugs or personal text on traditional Thai medicine. Section 19 says about the conditions of access to and utilisation of the knowledge for different purposes. It says that that whoever wishes to use the national traditional Thai drugs for registration and permission for production of drugs according to the Drug Law or wishes to use it for research on improvement or development of new drug formulas for commercial benefit or wish to research the national text on traditional Thai Drugs for development and improvement for commercial benefit, shall forward their application to obtain benefits and pay fees and the remuneration for making use thereof to the licensing authority as per rules. Section 20 is on the personal formula of traditional Thai drugs or personal text on traditional Thai medicine under section 16(3), which may be registered for protection of intellectual property rights and may be promoted according to the provisions of this Act by applying for registration to the registrar. Section 21 deals with the persons who have this kind of special right u/s 20. According to it, these persons must be of Thai

nationality and either (1) being an inventor of the formula on traditional Thai drugs or text on traditional Thai medicine; (2) being an improver of the developer of formula on traditional Thai drugs or text on traditional Thai medicine; or (1) being an inheritor of the formula on traditional Thai drugs or text on traditional Thai medicine. Section 22 puts some restrictions on the registration process. The registration for protection of intellectual property rights on traditional Thai medicine is prohibited if the registrar is of the opinion that: (1) the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine, or is a general formula on traditional Thai drug, or general text on traditional Thai medicine, or (2) the drug formula is a personal formula on traditional Thai drug that has been developed on non medical basis like the use of extracts of plants, animals or micro organisms that have not been obtained from natural extracts or the transformation that is not considered rough transformation. Next point is the duration of the right for commercialisation of the knowledge. Section 33 allows the right to intellectual property on traditional Thai medicine should be valid for a life time of the bearer of the registration and extend for another 50 years from time the owner of the registration has deceased and in joint ownership of the registration right, the intellectual property rights on traditional Thai medicine shall be valid for a life time of the bearer and extended for another 50 years from the date on which the last joint owner of the registration deceased. Section 34 gives some exclusive right to the right holder. He has the sole ownership on the production of the drug and has sole right over the research, distribution, improvement or development of formulas on traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine. But any act that is of benefit for studies, findings, tests or research according to the regulation specified by the Minister; or preparation of specific drugs according to prescription of holders of registration certificate on traditional Thai medicine, production of drugs for household use or production of drugs by sate hospitals or government or state agencies, for use in state hospitals, or the use of text on traditional Thai medicine for benefits in treatment of patients in state hospitals as per rules are excluded. The right holder may also allow others to use his right over the knowledge. In this law there is provision of revocation of right under some specific grounds. Section gives power to the registrar has the right to revoke the registration of intellectual property rights on traditional Thai medicine when (1) the right holder misuses the right against the public order and good morals; (2) the right holder violates or does not comply with the conditions or limitations outlined by the registrar in registration of the intellectual property rights on that traditional Thai medicine; or (3) the right holder exercised the right that may cause severe damage to the registered intellectual property on traditional Thai medicine.

SPECIAL MEASURES FOR PROTECTION OF HERBS

Section 44 states that for the purpose of herbs protection and conservation, the Minister with the advice of the Committee, shall have the power to issue a notification to specify the kind, characteristic, type, and names of herbs that are of study and

research value, or have important economic significance or may become extinct, as controlled herbs. As a follow up action of the above mentioned purposes, according to section 45, the Minister shall with the advice of the Committee can issue notification by (1) specifying the amount or quantity of controlled herbs under possession to make use of, under care, under conservation or under transportation which needs to be informed the registrar; (2) specifying rules, procedure and conditions in informing under (1); (3) specifying rules, procedure and conditions on the possession, to make use of, under care, under conservation or for transportation of controlled herbs; (4) specifying rules, procedure and conditions on studying and researching the controlled herbs; (5) specifying rules, procedure and conditions on exporting controlled herbs for commercial and non-commercial purposes, or distribution or transformation of controlled herbs for commercial purposes; (6) specifying other requirements to conserve, prevent or prohibit or reduce dangers or damage may be caused to controlled herbs. In furtherance of these broad measures for the protection and conservation of controlled herbs, some specific activities are fixed up in the subsequent sections.

FUND ON THAI TRADITIONAL MEDICINE INTELLIGENCE

There is a fund as is authorised by section 76. It is the "Fund on Traditional Thai Medicine Intelligence". It is to be set up in the office of the Permanent Secretary, Ministry of Public Health, as a revolving fund for expenses concerned with works on conservation and promotion of intelligence on traditional Thai medicine. The fund is to be created from (1) subsidy from the state; (2) money or property received from the private sector from within and outside the country, foreign governments or international organizations; (3) interests and benefits obtained from the fund. (4) other earnings obtained from the functioning of the fund. The earnings of the fund must be remitted to the Finance Ministry under the law on the treasury balance and the law on the budgetary procedures. The administration, management of benefits and use of money in the fund shall be in accordance with the rules prescribed by the Committee, with the approval of the Finance Ministry.

PENALTIES FOR VIOLATIONS

There are two types of punishment for different kinds of violations. Sections 78 to 82 deal with those violations and punishments-fine and/or imprisonment. Amount of fine starts from 2000 baht to 40,000 baht and imprisonment is from one month to two years.

PART II

LAW OF THE KYRGYZTAN FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE -SOME REFLECTIONS⁴

BASIC OBJECT

Traditional knowledge using genetic resources is an historical heritage and property of the people of this country. The legal framework secures general provisions of the State policy and legal, economic and social guarantees in the field of Traditional Knowledge using genetic resources. The aim is sustainable development of the country and arrangement of conditions for fair distribution of benefits arising from the use of Traditional Knowledge.

DEFINITION OF TK AND ITS HOLDERS

What is to be protected within the ambit of TK lies on the definition clauses. This is the significance of this. Article 2 is about the General Concepts in which TK is defined. **Traditional knowledge** shall mean knowledge, methods and manners, including use of genetic resources, used in different fields of the human activities, which have been transferred from one generation to another eventually in certain order and meaning. This knowledge have been kept and adapted for different needs of the local communities and the owners of traditional knowledge and represent particular value for the development of various fields of activities. About the question of who are the holders of TK-it is said that Traditional knowledge holders shall mean the local communities, natural persons and legal entities with any legal structure and with any pattern of ownership who are the possessors of Traditional Knowledge.

STATE REGULATION OF TRADITIONAL KNOWLEDGE

In this part Article 3 clarifies the objectives and tasks of the regulation, which is to be initiated by the state. These are legal protection, promotion of reservation and wide use of Traditional Knowledge in different fields of human activities, assistance in use of Traditional Knowledge, including knowledge based on genetic resources in industrial production, as well as further commercialization of objects produced as a result of their use. The State regulation in the field of Traditional Knowledge include (1) Creation of the preventive mechanism aimed at protection of Traditional Knowledge from illegal patenting of subject-matters created on the bases of Traditional Knowledge and use of associated genetic resources by the inclusion the Traditional Knowledge into database; (2) Fair distribution of benefits received due to usage of Traditional Knowledge in favour of local communities; (3) Establishment of

⁴ Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=179127. Visited 15th June 2011 at 6.15 PM.

the fund for development of local communities, which can be supported by financial transfers collected during the usage of Traditional Knowledge and genetic resources; (4) Establishment of the State fund for development of the system of usage of Traditional Knowledge; (5) conducting scientific researches on Traditional Knowledge and existing genetic resources as to their practical use, inter alia: reveal the priority trends in researches in the field of Traditional Knowledge using genetic resources, which may contribute significantly to the preservation of environment; development and improvement of new types of genetic resources utilization; making scientific studies in order to create the inventory on Traditional Knowledge in this country; reveal of well-known and widely used Traditional Knowledge. Article 4 is there to establish Authorised State Body. The state policy in the field of Traditional Knowledge shall be performed by it in the field of IP.

SUBJECT MATTERS CREATED ON THE BASE OF TK

Article 8 puts restrictions on patenting of subject-matters, which are representing Traditional Knowledge in this country. When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. Holder of a certificate, which name is indicated in the registered Traditional Knowledge shall be entitled to receive remuneration from the owner of a patent for invention created by use of Traditional Knowledge. The order of payment of remuneration for use of Traditional Knowledge with the purpose of creation of invention shall be determined by an agreement between the owner of certificate for Traditional Knowledge and the owner of a patent for invention. At the same time such agreement must specify assignments to be made for use of Traditional Knowledge to the Fund for development of local communities or the State fund for development of the system of Traditional Knowledge usage. In order to prevent illegal patenting of subject-matters created on the base of Traditional Knowledge the Traditional Knowledge database shall be maintained, which shall be used during examination of subject-matters to be patented.

AGREEMENT FOR TRADITIONAL KNOWLEDGE UTILISATION

Article 14 deals with this agreement and related matters. A person who is not the owner of Traditional Knowledge may receive a right to use Traditional Knowledge provided that appropriate agreement is concluded between him and the owner of Traditional Knowledge, who has registered TK in the Authorized Body. According to the agreement the owner of Traditional Knowledge shall grant the right to use TK to other person in the scope of transferred rights, time-limits, territory and order of payments established by this agreement. Conditions of the agreement are subject to the mutual consent of the parties concerned. The agreement must provide a provision of assignments for use of Traditional Knowledge to the Fund for the development of a

local community or the State Fund for development of the system of Traditional Knowledge usage. At the same time assignments for use of Traditional Knowledge provided by the agreement to the Fund for the development of a relevant local community or the State Fund for development of the system of Traditional Knowledge usage shall be not less than 20%.

FUNDS

Fund is another important part of the TK protection. The fixation of amount, collection, deposit and purposes of utilisation of the money etc., are some of the matters. Article 16 says that to reserve Traditional Knowledge and distribute fairly the benefits from use thereof, the owners of Traditional Knowledge shall establish the Fund for development of a local community. In order to develop the Traditional Knowledge system the State Fund for development of Traditional Knowledge usage shall be established under the Authorized Body.

USAGE OF TRADITIONAL KNOWLEDGE

According to Article 17, production, application, import, distribution, offer for sale, sale and other entering to economic turnover shall be deemed as a usage of Traditional Knowledge in subject-matters containing and created on their base. Usage in production with commercial purposes without conclusion of agreements with Traditional Knowledge holders shall be deemed as illegal use of Traditional Knowledge. Usage of Traditional Knowledge shall be allowed without consent of Traditional Knowledge holder if such a usage takes place for educational and research purposes provided that the source is indicated and exclusively for personal purposes. In case of force-majeure (disasters, catastrophes, accidents) as well as in the interest of national security the Government of the Kyrgyz Republic shall be entitled to issue permission to use Traditional Knowledge provided that reasonable compensation is paid to the owner of certificate; scope and duration of use of Traditional Knowledge shall be limited by the purposes for which permitted.

