CHAPTER 8
CONCLUSION

8.1. GRAY AREAS

The desire to protect traditional knowledge has generated a significant body of literature in different international fora. Various international instruments attempt to define traditional knowledge. However, all these definitions are illustrative or inclusive in nature since the global community, till date, has not agreed for a universally accepted exclusive definition. Although, through these conventions, there are some efforts to recognize indigenous communities’ right over their traditional knowledge, the real scope and extent of the rights are not settled so far.

Several proposals have been made, within and outside the IPR system, to protect traditional knowledge or indigenous knowledge. Such proposals often fail to set out clearly the rationale for its protection. The development of any regime for the protection of traditional knowledge should be grounded on a sound definition of the objectives sought and on the appropriateness of the instrument selected to achieve them. IPR may be one of the tools to be used, but their limits and implications should be clearly understood.

No clear formula has been reached to date as to the strategies that should be devised to protect various forms of TK. There are manifold complex issues that are impeding the legal recognition, protection and enforcement of rights attached to traditional knowledge.

8.1.1. Definitional Problem
Traditional knowledge lacks a globally agreed definition. Various instruments define the term differently. Given the highly diverse and dynamic nature of TK it may not be feasible to develop a singular and exclusive definition for ‘traditional knowledge’. The main issues that have hindered consensus on definitional aspects of traditional knowledge are:

8.1.1.1. Subject Matter

Assuming that the right should be something akin to intellectual property rights, there is no international consensus on what should be the subject matter of the right. The subject matter of traditional knowledge is particularly dynamic and variable and shaped by local and cultural factors than other forms of IP. Hence, there needs to be a systematic attempt to clarify the information categories that could be called traditional knowledge.

The clarity as to the subject matter of traditional knowledge is the first thing to be resolved.

8.1.1.2. Identification of Beneficiaries

Another issue is that of identification of beneficiaries of the right. There is no clarity as to, to whom the rights should be conferred or who will be entitled for TK protection. As mentioned earlier, identification of holders of TK is a difficult task. As the rights over the resources and knowledge are held collectively, there is seldom a single beneficiary. Hence, after defining the subject matter of TK, the countries have to attempt to identify the holders. Since the holders are generally belonging to economically and educationally backward areas, the original holders of TK may not volunteer to come forward and seek protection. This

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544 For detailed discussion, see, Chapter 2.
necessitates the states to initiate the necessary mechanism to identify the TK holders and enable them to obtain protection. It will be the task of each states to define the right as broadly as possible and so as to include all concerned indigenous and local communities as beneficiaries.

8. 1. 1. 3. Specific Attributes

Even apart from the subject matter of TK that could be considered for legal protection, the kind of right and its characteristics are another matter of disagreement. The issues here relate to the particular characteristics of the intellectual property right that will be chosen to be *sui generis*, such as the duration of the right, contents of the right and limitations or exceptions of the right and other details of enforcement.

8. 1. 1. 4. Implementation and Enforcement

After defining the subject matter and the content of right in TK, the next issue to be solved is that of its implementation and enforcement. So far, there is no consensus amongst the international community concerning the implementation mechanisms that can help enforce such *sui generis* rights. The disagreement surrounds primarily as to the (i) modalities for registration and certification of TK and (ii) implementation of prior informed consent and benefit sharing in case of appropriation of TK. Regarding the registration, the questions as to whether there should be a system of certification to ensure prior informed consent for traditional knowledge, and if so, whether there should be an international system of certification or a national one, etc. are yet to be settled.

8. 1. 1. 5. Intricacies involved in singular definition

However, a singular definition might not delimit the scope of subject matter for which protection is sought. This approach has been taken in a number of international
instruments dealing with intellectual property rights. Some international conventions in the field of intellectual property rights law do not define a singular term which describes the totality of protected subject matter. For instance, the Berne Convention for the Protection of Literary and Artistic Works, 1883 does not provide an exclusive definition for literary and artistic works but rather provides a non-exhaustive enumeration of subject matters that may be protected as original creations under the Convention.546

Following the same line, it would be highly desirable to have a global strategy of interested nations as to the subject matters that would be protected under the ambit of traditional knowledge. Countries may have two options: either define TK as an umbrella term - lato sensu547 or as a specific term denoting the subject of specific protection focused on the use of knowledge - stricto sensu.548 Besides to this, we need to develop an agreed formula as to the nature of TK and the content of right. The predominant task in defining TK is to demarcate the nature and content of the information that we seek to protect. The definition must consider certain key elements such as (i) the context of creation, (ii) association with the community, (iii) link to the community through a sense of ownership or responsibility and (iv) a community to identify traditional knowledge. Once this criterion is clear and the nature of the information can be clarified, countries have a wide range of intellectual property options, including options for sui generis protection, to choose from to make the right operative.

546 See, article 2 of the Berne Convention, 1886.
547 TK lato sensu covers, as WIPO/GRTKF/IC/7/6 defines ‘the ideas and expressions thereof developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as means for their cultural identification.’ See, WIPO/GRTKF/IC/7/6 p. 22.
548 TK stricto sensu refers to knowledge as such as the object of protection, and traditional cultural expressions. See, WIPO/GRTKF/IC/7/6 p. 22.
8.2. NEED TO HAVE CLARITY ON THE SUBJECT MATTER

For developing a system to protect traditional knowledge, the foremost thing to be done is to clarify the subject matter. Clarification of the subject matter involves (i) developing an acceptable and conceptually clear definition of TK and (ii) framing the contents of the right in a way suitable to the domestic requirements and demands of the respective national states.

The various working definitions of traditional knowledge represent different facets of the universe of traditional knowledge, which are related yet distinct in nature, and are in some way keeping with the spirit of article 8(j) of CBD. But it is generally said that article 8(j) is only a concept and not an exercisable right in itself. CBD leaves a lot of flexibility for parties to decide how to put its directives into action within their respective national spheres. Therefore, due to its broad mandate, defining traditional knowledge in a way corresponding to article 8(j) of CBD does not help to derive a functional regime for traditional knowledge in the respective national spheres. It would be more appropriate for the parties to define TK within their national and domestic contexts adhering to the spirit of CBD.

However, having regard to the wide range of subject matters it has to cover, a lone method of protection may not be advisable. Each form of TK may demand distinct treatment. Because, various components of TK, like traditional innovations or traditional practices relevant from a commercial perspective may require some form of intellectual property-like protection whereas traditional knowledge and practices that relate to biodiversity conservation and management systems may demand a different mode of protection. The traditional knowledge of farming communities may require still a diverse approach of protection. The traditional medicinal knowledge, folklore and various forms of
cultural expressions can very well be dealt with in a system akin to intellectual property protection. Different strategies may be followed to protect traditional knowledge under IPRs, including the application of existing modes of protection, the development of a *sui generis* regime, or a combination of both, or recognition of certain forms of ownership over TK through the enforcement of customary laws.

8. 3. NEED TO FILL THE VACUUM CREATED BY TRIPS AND TRIPS PLUS

TRIPS, which was the result of seven years’ long and arduous negotiations,\(^549\) is regarded as the most effective international instrument providing for the formal legal regime on IPR. While TRIPS agreement lays down in detail the kinds of IPR entitled for protection under the umbrella of TRIPS, it conveniently excludes the traditional knowledge from the list of subject matters qualified for IPR protection. This non-inclusion of TK took place in the agreement even when it extended protection for micro organisms and micro biological processes.\(^550\)

TK was not even considered for a *sui generis* protection as in the case of plant varieties. TRIPS agreement has made protection for plant breeders’ rights (PBRs) obligatory.\(^551\) To include plant varieties under the regime of IPR, the TRIPS has lowered the criteria standards and provided for weaker requirements. It substituted ‘distinctiveness’ for the requirements of utility and non-obviousness. Such an attempt was never endeavored in the case of TK.\(^552\)

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\(^{549}\) From September 1986 to December 1993.

\(^{550}\) Article 27.3(b) of the TRIPS agreement, 1994.

\(^{551}\) *Ibid.*

There were demands from the countries including India to accommodate traditional knowledge as a part of agenda for discussions and debates on TRIPS negotiations.\textsuperscript{553} However, the TK rich developing countries were not successful in incorporating their interests in the TRIPS due to the diverse and conflicting views of developed countries from the North.

It was not a casual omission. The omission was influenced by and resulted from the clever demand of bio industries of the North. More interestingly, the non-inclusion of TK occurred in TRIPS in 1994 immediately after two years of CBD which advocated protection for knowledge, innovations and practices of indigenous, traditional and local communities. Thus, TRIPS created an unprecedented vacuity in the international legal arena with reference to the protection of TK. Not only that it left out TK from the ambit of IPR and \textit{sui generis}, but the exclusion diluted the CBD obligations and the further works on TK also. Surprisingly, the post TRIPS regime also continued the same approach by giving no room for TK in the ministerial conferences held subsequent to the conclusion of TRIPS agreement.

\textbf{8. 4. NEED TO BALANCE THE CONFLICTING INTERESTS}

The recognition of the rights of indigenous and local communities over their traditional knowledge, innovations and practices associated with biological and genetic resources under article 8(j) of the CBD has been considered as a path breaking turning point in international law. The ongoing legal debates over the unresolved issues such as (i) where from this mandate ought to assume at national levels, (ii) how an effective implementation and enforcement can be effected at national as well as global levels and (iii) how it ought to

\textsuperscript{553} \textit{Ibid.}
be reconciled with the provisions of TRIPS agreement, etc. reveal the different levels of
ing interest involved in the protection traditional knowledge.554

The focus of the problem lies in the question how to reconcile the rigid, individualistic patenting system of the developed world with the community-held knowledge systems of developing and least developed countries. At the global level, there is a strong lobbying from the North and West against any positive protection of TK.

At the national level, one can witness in green rich countries a long term interest in conserving biogenetic resources associated with traditional knowledge. The source-nations which house the bio-genetic resources and traditional knowledge share a common interest to enact laws at national levels governing the use of traditional knowledge and the sharing of benefits that accrue from such use. They are encouraged by the sovereign recognition endorsed by the CBD.555 The source-nations’ interests are again split between the diverse conservation mechanism of biological diversity and traditional knowledge. There are differences of opinion regarding the terms and conditions that ought to be there in the benefit sharing agreements to ensure the allocation of the proceeds with the holders of these resources and the subsequent terms on transfer of technology.

At the local level are the interests of the local and indigenous communities to be part of such decision and rule making processes for access and benefit-sharing within national legal framework and to ensure that the use, exchange and benefit sharing aspects respect their customary laws and institutions.


555 Article 8(j) of CBD.
But one interest that infuses through all these levels is that of scientific research in the biotechnology industry that primarily depends on proper and reliable access to biogenetic resources situated within the territories ancestrally owned by local and indigenous communities and associated information on traditional knowledge exclusively held by them.

There is another ambiguity, which is the most controversial, at the international legal sphere. This is the conflict and inconsistency existing between CBD and TRIPS. On the one hand, CBD positively provides for the protection of TK and on the other hand, TRIPS excludes TK from the kinds of knowledge eligible for protection. The objectives of CBD are based on the recognition of community rights whereas the objectives of TRIPS are based on private monopoly rights. This has become the central point of controversy. In fact, removing the inconsistencies between TRIPS and CBD is the most important part of the TK rich countries’ demand for the review and amendment of TRIPS.