PART III

LAW OF PERU FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE-SOME REFLECTIONS⁵

OBJECTIVES OF THE LEGAL REGIME

The State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit. With this in mind the objectives of the legal framework is visualised. Article 5 is to set the sole objectives of the legal framework, which are: (a) to promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples; (b) to promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge; (c) to promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general; (d) to ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples; (e) to promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime; (f) to avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

Article 2 is to define some of the basic terms. From this, it is ample clear as to who are entitled the protection. As there are definitions of 'indigenous people' and 'collective knowledge', it is inferred that this group of people can have protection from their collective knowledge. The protective knowledge shall be that which belongs to an indigenous people and not to particular individuals. "**Indigenous peoples**" means aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. These include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. The term "indigenous" shall encompass, and may be used as a synonym of, "aboriginal," "traditional," "ethnic," "ancestral," "native" etc. "**Collective knowledge**" means the accumulated, trans-generational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity i.e biological resources.

⁵ LAW INTRODUCING A PROTECTION REGIME FOR THE COLLECTIVE KNOWLEDGE OF INDIGENOUS PEOPLES DERIVED FROM BIOLOGICAL RESOURCES-LAW NO 27811. Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=203365. Visited on 15th June 2011 at 6.30 PM.

GENERAL PRINCIPLES OF THE LEGAL FRAMEWORK

Article 6 says about the conditions of access to collective knowledge. It directs that who are interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge. Then the organization shall inform the greatest possible number of indigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs. Article 7 prescribes the method of access for the purposes of commercial or industrial application. In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving there from is guaranteed. Article 8 fixes up the percentage accruing to the Fund for the Development of Indigenous peoples. A percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples. Though the parties may agree on a greater percentage according to the degree of direct use or incorporation of the said knowledge in the resulting end product and the degree to which said knowledge contributed to the reduction of the cost of research and development work on derived products, among other things. Article 9 imposes some duties on the present generations. The role of the present generations of the indigenous peoples shall preserve, develop and administer their collective knowledge for the benefit of future generations as well as for their own benefit. Article 13 gives something new on the protection of existing traditional knowledge which is in the public domain. As per this arrangement, the collective knowledge which is in the public domain when it has been made accessible to persons other than the indigenous peoples by mass communication media such as publication or, when the properties, uses or characteristics of a biological resource are concerned, where it has become extensively known outside the confines of the indigenous peoples and communities. In cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples.

TRANSFER OF PROPERTY THROUGH LICENSING

Article 25 prescribes compulsory registration of license contracts between the traditional peoples holding the common knowledge and the manufacturers or producers. Article 27 suggests the required contents of the license contracts. The license contracts shall contain (a) Identification of the parties; (b) A description of the

collective knowledge to which the contract relates; (c) A statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be; (d) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge and its value where applicable; (e) The obligation on the licensee to inform the licensor periodically, in general terms, of progress in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the license relates; (f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources.

FUND FOR THE DEVELOPMENT OF INDIGENOUS PEOPLES

Article 37 explains the purpose of the Fund for the Development of Indigenous Peoples. The Fund for the Development of Indigenous Peoples and Communities is hereby created for the purpose of contributing to the comprehensive development of indigenous peoples through the financing of projects and other activities. Article 41 authorises the resources of the Fund for the Development of Indigenous Peoples to get from the State budget, international technical cooperation, donations, the percentage of economic benefits.

PROTECTION CONFERRED BY LAW

Rights of indigenous peoples possessing collective knowledge are recognised in Article 42. The right is such that Indigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain.

SANCTIONS

Article 62 deals with the Sanctions. Violations of the rights of indigenous peoples shall give rise to the imposition of a fine, without prejudice to such measures as may be ordered to cause the infringing acts to cease or to prevent them from being committed. The fines that may be imposed shall be up to 150 tax units. The imposition and gradation of fines shall be determined according to the economic benefit secured by the infringer, the economic prejudice caused the indigenous peoples and communities and the conduct of the infringer throughout the proceedings. Recidivism shall be considered an aggravating circumstance, and the sanction applicable shall therefore not be less severe than the previous one. Where the defendant fails to comply within a period of three days with the terms of the ruling

that concludes a proceeding, he shall be subjected to a sanction not exceeding the maximum of the fine allowed. Where the defendant persists in failing to comply, the fine imposed may be successively doubled without limitation. It is without prejudice to the possibility of being reported to the Public Prosecutor with a view to the initiation of the appropriate criminal proceedings against him.

INDIGENOUS KNOWLEDGE PROTECTION BOARD

Article 65 constitutes Indigenous Knowledge Protection Board. Article 66 determines the functions of the Indigenous Knowledge Protection Board which are: (a) to monitor and oversee the implementation of this protection regime; (b) to support the Administrative Committee of the Fund for the Development of Indigenous Peoples and the Office of Inventions and New Technology of INDECOPI in the performance of their functions; (c) to give its opinion on the validity of contracts for the licensing of the collective knowledge of indigenous peoples; (d) to give advice and assistance to the representatives of indigenous peoples who so request regarding matters connected with this regime, and in particular in the planning and implementation of projects within the framework thereof; (e) To supervise the Administrative Committee of the Fund for the Development of Indigenous Peoples in the exercise of its functions etc.

PART IV

BRAZILIAN LAW FOR TRADITIONAL KNOWLEDGE PROTECTION- SOME GENERAL REFLECTIONS⁶

GENERAL PROVISIONS

The first part is about general provisions. Article 1 says about the subject matters or assets (the rights and obligations are set forth later on). These are (a) the access to components of genetic heritage existing within the Brazilian territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or bio-prospecting; (b) Access to traditional knowledge associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the use of its components; (c) the fair and equitable sharing of the benefits arising from the use of genetic heritage component and the associated traditional knowledge; etc. (d) access to technology and transfer of technology for the conservation and use of biological diversity. It directs that Access to components of genetic heritage for the purpose of scientific research, technological development or bio-prospecting shall be carried out under the terms of this Act, without prejudice to material or intangible property rights that are incident upon the accessed genetic heritage components or upon the site of occurrence. Article 2 states that access to genetic heritage existing in the country shall only be take place with an authorization from the government and its use,

⁶ PROVISIONAL ACT NO. 2,186-16, DATED AUGUST 23, 2001.

commercialization and employment for any purpose shall be submitted to inspection, restrictions and sharing of benefits in the terms and conditions established in this Act and its complementary legislation. Article 4 declares that the exchange and dissemination of components of genetic heritage and of associated traditional knowledge practiced within indigenous communities and local communities for their own benefit and based on customary practices is preserved.

DEFINITIONS OF KEY CONCEPTS

Article 7 is the definition clause. From this part, it becomes clear what is to be protected and what is not. It also becomes clear who are entitled for protection. The term genetic heritage, associated traditional knowledge and local community are defined. Genetic heritage is the information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated, or kept in *ex situ* collections, if collected from *in situ* conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone. Associated traditional knowledge is individual or collective information or practice of the indigenous community or local community, with real or potential value, associated to genetic heritage. Local community means human group, including descendants of *Quilombo* communities, differentiated by its cultural conditions, which is, traditionally, organized along successive generations and with its own customs, and preserves its social and economic institutions.

PROTECTION TO ASSOCIATED TRADITIONAL KNOWLEDGE

The traditional knowledge of the indigenous communities and of the local communities, associated to genetic heritage, from illicit use and exploitation and other harmful actions or those actions not authorized by the Management Council, or by an accredited institution by Article 8. The State recognizes the right of the indigenous communities and of the local communities to decide on the use of their traditional knowledge related to the genetic heritage of the country, in the terms of this Act and its complementary legislation. Article 9 assures some of the rights. Accordingly, the indigenous communities and local communities that create, develop, hold or conserve traditional knowledge associated to genetic heritage are assured the right to: (I) have acknowledged the origin of the access to the traditional knowledge in all publications, uses, exploitations and dissemination; (II) prevent non-authorized third-parties for: (a) Use, test, research or exploit of associated traditional knowledge and (b) Disseminate, transmit or forward data or information that constitute associated traditional knowledge, or part thereof; (III) receive benefits from the economic use by third parties, directly or indirectly, of associated traditional knowledge to which they hold rights, in accordance with this Act.

INSTITUTIONAL MANDATE AND COMPETENCE

There is Article 10 to establish The Genetic Heritage Management Council under the Ministry of Environment, a regulatory body. Its responsibility is determined by Article 11. These are: (I) Coordinating implementation of genetic heritage management policies; (II) Establishing: (a) Technical standards; (b) Criteria for access and shipment authorizations; (c) Guidelines for drafting the Contract for Use of Genetic Heritage and Benefit-Sharing; (d) Criteria for creation of a database for recording information on associated traditional knowledge; (III) -Overseeing, in coordination with other federal bodies, or by means of an agreement with other institutions, the activities of access and shipment of samples of genetic heritage components and access to associated traditional knowledge; (IV) - Deliberating on: (a) Authorizations for access and shipment of samples of genetic heritage components, with prior consent of its holder; (b) Authorizations for access to associated traditional knowledge, with the prior consent of its holder; (c) Special authorizations for access and shipment of samples of genetic heritage components to the Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to the Brazilian university. (d) Special authorization for access to associated traditional knowledge to a Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to a Brazilian university. (V) Approving Contracts for Use of Genetic Heritage and Benefit-Sharing with regard to their complying with the requirements of this Provisional Act and its complementary legislation.

BENEFIT-SHARING FORMULA

Another important part of this Act is that it ensures of benefit-sharing. Article 24 states that the benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign-based institution, shall be shared in a fair and equitable manner among the contracting parties, as per rules. The benefits arising from the economic use of the product or process developed from a sample of a genetic heritage component or from associated traditional knowledge, may be (I) Sharing of profits; (II) Payment of royalties; (III) Access and transfer of technologies; (IV) licensing, without cost, of products and processes; and (V) Capacity building of human resources as per Article 25.

PUNISHMENTS AND ADMINISTRATIVE SANCTIONS

Article 30 is for this purpose to define violation and prescribes punishments. An administrative violation against the genetic heritage or the associated traditional knowledge is considered to be every act or omission that violates the rules in the Act relevant legal provisions. These are: I-Warning; II Fine; III-Seizure of samples of the genetic heritage components and the instruments used in the collection or processing

or the products obtained as a result of information on associated traditional knowledge; IV-Seizure of all products derived from a sample of a genetic heritage component or of associated traditional knowledge; V-Suspension of the sale of the product derived from the sample of the genetic heritage component or of the associated traditional knowledge and its seizure; VI-Embargo of the activity; VII-Partial or total closure of the business, activity or undertaking; VIII-Suspension of the register, patent, license or authorization; IX-Cancelling of the register, patent, license or authorization; X-Loss or reduction of fiscal incentives and benefits granted by the government; XI-Loss or suspension of the right to receive financing from an official financing agency; XII-Intervention in the establishment; XIII-Prohibition of entering into contracts with the Public Administration for a period of up to five years.

Moreover Article 26 has prescribed some economic punishments. It authorises that if the economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained from commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of the technology, whether or not they are protected by intellectual property, without prejudice to administrative sanctions and the appropriate penalties.