The focal point is that CBD is outside TRIPS agreement. While the CBD recognizes members’ sovereign rights over their biological resources, the TRIPS agreement allows members to provide patents over biological resources. Currently, the TRIPS agreement contains no provisions preventing biopiracy acts, in which a person may claim patent rights in one country over genetic resources that are under the sovereignty of another country. In particular, the TRIPS agreement also contains no provision ensuring the prior informed consent of the owners of the biological resources used in the invention. TRIPS agreement has no provision allowing a member’s claims to enforce its national regimes for fair and equitable sharing of benefits from the patenting of its own genetic resources in
another country. Thus, TRIPS as it stands today certainly hinders the implementation of the CBD.

The relationship between the TRIPS Agreement and the CBD has been addressed by the Secretariat of the WTO.556 This relationship, including the protection of traditional knowledge, was examined by the Committee on Trade and Environment (CTE) at the WTO. The CTE was formally established in 1995 by the WTO General Council to examine the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to Multilateral Environmental Agreements (MEAs). The CTE considered the provisions of the TRIPS Agreement relevant to its work on the environment under item 8 of its agenda. Some developing countries have argued that the TRIPS agreement must be reviewed in light of the obligations on states under article 8(j) of the CBD.557 However, till date no concrete step has been taken to ensure legal protection of traditional knowledge. Hence, the TRIPS provisions should be harmonized with the provisions of CBD to protect the rights of indigenous and local communities over traditional knowledge and associated biogenetic resources.

The design of successful legal instruments for the positive protection of traditional knowledge depends on the way the above stated levels of interests are balanced with the needs of R&D.558 When viewed within the process of biotechnological R&D, the right to traditional knowledge has to be functional and flexible vis-à-vis its interactions with the

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556 See, Environment and TRIPS (WT/CTE/W/8 and W/8/Corr.1); the CBD and TRIPS (WT/CTE/W/50); and the Relationship Between the CBD and TRIPS with a Focus on Article 27.3(b) (WT/CTE/W/125).
557 See, “Protection of Biodiversity and Traditional Knowledge – the Indian Experience,” Submission by India to the WTO, WT/CTE/W/156.
558 Supra note 11.
other rights in question. Failing this, issues of overlap between the right to traditional knowledge and other rights can, in the process, hamper efficient contract formation.

8.5. DEVISING OF WELFARE MAXIMIZING CONTRACTS

From an economic perspective an ideal contract should maximize the aggregate surplus that can be bargained upon. It also should allow for the distribution of surplus in a fair and equitable way. Contracts to grant access to TK need to necessarily have the essential elements of welfare maximizing contracts. Welfare-maximizing contracts result only when the following specific conditions are satisfied.

8.5.1. Mutual Consent

One pre-condition in welfare-maximizing contracts is the presence of well-defined, enforceable property rights that can be exchanged only by mutual consent of the property rights holders. It is the fundamental principle of contract law that the contract must be arrived at by the mutual consent of the parties.\(^\text{559}\) There must be consensus ad idem between the parties, to mean that parties to the contract must agree on the same thing in the same sense.\(^\text{560}\) Mutual consent in the bioprospecting contracts ensures that the estimated value of the resource incorporates all the conditions of its usage — the opportunity cost of using the resource — apart from the subjective benefits that the user associates with the resource which includes social, cultural and spiritual values.


\(^{560}\) See, Raffles v. Wichelhaus, (1864) 2 H & C 906, wherein it was held that it is essential to the creation of a contract that both parties should agree to the same thing in the same sense; and Smith v. Hughes (1871) L R 6 Q. B. 579, wherein it was held that an agreement upon the same thing in the same sense is known as true consent or consensus ad idem and is the root of every contract.
8. 5. 2. *Equal Bargaining Power*

The second condition for welfare-maximizing contracts is the presence of equal bargaining power amongst the parties. There should be no inefficiencies resulting from imperfect competition in the bargaining process. Inequality of bargaining power vitiates the genuineness in a contract.\(^{561}\) Since the TK holders generally do not possess equal bargaining power, usually they are at a disadvantageous position. There must be a mechanism to ensure that the TK holders’ rights are well protected and their interests are not prejudiced in the contract.

8. 5. 3. *Absence of Externality Effects*

The next condition for the efficiency of contracts is that of absence of externality effects, such as biodiversity depletion. This principle is getting more momentum along with the principle of sustainable development. The activities in relation to bio research and innovation must not result in diminution and exhaustion of biogenetic research. The contract must guarantee that bioprospecting will not lead to biodiversity erosion and extinction of species. The prospecting and allied activities must not create any potential threat to the ecosystem and the indigenous community’s survival over there.

8. 5. 4. *Prior Informed Consent*

The notion of prior informed consent (PIC) is a concept closely associated with TK ever since the introduction of CBD. This concept is envisaged in the CBD to ensure that the consent of the indigenous people and the local community is received before the

resources are accessed. It is a pre condition for bioprospecting and the subsequent invention. It is also the step prior to the benefit sharing agreement.

However, CBD does not define the term, ‘prior informed consent.’ Many justifications have placed for not defining the term in the instrument. As per one view, the degree of knowledge may vary depending on the people and the material in question. Another argument for not mentioning the degree of understanding of the people is that the indigenous people may not give consent so easily if they are aware of the monetary benefits received from taking their resources. However, the lack of definition and conditions for a legally valid pre informed consent operates detrimental to the genuine interest of the TK holders.

There are so many ambiguities around the concept. Primarily, the failure to define the phrase leaves open the opportunity for misuse by the bioprospectors. Hence, there must be clear guidelines as to the components of ‘fully informed prior consent.’ The requirements to make the consent fully adequate must be detailed and clarified. There should also be emphasis on the extent of information that is to be provided in order to get the consent.

Though, the UN Declaration also discusses free and informed consent, there is no definition of what amounts to a “free” and “informed” consent. It is unclear whether the information should relate to the potential future commercial benefits to the user of the knowledge or the potential benefits of continuing to keep the knowledge a secret. From the existing legal literature on the subject, it is unclear whether the indigenous people should be informed about the possibility of taking an intellectual property right, more or less akin
to a monopoly right to a certain extent, over their resource before the resources are accessed.

There is also an attempt to define and explain the concept PIC as the consent from the government. There must be clear provisions, though with governmental involvement it is the consent of the concerned local and indigenous communities who are the custodians of resources and TK. Again, with reference to free and informed consent, in a community setting, free consent may require consent of the whole community or consent from a person who has the customary authority to represent the entire community. Hence the definition of free consent will not only place the community at a better position in the negotiation process but it will also eliminate many issues at a later period.562

Uncertainty also exists as regards to partial or false information which a bioprospector may provide. The CBD has not clarified any future course of action in cases where information was not acquired with adequate consent. Statutorily invalidating information when the crux of the information has already been made public or known by virtue of a patent application is neither a deterrent nor a protective mechanism.

8. 5. 5. Control of Access to Biogenetic Resources and Associated Traditional Knowledge

Access to genetic resources and to associated traditional knowledge is not in itself a new issue. Access regimes have developed in earnest as a result of the increased value

562 For instance, a research from blood samples of members of Soloman Island showed a strain with immunity to a virus and gave raise to a drug for which a US Patent was applied. The indigenous people who have become aware of the market potential of the drugs were demanding compensation for the samples. The donee company argued that the blood and the spleen were given with consent. However, the extent of information given to the donor was never known, nor was the islanders aware of the commercial benefit the donee multinational would obtain in the future. In any case, had the donor known the full potential of his donation, he would have had a better bargaining power.
ascribed to genetic resources and traditional knowledge in the era of genetic engineering. Intellectual property protection, in areas such as genetic engineering, is often associated with genetic resources used in the product or process or the knowledge incorporated in the product or process. Similarly, R&D in pharmaceutical industry is largely depending on the bioresources and associated traditional knowledge. This has led to the development of increasingly complex and controversial legal frameworks concerning the rules that should govern access to genetic resources and related knowledge. The question of access to genetic resources and to traditional knowledge thus mainly concerns the conditions under which potential users can obtain the resources or knowledge they need.

Access regime is usually divided into two different categories. Firstly, there is the question of transborder access which is an international law issue. Secondly, there is the question of domestic access which concerns the conditions under which users can get access to resources and knowledge held by traditional knowledge holders. Issues concerning access arise both at the international level where they focus mostly on North-South relations and at the national level where they concern the rights or absence thereof that individuals and communities have to control access to their resources and knowledge. In international law, the question of access is one subset of broader issues related to state sovereignty. At the national level, the access regime is defined as important not only as a marker for benefit sharing arrangement but also indicating more broadly the kind of control and the rights of ownership or absence thereof that holders of biological resources and traditional knowledge can assert.

From the point of view of international law, states have been granted the right to regulate access to their resources. The position under both the CBD and the PGRFA Treaty
is that countries have sovereign rights over their biological resources as well as their plant genetic resources for food and agriculture. However, sovereign rights are asserted with specific commitments to facilitate access to resources. In other words, countries have the right to regulate access to their resources but should not adopt legal frameworks which generally deny access to all national resources. The current legal framework therefore seeks to foster exchanges of biological and plant genetic resources. One of the reasons which led the international community to agree on states’ duties to facilitate access is that most countries are highly inter-dependent with regard to plant genetic resources for food and agriculture. This is also one reason for most states agreeing to foster a system built not exclusively on sovereign control but also on exchanges.

Access can take different forms in practice. In situations where resources are held ex situ, the main issue is to formalize the terms of access of the user. Access is a much more complicated issue where resources are found in situ. In this case, bioprospecting covers all activities related to the search and collection of biological resources, the use of information regarding traditional uses of the biological resources as well as research towards commercial exploitation. The regulation of access at the international and national levels is a step forward from the point of view of asserting control over resources and knowledge by countries and holders themselves.

On this background, the mutual consent requirement in the welfare contract indicates that, if communities associate high values with their resources, both tangible and intangible, they will not have to contract away such resources. This suggests that in special

circumstances the community can control and even deny access to their resources. A strictly regulated access regime gives the country more effective control over transfers of resources outside the country while being also likely to discourage some bioprospectors who may find the conditions too stringent. A strictly regulated regime also has the potential to provide more protection to holders or resources and knowledge but this would occur only if the national legal framework provides for effective control by original holders. Further, a controlled regime of access also provides the country with more control over biodiversity conservation and use policies. Conversely more liberalized approach to access is likely to increase bioprospectors’ interests in accessing resources and knowledge. Though it may yield economic benefits for the country, it is likely to further reduce the control that the original holders have in respect of their TK.564 In practice, access must be based on mutually agreed terms and on the prior informed consent of the state of origin.565

Effective regulation of access to bio genetic resources has been an area of international debates. CBD provides for appropriate access to genetic resources thought it does not explain what is ‘appropriate.’ Moreover, the CBD has recognized the sovereign rights of nations on their biological and genetic resources. The countries those are rich with biological and genetic resources and related traditional knowledge must develop suitable mechanisms to control the access to their nature and resources. Nevertheless, care must be taken to ensure that there will be no over control restricting complete access and hindering biotechnology and other potential industries. There must be a balancing approach between control over resources and benefit sharing. The promise of property rights on traditional

565 This often takes the form of a material transfer agreement.
knowledge is recognition and benefit sharing for communities, apart from incentive for biodiversity conservation. But control over resources is theoretical and incomplete if exchange of the resources is not possible or is somehow hindered.

8.5.6. Agreements for Benefit Sharing

The pharmaceutical companies often base their products primarily on medicinal plants and traditional knowledge. In the United States of America, it is estimated that nine out of ten prescription drugs used are based on natural compounds from plants, fungi, animals, and microorganisms, which is solely based on the products of biodiversity.566 It has also been estimated that the total market value of plant-derived medicines sold in OECD countries was US$43 billion.567

The custodians of these knowledge are in most cases, poor and indigenous people. However, in majority of bioprospecting cases, the TK holders and custodians of associated resources did not receive any share of enormous sale proceeds. In contrast, the developing countries which house TK and associated biogenetic resources were required to engage in costly legal battles to retain their rights over their traditional knowledge. For instance, India had to spend millions of dollars for challenging neem and turmeric related inventions patented by USA.

Benefit sharing is a relatively new notion which has been developed as a consequence of the rapidly changing paradigm concerning claims over biogenetic resources.

and traditional knowledge. Benefit sharing is the response which has been given to the fact that holders of biogenetic resources and traditional knowledge are not granted rights to restrict exploitation of their resources and knowledge but only rights to put conditions on access to them by outsiders. In other words, benefit sharing has evolved as an indirect mechanism for recognition and reward which the traditional knowledge holders can resort to when their knowledge constitutes the basis for product or process protectable under existing intellectual property rights. Benefit sharing is the compensation mechanism which has been introduced as an additional indirect control mechanism that prolongs the access regime. It is based on the compensatory liability approach which aims at providing for some form of equitable remuneration or compensation to TK holders for the use of their TK.  

There is another side of the coin. In the present era of biotechnology, it would be mere absurdity to put complete ban on inventions based on TK. On the other hand, the source nations and the concerned indigenous local communities must get their due for the appropriation of their knowledge and resources which they have preserved over years. In the current legal framework for intellectual property, which does not provide protection to farmers, breeders or traditional knowledge holders, there must be a compensation mechanism to provide at least an indirect recognition of their contribution to technological progress and new lines of investment.

In the light of the above mentioned facts, it would be prudent and most cost-efficient, than to litigate, to develop legal frameworks for recognition and protection of traditional knowledge including provisions for benefit sharing.

568 WIPO/GRTKF/IC/7/6.
Accordingly, subsequent to the conclusion of CBD and the Plan of Implementation arising from the World Summit on Sustainable Development (WSSD) in 2002 the various mechanisms for benefit sharing are of the principal focus of international negotiations relating to TK. The principle of benefit sharing indicates that a fair and equitable share of the benefits arising from commercialization of TK should be given to the TK holders.

On the whole, benefit sharing is a tool which has been found acceptable to developed and developing countries though for partly different reasons. For countries of origin, benefit sharing has proved to be until now an avenue through which governments can acquire more authority towards other countries and towards holders of biological resources and traditional knowledge. For countries of origin, benefit sharing has the advantage of granting rights to original holders and thereby proving a role for the state in managing the resources and the compensation that comes in return.

*Kani-TBGRI Kerala Model* ABS provides one of the best examples for benefit sharing which actually distributed benefits with the tribal community for providing leads in the bioprospecting. It was an accidental discovery made by the scientists of TBGRI during the Ethnomedico-Botanical exploration to the Agastyar valley areas of Trivandrum, Kerala, India, which is located in the southern most part of the Western Ghats that the plant, *Trichopus zeylanicus* (*Arogyapacha*), abundant in that area, has restorative and anti-fatigue properties. The discovery of the unique property of the plant was based on the leads obtained from disclosures by the Kani tribe people who accompanied the group as porters and guides. Kanis are traditionally a nomadic community, but most of them are settled now for long time. Their population is 16,181 which is approximately 1.85 of the
total population of the district. The unripe fruits of ‘Arogyapacha’ are eaten fresh to remain healthy and agile by Kanis during their long trekking trips in the forest for procuring their livelihood requirements. Ethnopharmacological screening of *Arogyapacha* revealed various activities such as anti-fatigue, anti-tumour, anti-gastric ulcer, anti-stress, anti-allergic, anti-oxidant, adaptogenic, aphrodisiac, immuno-modulatory and hepatoprotective.

The researches resulted into bioprospecting and development of a new drug discovery. Based on Ayurvedic fundamental principles, the drug was named *Jeevani*. Out of four patent applications filed for the new drug, two were granted. The government negotiated for benefit sharing. This ABS is commonly known as ‘TBGRI Kerala model for benefit sharing’. The TBGRI in consultation with the tribal community has worked out an arrangement for benefit sharing. After negotiations with various interested parties, the technology for production of the drug ‘*Jeevani*’ has been transferred through a manufacturing license to the Aryavaidya Pharmacy, for fee of Rs. 10 lakhs for a period of 7 years with 2.0% royalty at ex-factory sales price. Council for Scientific and Industrial Research (CSIR) norms were adopted for the technology transfer in November 1995. According to this arrangement, the TBGRI has agreed to share 50% of the licence fee and royalty with Kani tribes who provided the original lead for the development of the drug. Kani tribes registered a trust called ‘Kerala Kani Samudaya Kshema Trust’, with the guidance of TBGRI and the benefits received by the technology transfer and royalty were

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remitted to the Trust’s account. Later, in consultation with TBGRI, the executive committee of the trust had decided to felicitate the three Kani tribes who provided the information about Arogyapacha. TBGRI model of Benefit sharing was acclaimed world over and was given UN Equator Initiative Award.

As per CBD, benefit sharing must be fair and equitable. It defines benefit sharing as fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. The CBD suggests that benefit sharing arrangements can be used to implement provisions of prior informed consent and equitable sharing of benefits from use of biological resources. However, the experiences evidenced from most of the benefit sharing models experimented with so far show that they have not been successful in fulfilling the objectives of CBD. While the concept is clear in principle, in practice it brings difficulty in the process of implementation. Benefit sharing has become a concept that has been developed in different ways in different countries. To date, very little of the modest benefits successfully claimed by countries for access to their genetic resources and associated TK has actually made its way to the TK holding communities.

The failure of various benefit sharing agreements illustrates this point at hand. Over the last decade, several pharmaceutical companies involved in pharmaceutical prospecting have developed models with the indigenous and local communities for benefit sharing from successful drug discovery. The Shaman Pharmaceuticals model is a famous
example amongst these models.\textsuperscript{571} Their research project was extremely time consuming and highly costly. Adding to this, the risk involved in clinical trials and R&D in drug development resulted in the bankruptcy and closure of Shaman Pharmaceuticals!

Even in the Kani-TBGRI Kerala model, though the research project resulted in the discovery of a drug called \textit{Jeevani} and a decent remuneration to the TK holders critics still find several problems with the model. The problems are mainly related to (i) access to the plant resource, (ii) market establishment, and (iii) in balancing competing claims of representation for benefit sharing and calculation of shares in distributing the benefits from royalties and licence fees etc. Still there are unresolved issues.\textsuperscript{572}

In many other models, though several leads have been obtained, the commercial drugs are yet to be completely developed. Pharma companies feel that there are also very high transaction costs in obtaining consent and collection of samples from indigenous peoples and in further clinical trials for R&D. Hence any system for benefit sharing needs to take account of all these issues.

Despite the broad acceptance of the notion of benefit sharing which now prevails at least at the international level, there remain major debates concerning the exact benefits that should be shared, under what circumstances they should be shared and in which fields


\textsuperscript{572} The commercial value of \textit{Jeevani} is estimated in the range of US $ 50 million to 1 billion. However, the Kani tribes did not receive royalties correspondingly. See, Devinder Sharma, Selling \textit{Biodiversity, Benefit Sharing is a Dead Concept}, <http://www.mindfully.org/WTO/2004/Selling-Biodiversity-Sharma3may04.htm>, visited on January 01, 2009.
they should be taken place. One of the major problems is that it is difficult to conceive of benefit sharing exclusively at the national level. This is due to the fact that countries of origin are not in a position to impose extra-territorial measures on user countries. Therefore, an effective benefit sharing system for transboundary transactions either must involve an international law framework or must be coordinated between all countries. Countries of origin can take measures at the point of access of the resources, but it is often difficult to judge at the outset what exact use will be made of the resources and what benefits will eventually be derived. Further, even when an estimate is made, if respect for benefit sharing arrangement is not made a condition of patentability or commercialization of derived products, it would become much more difficult to enforce benefit sharing arrangements.

8.5.7. Identification of Beneficiaries

One of the most important issues in the implementation of the benefit sharing models is the identification of beneficiaries. Hardly there is a single beneficiary. Usually the knowledge is held collectively. As the rights over the resource and knowledge are held collectively, questions revolve around how the communities are defined. They may be defined geographically, ethnically or politically for the purpose of sharing benefits keeping in view the optimal benefits to TK holders.

There can be situations where TK is held by communities of more than one country. There can also be situations where TK is held in a country by more than one community or indigenous peoples. At national level too identification of beneficiaries will be a difficult
task when the knowledge holders are spread and when the knowledge is held by more than one community. In such occasions the benefits may be paid into a community fund.

However, the reservation was expressed that such funds can have high overheads, with limited benefits reaching the TK holders. There is a criticism that more often benefits go to research institutions or government departments.\(^{573}\) In each case, the beneficiaries must be defined in such a way as to prevent accumulation of benefits in few hands and to cover all the deserved.

### 8.5.8. Valuation of the Monetary Benefits

The other problem regarding benefit sharing is the valuation of the monetary benefits after drug development. A central aspect of valuing any tradable resource is the right of action available on this resource and how these rights of action are to be enforced.\(^{574}\)

The value of TK can be assessed and the monetary benefits can be fixed only on the basis of non-market and market use of the traditional knowledge. Traditional knowledge is a form of basic research, which on its own commands no commercial value, but in turn, derives its value from the value of future innovations facilitated by it. There are two notions of value in the context of TK: market and non market values. The market value of traditional knowledge is determined when members outside the community that

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traditionally own the rights over traditional knowledge use the knowledge to develop further products or cost-reducing processes. One is the value of traditional knowledge derived from the traditional use of the resources and associated knowledge within the local context of the community and the other is derived from its use outside the local context of the community. These may be broadly classified as the non-market and market use of the traditional knowledge relating to biological resources.

The scope for sequential innovations must not be disregarded while fixing the benefits. There is usually a sequence of innovations based on the original innovation. Pharmaceutical and bioengineered products usually undergo a series of improvements subsequent to the basic research and ‘primary innovation’. The system of sequential innovations, which include several stages of innovation over the basic research, is common in the genetic engineering and biotech industries. For example, the medicinal properties of the drug *Jeevani* in Kerala could in turn serve as the basic knowledge for further improved drugs or cost reducing processes. There can be infinite sequence of quality improvements.

Valuation of monetary benefits must take into consideration the social value of TK also. The social value of the basic traditional knowledge innovation is greater than the private market value of the knowledge as it is compounded by the value of the subsequent innovations also. The social value of traditional knowledge further includes any costs borne by the community due to its loss of traditional knowledge on commercialization. Because, commercialization of the traditional knowledge, closely held within a community may involve a loss to the community in terms of changes in access to and the traditional use of the resources and knowledge. Similarly, it also includes any gains to the community that accrue from sharing of the profits from subsequent innovations developed. Thus, in
addition to the market value of the basic innovation, the social value of traditional knowledge includes the market value of the subsequent innovation. Given the cumulative nature of traditional knowledge innovations the value of traditional knowledge is compounded by the value of future innovations that are developed based on the initial stock. The traditional medicinal knowledge, once obtained by pharmaceutical companies becomes the base for developing further marketable drugs. The concept of social value of innovation captures the additional value generated from cumulative innovations.

On the basis of these valuation royalties are to be fixed. Short term assessment of the economic benefits of the end product will not be of much benefit. What is needed is a continuous assessment and evaluation of the product in the global market and premium out of the performance. The benefit sharing agreement should last as long as the intellectual property protection on the product will last. There must be share of each and every profit that discoveries might produce.