PART V

LAW OF BHUTAN TO PROTECT TRADITIONAL KNOWLEDGE-SOME REFLECTIONS⁷

PREAMBLE

Taking note on the sovereignty of the States over their genetic resources and the need to promote the conservation and sustainable use of these resources as well as the fair and equitable sharing of benefits arising from its utilization according to CBD and recalling decisions about promoting and encouraging the Parties to implement legal, administrative and policy measures to regulate access to genetic resources and benefit sharing it realises the value of biological and genetic resources in the development of products compounds and substances that have medicinal, industrial and agricultural and related applications and its necessity to protect and encourage cultural diversity giving due value to the knowledge, innovations and practices of local communities in Bhutan.

It is fully aware of the fundamental principle that prior informed consent and mutually agreed terms for benefit sharing shall be secured before access can take place.

⁷ The Biodiversity Act of Bhutan, 2003.

DEFINITIONS

Access: means obtaining, collecting, utilizing and/or exporting genetic or biochemical resources covered by this Act for purposes of conservation, research, bio-prospecting or commercial use.

Biochemical Resources: means any material derived from plants, fungi, animals or micro-organism, which contains specific characteristics and special molecules.

Bioprospecting: means the systematic search, classification and research of new sources of chemical compounds, genes, proteins and microorganism for commercial purposes with real or potential economic value, which are found in biodiversity.

Genetic resources: means any material derived from plants, animals, fungi or microorganisms which contains functional unit of heredity..

Traditional Knowledge: means the knowledge, innovation and practices of local communities relating to the use, properties, values and processes of any biological and genetic resources or any part thereof.

PURPOSES AND OBJECTIVES, SCOPES AND EXCEPTIONS⁸

PURPOSES AND OBJECTIVES

a. To ensure national sovereignty of the government over genetic resources in accordance with relevant National and International Law. b. To ensure the conservation and sustainable use of the biochemical and genetic resources. c. To promote the equitable sharing of benefits derived from the use of genetic resources. d. To promote technology transfer and capacity building at the national and local levels, including the building of scientific and technological capacity relevant to the conservation and sustainable use of biological diversity. e. To recognize and protect Traditional Knowledge, innovation and practices of local communities associated with biodiversity. g. To prevent illegal access to genetic and biochemical resources and associated Traditional Knowledge.

SCOPE

A. The provision of this Act shall apply to the Traditional Knowledge, innovation and practices associated with biodiversity. **B.** The Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions: (i) is or has been transmitted from generation to generation. ii) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan. (iii) is collectively originated and held.

⁸ Ibid, Chapter 1.

EXEMPTIONS

A. Where the biological material is used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority, based on the processes and end use of genetic resources, in accordance with the provisions of the Act. **B.** To access, use and exchange of biological and genetic resources among local communities resulting from their traditional and customary practices.

ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING: CONDITIONS OF ACCESS⁹

Conditions of access to biodiversity shall be subject to the prior informed consent of the Competent Authority of Bhutan, representing national interests and the interests of the local communities harbouring, cultivating, developing and maintaining the biological diversity concerned. **But in case of conditions of access to Traditional Knowledge, innovation and practices of local communities, the procedure and conditions set out in Chapter 4 shall apply.**

PROTECTION OF TRADITIONAL KNOWLEDGE¹⁰

Part I: CONDITIONS FOR PROTECTION

Applicability. It applies to Traditional Knowledge that was in existence before the commencement of this Act or is created on or after the commencement of this Act for both.

Customary uses. The customary use of Traditional Knowledge among the local communities does not give rise to any criminal or civil action for liability under this Act.

Rights owners. The owners of Traditional Knowledge are the holders of the rights in the Traditional Knowledge.

Material form not required. The rights exist in Traditional Knowledge whether or not the Traditional Knowledge is in material form.

Duration. Rights conferred by this Chapter continue in force in perpetuity and are inalienable.

Additional rights. The Rights in Traditional Knowledge are in addition to and do not affect, any rights that may subsist under any intellectual property laws.

Part II: PROCEDURES

Application

The applicant shall obtain the prior informed consent of the traditional owners of the Traditional Knowledge for use of Traditional Knowledge for a non-customary use.

⁹ Ibid, Chapter 2.

¹⁰ Ibid, Chapter 4.

Appraisal of application

The owners of the Traditional Knowledge must decide whether: a. To reject the application. b. To accept the application and enter into negotiations for a written authorized user agreement in relation with the application containing the appropriate benefit sharing arrangements.

Proposed agreement

Before entering into an authorized user agreement the owners of the Traditional Knowledge must submit the proposed agreement for comments to the Competent Authority for final approval.

User agreement and prior informed consent

If the applicant and the traditional owners enter into an authorized agreement, the owners of the Traditional Knowledge are deemed to have given their prior informed consent to the proposed use. A final copy of the agreement must be forwarded to the Competent Authority.

Advice of Competent Authority

The Authority, upon request, may provide advice to the owners of the Traditional Knowledge during the negotiations of the user agreement or during the processing of the access application.

Inventory of Traditional Knowledge

The Authorized Agency in collaboration with the owners of the Traditional Knowledge will carry out an inventory and documentation of Traditional Knowledge.

OFFENCES AND PENALTIES¹¹

Among other offences these two are directly related to TK: Non-compliance with the traditional knowledge rights as provided in Chapter 4 and Failure to comply with any other provisions of this Act or Regulations.

Civil Liability: For that reason there is civil liability. Any violation of material terms and agreement of this Act is a breach of contract.

Penalties: Punishment for the failure to comply with or contravenes with Chapter 4 of the Act, is imprisonment for a term of one year to three years or with fine. The amount of fine is equivalent to minimum daily wage rate of two years to six years according to wage rate rules. There is a provision for confiscation of such genetic resources collected in contravention of the provisions of this Act and imposition of liability to pay damages.

Revocation of access permit

Access permits may be withdrawn if the permit was obtained by providing false or misleading information under Section 8 and for reasons of public interest, including the protection of the environment and biological diversity.

¹¹ Ibid, Chapter 5.

CONCLUSION

There are some common concerns of India and these countries for traditional knowledge protection, as day by day, their traditional knowledge is being taken away by foreign countries and companies. It is good that at least these countries have enacted special laws for traditional knowledge protection. Yet there are some drawbacks and the laws vary from each other on various aspects. This is due to the reason that either laws are the reflections of particular situations and special needs of those countries, a country's traditional knowledge may have some unique features different from others or the laws are in furtherance of the national policies of these countries, which were adopted after due consideration. Vision of the political establishments might be different from each other along with the standard and availability of legal expertise, hence is reflected in these laws. Aiming at the traditional knowledge protection, these countries thought it right to set various types of objectives to achieve that goal and conditioned their national laws also accordingly. These diverse aims and objects get reflected in their legal provisions. These laws have some persuasive values to persuade India to have a law on TK and shape its law. Some good provisions can be incorporated into the Indian legal framework.

It is hoped that all TK enriched countries would be joining with this group. Its presence would be felt in the international forum; its voice would be stronger enough that cannot be ignored by the developed countries. They can work as enblock and would be able to exert pressure on the world body to just strike down the biased laws. India does not feel any necessity to have such a law. In this context, at present there is no comprehensive positive law especially for traditional knowledge protection, preservation and its utilisation. Biological Diversity Act offers a very limited protection. Hence, it is suggested that India must have a sui generis effective law to safeguard and utilisation of its vast traditional knowledge. To make a model law for India, new, innovative, radical and comprehensive thinking are necessary.

There is a necessity to have a uniform standard with some flexibility to suit the special needs of a particular country. This is because though TK per se has some common characteristics, face same types of challenges but each country has its own socio-cultural and economic environments which are different from others. Apart from those common grounds which have to be uniform in nature in all the national laws of each and every country, laws must be uniform. But in other matters there can be diversity. There must have some flexibility and relaxation to adjust and adapt with the particular social, scientific, economical and cultural environments of India.

CHAPTER VII

MARCH TO EVOLVE A LEGAL FRAMEWORK FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH MEDICINAL PLANTS

A. ANALYSIS OF TWO PRIVATE DRAFT BILLS OF INDIA FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

PART I

INTRODUCTION

In spite of an urgent need to enact a law exclusively dedicated for protection for traditional knowledge of India, there is such law in India yet. Whatever laws that are in existence in India, offer indirect protection, that is also negative in approach and inappropriate in consequence. Among all other urgencies, the priority should be to have a law exclusively on protection of traditional knowledge. Otherwise India would be losing all its control and right over all its medicinal plants. It is not clear whether the government is contemplating legislation. At the international level there is no such legislative framework that is binding upon all countries. At a preliminary level, WIPO has been struggling to frame something positive. There is pressure from the third world countries on WTO to accommodate this concern. But it is yet to come up with any specific and unanimous international treaty which will be binding on all countries.

In this backdrop, there are two draft bills-first one prepared by National University of Juridical Sciences, Kolkata and the second prepared by National Law School of India University, Bangalore. In addition to their efforts at the international level there are some special laws of some TK of medicinal plants enriched countries such as China, Kyrgyzstan, Peru, Brazil and Thailand etc. These countries are proactive and advanced for traditional knowledge protection, including medicinal values of the biological resources. But the national sentiment to safeguard the century old traditional knowledge of bio-medicine is yet to be honoured.

In this chapter an attempt is made to analyse all the draft bills and the laws of the countries having legal framework for the protection of TK of medicinal plants and assess their legal efficacy.

BIOLOGICAL RESOURCES, TRADITIONAL KNOWLEDGE AND EXPRESSIONS OF FOLKLORE (PROTECTION & REGULATION) BILL, 2003¹-SOME REFLECTIONS

PREAMBLE TO THE BILL

Every enactment has its own preamble. Preamble is the guiding principle or core values over which the law is based. It is an Act to provide for the establishment of an effective regime to prevent the misappropriation of biological resources, traditional knowledge systems that may be found in the country and to secure the rights of the communities in relation to them. As India is rich in biological diversity and traditional knowledge systems, hence, it is recognised that it is considered necessary to reward and respect the contribution of the communities, made over generations, in conserving, improving and making available these resources for the development of nation's bio-diversity. It is said that it is necessary to regulate the access to, and utilisation of the biological resources, traditional knowledge systems. It is also opined that it is considered necessary to provide for the sustainable use of the components of the resources and fair and equitable sharing of the benefits arising out of utilisation of these resources in accordance with CBD and involve maximum community participation in these process.

DEFINITION OF TK AND BIOLOGICAL RESOURCE

“**Traditional Knowledge**” is a body of knowledge, practice, technology and belief, evolved by adaptive processes and handed down through generations by cultural transmission, within a community and it includes knowledge and belief associated with a biological resource. “**Biological resources**” are plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.