8. 5. 9. Non Monetary Benefits

Another important issue is that of the ‘other non monetary benefits’ in the agreement to benefit sharing (ABS). The benefits need not be always shared in terms of money. It can be shared even in terms of ‘kind’. According to the requirements of the TK holders and indigenous local community exchanging the resources or information, they can have the following demands in the ABS:

i. transfer of technology

ii. participation in sample collection

iii. participation in all stages of bioprospecting
iv. local employment opportunities
v. partnership in the invention
vi. employment opportunities abroad subsequent to bioprospecting
vii. improving of their infrastructures, and
viii. appropriate funding schemes

8.6. NEED TO FORMULATE POSITIVE LEGAL MECHANISM

Most of the countries lack a positive legal mechanism (i) to control the access to resources and knowledge and (ii) to ensure benefit sharing. Many a time, in the absence of national protective systems, contractual obligations are being concluded between knowledge holders and bioprospectors. The knowledge holders with their weak negotiation capacity eventually gain nothing or merely something in return.

As regards to the community knowledge, since the contracts are not being concluded with the community as such or sometimes even without their proper knowledge, only parties to the contract receive benefits. Moreover, the communities have limited negotiation capacity and experience.

High transaction cost is another shortcoming of contractual approaches. Legally supported guidelines for ABS can very well address these concerns and settle terms and conditions without causing detriment to both the parties.

Though there are few voluntary guidelines and options for equitable sharing of benefits and technology transfer, the fact remains that misappropriation of proprietary rights over genetic resources and traditional knowledge of the indigenous local communities is taking place continuously. Quite often the rights of the native communities
who preserve the TK are being undermined while policy makers, the researchers and the international agencies like WTO, WIPO, UNEP interpret the definition very cleverly to push forth the industrial interests.

In the absence of a fair and equitable benefit sharing, the end result would be blatant biological theft, misappropriation of biodiversity and the traditional knowledge that comes along with it, disempowerment of indigenous local people and undermining of local communities’ capacity to maintain their own biodiversity based livelihood strategies.

In recent years, urgent efforts are being made all over the world along this line. India also must have a legal framework to regulate the contractual approaches in favour of her local and indigenous community.

8.7. DATABASE FOR TRADITIONAL KNOWLEDGE

The traditional knowledge is transferred from generations to generations verbally or by use. Anticipation of invention by use in foreign country is not a prior art in some countries like U.S. However, the international IP regime, with no exception, treats documented knowledge as knowledge in public domain. Since the documentation of TK makes the knowledge in the public domain, there has to be a systematic and exhaustive documentation of traditional knowledge. India has documented knowledge related to traditional medicine. On the same line, there must be efforts to document knowledge relating to other traditional practices and innovations of indigenous community. The information so collected must be digitized and made available to all intellectual property registries for the purpose of examination. While examining the IP applications, the

\footnote{US Code: Title 35; § 102 which deals with conditions for patentability; novelty and loss of right to patent.}
examiners can refer to this information as a process of prior art. This will bring to light the misappropriation of TK, if any.

8. 8. SETTING UP OF GLOBAL BIOCOLLECTING SOCIETY

Another mechanism for the implementation of TK holders’ rights is establishing a Global Biocollecting Society. It was originally proposed by Peter Drahos. This concept is similar to copyright societies and performing right societies. Such biocollecting society would serve the following purposes:

i. the society would link country and community biodiversity registers,
ii. license TK to potential users,
iii. monitor use and commercialization of TK,
iv. receive and distribute royalties, and
v. settle disputes.

Setting up of such a society involves some potential challenges including effective monitoring of use and distribution of benefits when several communities or countries claim ownership over the same or similar knowledge.

8. 9. SETTING UP OF BIOCOLLECTING SOCIETIES AT NATIONAL, STATE AND LOCAL LEVELS

On the same line of global biocollecting societies, biocollecting societies can be set up at national, state and local levels.

577 See, section 33 of the Indian Copyright Act, 1957. Chapter VII, sections 33 to 36A provide for the administration of rights owned by societies, payment of remuneration by societies, rights and liabilities of societies etc.
8.10. ROLE OF WIPO

There must be a comprehensive global study on indigenous peoples’ right over their TK and IK with the aim to (a) identify the nature and scope of TK, (b) to identify possible practical and legal ways of promoting and protecting indigenous and local communities’ rights over biogenetic resources and associated traditional knowledge and (c) to explore the possibility of accommodating some forms of TK within the framework of IPRs system. Having regard to the strong interrelation between intellectual property rights and traditional knowledge and since many intellectual properties are depending on traditional knowledge and related biodiversity, the WIPO should undertake necessary steps for such a comprehensive global study. In such studies there must be full and effective participation of all indigenous and local peoples who are the holders of TK.

A fundamental revision of multilateral trade rules is essential if the injustice inflicted by biopiracy and misappropriation of TK on local communities and their indigenous knowledge is to be corrected.

8.11. AMENDMENTS RECOMMENDED IN THE TRIPS

The TRIPS has totally weakened the objectives of CBD. Intellectual property rights under TRIPS absolutely disregard traditional knowledge and contributions made by indigenous and traditional communities. The efforts by individual countries, as per the TRIPS mandate to review their national laws on intellectual property, in order to bring them in line with their obligations under the TRIPS agreement, are accelerating the biopiracy and misappropriation of TK. The lacunae in the TRIPS, now permit the patent system, which is supposed to reward ingenuity, inventiveness and creativity, to systematically reward piracy. If the patent system fails to candidly apply criteria of novelty
and inventiveness in awarding patents on invention related to TK, then the system is blemished, and it needs to be rectified. For this TRIPS must be reviewed.

Since, as part of the implementation of the CBD, all bio rich countries have to establish national arrangements for collecting and using biological resources and the knowledge associated with them and for sharing benefits from any commercial transactions with those communities which have developed this knowledge, the TRIPS agreement must be revised urgently to provide for *sui generis* system of protection for TK. The protection must be made mandatory. Principles of ‘prior informed consent’ and ‘fair and equitable benefit sharing’ must be incorporated in TRIPS. These would prevent biopiracy and misappropriation of TK to a certain extent.

TRIPS must incorporate provisions requiring the prior approval of countries of origin before patent applications involving a biological resource, or traditional knowledge about its use, are granted. This would enable countries of origin either to prevent such patent applications or to require benefit sharing arrangements with the applicants.

TRIPS agreement, which denies the knowledge and innovations of the Third World and developing countries and indirectly permits IPRs on inventions based on TK, needs instantaneous amendment. Having regard to India’s special interest in the matter concerning biogenetic resources and associated TK, the government must voice our concern at appropriate forums such as WTO, WIPO, etc. to implement the requirements of PIC, ABS and disclosure of origin. It must encourage the international community to amend TRIPS accordingly.
8.12. NEED TO TIGHTEN INTELLECTUAL PROPERTY RIGHTS LAWS

Principally, intellectual property system rewards innovation. The reward for innovating is the opportunity to collect, for a limited period, the benefits – the monopoly rents available from devising a successful innovation. Discoveries, even with a scientific veil, are not innovations. Hence there is an emergency to tighten the IPR laws on this basis. There should be no grant of intellectual property rights, in any forms, without the promise of additional innovations. In particular, the granting of intellectual property rights on discoveries can only act to reduce innovations. Most often, IPRs are being claimed on traditional use of resources, as in the case of neem patent. These must not be considered as inventions but as mere discoveries. Granting intellectual property rights to discoveries will not only induce additional discoveries but also will add to the cost of innovation, contrary to the very philosophy of IPR system. There must be clear distinction in international patent law between those scientific innovations that enhance the process of discovery and those that use the information derived from discovery to innovate.

For this reason, strong efforts should be made to ensure that prospectors or TK pirates are not able to use the monopoly granted as a reward for innovation to generate additional opportunities for monopoly rents through practices such as tied sales, input bundling, failure to disclose crucial information to patent authorities, etc. The TRIPS could be strengthened to make it easier for developing countries to obtain recourse if uncompetitive practices are observed among transnational biotechnology firms. The international intellectual property regime should bring strong competition policy disciplines on the private restraint of trade in those industries that produce and distribute innovations’’ derived from bio genetic materials and TK.
On the other hand, if international conventions on intellectual property rights including TRIPS continue to extend intellectual property rights to technologies that merely enhance discovery or the discoveries themselves, then they should also extend intellectual property rights to traditional knowledge without demarcating whether a discovery has arisen as a result of experience based traditional methods or through the use of modern scientific methods. The element of ‘innovation’ is more or less same in both the cases. It would not be equitable to award one with intellectual property rights while excluding the other.

8.13. CAPACITY BUILDING OF TK HOLDERS THROUGH EMPOWERMENT

There is no dispute on the fact that the capacity to use science for the development of innovations is not distributed evenly among societies. Traditional societies forming part of ‘have-nots’ typically have little scientific capacity and therefore, have no opportunity to participate or compete with the ‘haves’ in the process of innovation. Hence, there is a need to increase and enhance the scientific capacity of ‘have-nots’ who have resources and TK. Any protection for the benefit of the holders of TK should be both effective in practice, and should be tailored to the specific context and resource constraints of TK holding communities.\(^{578}\) It underscores the need for coordinated capacity-building amongst the TK holders. Until the capacity of traditional societies to undertake scientific innovation is increased considerably, they will not be able to share equally in the benefits associated with the knowledge economy. Hence through capacity building including transfer of technology and know-how, the indigenous local communities must be empowered.

\(^{578}\) WIPO/GRTKF/IC/7/6.
8. 14. ROLE OF NGOS

The NGOs along with the government must work together to create awareness amongst the indigenous and local community regarding the importance of knowledge they possess and the need and ways to protect it. There is a need for awareness-raising to ensure the practical effectiveness of any protection. There must be community empowerment to stop biopiracy and misappropriation of traditional knowledge. They must promote a better understanding amongst the indigenous and local community about the value, use and potentials of the traditional knowledge that they own. The CBD stresses the important role of non-governmental sectors in promoting the conservation of biological diversity and sustainable use of its various components.579

8. 15. NEED FOR REGIONAL COOPERATION

India shares a considerable part of its biodiversity and associated TK including forests, life forms, and a huge variety of plants with one or more adjoining countries of South and South Asia particularly Nepal, Bhutan, Burma, Bangladesh, Maldives, Sri Lanka. Any one of these countries could undermine the position of others by offering commonly held biogenetic resources on less stringent terms and conditions. The importance of regional cooperation in conservation has been recognized but regional agreements are still far from being adequate.580 It is therefore critical that the South Asian Association for Regional Cooperation (SAARC) and other regional grouping reach agreement on minimum set of conditions under which bio resources and associated knowledge can be given to the prospectors of the North.

8. 16. NEED FOR INTERNATIONAL COOPERATION

Protection of TK is not an issue which can be resolved by municipal laws or by regional agreements. It is an international issue, and it can be resolved only by international cooperation. CBD also requires international cooperation in the conservation of resources and mutually beneficial agreements on its utilization. There is a need for unanimity amongst the international community to refuse patent or any kind of IPR on TK based inventions. All countries must treat TK, in any form, existing elsewhere in the world as ‘prior art’ anticipating an invention.

Countries with a high degree of scientific capacity and enforceable intellectual property rights systems should also ensure that their domestic patent laws do not allow the granting of intellectual property rights to what are traditional discoveries that have been acquired through biopiracy. If societies that have a high degree of scientific capacity need cooperation from developing countries in protecting their intellectual property through TRIPS, then they need to ensure that their own patent institutions provide good models and not ones detrimental to the interests of developing countries.

Some patent systems such as American patent system require a special mentioning in this aspect. The United States has granted patent for hundreds of products based on Indian TK. This is in spite of the fact that the United States’ IPR system is globally being treated as strong and stringent. But, in reality, the U.S. system is inherently flawed in dealing with traditional knowledge. The U.S. patent law as existing today can only pirate TK. The main reason for this is the existing patent regime in U.S. which does not treat as prior art the traditional knowledge of other countries. §102 of the U.S. Patent Law, which defines prior art, does not recognize technologies and methods in use in other countries as
prior art. If knowledge is new for the U.S., it is novel for the purpose of patents, even if it is part of an ancient tradition of other countries.\textsuperscript{581} Thus, use in a foreign country does not constitute ‘prior art' in U.S. patent law. The denial or non-recognition of ‘prior art' elsewhere allows patents to be granted in U.S. for existing knowledge and use in other countries. This is the basis of long record of biopiracy cases and patents of Indian TK based ‘inventions’ in the U.S. § 102 thus enables the U.S. to pirate knowledge freely from other countries, patent it, and then enforce this stolen knowledge as intellectual property.

\textsuperscript{581} \textit{US} Code: Title 35; § 102 which deals with conditions for patentability; novelty and loss of right to patent reads as follows:

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in

(1) an application for patent, published under section 122 (b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

\textit{(g) \textsuperscript{*** *** ***}}

(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.
Knowledge flows freely into the U.S. but is prevented from flowing freely out of the U.S.\textsuperscript{582}

Thus, if biopiracy from India has to be stopped, then the U.S. patent law must be amended, and §102 must be redrafted to recognize prior art of other countries.\textsuperscript{583} In the same line, all countries must devise defensive and protective legal mechanism to protect TK and biogenetic resources belonging to other countries. To protect TK in developing counties, as Gustavo Ghidini suggests, the first step is the development of an international cooperative approach, not confrontational approach.\textsuperscript{584}

8. 17. NEED TO FORMULATE INTERNATIONAL TREATIES ON TK

There is a high need to formulate a long term strategy to protect bioresources and associated TK. Many countries including US have refused to rectify CBD. Bio rich nations should jointly put pressure on those countries yet to join the Convention to fall in line with CBD. The CBD must be given enforceability.

International treaties are extremely essential for the protection of traditional knowledge as they set standards, regulations and guidelines with reference to intellectual property, human rights, access and benefit sharing, conservation and management of biological resources, related trade etc. All these are interlinked and have impact on traditional knowledge protection.


India should mobilize the biodiversity owning countries of the world to develop an international treaty dealing with the use of biogenetic resources and TK. The treaty must have enforceability as in the case of TRIPS. India should take the lead in building consensus among biodiversity rich countries on a uniform policy for bioresources and associated TK’s use.

8.18. **NEED TO DEVELOP A SUI GENERIS SYSTEM**

As stated elsewhere, the need to promote and preserve traditional knowledge was, for the first time, highlighted internationally in 1992 with the conclusion of the Convention on Biological Diversity. However, the ray of hope brought about by the CBD did not last long due to the non-inclusion of TK in the legally binding TRIPS agreement. Consequent upon the severe criticism on the non-inclusion of TK in TRIPS, the WTO Ministerial Conference at Doha in 2001, mandated review of relationship between the TRIPS Agreement and CBD with reference to the protection of traditional knowledge. TK has a bearing on debates in several international forums. There were few attempts, as discussed in previous chapters, at global and national levels in designing appropriate intellectual property rights for indigenous and traditional knowledge. Nevertheless, no international system has yet been designed and implemented that effectively preserves TK, protects the rights of TK holders, and compensates them equitably for its use. Until now, these exercises have thrown up more unresolved questions than satisfactory answers.

The arguments surrounding the extension of intellectual property rights to TK are complex. Given the criteria for current intellectual property regime, TK is out of its purview. It fails to meet many of the requisites required for various kinds of IPRs.
In this background, there is a need to design successful legal instruments at both national and international level for the positive protection of traditional knowledge. As reflected in Article 8(j) of the CBD, there is the overall global long-term interest in conserving genetic resources and related knowledge with respect to both use and conservation techniques. At the national level, there are the interests of the source nations - nations who host such resources - who have the authority, as per Article 8(j), to enact laws governing the use of traditional knowledge and the sharing of benefits that accrue from such use. Source nations’ interests are split between the conservation of biological diversity and the short term benefits that they may accrue through the exchange of information and natural resources. The source nations demand assurance that the benefits resulting from the use of genetic resources and traditional knowledge are, in fact, shared with the holders of these resources.

Having regard to the intricacies involved in its protection, the primary requirement for a successful legislative instrument is to break up the mandate of Article 8(j) into successful compartments, and legislate vis-à-vis each of them, according to the kind of knowledge in question. This is essential for a number of reasons.

Firstly, such a clear conceptualization is, under Article 15 of the CBD, necessary for resolving the inter-linkages between the right to traditional knowledge and the rights-over-access regulation. To make it clear, TRIPS under Article 27.3(b) envisages a sui generis protection for plant varieties. Following its mandate India legislated Plant Variety Protection and Farmers Rights Act, 2000. On the same line, there can be new specific legislations on distinct kinds of traditional knowledge and for traditional practices, viz, Protection of Traditional Medicines and Practices, Right of Traditional Medicinal Practitioners Act, etc.
Secondly, the property right that can be used to protect various kind of traditional knowledge may vary according to the subject matter of protection. For example, when a copyright-like \textit{sui generis} system can effectively protect folklore, a patent-like \textit{sui generis} system can be envisaged for traditional medicines. For the farming communities, a \textit{sui generis} system akin to geographical indication may be more suitable. Hence, a legal framework having regarded to the subject matter of protection, must be designed.

Thirdly, why such a utility-based compartmentalization is extremely important is because the beneficiary categories change from area to area. Thus, identifying the subject matter of the right will automatically pave the way for decisions on (i) identification of beneficiaries who will exercise the right, (ii) the link between the right and biodiversity conservation, and (iii) the kind of right that will best suit the demands of the knowledge category and the beneficiaries.

For the larger goals of empowering indigenous and local communities, broader right structures are required. But for the purpose of practically protecting their specific knowledge pools, more rights and implementation structures need to be designed, failing which broad and overlapping property rights structures could hinder meaningful contractual exchange.

Even after litigating in foreign countries on a series of biopiracy cases involving TK\textsuperscript{585}, the government has neither formulated nor implemented any policy decisions. Therefore, there is an extreme emergency to legally recognize and protect TK. Since the entire global community is divided on the issue, there is no point in waiting for an international instrument having enforceability. Having regard to the plenty of the resources

\textsuperscript{585} See, chapter 3 for important cases on biopiracy and misappropriation of TK.
and associated TK India has, it is high time we envisaged a national level protection reaching at grass root level for the local indigenous community.

Hence, it is recommended to enact a *sui generis* legislation for the protection of TK in India. *Sui generis* systems can be developed to define the rights of the communities over their knowledge. *Sui generis* is a Latin phrase which literally means ‘of its own kind’. A *sui generis* system is a system specifically designed to address the needs and concerns of a particular issue. A *sui generis* system for the protection of traditional knowledge would mean a system entirely separate from and different from the contemporary intellectual property regime. A *sui generis* system can be treated as a new form of intellectual property or intellectual property like rights. There are several examples of *sui generis* rights in the field of intellectual property rights law, such as plant breeders’ rights as reflected in the International Convention on the Protection of New Varieties of Plants, 1991 and the intellectual property protection of integrated circuits as reflected in the Washington Treaty on Intellectual Property in Respect of Integrated Circuits, 1989. Some examples of countries that are developing *sui generis* systems have already been discussed in the last chapter. These systems enable the government and the communities holding traditional knowledge to regulate access to and use of biological resources and the associated traditional knowledge.

However, the protection of TK under a *sui generis* IP regime raises a number of policy issues:

i. About the role of communities and the functions of communally held knowledge in traditions that are part of heritage and culture as well as living traditions of habitat preservation and human interactions. TK is an integral part of the indigenous/local communities, closely linked to the land and habitat
where they reside, their culture, their socio-political and economic systems and institutions. The natural environment has provided sustenance and healing, given an abiding spiritual basis for cultural and artistic expressions and helps in the communities’ conservation and growth. The real issue in this context seems to be the protection of the communities as such and preservation of their lifestyles and cultures rather than the protection of TK as a separate and independent subject matter.

ii. About the structuring of economic incentives for the protection of TK and rights and obligations that are anchored in responses and behaviour rather than in resources. For many, their TK holds a sacred value which they would not part with for money. They want to safeguard their knowledge from plunder. Holders of TK should be rewarded for their care and feeding of ideas. They need to be further encouraged for continuous preservation of TK. For that, there needs to be community empowerment and capacity-building.

iii. About the objectives to be reached by TK protection and the measures necessary towards that end. In this context, the issues that need to be examined are: what is to be protected and from whom is it to be protected; for what purpose; for whose benefit and in what form; will a protection be confined to TK in the public domain or will it cover knowledge held as secrets; and the sacred/religious aspects of TK.

iv. About the scope of protection. As the TK protected under a *sui generis* regime would have an economic/pecuniary thrust which would aim at protecting it against unauthorized use rather than promoting and preserving its further use
and diffusion, the following issues need to be addressed: when and how the right will accrue; the nature of entitlements and share in benefits; scope of protection, duration of protection or whether it be protected indefinitely and the rights conferred; and the monitoring/administration/enforcement of the TK-related rights.

v. About the nature of the regime. Whether it is to be legally binding instrument or a voluntary code.

vi. About the suitability of uniform law targeting at a totally diverse stakeholders. Whether or not a uniform system for the recognition and protection of traditional knowledge of the local and indigenous community will meet the expectations of this diverse group, for whom diversity is the lifeblood.

These issues need to be considered carefully and addressed astutely in the international context. Given the dynamic nature of TK, it can be protected by a holistic approach of protection at the national level and a restricted agenda at the international level with a legally enforceable regime.

India should choose a *sui generis* system, by way of a central legislation, as in the case of Plant Variety Protection Act to protect the biogenetic resources and TK. The New Act must endorse the role and value of traditional knowledge as well as the rights of indigenous people and of local communities who are the holders of his knowledge. Such a system could enable the country to protect the bio resources in a way that also protects the knowledge and innovations of local communities.
This new piece of legislation must translate the existing policy objectives into a binding legal instrument. It should provide for a system that will recognize and protect the rights of an individual as well as communities in regard to TK and IK and, at the same time, ensure fair and equitable benefit-sharing with communities from those who are using that knowledge and reaping benefits thereby.

8. 19. AMENDMENTS RECOMMENDED IN THE BIOLOGICAL DIVERSITY ACT, 2002

The Biological Diversity Act, 2002 requires some crucial amendments to convert the legislation as a legal tool to protect TK and associated resources.

8. 19.1. Need to clarify the concept of prior informed consent

Now, the interpretation of the concept of PIC is more about taking the consent of governments than of local communities. In the scheme of the Biodiversity Act, 2002, which is enacted in furtherance of CBD, powers regarding access to bioresources for obtaining IPRs vest largely with the National Biodiversity Authority (NBA) and the State Biodiversity Boards (SBB). Hence, in India if a pharmaceutical company wants to make commercial use of a plant and its traditional uses, it needs to get the PIC of the government, but not necessarily of the communities concerned. This provision must be amended as to mean the consent officially given through government but only after having the full consultation with the concerned indigenous communities and knowledge holders and after having obtained their PIC.