GENERAL PRINCIPLES

In Chapter II there are general principles about the rights relating to biological resources and traditional knowledge. It vests the nation with sovereign rights over its bio-diversity to be known as national heritage rights and the State is to hold these resources in trust for the communities. The community identifiable with a biological resource and traditional knowledge has inalienable right to share benefits arising from biological resource and traditional knowledge and is to be known as community heritage rights. Where the biological resource or traditional knowledge cannot be identified with a specific community, then it would vest in the nation as national heritage rights. As the community has a heritage right over a biological resource and

¹ BIOLOGICAL RESOURCES, TRADITIONAL KNOWLEDGE AND EXPRESSIONS OF FOLKLORE (PROTECTION & REGULATION) BILL, 2003, Anirban Majumder, Published by The W.B. NUJS, Kolkata, 2004.

traditional knowledge, it has the power to commercialise them subject to the condition that benefits of such exploitation is of that community and subject to environmental laws. Moreover, while allowing conditional grant of access to the biological resources and traditional knowledge, prior informed consent of the community and fair and equitable sharing of benefits with them, have to be ensured.

AUTHORITIES UNDER THE ACT

Chapter III deals with the establishment of National Heritage Authority which shall consist of various committees along with Committee on Biological Resources and Traditional Knowledge. It has different functions to discharge the responsibilities of protection and regulation of biological resources and traditional knowledge: (a) to create, consolidate and maintain a database, which is to be a public document, by way of documentation of the available biological resources and traditional knowledge systems in the country and attempt to trace their origin to individual communities or geographical territories. (b) to create and maintain a website, which is to contain the database and the consolidated report of licenses and certificates granted for the biological resource and traditional knowledge. (c) to initiate proceedings against wrongful intellectual property rights obtained by violating the national or community heritage in India.

The functions of the Committee on Biological Resources and Traditional Knowledge are to process the application for accessing biological resources and traditional knowledge; to enter into licence agreement for access and utilisation and to coordinate between the applicant and the communities if they are more.

In this chapter, there is provision for the establishment of the State Heritage Authority and Local Heritage Authority. These authorities have various functions under this Act. The functions of the SHA are (a) to notify the local authorities of the publication of the periodical reports and supplying them with the reports; (c) to monitor and supervise the functions of the local authorities.

Functions of the LHA are more important because it has to perform some primary functions. These are: (a) to determine the communities identifiable with the biological resources and traditional knowledge; (b) to oversee the procedure and aid such community in the process of formulating the licence agreement for access to the biological resource and traditional knowledge; (c) to ensure the proper implementation and enforcement of access and benefit sharing agreement; (d) to locate, acknowledge and document information of biological resources and traditional knowledge etc.

Another important provision of this Act is the creation of National Heritage Fund. This fund shall be credited all charges and royalties received by NHA from the licensing of national heritage rights, compensation, fines and damages accrued from the infringement proceedings relating to national heritage rights. The fund is to be applied for the conservation and promotion of biodiversity, biological resources and

traditional knowledge. The fund is to be applied also for the development of incentive models to support the communities applying for commercial development of biological resources.

REGULATION OF ACCESS TO BIOLOGICAL RESOURCE AND TRADITIONAL KNOWLEDGE

Chapter IV deals with many things about procedural matters. Its subject matters are (a) application to NHA; (b) information to be provided in the application; (c) procedure on receipt of application; (d) procedure in cases of National Heritage Applications; (e) procedure in case of community heritage; (f) procedure after grant of certificate of permission; (g) right to deny access; (h) licence agreement; (j) conflict of rights; (k) exception to public sector research; (l) standard licensing terms ; (m) void license agreements etc. Among other subject matters of this chapter 'information to be provided in the application' and 'standard licensing terms' need some special attention.

The former would require the informations: (1) type and quantity of biological resources, traditional knowledge to which access is sought; (2) identification of place of origin of biological resource and source of traditional knowledge; (3) evaluation of the possible impact of the access activity on conservation and sustainable use of the resource; (4) accurate information for the purpose of collection, research, expected results and nature and extent of intended use; (5) information on how and where the research and development is to be carried out; (6) types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from commercial and other utilisation of the resource and (7) indication of benefit sharing arrangements etc.

The latter shall compulsorily include (1) description of biological resource, traditional knowledge including accompanying information; (2) permitted uses and any limitation on it including its potential uses and related products and derivatives; (3) the licence must make a disclosure of the source of the origin of the biological resource, traditional knowledge; (4) terms of benefit sharing agreements, including commitment to share monetary and non-monitory benefits.

INFRINGEMENT

This Chapter V deals with acts which constitute infringement. Infringement is of two types- civil penalties for infringement and criminal penalties in certain cases. Infringement occurs when there is breach of procedure established under this Act for gaining access to or for the utilisation of a biological resource, traditional knowledge or the breach of any term of the license agreement by the licensee or non-inclusion of any standard licensing terms. Civil penalties for the infringement are: (a) no certificate u/s 23 and no license u/s 24 will be issued for a minimum period of twenty or more years; (b) imposing of liability to pay damages to the community whose community heritage right has been infringed in addition to damages to NHA. The

amount of compensation will be determined on the basis of profits or value of biological resource, traditional knowledge; (c) for breach of procedure or breach of term of license agreement, there is a provision of injunction prohibiting the sale of such product; (d) no intellectual property rights in India shall be conferred on any product owing to its origin to the biological resource, traditional knowledge it has been obtained or utilised by infringement and if any such right was conferred, it is subject to immediate revocation.

Criminal penalties in certain cases are imprisonment from one to three years and fine of Rs five lac to twenty lac for knowing infringement or abetment for infringement.

PROVISIONS RELATING TO THE CONSERVATION OF BIODIVERSITY

This chapter is about conservation of biodiversity-a widened measure of protection of biological resources, traditional knowledge. Central government is empowered to develop national strategies, plans and programmes for the conservation, promotion and sustainable use of biological diversity which includes measures for the identification and monitoring of areas rich in biological resources, promotion of in situ and ex situ conservation, incentives for research etc. There are some duties of the local authorities i.e. to anticipate, prevent any activity that can cause the loss or cause a threat to biodiversity. If the local authority thinks that any area rich in biological diversity is being threatened by overuse, abuse or neglect, it can issue directives. Any person who wants to import, export, experiment, mobilise, release in to the environment, multiply, commercialise or use for research genetically modified organisms, can do so with the previous permission. Apart from these, the authority can regulate the use of pesticides and fertilizers used for agricultural purposes and causing danger to biological diversity.

ANALYSIS OF THE BILL

This bill is an welcome step to explore a model law of India for the protection of traditional knowledge. This bill has many positives for the traditional knowledge protection- name of the right-community heritage right and national heritage right, protection of existing knowledge, prior informed consent, benefit sharing formula, regulation of access and utilisation, conservation of biodiversity etc. But much water has flown down the rivers since its proposal and new situations have arisen which needs new strategy and new approach. Moreover, from the point of view of the present research work, there is further opportunity of improvement for a better model law to offer better protections, as indicated below.

A. Traditional knowledge and biological resources are not two different subject matters and so need not be treated differently. Traditional knowledge associated with biological resources is an intangible component of the resource itself. Traditional knowledge and biological resources i.e. medicinal plants have a unifying subject rather than two distinct categories. It also may be that traditional knowledge has many categories deserving legal protection and 'medicinal products' is one such category.

The main object of the law is to protect the medicinal plants or all biological resources over which there exists traditional knowledge of the medicinal, aromatic and agricultural values. If this is the object of the law, the nomenclature of the bill is overlapping and not specific.

B. Traditional knowledge enjoys dual ownership, one by the specific community and the other by the nation. This is the basic premise of the present research work. The distinction is important to understand. Some traditional knowledge of medicinal plants are identified with some indigenous communities where the members of those communities know the knowledge and apply it for their purposes and pass down the knowledge from one generation to the next or a few persons in these communities possess the knowledge and pass down to a few others of the next generation. There is also a TK which belongs and is of the whole society, either documented or non-documented. For example, haldi, neem etc. Hence these are to be considered as the intellectual property of India and Indians. These distinctions are narrow and negatively worded in this bill and not properly recognised. Such recognition is important for enforcement of the right on one hand and benefit sharing on the other.

C. Though the Bill makes provision for both civil and criminal liability, it does not deal with the refund of the profits. Mere compensation or stopping of grant of licence are insufficient if a person or company does not refund the profits arising out of wrongful use of TK.

D. Present national and international legal frameworks of intellectual property rights protect only new and novel knowledge. There is no protection of the existing knowledge so far. In the name of public domain, existing knowledge is researched, experimented and utilised to build and derive something new or novel. When something new or novel is found out of existing knowledge, this non-original invention gets IPR protection and very strangely holders of the existing traditional or individual knowledge do not get anything. This is exploitation in nature. The bill does not address these concerns adequately. This bill, if becomes an Act, does not have retrospective effect. Moreover, there is small and large-scale legal and illegal business in India for selling of medicinal plants, raw materials and the end products. As this manufacturing and selling business is the use of intellectual property right, there is no such royalty given to the holders of the knowledge. This present bill is silent on this. Moreover, there is a tendency to appropriate the medicinal plants associated with TK and using the resources in the name of individuals and groups of individuals as if they are new inventions by them for obtaining patents. This how the knowledge in the public domain becomes individual property. The present bill is silent regarding this. Hence the protection contemplated under the Bill is not adequate or comprehensive.

E. The concept of protection is manifold. It includes creating rights, preventing misuse, regulation, management, conservation, augmentation of the resources, sustainable use, commercialisation etc. From this perspective, protection of traditional knowledge of biological resources is limited in this Bill and is positive only to a

certain extent. In this Bill, though there are provisions for the commercialisation of traditional knowledge related biological resources, it is to be done by the others. There is no such advice to establish government company-autonomous and professionally managed, to commercialise the vast potentiality of the traditional knowledge related biological resources i.e. medicinal plants, on its own, without depending others, either by producing medicines independently or making an offer to start a joint venture with others. This would benefit the national economy either by creating new jobs and earning foreign currency and generating income from within the country itself. There is no advice to establish research institutes exclusively dedicated for the invention of new, novel or innovative products and processes out of the existing knowledge. It can do on its own or can finance the research activities or can initiate to enter into agreement with other research institutes and individuals to pursue research activities and as such this Bill does not create a holistic positive intellectual property right on traditional knowledge.

E. Inter-relationship between this proposed law and national and international patent laws is not clear.

F. There are various ways to commercialise the bio-medicine related traditional knowledge. This is most important to create job opportunities. Additionally, it can be a good source to earn foreign exchange. It also can be done by setting up hospitals under the management and control of Traditional Knowledge Authority in India and abroad. This novel approach has not been explored in this Bill.

The concern for umbrella protection traditional knowledge is not adequately reflected in the preamble or statement of the reasons.

PART II

TRADITIONAL KNOWLEDGE (PROTECTION AND MANAGEMENT) BILL 2010²-SOME REFLECTIONS

PRELIMINARY

It is to provide for protection, conservation and effective management of traditional knowledge and related matters.