Community representation of the indigenous community in state and national biodiversity boards is weak in the present Act. There is no provision for the participation and decision-making of local communities. It is largely left to the national authority to take
the views of communities into consideration. The local committee only responds when consulted, and in any case consulting does not necessarily include obtaining PIC of the local community.

The Indian government and the international community must interpret PIC to mean not simply the consent of the national government or any department of the bureaucracy but participation and involvement in decision making and obtaining prior informed consent of the concerned indigenous community. The local committees’ participation is limited to documenting local knowledge in biodiversity registers. It does not even have the right to protect these registers from misuse or theft.

8. 19. 2. Need to clarify the concept of equitable benefit sharing

Both CBD and The Biological Diversity Act, 2002 speak about equitable benefit sharing. However there has been no attempt to define the term so far. It remains more as an idle concept than as a working principle. There must be some guidelines and regulations, at national and international level, to explain the concept and for its proper interpretation and implementation.

Mechanisms of benefit sharing must be on terms mutually agreed between the concerned community and the outsider who desires access, and the benefits must flow directly to communities. The Biodiversity Act, 2002 gives discretionary powers to the National Biodiversity Authority established under section 8 in matters of paying monetary benefits to the resource and knowledge providers. The National Biodiversity Authority can even direct the amount to be deposited in the National Biodiversity Fund.\(^{586}\) It is not

\(^{586}\) Section 21 (3).
mandatory that the benefits must be shared directly to the community. The Act, on these accounts, does not ensure transparency and accountability.

8.19.3. Need to include customary laws of the indigenous and local communities

The Biodiversity Act, 2002 totally ignores the rules, customs and practices existing amongst the indigenous and local communities. Since biodiversity and TK are more associated with indigenous and local communities, their customary laws must be given due importance than on arbitrarily imposing state made laws on them. The Act has to be modified taking into consideration these aspects.

8.19.4. Need to ensure participation of indigenous and local communities in decision making

In the scheme of the Act, the National Biodiversity Authority is empowered to grant approval to foreigners and non resident Indians to access biological resources and traditional knowledge.\textsuperscript{587} NBA is also empowered to grant approval for applications for intellectual property rights on innovations based on biological resources and knowledge.\textsuperscript{588} NBA, under section 21, has power to determine and ensure benefit sharing with the benefit claimers.

However, the indigenous and local communities have no effective representation in the NBA though the NBA is the sole authority to decide on the management, appropriation, use, conversion etc. of the resources and knowledge associated with the indigenous and

\textsuperscript{587} Section 4.
\textsuperscript{588} Section 6.
local community.\textsuperscript{589} It is an utter flaw of the Act. Their actual and effective participation must be ensured. The Act needs amendment to this effect.

State Biodiversity Board established under section 22 of the Act is the concerned authority to grant approvals for commercial utilization, bio-survey and bio-utilization of biological resources by Indians. More surprisingly, in SBBs, there is no representation of indigenous and local community who are the custodians of resources and TK and who are the benefit claimers.\textsuperscript{590} This is another major drawback of the Act. The Act needs an amendment to make provisions for the representation of indigenous local communities in SBBs.

Biodiversity Management Committees are the grass root management mechanism in the Act. But, the BMCs have no power and no role in any decision making process. The power to take all major decisions concerning the research and commercial utilization of the resources and knowledge by foreigners,\textsuperscript{591} approval to foreigners for IPR application,\textsuperscript{592} determination of equable benefit sharing,\textsuperscript{593} granting approvals for Indians for commercial utilization etc. of resources\textsuperscript{594} are vested with the National Biodiversity Authority and State Biodiversity Authority. The local level management mechanism might have also been given powers relating to these aspects.

Section 41(2) simply states that National Biodiversity Authority and State Biodiversity Authorities shall consult the concerned Biodiversity Management Committee while taking decisions relating to the use of biological resources and knowledge associated

\begin{footnotes}
\item[589] Section 8 (4).
\item[590] Section 22 (4).
\item[591] Section 3.
\item[592] Section 6.
\item[593] Section 21.
\item[594] Section 23.
\end{footnotes}
with the resources. What is needed is a mere consultation. The advice of the Biodiversity Management Committees is not binding on the National Biodiversity Authority and State Biodiversity Authorities. There must be provisions in the Act to ensure that the National Biodiversity Authority’s and State Biodiversity Authorities’ decisions are not detrimental to the long term interest and benefits of the local indigenous community but rather highly beneficial to them. The Act must incorporate provisions to ensure that NBA and SBSs are taking decisions as per the genuine interest and requirement of the local indigenous community.

8. 20. AMENDMENTS RECOMMENDED IN THE CONSTITUTION OF INDIA

Giving special protection to the vulnerable sections is not a concept alien to our Constitution. The Constitution of India provides special provisions for the protection of minorities, for socially and economically backward classes by reservation and for the people belonging to tribal area. The objective of this special protection is their empowerment to bring them to the forefront of the society. However, there is no special protection for the indigenous and local communities with reference to their unique TK and associated bio resources which they preserve, conserve and guard over centuries.

The issues of the protection of the rights of the indigenous communities over their traditional knowledge are not directly addressed in the Constitution of India which is the basic law of the land. Though Article 29 of the Constitution recognizes as a fundamental right the protection of the cultures of the minorities, it fails to recognize their right over

595 Constitution of India, Article 30.
596 Ibid., Article 15(4).
597 Article 371 read with Sixth Schedule of the Constitution.
indigenous and traditional knowledge.\textsuperscript{598} Though it is possible to protect the cultures of the distinct groups in India based on this provision it is not possible to protect the indigenous and traditional knowledge.

To value and preserve the heritage of our composite culture is a fundamental duty of every citizen under Article 51(f). However, we have not enacted so far any legislation based on this provision for translating this constitutional objective into reality. Thus we fail to protect not only the indigenous knowledge but their culture and heritage also.

The Constitution, considering the special cultural identity of the tribal population in India, envisages special protection for the indigenous communities, but not for their knowledge. Since they are scattered all over India, some living separately and others along with other sections of the society, the Constitution adopts different approaches to protect their cultural identities. The areas where there are tribal communities, as per Article 371 read with Sixth Schedule of the Constitution, the tribal communities are permitted to have separate autonomous council for self governance in accordance with their customary laws. The normal laws of the land are applicable only if accepted by the community and the council has the power to make laws even to protect their several customs. For other parts of the country as per Fifth schedule of the Constitution, the government has the power to create scheduled areas to protect the interest of the tribal community.\textsuperscript{599}

Irrespective of the constitutional provisions envisaging protection and preservation of distinct groups, there are no special laws prohibiting the exploitations of rights of these communities. There are many customary norms in these communities prohibiting the use of

\textsuperscript{598} Article 29: Any section of the citizens residing in the territory of India or any part thereof having distinct language, script or culture of its own shall have the right to conserve the same.

\textsuperscript{599} The tribal people not falling in the above categories are subjected to the normal laws of the land.
some of their culture by outsiders and use of some even confined only to customary practices. Since there are no penal laws prohibiting the use of these resources by outsiders, increasingly they are being used for commercial benefits.

8.20.1. Special Legal and Constitutional Status to TK Holders

In the absence of any law to protect the traditional knowledge and practices of the indigenous communities, there is no obligation from a purely legal perspective to reward or compensate the communities responsible for the development and maintenance of such knowledge. This can be better achieved by giving special protection in the Constitution itself to the indigenous and local communities with reference to their knowledge. The indigenous communities’ right over their indigenous and traditional knowledge should be considered as a constitutional right and they must be given due place in the Constitution. Therefore, there is a need to amend the Constitution to incorporate provisions for the protection and preservation of indigenous and local communities’ knowledge and their biogenetic resources. It must be incorporated in the Part III of the Constitution dealing with enforceable fundamental rights as in the case of cultural rights of the minorities. Consequently the states have to devise their own legal mechanisms to enforce these rights. An amendment is desired in the Constitution to give special legal and constitutional status to TK holders.

8.21. CONCLUSION

The system of intellectual property rights, by principle, exists to encourage innovations and discourage embezzlement of knowledge. TRIPS agreement has established that knowledge is goods which can be traded. If so, there is no logic in distinguishing and discriminating between the ‘knowledge eligible for intellectual property protection in the
formal system’ and ‘traditional knowledge in the informal system’. There is no justification for the totally different treatment, existing under the TRIPS IPR regime, for innovations using modern technology and traditional knowledge. Both should be given same legal status and recognition.

The preservation and protection of traditional knowledge is not only a key component of the basic right to self-identification and a condition for the continuous existence of indigenous and traditional peoples; it is also a central element of the cultural heritage of humanity.

Hence, the rights of the indigenous local communities who preserve and conserve the bio genetic resources and associated traditional knowledge require immediate legal recognition and protection. There should not be any hesitation or delay to bestow property rights on the holders of traditional knowledge. The concept of ‘community/collective right over traditional knowledge’ must be developed urgently in the global IPR regime. The property rights of local and indigenous people who hold TK must be recognized and given effective protection both in national legislation and in international legal instruments. The national and international legal instruments in this field must be developed as soon as possible.

TRIPS have failed to provide for the positive protection of traditional knowledge, innovations and practices. Many countries are misappropriating TK using this lacuna existing in TRIPS. Hence, a revision is needed of IPR laws as reflected in TRIPS. Article 27.3(b) of the TRIPS agreement needs to be reviewed to provide for *sui generis* protection of traditional knowledge, innovations and practices, as in the case of plant varieties. If
TRIPS will remain unchanged, the developed countries will continue to import TK and other unprotected resources from our country which in turn, to our detriment, will be converted into intellectual property.

At the global level, traditional knowledge is still a relatively novel concern in international law. At present there is no binding and effective international law that safeguards and protects traditional knowledge and rights of the TK holders. Moreover, the TRIPS agreement does not mention traditional knowledge and there is no special treatment even by way of *sui generis* protection for traditional knowledge under TRIPS. The TRIPS has thus diluted the CBD objectives. The CBD mandate which stresses the importance of and the need to promote, international, regional and global cooperation amongst national states, intergovernmental organizations and non-governmental sectors for the conservation of biological diversity and sustainable use of its components, must be transformed into reality by devising appropriate legal and policy measures at international, regional and national levels. For this, traditional knowledge must be recognized by the global community as a scientific knowledge system developed, nurtured and preserved by the indigenous, local and rural people, traditional healers, artisan communities etc., which is inseparably linked with their economic life, social culture and very existence.

Biopiracy must be condemned and forsaken by the international community as illegal and unethical appropriation of bioresources owned by the indigenous and local communities which would perturb the continuous improvement, evolution and development of TK and which in turn would lead to the complete erosion of traditional knowledge systems existing in different parts of the globe. Hence, as submitted by India at
WIPO, there is a need to provide appropriate legal and institutional means for recognizing the rights of tribal communities on their TK based on biological resources at the international level. There is also a need to institute mechanisms for sharing of benefits arising out of the commercial exploitation of biological resources using such TK. This can be done by harmonizing the different approaches of the Convention on Biological Diversity on the one hand, and the TRIPS agreement on the other, as the former recognizes sovereign rights of States over their biological resources and the latter treats intellectual property as a private right.

Piracy of indigenous knowledge will continue until global patent law regime directly address this issue, exclude patents on indigenous knowledge and trivial modifications of it, and create *sui generis* systems for the protection of collective and cumulative innovations of indigenous and local communities. The protection of diverse knowledge system of traditional practices and innovations requires a diversity of IPR systems, or combination of IPRs including systems that do not reduce knowledge and innovation to private property for monopolistic profits. Systems of common property in knowledge need to be evolved as in the case of geographical indication for preserving the integrity of indigenous knowledge systems on the basis of which everyday survival of indigenous community is based.

TRIPS must devise an international intellectual property regime that maximizes the potential for both traditional knowledge and modern scientific innovation to contribute to

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economic progress. To achieve this effect, the TRIPS must be reviewed and amended with the following aims:

i. To establish the concept of community property right with respect to traditional knowledge

ii. To recognize communities' rights over their resources and TK

iii. To recognize, safeguard and protect the traditional knowledge, innovations, practices and technologies of indigenous and local people and communities

iv. To mandate legal protection for TK

v. To recognize the sovereign rights of states over their biodiversity and genetic resources, and

vi. To mandate the principles of prior informed consent and benefit sharing when other countries access the biogenetic resources and associated TK of indigenous and local communities.

Such an amendment will remove the inherent tension between CBD and TRIPS. It also will resolve the conflict between private rights of IPRs holders and community rights of traditional knowledge holders. It will ensure that the provisions of the CBD take precedence over TRIPS agreement.

Having considered its richness in traditional knowledge and associated resources, India should lose no time in starting the movement for amendment of TRIPS. An international mechanism is urgently needed to stop free import of knowledge from India. Being the champion for developing countries at international fora, India must coordinate
amongst other green rich and bio rich nations blessed with TK and voice their concern in all appropriate forums like, WTO, WIPO, UN etc.

Now, coming to the national scenario, past experiences reiterate that our traditional, indigenous and local knowledge and associated resources are being used to make patented commodities for global trade. India could, certainly revoke certain patents based on our precious TK. But, how long and how many times should Indian government indulge in this legal battle? Having a law in place to protect TK would have made it difficult for foreign countries to patent products based on our traditional knowledge associated with plants like neem, turmeric, karela, brinjal etc. so unique to India. Issues like neem patents and turmeric patents should not reoccur.

Biopiracy threatens the every day survival of ordinary Indians who belong to indigenous and local community and who hold valuable TK. If biopiracy is not stopped, our unique TK will be continuously threatened, misappropriated and patented by foreigners. Failure to enact appropriate legislation for the protection and conservation of TK is costing the country dearly.

What is common community knowledge cannot be allowed to be a subject of patent in the garb of IPR. It is the urgent need of the hour to rejuvenate the traditional systems of community management in order to counter the idea of biopirating, privatizing and converting the community knowledge into IPR. Care must be taken to ensure that IPR systems do not reduce valuable and highly potential traditional knowledge and innovations into private property for monopolistic profits of others.
India should undertake a more proactive legal policy to secure, safeguard and protect its TK and enforce the rights of TK holders in the new world order. An effective protection would serve as a mechanism to prevent third parties from unduly appropriating traditional knowledge. However, it requires the documentation of all categories of traditional knowledge, innovations and practice, identification of beneficiaries and devising of an appropriate legal tool for implementation. An effective protection for TK would address all matters affecting the availability, acquisition, scope, maintenance, and enforcement of rights and interests related to TK, as well as those matters affecting the use, exercise and administration of rights and interests in TK.

The crucial importance of indigenous, traditional and local communities in preserving and nurturing biodiversity, biogenetic resources and associated traditional knowledge must be legally recognized by establishing the concept of community right. The legal recognition of community rights over biogenetic resources and associated traditional knowledge is fundamental to the protection of TK. The Indian government must develop suitable strategies including legal mechanism and policy decisions for safeguarding and enforcing the community rights of indigenous local communities over their traditional knowledge and associated biogenetic resources.

The government must also develop appropriate policy measures to implement the recommendations of National Knowledge Commission (NKC). NKC has made several recommendations on strategies to promote the knowledge systems of traditional medicine which include transformation of traditional medicine education by introducing evidence-based approaches, strengthening research on traditional health systems, strengthening pharmacopoeial standards, promoting traditional medicine by increasing quality and
quantity of clinical trials and certification process, by digitizing traditional knowledge and by creating suitable framework of intellectual property rights, by establishing goals for conservation of natural resources, by promoting international cooperation, by supporting primary healthcare in rural areas creating a major re-branding exercise of Indian traditional medicine.602

The protection of traditional knowledge raises a number of issues such as the objectives and modalities of such protection and its impact. Such issues are extremely complex since there are broad differences about the definition of the subject matter, the contents of right, the rationale for protection, enforcing mechanisms, etc. The possible protection regime largely depends on how traditional knowledge is defined. The issues relating to traditional knowledge should be addressed in a holistic manner, including ethical, environmental and socio-economic concerns. Because, the social value of the basic traditional knowledge innovation is greater than the private market value of the knowledge as it is compounded by the value of the subsequent innovations also. The social value of traditional knowledge further includes any costs borne by the community due to its loss of traditional knowledge on commercialization. Similarly, it also includes any gains to the community that accrue from sharing of the profits from subsequent innovations developed.

There are, in addition, still many unresolved technical issues such as the problem of collective ownership and the modes of enforcement of rights. One reason for lack of clarity about the rationale for protection stems from the different meanings given to the concept of protection. Some understand this concept in the context of IPRs, where protection

essentially means to exclude the unauthorized use by third parties. Others regard protection as a tool to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. Protection has a more positive role in supporting traditional knowledge-based communities’ livelihoods and cultures, as proposed by the Organization of African Unity’s (OAU’s) Model Law and its definition of community rights.

The consideration of traditional knowledge protection should not overshadow the fact that the preservation and use of traditional knowledge require ensuring the survival and improvement of living conditions and cultural milieu of such communities. Indigenous and local communities must be given right to participation in rule making process. At the local level, the local and indigenous communities have interests to ensure that the use, exchange and benefit sharing aspects respect their customary laws and institutions. Indigenous communities need to be included and involved at every stage of such rule-making process involving the issue of access and benefit sharing.

Hence, there is an urgent need to design a *sui generis* legal mechanism in India for the purpose of

i. promoting respect, preservation, wider application and development of TK

ii. preserving and conserving its rich traditional knowledge base of all categories

iii. recognizing and promoting the collective legal rights of indigenous and local communities over their TK

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605 A Model Law on the Protection of Traditional Knowledge and Community Rights is drafted and attached as part of this research.
iv. enabling traditional, indigenous and local communities to continue using TK in the context of their traditional practices, customs and lifestyles

v. preventing the unauthorized use and misappropriation of TK

vi. providing mechanisms for the enforcement of rights of TK holders

vii. encouraging TK based innovations

viii. ensuring fair and equitable sharing of the benefits arising from the commercialization of TK

ix. promoting the conservation and sustainable use of biological resources and associated TK

x. guaranteeing the participation of local and indigenous communities in the policy and decision-making processes related to TK

xi. facilitating reasonably controlled access to TK for research activities, and

xii. balancing the conflicting claims between intellectual property rights and traditional knowledge.
PROPOSED MODEL LAW
FOR
THE PROTECTION OF TRADITIONAL KNOWLEDGE

PROTECTION OF TRADITIONAL KNOWLEDGE AND COMMUNITY RIGHTS BILL, 2009

INTRODUCTION

Knowledge, practices, innovations, methods and manners or technologies created or developed over generations by local communities on the conservation and use of genetic resources or used in different fields of human activities play a vital role in many fields including healthcare, agriculture, food preservation and sustainable development. All forms of knowledge with whatsoever name they may be called including indigenous knowledge, local knowledge, folklore, knowledge regarding traditional medicines, its uses, preparation, handicrafts, expressions of culture, method of treatment, or any process of manufacturing product, knowledge about the use of plants, seeds etc. fall within the concept of traditional knowledge. Traditional knowledge, in most of the cases is interlinked or closely associated with the biological resources and/or genetic resources.

STATEMENT OF OBJECTS AND REASONS

Protection of traditional knowledge is important in many ways. India is abundantly rich in biogenetic resources and associated traditional knowledge which is equally important as its modern scientific knowledge. India’s traditional knowledge is being severely threatened and misappropriated by the foreign citizens, corporations and countries
and had to litigate in foreign countries in several occasions to invalidate patents claimed by foreigners based on Indian traditional knowledge. It is also necessary to involve communities in the making of decisions concerning the use of traditional knowledge and use of biogenetic resources and sharing of benefits derived from the utilization thereof. At present, India does not have a law, either to recognize, protect, promote traditional knowledge, involve the holders of such knowledge, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices or prevent abuse or misappropriation, of traditional knowledge. Moreover, India is a party to the United Nations Convention on Biological Diversity 1992, signed at Rio Janerio on June 05, 1992, which came into force on December 29, 1993. The protection of traditional knowledge is necessary to fulfill our obligation under the said Convention which recognizes the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from use of traditional knowledge, innovations and practices. The said Convention requires contracting parties, through national legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and to promote the wider application of traditional knowledge, innovation and practice with the approval and involvement of the holders of such knowledge, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Hence, it is deemed fit to introduce this Bill to provide for the protection of traditional knowledge and to recognize the community rights of holders of traditional knowledge and for matters connected therewith or incidental thereto.
CHAPTER I
PRELIMINARY

1. Short title, extent and commencement

1). The Bill may be called the Protection of Traditional Knowledge and Community Rights Bill, 2009

2). It extends to the whole of India.

3). It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint; and different dates may be appointed for different provisions of this Bill, and any reference in any such provision to the commencement of this Bill shall be construed as a reference to the coming into force of that provision.

2. Definitions

In this Bill, unless the context otherwise requires

(1) Access permit means the permit issued by the Registrar to a third party on the recommendation of Traditional Knowledge Management Board;

(2) Benefit sharing means equitable sharing of benefits, on agreed terms, arising form the commercialization of knowledge by a registered user or a third party with the knowledge holders. It will also include commercialization of biogenetic resources and associated knowledge.

(3) Biological resource includes genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystem with actual or potential value for humanity;
(4) *Community* means a human population permanently residing in a distinct geographical area in India as a custodian of a given bio resources or genetic resource or creator of a given community knowledge. The community may include, all groups known by whatsoever category, indigenous people, local people, aboriginal people, etc. maintaining a culture of their own, occupying a specific territorial area, practicing or holding any special knowledge and recognizing themselves as such;

(5) *Community knowledge* means codified or uncodified knowledge accumulated or evolved by the communities refereed above concerning the properties, uses and characteristics of components of biological diversity;

(6) *Commercial exploitation* means any misuse or abuse or management or appropriation of the traditional knowledge with the intention of making profit;

(7) *Community rights* means rights given to the communities holding traditional knowledge;

(8) *Community traditional knowledge* means knowledge that which belongs to a community and not to particular individual. It may also include knowledge belonging to two or more persons in the community;

(9) *Ex situ* means a condition in which biogenetic resource is found outside of its natural habitat;

(10) *Genetic resource* means any genetic material of biological resource containing genetic information having actual or potential value for humanity and it includes derivatives;

(11) *In Situ* means a condition in which genetic resource is found in its natural habitat or ecosystem;
(12) *Individual traditional knowledge* means knowledge that belongs to a particular person.