PREAMBLE

Preamble sets the tone and tune of the entire of legal framework. In this preamble, recognising India as rich in traditional knowledge which is also an important part of India's living heritage, it is admitted that the forms of traditional knowledge have the potentiality of wealth creation for these communities and the nation. So the traditional

² Available at http://www.brainleague.com/files/NLSIU_TK_Bill_Draft.pdf. Visited on 11th June, 2011 at 2.35 PM.

knowledge needs to be conserved, protected and promoted for the cultural enjoyment and commercial gain for the knowledge holders. It is also emphasised that for the protection of traditional knowledge and the rights of the traditional communities to practice, use, share and sell the products of the use of traditional knowledge as per their customary practice. It is also accepted that there exists a need to protect the integrity and sentiments of the communities against distortions and disrespectful representations of traditional knowledge and to prevent improper commercial exploitation of traditional knowledge. It is in a way prejudicial to the interests of the nation and the communities. Moreover, it is also recognised that there is need to ensure that traditional knowledge is accessed only with the consent of the traditional communities and to regulate third parties wishes to research, access or utilisation of TK.

DEFINITION OF TRADITIONAL KNOWLEDGE

TK means the collective knowledge of a traditional community of a family related to a particular subject or a skill passed down from generation to generation and includes (a) medicinal products and processes developed from indigenous or traditional material, custom and knowledge by traditional communities; (b) all other products or processes not made by person which was discovered through a community process or when the person making the innovation does not claim the knowledge as his own or when the person has discovered it to be used openly for common purposes; (c) discoveries, innovations and technologies made by communities that are usually not recorded in written form and are transmitted orally from generation to generation.

RIGHTS AND DUTIES OF TRADITIONAL COMMUNITIES

Here it is found that not only rights are recognised. Together with rights, duties are also enforced. These are: (a) every member of a traditional community shall have right to practice their own traditional knowledge; (b) every member of a traditional community shall have right to use, modify and derive benefits from their own traditional knowledge for their livelihood, provided the use modified or carried out in a sustainable manners; (c) collective traditional knowledge forming part of cultural heritage of traditional community shall be inalienable; (d) where the traditional community as a whole or a member of a traditional community has provided an informed consent to an Accessor and/or entered into a Licence to use agreement with the Accessor, the traditional community or a member thereof has duty to inform the TKA along with the details of the agreement; (e) every member of the community shall ensure the continuum of the practice of TK and the conservation of associated resources from undue exploitation and its possible extinction.

ESTABLISHMENT OF TRADITIONAL KNOWLEDGE AUTHORITY

The important functions of TKA are: (a) to prepare a national policy, strategy and action plan for ensuring the protection, continuum of use and practice of traditional

knowledge and to ensure the sustainability of the resources including the human resources on which the TK is dependent, prevent biopiracy and other misuse of traditional knowledge and take preventive and/or punitive action if required (b) to ensure that any access to traditional knowledge is brought under the purview of the Authority and is fair by way of non-exclusive informed consent of the traditional communities; (c) to ensure through required instruments and proceedings that no Traditional Knowledge in the country is the subject to any IPR application; (d) to provide the informed consent or prior informed consent as the case may be, to the Accessor, in case where a traditional community is not identifiable; (e) to help and facilitate the traditional communities to negotiate the terms and conditions of benefit sharing upon access to use the traditional knowledge; (f) to set up a watch cell to monitor the applications and/or use of traditional knowledge, both in the country or any part of the world, and to take appropriate corrective action if there is a violation of any provision under this Act, including taking measure on behalf of the Central Government for the opposition/revocation of grant of IPR on traditional knowledge in any part of the world; (g) to administer the traditional knowledge fund for protection of traditional communities and ensuring the continuum and sustainable use of traditional knowledge by traditional communities etc.

REGULATION OF ACCESS TO TRADITIONAL KNOWLEDGE AND INFORMED CONSENT

In this chapter, there are two separate systems and procedures for the regulation of access i.e. acquisition of information pertaining to traditional knowledge for commercial gain or purposes of scientific research, technological development or biological prospection with a view to commercial gain, to traditional knowledge. The first one is for the traditional knowledge owned by traditional community and another is for the traditional knowledge which is not owned by any traditional community or communities and which is in the public domain. These systems include 'informed consent', 'prior informed consent', 'consultation process,' 'negotiation process', 'assessment on sustainability of the resources-social and environmental', 'potential value of traditional knowledge', 'terms and conditions of access to traditional knowledge', 'benefit sharing formula' and 'license for use' etc. Here there is provision to oppose the move for giving access to and revocation of the grant. About the sharing of benefits, it says that sharing of all benefits arising out of the access to traditional knowledge and/or its consequential commercial use shall be as negotiated between the traditional community and the applicant and facilitated by STKB through TKMC and all benefit shares shall directly be paid to the traditional community. In case of benefits that arise from an agreement between Traditional Knowledge Authority and the applicant shall accrue to the Traditional Knowledge Fund.

As there is provision for the establishment of TKF, its functions are also decided. The fund shall be used for the protection, conservation and development of traditional knowledge and the traditional communities which includes (a) conservation and sustainability of traditional resources, welfare and livelihood support for traditional communities and traditional practitioners; (b) ecological and cultural restoration

programmes related to traditional knowledge practices; (c) socio-economic and cultural development and promoting the use and practice of common public domain traditional knowledge etc.

In this chapter the functions of TKA has also been assigned. These include (a) to develop national strategies, plans and programmes for the conservation, development and sustainable use of traditional knowledge including measures for identification and monitoring of areas rich in traditional knowledge, incentives in support systems for traditional communities and traditional practitioners and incentives for training and public education to increase awareness about TK; (b) to issue directives to state governments to take immediate measures and offer for assistance where TKA thinks that any area or traditional community rich in traditional knowledge and resources is being threatened by overuse, abuse or neglect; (c) to recommend in appropriate circumstances the integration, conservation, and to sectoral plans, programmes and policies; (d) to undertake measures for assessment of socio-cultural, economic and environmental impact of that project which is likely to impact or has adverse effect on TK and traditional practices with a view to avoiding or minimising such effects etc. and to prevent the risks associated with the use of any technology or process that is likely to impact the conservation and continuum of the use and practice of traditional knowledge. Excluding this, there are also special provision for traditional knowledge and resource which are on the verge of extinction and establishment of Traditional Knowledge Heritage Zones.

DUTIES OF THE GOVERNMENTS

In Chapter 7, there are duties to be performed by the Central and State governments. They are to develop national strategies, plans etc., for conservation etc., of traditional knowledge and resources likely to TKA.

OFFENCES AND PUNISHMENTS

Chapter 8 is about offences, penalties and procedures. Whoever contravenes or attempts to contravene any of the provisions of the Act is offence. Punishment for the offence is of two types either one or both-imprisonment upto five years or fine upto Rs ten lacs and where the damage caused exceeds Rs ten lacs such fine may commensurate with the damage caused. Apart from these there are offences by companies. If the decision or the activity of the company constitutes offence, as a legal person, company is to be accountable and under certain situations also there would be individual liability to face punishment, for those persons who took the decisions.

ANALYSIS OF THE DRAFT BILL

There are many good provisions for the protection of traditional knowledge in this Bill drafted by NLSUI. Take for example, medicinal products related TK, recognition of rights and emphasis of duties of the indigenous communities, establishment of Traditional Knowledge Authority and assigning on it some important functions,

widened concept of protection of TK, regulation of access mandating prior informed consent and benefit sharing scheme, duties of the governments and punishment for contraventions etc. In spite of all these good things in this draft Bill, there are still further scopes of improvement from the perspective of some fundamental premises over which this research work seeks to explore a model law. The NUJS draft Bill and NLSUI draft Bill have same view in some areas and on some other areas have divergent view. The TRADITIONAL KNOWLEDGE (PROTECTION AND MANAGEMENT) BILL 2010 has to theoretically improve in some of the areas. These are (1) admission and recognition of two types of traditional knowledge-traditional community and traditional knowledge of the society in general; (2) apart from negative rights to protect TK associated medicinal plants, perfectly positive traditional knowledge rights-including power to offer proposal to enter into contract within the country and abroad for the purpose of commercialisation in different ways medicinal plants associated TK, rather than relying on others to come forward to do that; (3) power has also to be given to TKA or a professional managed government company (fully autonomous) to start commercialising TK by setting factories or manufacturing units on its own to produce medicines and establishment of research institutes for various purposes; (4) legal protection of existing knowledge of the public domain by making some provisions to deal with non-original inventions; (5) appropriate legal framework for punishment-including refund of profit and moratorium of all future grant of licenses; (6) making the application of the law with extra-territorial operations; (7) its relationship with national and international patent laws; (8) utilisation of TK Fund money not only for the life standard improvement of the traditional communities but also for the life standard improvement of BPL families out of the proceeds of royalties etc., from the commercialisation of traditional knowledge of the society; (9) it also would be a very good idea to start hospitals in India and in foreign countries where this type of medicine and Indian treatment method would be applied under the aegis of TKA.

These concerns for the positive and overall traditional knowledge protection are not adequately reflected in the preamble or statement of the reasons. Even then whatever ii there for these above mentioned reasons the bill cannot fulfil the statement of the objects and not in consonance with its preamble.

PROTECTION OF TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS THROUGH BIODIVERSITY PROTECTION ROUTE IN INDIA-SOME REFLECTIONS

India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th June, 1992. The Convention came into force on 29th December, 1993. In the backdrop of India being exceptionally rich in biological diversity and associated traditional and contemporary knowledge system and reaffirmation of the sovereign rights of the States over their biological resources by the Convention with the main objective of conservation of biological diversity,

sustainable use of its components and fair and equitable sharing of the benefits arising out of utilization of genetic resources. Biological Diversity Act was passed in 2002 to give effect to the objects of CBD i.e., to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and related matters.

ANALYSIS OF BIODIVERSITY ACT OF INDIA REGARDING PROTECTION OF TK

1. There is no definition of traditional knowledge associated with biological diversity or categories of it.
2. In general, as sovereign right over the biological diversity is given to the State, there might be possibility of conflict between State exercising sovereign rights over biological resources and the exercise of ownership right of the traditional knowledge associated biological diversity holders.
3. The TK protection is one component of whole biological diversity protection. It is not a special law wholly for the purpose of TK associated with medicinal plants protection.
4. One provision of the biological diversity regulation says that no person shall apply for any intellectual property right, in any form in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making the application. This poses a serious challenge to the traditional knowledge associated with medicinal plants protection. It means that invention based on any information from the traditional knowledge can get intellectual property protection and NBA also can approve it. As a result, the inventors of non-original invention and non-original innovation can claim intellectual property right. This provision is tacitly legalising biopiracy. Though while granting IP protection NBA can impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights, it is totally a different issue and should not be mixed up with the granting of TK protection to the non-original innovators and non-original inventors.
5. There is no comprehensive positive and negative protection as well.
6. There is no sufficient and appropriate civil and criminal liability for the violation.

FOREIGN LAWS FOR TK PROTECTION

PART I

SALIENT FEATURES OF THE LAWS FOR TRADITIONAL KNOWLEDGE PROTECTION-EXAMPLES OF SOME COUNTRIES

LAW OF THAILAND FOR THE TRADITIONAL KNOWLEDGE PROTECTION--SOME REFLECTIONS³

BASIC OBJECT

There is an expediency to have a law on protection and promotion of traditional Thai medicinal intelligence. Basically this law contains certain provisions that restrict the rights and liberties of the people, which are permissible under section 29, along with section 35, section 48 and section 50 of the Constitution of Thailand.

DEFINITIONS OF SOME KEY CONCEPTS

It is important to understand the nature and scope of the traditional knowledge protection in Thailand's legal framework. The definitions of some of the concepts serve that purpose preliminarily. Here some of the definitions are quoted from the Act with that objective. "**Traditional Thai medicinal Intelligence**" means the basic knowledge and capability concerned with traditional Thai medicine. "**Traditional Thai medicine**" means the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention of, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production of traditional Thai drugs and the invention of medical devices on the basis of knowledge on text that has been passed on generation to generation. "**Text on traditional Thai medicine**" means technical knowledge concerned with traditional Thai medicine which has been written or recorded in Thai books, palm leaf, stone inscription or other materials or that have not been recorded but passed on from generation to generation. "**Thai traditional drugs**" means medicines obtained directly from herbs or derived from mixture, blended or transformed herbs and also includes Thai traditional drugs under laws on drugs. "**Formula on traditional Thai drugs**" means a formula stated as the production process and ingredients which contain Thai traditional drugs, no matter what form the ingredients are. "**Herbs**" means plants, animals, bacteria, minerals, extracts of plants or animals used, or transformed or mixed or blended as drugs or food for diagnosis, therapy, treatment or prevention of diseases, or for promotion of the health of humans or animals. The meaning also includes the origin or the areas in which the products exist.

COMMITTEE ON PROTECTION AND PROMOTION OF TRADITION THAI MEDICINAL INTELLIGENCE

For the stated objects of this Act, it has constituted a committee to take care the all matters of traditional knowledge protection. According to section 6, this committee

³ ACT ON PROTECTION AND PROMOTION OF TRADITIONAL THAI MEDICINAL INTELLIGENCE, H.E. 2542. Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=179713. Visited on 15th June 2011 at 6 PM.

shall have some important power and duties to carry forward its functions. These are (1) to provide consultation or advice to the Minister in issuing the Ministerial Regulations, Rules or Notifications under this Act; (2) to promote and develop the use of intellectual traditional Thai medicine and herbs; (3) outline measures to strengthen stability and coordination between government agencies, state enterprises, communities and non government organisations on issues concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs; (4) to approve the withdrawal of registration on intellectual property rights on traditional Thai medicine; (5) to consider the appeal against the order or decision of the registrar or the licensing authority under this Act; (6) to lay down rules about the standards and procedures on lodging an appeal and consideration of appeal, registration of intellectual property rights on traditional Thai medicine, the administration and arrangement of benefits and expenses of the fund and works concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs etc.

PROTECTION AND PROMOTION OF INTELLIGENCE ON TRADITIONAL THAI

MEDICINE

Section 14 lays down that the intellectual property rights on traditional Thai medicine which is to be protected, shall be the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine. According to section 15, the Institute for Traditional Thai Medicine shall be responsible for compiling information on traditional Thai medical intelligence concerned with formulas of traditional Thai drugs and text on traditional Thai medicine from throughout the country for registration. Section 16 distinguishes traditional Thai medicinal intellectual property rights into three categories: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine; (2) the general formula of traditional Thai drugs or general traditional Thai medicine document; and (3) the personal formula of traditional Thai drugs or personal text on traditional Thai medicine. Section 19 says about the conditions of access to and utilisation of the knowledge for different purposes. It says that that whoever wishes to use the national traditional Thai drugs for registration and permission for production of drugs according to the Drug Law or wishes to use it for research on improvement or development of new drug formulas for commercial benefit or wish to research the national text on traditional Thai Drugs for development and improvement for commercial benefit, shall forward their application to obtain benefits and pay fees and the remuneration for making use thereof to the licensing authority as per rules. Section 20 is on the personal formula of traditional Thai drugs or personal text on traditional Thai medicine under section 16(3), which may be registered for protection of intellectual property rights and may be promoted according to the provisions of this Act by applying for registration to the registrar. Section 21 deals with the persons who have this kind of special right u/s 20. According to it, these persons must be of Thai

nationality and either (1) being an inventor of the formula on traditional Thai drugs or text on traditional Thai medicine; (2) being an improver of the developer of formula on traditional Thai drugs or text on traditional Thai medicine; or (1) being an inheritor of the formula on traditional Thai drugs or text on traditional Thai medicine. Section 22 puts some restrictions on the registration process. The registration for protection of intellectual property rights on traditional Thai medicine is prohibited if the registrar is of the opinion that: (1) the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine, or is a general formula on traditional Thai drug, or general text on traditional Thai medicine, or (2) the drug formula is a personal formula on traditional Thai drug that has been developed on non medical basis like the use of extracts of plants, animals or micro organisms that have not been obtained from natural extracts or the transformation that is not considered rough transformation. Next point is the duration of the right for commercialisation of the knowledge. Section 33 allows the right to intellectual property on traditional Thai medicine should be valid for a life time of the bearer of the registration and extend for another 50 years from time the owner of the registration has deceased and in joint ownership of the registration right, the intellectual property rights on traditional Thai medicine shall be valid for a life time of the bearer and extended for another 50 years from the date on which the last joint owner of the registration deceased. Section 34 gives some exclusive right to the right holder. He has the sole ownership on the production of the drug and has sole right over the research, distribution, improvement or development of formulas on traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine. But any act that is of benefit for studies, findings, tests or research according to the regulation specified by the Minister; or preparation of specific drugs according to prescription of holders of registration certificate on traditional Thai medicine, production of drugs for household use or production of drugs by state hospitals or government or state agencies, for use in state hospitals, or the use of text on traditional Thai medicine for benefits in treatment of patients in state hospitals as per rules are excluded. The right holder may also allow others to use his right over the knowledge. In this law there is provision of revocation of right under some specific grounds. Section gives power to the registrar has the right to revoke the registration of intellectual property rights on traditional Thai medicine when (1) the right holder misuses the right against the public order and good morals; (2) the right holder violates or does not comply with the conditions or limitations outlined by the registrar in registration of the intellectual property rights on that traditional Thai medicine; or (3) the right holder exercised the right that may cause severe damage to the registered intellectual property on traditional Thai medicine.

SPECIAL MEASURES FOR PROTECTION OF HERBS

Section 44 states that for the purpose of herbs protection and conservation, the Minister with the advice of the Committee, shall have the power to issue a notification to specify the kind, characteristic, type, and names of herbs that are of study and

research value, or have important economic significance or may become extinct, as controlled herbs. As a follow up action of the above mentioned purposes, according to section 45, the Minister shall with the advice of the Committee can issue notification by (1) specifying the amount or quantity of controlled herbs under possession to make use of, under care, under conservation or under transportation which needs to be informed the registrar; (2) specifying rules, procedure and conditions in informing under (1); (3) specifying rules, procedure and conditions on the possession, to make use of, under care, under conservation or for transportation of controlled herbs; (4) specifying rules, procedure and conditions on studying and researching the controlled herbs; (5) specifying rules, procedure and conditions on exporting controlled herbs for commercial and non-commercial purposes, or distribution or transformation of controlled herbs for commercial purposes; (6) specifying other requirements to conserve, prevent or prohibit or reduce dangers or damage may be caused to controlled herbs. In furtherance of these broad measures for the protection and conservation of controlled herbs, some specific activities are fixed up in the subsequent sections.

FUND ON THAI TRADITIONAL MEDICINE INTELLIGENCE

There is a fund as is authorised by section 76. It is the "Fund on Traditional Thai Medicine Intelligence". It is to be set up in the office of the Permanent Secretary, Ministry of Public Health, as a revolving fund for expenses concerned with works on conservation and promotion of intelligence on traditional Thai medicine. The fund is to be created from (1) subsidy from the state; (2) money or property received from the private sector from within and outside the country, foreign governments or international organizations; (3) interests and benefits obtained from the fund. (4) other earnings obtained from the functioning of the fund. The earnings of the fund must be remitted to the Finance Ministry under the law on the treasury balance and the law on the budgetary procedures. The administration, management of benefits and use of money in the fund shall be in accordance with the rules prescribed by the Committee, with the approval of the Finance Ministry.

PENALTIES FOR VIOLATIONS

There are two types of punishment for different kinds of violations. Sections 78 to 82 deal with those violations and punishments-fine and/or imprisonment. Amount of fine starts from 2000 baht to 40,000 baht and imprisonment is from one month to two years.

PART II

LAW OF THE KYRGYZTAN FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE -SOME REFLECTIONS⁴

BASIC OBJECT

Traditional knowledge using genetic resources is an historical heritage and property of the people of this country. The legal framework secures general provisions of the State policy and legal, economic and social guarantees in the field of Traditional Knowledge using genetic resources. The aim is sustainable development of the country and arrangement of conditions for fair distribution of benefits arising from the use of Traditional Knowledge.

DEFINITION OF TK AND ITS HOLDERS

What is to be protected within the ambit of TK lies on the definition clauses. This is the significance of this. Article 2 is about the General Concepts in which TK is defined. **Traditional knowledge** shall mean knowledge, methods and manners, including use of genetic resources, used in different fields of the human activities, which have been transferred from one generation to another eventually in certain order and meaning. This knowledge have been kept and adapted for different needs of the local communities and the owners of traditional knowledge and represent particular value for the development of various fields of activities. About the question of who are the holders of TK-it is said that Traditional knowledge holders shall mean the local communities, natural persons and legal entities with any legal structure and with any pattern of ownership who are the possessors of Traditional Knowledge.

STATE REGULATION OF TRADITIONAL KNOWLEDGE

In this part Article 3 clarifies the objectives and tasks of the regulation, which is to be initiated by the state. These are legal protection, promotion of reservation and wide use of Traditional Knowledge in different fields of human activities, assistance in use of Traditional Knowledge, including knowledge based on genetic resources in industrial production, as well as further commercialization of objects produced as a result of their use. The State regulation in the field of Traditional Knowledge include (1) Creation of the preventive mechanism aimed at protection of Traditional Knowledge from illegal patenting of subject-matters created on the bases of Traditional Knowledge and use of associated genetic resources by the inclusion the Traditional Knowledge into database; (2) Fair distribution of benefits received due to usage of Traditional Knowledge in favour of local communities; (3) Establishment of

⁴ Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=179127. Visited 15th June 2011 at 6.15 PM.

the fund for development of local communities, which can be supported by financial transfers collected during the usage of Traditional Knowledge and genetic resources; (4) Establishment of the State fund for development of the system of usage of Traditional Knowledge; (5) conducting scientific researches on Traditional Knowledge and existing genetic resources as to their practical use, inter alia: reveal the priority trends in researches in the field of Traditional Knowledge using genetic resources, which may contribute significantly to the preservation of environment; development and improvement of new types of genetic resources utilization; making scientific studies in order to create the inventory on Traditional Knowledge in this country; reveal of well-known and widely used Traditional Knowledge. Article 4 is there to establish Authorised State Body. The state policy in the field of Traditional Knowledge shall be performed by it in the field of IP.

SUBJECT MATTERS CREATED ON THE BASE OF TK

Article 8 puts restrictions on patenting of subject-matters, which are representing Traditional Knowledge in this country. When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. Holder of a certificate, which name is indicated in the registered Traditional Knowledge shall be entitled to receive remuneration from the owner of a patent for invention created by use of Traditional Knowledge. The order of payment of remuneration for use of Traditional Knowledge with the purpose of creation of invention shall be determined by an agreement between the owner of certificate for Traditional Knowledge and the owner of a patent for invention. At the same time such agreement must specify assignments to be made for use of Traditional Knowledge to the Fund for development of local communities or the State fund for development of the system of Traditional Knowledge usage. In order to prevent illegal patenting of subject-matters created on the base of Traditional Knowledge the Traditional Knowledge database shall be maintained, which shall be used during examination of subject-matters to be patented.

AGREEMENT FOR TRADITIONAL KNOWLEDGE UTILISATION

Article 14 deals with this agreement and related matters. A person who is not the owner of Traditional Knowledge may receive a right to use Traditional Knowledge provided that appropriate agreement is concluded between him and the owner of Traditional Knowledge, who has registered TK in the Authorized Body. According to the agreement the owner of Traditional Knowledge shall grant the right to use TK to other person in the scope of transferred rights, time-limits, territory and order of payments established by this agreement. Conditions of the agreement are subject to the mutual consent of the parties concerned. The agreement must provide a provision of assignments for use of Traditional Knowledge to the Fund for the development of a

local community or the State Fund for development of the system of Traditional Knowledge usage. At the same time assignments for use of Traditional Knowledge provided by the agreement to the Fund for the development of a relevant local community or the State Fund for development of the system of Traditional Knowledge usage shall be not less than 20%.

FUNDS

Fund is another important part of the TK protection. The fixation of amount, collection, deposit and purposes of utilisation of the money etc., are some of the matters. Article 16 says that to reserve Traditional Knowledge and distribute fairly the benefits from use thereof, the owners of Traditional Knowledge shall establish the Fund for development of a local community. In order to develop the Traditional Knowledge system the State Fund for development of Traditional Knowledge usage shall be established under the Authorized Body.

USAGE OF TRADITIONAL KNOWLEDGE

According to Article 17, production, application, import, distribution, offer for sale, sale and other entering to economic turnover shall be deemed as a usage of Traditional Knowledge in subject-matters containing and created on their base. Usage in production with commercial purposes without conclusion of agreements with Traditional Knowledge holders shall be deemed as illegal use of Traditional Knowledge. Usage of Traditional Knowledge shall be allowed without consent of Traditional Knowledge holder if such a usage takes place for educational and research purposes provided that the source is indicated and exclusively for personal purposes. In case of force-majeure (disasters, catastrophes, accidents) as well as in the interest of national security the Government of the Kyrgyz Republic shall be entitled to issue permission to use Traditional Knowledge provided that reasonable compensation is paid to the owner of certificate; scope and duration of use of Traditional Knowledge shall be limited by the purposes for which permitted.

PART III

LAW OF PERU FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE-SOME REFLECTIONS⁵

OBJECTIVES OF THE LEGAL REGIME

The State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit. With this in mind the objectives of the legal framework is visualised. Article 5 is to set the sole objectives of the legal framework, which are: (a) to promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples; (b) to promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge; (c) to promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general; (d) to ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples; (e) to promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime; (f) to avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

Article 2 is to define some of the basic terms. From this, it is ample clear as to who are entitled the protection. As there are definitions of 'indigenous people' and 'collective knowledge', it is inferred that this group of people can have protection from their collective knowledge. The protective knowledge shall be that which belongs to an indigenous people and not to particular individuals. "**Indigenous peoples**" means aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. These include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. The term "indigenous" shall encompass, and may be used as a synonym of, "aboriginal," "traditional," "ethnic," "ancestral," "native" etc. "**Collective knowledge**" means the accumulated, trans-generational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity i.e biological resources.

⁵ LAW INTRODUCING A PROTECTION REGIME FOR THE COLLECTIVE KNOWLEDGE OF INDIGENOUS PEOPLES DERIVED FROM BIOLOGICAL RESOURCES-LAW NO 27811. Available at

http://www.wipo.int/wipolex/en/text.jsp?file_id=203365. Visited on 15th June 2011 at 6.30 PM.

GENERAL PRINCIPLES OF THE LEGAL FRAMEWORK

Article 6 says about the conditions of access to collective knowledge. It directs that who are interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge. Then the organization shall inform the greatest possible number of indigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs. Article 7 prescribes the method of access for the purposes of commercial or industrial application. In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving there from is guaranteed. Article 8 fixes up the percentage accruing to the Fund for the Development of Indigenous peoples. A percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples. Though the parties may agree on a greater percentage according to the degree of direct use or incorporation of the said knowledge in the resulting end product and the degree to which said knowledge contributed to the reduction of the cost of research and development work on derived products, among other things. Article 9 imposes some duties on the present generations. The role of the present generations of the indigenous peoples shall preserve, develop and administer their collective knowledge for the benefit of future generations as well as for their own benefit. Article 13 gives something new on the protection of existing traditional knowledge which is in the public domain. As per this arrangement, the collective knowledge which is in the public domain when it has been made accessible to persons other than the indigenous peoples by mass communication media such as publication or, when the properties, uses or characteristics of a biological resource are concerned, where it has become extensively known outside the confines of the indigenous peoples and communities. In cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples.

TRANSFER OF PROPERTY THROUGH LICENSING

Article 25 prescribes compulsory registration of license contracts between the traditional peoples holding the common knowledge and the manufacturers or producers. Article 27 suggests the required contents of the license contracts. The license contracts shall contain (a) Identification of the parties; (b) A description of the

collective knowledge to which the contract relates; (c) A statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be; (d) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge and its value where applicable; (e) The obligation on the licensee to inform the licensor periodically, in general terms, of progress in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the license relates; (f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources.

FUND FOR THE DEVELOPMENT OF INDIGENOUS PEOPLES

Article 37 explains the purpose of the Fund for the Development of Indigenous Peoples. The Fund for the Development of Indigenous Peoples and Communities is hereby created for the purpose of contributing to the comprehensive development of indigenous peoples through the financing of projects and other activities. Article 41 authorises the resources of the Fund for the Development of Indigenous Peoples to get from the State budget, international technical cooperation, donations, the percentage of economic benefits.

PROTECTION CONFERRED BY LAW

Rights of indigenous peoples possessing collective knowledge are recognised in Article 42. The right is such that Indigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain.

SANCTIONS

Article 62 deals with the Sanctions. Violations of the rights of indigenous peoples shall give rise to the imposition of a fine, without prejudice to such measures as may be ordered to cause the infringing acts to cease or to prevent them from being committed. The fines that may be imposed shall be up to 150 tax units. The imposition and gradation of fines shall be determined according to the economic benefit secured by the infringer, the economic prejudice caused the indigenous peoples and communities and the conduct of the infringer throughout the proceedings. Recidivism shall be considered an aggravating circumstance, and the sanction applicable shall therefore not be less severe than the previous one. Where the defendant fails to comply within a period of three days with the terms of the ruling

that concludes a proceeding, he shall be subjected to a sanction not exceeding the maximum of the fine allowed. Where the defendant persists in failing to comply, the fine imposed may be successively doubled without limitation. It is without prejudice to the possibility of being reported to the Public Prosecutor with a view to the initiation of the appropriate criminal proceedings against him.

INDIGENOUS KNOWLEDGE PROTECTION BOARD

Article 65 constitutes Indigenous Knowledge Protection Board. Article 66 determines the functions of the Indigenous Knowledge Protection Board which are: (a) to monitor and oversee the implementation of this protection regime; (b) to support the Administrative Committee of the Fund for the Development of Indigenous Peoples and the Office of Inventions and New Technology of INDECOPI in the performance of their functions; (c) to give its opinion on the validity of contracts for the licensing of the collective knowledge of indigenous peoples; (d) to give advice and assistance to the representatives of indigenous peoples who so request regarding matters connected with this regime, and in particular in the planning and implementation of projects within the framework thereof; (e) To supervise the Administrative Committee of the Fund for the Development of Indigenous Peoples in the exercise of its functions etc.

PART IV

BRAZILIAN LAW FOR TRADITIONAL KNOWLEDGE PROTECTION- SOME GENERAL REFLECTIONS⁶

GENERAL PROVISIONS

The first part is about general provisions. Article 1 says about the subject matters or assets (the rights and obligations are set forth later on). These are (a) the access to components of genetic heritage existing within the Brazilian territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or bio-prospecting; (b) Access to traditional knowledge associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the use of its components; (c) the fair and equitable sharing of the benefits arising from the use of genetic heritage component and the associated traditional knowledge; etc. (d) access to technology and transfer of technology for the conservation and use of biological diversity. It directs that Access to components of genetic heritage for the purpose of scientific research, technological development or bio-prospecting shall be carried out under the terms of this Act, without prejudice to material or intangible property rights that are incident upon the accessed genetic heritage components or upon the site of occurrence. Article 2 states that access to genetic heritage existing in the country shall only be take place with an authorization from the government and its use,

⁵ PROVISIONAL ACT NO. 2,186-16, DATED AUGUST 23, 2001.

commercialization and employment for any purpose shall be submitted to inspection, restrictions and sharing of benefits in the terms and conditions established in this Act and its complementary legislation. Article 4 declares that the exchange and dissemination of components of genetic heritage and of associated traditional knowledge practiced within indigenous communities and local communities for their own benefit and based on customary practices is preserved.

DEFINITIONS OF KEY CONCEPTS

Article 7 is the definition clause. From this part, it becomes clear what is to be protected and what is not. It also becomes clear who are entitled for protection. The term genetic heritage, associated traditional knowledge and local community are defined. Genetic heritage is the information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated, or kept in *ex situ* collections, if collected from *in situ* conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone. Associated traditional knowledge is individual or collective information or practice of the indigenous community or local community, with real or potential value, associated to genetic heritage. Local community means human group, including descendants of *Quilombo* communities, differentiated by its cultural conditions, which is, traditionally, organized along successive generations and with its own customs, and preserves its social and economic institutions.

PROTECTION TO ASSOCIATED TRADITIONAL KNOWLEDGE

The traditional knowledge of the indigenous communities and of the local communities, associated to genetic heritage, from illicit use and exploitation and other harmful actions or those actions not authorized by the Management Council, or by an accredited institution by Article 8. The State recognizes the right of the indigenous communities and of the local communities to decide on the use of their traditional knowledge related to the genetic heritage of the country, in the terms of this Act and its complementary legislation. Article 9 assures some of the rights. Accordingly, the indigenous communities and local communities that create, develop, hold or conserve traditional knowledge associated to genetic heritage are assured the right to: (I) have acknowledged the origin of the access to the traditional knowledge in all publications, uses, exploitations and dissemination; (II) prevent non-authorized third-parties for: (a) Use, test, research or exploit of associated traditional knowledge and (b) Disseminate, transmit or forward data or information that constitute associated traditional knowledge, or part thereof; (III) receive benefits from the economic use by third parties, directly or indirectly, of associated traditional knowledge to which they hold rights, in accordance with this Act.

INSTITUTIONAL MANDATE AND COMPETENCE

There is Article 10 to establish The Genetic Heritage Management Council under the Ministry of Environment, a regulatory body. Its responsibility is determined by Article 11. These are: (I) Coordinating implementation of genetic heritage management policies; (II) Establishing: (a) Technical standards; (b) Criteria for access and shipment authorizations; (c) Guidelines for drafting the Contract for Use of Genetic Heritage and Benefit-Sharing; (d) Criteria for creation of a database for recording information on associated traditional knowledge; (III) -Overseeing, in coordination with other federal bodies, or by means of an agreement with other institutions, the activities of access and shipment of samples of genetic heritage components and access to associated traditional knowledge; (IV) - Deliberating on: (a) Authorizations for access and shipment of samples of genetic heritage components, with prior consent of its holder; (b) Authorizations for access to associated traditional knowledge, with the prior consent of its holder; (c) Special authorizations for access and shipment of samples of genetic heritage components to the Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to the Brazilian university. (d) Special authorization for access to associated traditional knowledge to a Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to a Brazilian university. (V) Approving Contracts for Use of Genetic Heritage and Benefit-Sharing with regard to their complying with the requirements of this Provisional Act and its complementary legislation.

BENEFIT-SHARING FORMULA

Another important part of this Act is that it ensures of benefit-sharing. Article 24 states that the benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign-based institution, shall be shared in a fair and equitable manner among the contracting parties, as per rules. The benefits arising from the economic use of the product or process developed from a sample of a genetic heritage component or from associated traditional knowledge, may be (I) Sharing of profits; (II) Payment of royalties; (III) Access and transfer of technologies; (IV) licensing, without cost, of products and processes; and (V) Capacity building of human resources as per Article 25.

PUNISHMENTS AND ADMINISTRATIVE SANCTIONS

Article 30 is for this purpose to define violation and prescribes punishments. An administrative violation against the genetic heritage or the associated traditional knowledge is considered to be every act or omission that violates the rules in the Act relevant legal provisions. These are: I-Warning; II Fine; III-Seizure of samples of the genetic heritage components and the instruments used in the collection or processing

or the products obtained as a result of information on associated traditional knowledge; IV-Seizure of all products derived from a sample of a genetic heritage component or of associated traditional knowledge; V-Suspension of the sale of the product derived from the sample of the genetic heritage component or of the associated traditional knowledge and its seizure; VI-Embargo of the activity; VII-Partial or total closure of the business, activity or undertaking; VIII-Suspension of the register, patent, license or authorization; IX-Cancelling of the register, patent, license or authorization; X-Loss or reduction of fiscal incentives and benefits granted by the government; XI-Loss or suspension of the right to receive financing from an official financing agency; XII-Intervention in the establishment; XIII-Prohibition of entering into contracts with the Public Administration for a period of up to five years.

Moreover Article 26 has prescribed some economic punishments. It authorises that if the economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained from commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of the technology, whether or not they are protected by intellectual property, without prejudice to administrative sanctions and the appropriate penalties.

PART V

LAW OF BHUTAN TO PROTECT TRADITIONAL KNOWLEDGE-SOME REFLECTIONS⁷

PREAMBLE

Taking note on the sovereignty of the States over their genetic resources and the need to promote the conservation and sustainable use of these resources as well as the fair and equitable sharing of benefits arising from its utilization according to CBD and recalling decisions about promoting and encouraging the Parties to implement legal, administrative and policy measures to regulate access to genetic resources and benefit sharing it realises the value of biological and genetic resources in the development of products compounds and substances that have medicinal, industrial and agricultural and related applications and its necessity to protect and encourage cultural diversity giving due value to the knowledge, innovations and practices of local communities in Bhutan.

It is fully aware of the fundamental principle that prior informed consent and mutually agreed terms for benefit sharing shall be secured before access can take place.

⁷ The Biodiversity Act of Bhutan, 2003.

DEFINITIONS

Access: means obtaining, collecting, utilizing and/or exporting genetic or biochemical resources covered by this Act for purposes of conservation, research, bio-prospecting or commercial use.

Biochemical Resources: means any material derived from plants, fungi, animals or micro-organism, which contains specific characteristics and special molecules.

Bioprospecting: means the systematic search, classification and research of new sources of chemical compounds, genes, proteins and microorganism for commercial purposes with real or potential economic value, which are found in biodiversity.

Genetic resources: means any material derived from plants, animals, fungi or microorganisms which contains functional unit of heredity..

Traditional Knowledge: means the knowledge, innovation and practices of local communities relating to the use, properties, values and processes of any biological and genetic resources or any part thereof.

PURPOSES AND OBJECTIVES, SCOPES AND EXCEPTIONS⁸

PURPOSES AND OBJECTIVES

a. To ensure national sovereignty of the government over genetic resources in accordance with relevant National and International Law. b. To ensure the conservation and sustainable use of the biochemical and genetic resources. c. To promote the equitable sharing of benefits derived from the use of genetic resources. d. To promote technology transfer and capacity building at the national and local levels, including the building of scientific and technological capacity relevant to the conservation and sustainable use of biological diversity. e. To recognize and protect Traditional Knowledge, innovation and practices of local communities associated with biodiversity. g. To prevent illegal access to genetic and biochemical resources and associated Traditional Knowledge.

SCOPE

A. The provision of this Act shall apply to the Traditional Knowledge, innovation and practices associated with biodiversity. **B.** The Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions: (i) is or has been transmitted from generation to generation. ii) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan. (iii) is collectively originated and held.

⁸ Ibid, Chapter 1.

EXEMPTIONS

A. Where the biological material is used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority, based on the processes and end use of genetic resources, in accordance with the provisions of the Act. **B.** To access, use and exchange of biological and genetic resources among local communities resulting from their traditional and customary practices.

ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING: CONDITIONS OF ACCESS⁹

Conditions of access to biodiversity shall be subject to the prior informed consent of the Competent Authority of Bhutan, representing national interests and the interests of the local communities harbouring, cultivating, developing and maintaining the biological diversity concerned. **But in case of conditions of access to Traditional Knowledge, innovation and practices of local communities, the procedure and conditions set out in Chapter 4 shall apply.**

PROTECTION OF TRADITIONAL KNOWLEDGE¹⁰

Part I: CONDITIONS FOR PROTECTION

Applicability. It applies to Traditional Knowledge that was in existence before the commencement of this Act or is created on or after the commencement of this Act for both.

Customary uses. The customary use of Traditional Knowledge among the local communities does not give rise to any criminal or civil action for liability under this Act.

Rights owners. The owners of Traditional Knowledge are the holders of the rights in the Traditional Knowledge.

Material form not required. The rights exist in Traditional Knowledge whether or not the Traditional Knowledge is in material form.

Duration. Rights conferred by this Chapter continue in force in perpetuity and are inalienable.

Additional rights. The Rights in Traditional Knowledge are in addition to and do not affect, any rights that may subsist under any intellectual property laws.

Part II: PROCEDURES

Application

The applicant shall obtain the prior informed consent of the traditional owners of the Traditional Knowledge for use of Traditional Knowledge for a non-customary use.

⁹ Ibid, Chapter 2.

¹⁰ Ibid, Chapter 4.

Appraisal of application

The owners of the Traditional Knowledge must decide whether: a. To reject the application. b. To accept the application and enter into negotiations for a written authorized user agreement in relation with the application containing the appropriate benefit sharing arrangements.

Proposed agreement

Before entering into an authorized user agreement the owners of the Traditional Knowledge must submit the proposed agreement for comments to the Competent Authority for final approval.

User agreement and prior informed consent

If the applicant and the traditional owners enter into an authorized agreement, the owners of the Traditional Knowledge are deemed to have given their prior informed consent to the proposed use. A final copy of the agreement must be forwarded to the Competent Authority.

Advice of Competent Authority

The Authority, upon request, may provide advice to the owners of the Traditional Knowledge during the negotiations of the user agreement or during the processing of the access application.

Inventory of Traditional Knowledge

The Authorized Agency in collaboration with the owners of the Traditional Knowledge will carry out an inventory and documentation of Traditional Knowledge.

OFFENCES AND PENALTIES¹¹

Among other offences these two are directly related to TK: Non-compliance with the traditional knowledge rights as provided in Chapter 4 and Failure to comply with any other provisions of this Act or Regulations.

Civil Liability: For that reason there is civil liability. Any violation of material terms and agreement of this Act is a breach of contract.

Penalties: Punishment for the failure to comply with or contravenes with Chapter 4 of the Act, is imprisonment for a term of one year to three years or with fine. The amount of fine is equivalent to minimum daily wage rate of two years to six years according to wage rate rules. There is a provision for confiscation of such genetic resources collected in contravention of the provisions of this Act and imposition of liability to pay damages.

Revocation of access permit

Access permits may be withdrawn if the permit was obtained by providing false or misleading information under Section 8 and for reasons of public interest, including the protection of the environment and biological diversity.

¹¹ Ibid, Chapter 5.

CONCLUSION

There are some common concerns of India and these countries for traditional knowledge protection, as day by day, their traditional knowledge is being taken away by foreign countries and companies. It is good that at least these countries have enacted special laws for traditional knowledge protection. Yet there are some drawbacks and the laws vary from each other on various aspects. This is due to the reason that either laws are the reflections of particular situations and special needs of those countries, a country's traditional knowledge may have some unique features different from others or the laws are in furtherance of the national policies of these countries, which were adopted after due consideration. Vision of the political establishments might be different from each other along with the standard and availability of legal expertise, hence is reflected in these laws. Aiming at the traditional knowledge protection, these countries thought it right to set various types of objectives to achieve that goal and conditioned their national laws also accordingly. These diverse aims and objects get reflected in their legal provisions. These laws have some persuasive values to persuade India to have a law on TK and shape its law. Some good provisions can be incorporated into the Indian legal framework.

It is hoped that all TK enriched countries would be joining with this group. Its presence would be felt in the international forum; its voice would be stronger enough that cannot be ignored by the developed countries. They can work as enblock and would be able to exert pressure on the world body to just strike down the biased laws. India does not feel any necessity to have such a law. In this context, at present there is no comprehensive positive law especially for traditional knowledge protection, preservation and its utilisation. Biological Diversity Act offers a very limited protection. Hence, it is suggested that India must have a sui generis effective law to safeguard and utilisation of its vast traditional knowledge. To make a model law for India, new, innovative, radical and comprehensive thinking are necessary.

There is a necessity to have a uniform standard with some flexibility to suit the special needs of a particular country. This is because though TK per se has some common characteristics, face same types of challenges but each country has its own socio-cultural and economic environments which are different from others. Apart from those common grounds which have to be uniform in nature in all the national laws of each and every country, laws must be uniform. But in other matters there can be diversity. There must have some flexibility and relaxation to adjust and adapt with the particular social, scientific, economical and cultural environments of India.