(13) *Prior informed consent* means the written consent issued by the concerned authority indicating the purpose and conditions of the consent;

(14) *Protection* of traditional knowledge means preservation, conservation, promotion, sustainable development, encouragement, perpetuation and maintenance of traditional knowledge and associated resources;

(15) *Third party* includes any citizen of India, body corporate, partnership firm, foreign national, foreign firms doing business in India;

(16) *Traditional knowledge* means knowledge, practices, innovations, methods and manners or technologies created or developed over generations by local communities on the conservation and use of genetic resources or used in different fields of human activities. It will include but not limited to all forms of knowledge with whatsoever name they may be called including indigenous knowledge, local knowledge, folklore, knowledge regarding traditional medicines, its uses, preparation, handicrafts, expressions of culture, method of treatment, or any process of manufacturing product, knowledge about the use of plants, seeds etc;

(17) *Traditional knowledge holder* means any natural person or local community that holds or possesses traditional knowledge;

(18) *Traditional Knowledge Management Board* unless the context otherwise specifies, means the Board constituted under Section 19 of this Bill;

(19) *Traditional knowledge Registry* means the Registry established under the Bill for the purpose of registering traditional knowledge;
(20) *Use of traditional knowledge* means use of individual traditional knowledge and/or use of genetic and bio resources found in *in situ* or *ex situ* conditions, associated with the application of traditional knowledge.

**CHAPTER II**

**SCOPE OF PROTECTION**

3. **Scope of Protection of Traditional Knowledge**

(1) The following shall be the scope of protection under the Bill;

a) To promote respect for and for the protection, preservation, wider application and

b) development of the collective knowledge of communities holding and practicing traditional knowledge;

c) To promote the fair and equitable distribution of the benefits derived from the use of that collective community knowledge;

d) To ensure that the commercial use of the knowledge by third parties takes place with the prior informed consent of the concerned communities;

e) To promote the strengthening and development of the potential of the communities and of the machinery traditionally used by them to share and distribute collectively generated benefits

f) To ensure that the country and its communities obtain fair and equitable share from the benefits arising out of the use of biogenetic resources so as to promote the conservation and sustainable utilization of the country’s biodiversity resources

g) To avoid misappropriation of traditional knowledge and situations where intellectual property rights are granted for inventions made or developed on the
basis of collective knowledge of the Indian communities holding traditional knowledge

(2) The traditional knowledge shall be protected in its existing form. The Bill will apply to traditional knowledge associated with biological resources and genetic resources found in in situ or ex situ conditions and traditional knowledge.

CHAPTER III
REGISTER AND PROCEDURE FOR REGISTRATION

4. Registry of traditional knowledge

The central government may establish a Registry known as Traditional Knowledge Registry for the purpose of registration and protection of traditional knowledge. However, the non-registration of any community knowledge shall not render it unprotected by community rights.

5. Register of traditional knowledge

For the purpose of the Bill, a record called register shall be kept at the office of the Registry for Traditional Knowledge wherein description of the holder of the traditional knowledge and description, details and such other matters relating to the registered of the traditional knowledge shall be shown.

6. Application for registration

1) (a) Any individual or (b) association or organization representing the true interest of local community, as the case may be, may register his/ her or their traditional knowledge in the respective parts of the register under various classes.
2) Application to the Registrar shall be filed by the intended registered user jointly with the traditional knowledge holder.

3) The Registrar will forward the application to the Traditional Knowledge Management Board for its recommendation.

4) The Board shall cause the matter to be advertised for wide dissemination in national newspapers and receive comments/objections of interested parties.

5) The Board shall then hear all the interested parties and give its recommendation to the Registrar.

6) The Registrar shall then take a decision in the matter in accordance with the recommendation of the Traditional Knowledge Management Board.

7. Nature of the traditional knowledge

The Registrar shall classify the traditional knowledge that may be protected under the Bill as individual traditional knowledge or community traditional knowledge.

8. Part A and Part B of register

Individual traditional knowledge may be registered in Part A of the Register.

Community traditional knowledge may be registered in Part B of the Register.

9. Classes of traditional knowledge

The Registrar can notify various classes of traditional knowledge. The traditional knowledge is to be registered under the respective classes. In appropriate cases there can be multi class registration.
10. Certificate of registration

On registration the Registry will provide the holder of traditional knowledge a certificate of registration.

CHAPTER IV
EFFECT OF REGISTRATION

11. The certificate of registration will be conclusive proof as far as the title of the holder is concerned.

12. The 50% benefits arising out of the use of traditional knowledge by the registered user shall be shared with the holder through the Traditional Knowledge Management fund.

13. The holder of traditional knowledge or the local community, as the case may be, will be entitled to prevent the access genetic resources or community knowledge unless with a written access permit granted by the Registry based on prior informed consent.

14. Regulation to access to traditional knowledge

1) No third party shall access genetic resources or community knowledge unless with a written access permit granted by the Registry based on prior informed consent.

2) The granting of permit to access Traditional Knowledge and associated resources shall not be construed to constitute permit to access the traditional knowledge associated therewith and vice versa.

3) Every application must reveal the following essential information:
   a) the identity of the parties to the agreement
b) the class and description of the traditional knowledge permitted to be accessed

c) the description of the resources associated with the traditional knowledge permitted to be accessed

d) the intended use of the traditional knowledge and associated resources

e) the benefit to the community and the state if access is permitted

f) the duration of the access agreement

The Registrar may ask for any further information.

4) All such applications will be forwarded to the concerned Traditional Knowledge Management Board/Boards. The Board/s must disseminate the application to all the concerned traditional knowledge holders and registered users. After forming the interest of the traditional knowledge holders, the Board will communicate its opinion to the Registrar.

5) On the recommendations of the Traditional Knowledge Management Board/Boards, the Registrar may decide to grant permit to access traditional knowledge or related resources.

6) The Registrar will permit access to resources ONLY IF it is necessary to use and access the traditional knowledge.

7) The permit will be subject to the following conditions.

a) No intellectual property right over any product based on the traditional knowledge accessed shall be sought in any country without the explicit
written prior informed consent of the traditional knowledge holder or the local community given through the traditional Knowledge Management Board.

b) Undertaking not to transfer resources and/or the community knowledge accessed to any other third party or to use same for any purpose other than that originally intended, without the prior written permit of the Registrar.

c) Share the benefit that may be obtained from the utilization of the genetic resource or traditional knowledge or associated resources accessed with the traditional knowledge holder or the local community as the case may be.

d) Respect the cultural practices, traditional values and customary laws of the local community in matters of access and use of the traditional knowledge and associated resources.

8. In case of non compliance of terms and conditions in the access permit the Registrar, on the recommendation of the Traditional Knowledge Management Board will suspend or terminate an access agreement. If the access causes risk of damage to resources or the environment or affects overriding public interest, the registrar may cancel the permit.
CHAPTER V
OWNERSHIP

15. Ownership

1) The ownership of biological resources and genetic resources shall be vested in the state and the Indian people.

2) The ownership of community knowledge shall be vested in the concerned local individual or local community.

16. Rights of local communities

The local communities shall have the following rights over their community knowledge:

1) The right to regulate the access to their community knowledge: it will consists of the right to give prior informed consent for access to their community knowledge; and the right to deny access or give conditional access to their community knowledge if they deem fit to do so.

2) An inalienable right to use their resources and community knowledge in the course of sustaining their livelihood systems in accordance with their customary practices or norms.

3) The right to share from the benefit arising out of the utilization of their genetic resources and community knowledge: The communities shall have the right to obtain minimum of 50% of the benefit shared by the state in the form of money from the benefits derived out of the utilization of their traditional knowledge and associated resources.
17. Joint ownership

If there is more than one claims in respect of a particular traditional knowledge, and if the Registrar is satisfied as to its possession by both the claimant, on the evidence furnished by the Traditional Knowledge Management Board, may register the traditional knowledge in respect of both the holders.

18. Transferability and assignability

Both Individual and community traditional knowledge shall not be transferred, licensed, sold or gifted. Both Individual and community traditional knowledge shall not be assigned.

CHAPTER VI

TRADITIONAL KNOWLEDGE MANAGEMENT BOARD

19. Traditional Knowledge Management Board

1) Every District will have a Traditional Knowledge Management Board.

The Board will have the following functions:

(a) to identify, interpret and ascertain various categories of traditional knowledge existing within its jurisdiction

(b) to identify the holders of traditional knowledge

(c) to ensure for the preservation and protection of the traditional knowledge

(d) to assist the traditional knowledge holder in the registration of traditional knowledge

(e) To assist and guide the Registrar in case of counter claims on traditional knowledge
(f) To assist the community in determining the terms favorable to then in access contracts and benefit sharing agreement

(g) To educate the members with in their jurisdiction about the importance of traditional knowledge and the need to protect traditional knowledge and associated resources

(h) to start institutions or associate with existing institutions on research and development of the traditional knowledge

(i) To facilitate protection and preservation of traditional knowledge

(j) To start units for commercial exploitation of the traditional knowledge involving the members of the locality.

(k) To represent the interest of the traditional knowledge holders to Registrar

(l) To represent the interests of the traditional knowledge holder/s in all appropriate forums and to defend the traditional knowledge holder/s in all the disputes.

(m) Continuously evaluate the research activities undertaken by a third party subsequent to an access permit

(n) To create a traditional knowledge fund for the district and determine its utilization

(o) To initiate billion against persons exploiting traditional knowledge owned by the authorities without prior informed consent.

(p) To constitute Dispute Settlement Committee

2). The Traditional Knowledge Management Board shall have the powers to formulate necessary regulations for the purpose of discharging its function.

3). The Traditional Knowledge Management Board shall consist of nine Members. The District Magistrate will be the chairman of the Board. Three members shall be
nominated by the District Magistrate having regard to the knowledge and expertise in anthropology, environmental issues and legal matters. Five members, of which two shall be women, shall be selected from the indigenous and local communities having regard to their expertise and practice in various traditional knowledge systems. The right to select the representatives shall lie with the community.

CHAPTER VII
BENEFIT SHARING

20. (1) All access permits will be subject to a benefit sharing agreement.

(2) Along with the monetary benefits the non monetary benefits may include:

a) Joint ownership of intellectual property;

b) Employment opportunity;

c) Participation of Indian nationals in the research based on the knowledge or/and resources assessed.

d) Access to products and technologies developed from the use of genetic resource or community knowledge accessed

e) Training, both at institutional and local communities levels, to enhance local skills in biogenetic resources conservation, evaluation, development, propagation and use.

CHAPTER VIII
SETTLEMENT OF DISPUTES

21. Dispute Settlement Committee

(1) The Traditional Knowledge Management Board shall constitute a Dispute Settlement Committee for the purpose of settlement of the dispute regarding the exclusive right to
manage the traditional knowledge; disputes arising out of access permit and benefit sharing agreement.

(2) Decisions of Traditional Knowledge Management Board may be appealable to the Registrar.

22. Civil remedies for commercial exploitation of the traditional knowledge without prior permission

Where traditional knowledge or associated resources has been commercially exploited without the prior permission of the concerned managing committee of the authorities, the authority shall be entitled to all such remedies by way of injunction, damages and accounts of profits.

CHAPTER IX
OFFENCES, PENALTIES AND PROCEDURE

23. Penalty for commercial exploitation of traditional knowledge without prior permission

Any person who commercially exploit or attempt to exploit or abet the commercial exploitation of any traditional knowledge or associated resources shall, be punished with imprisonment for a term which shall not be less than six months but which may extend to three years and with fine which shall not be less than one lakh rupees but which may extend to three lakh rupees.

24. Enhanced penalty

Whoever having already been convicted of an offence under this Bill is again convicted of any such offence shall be punishable for the second and for every subsequent offence, with
imprisonment for a term which shall not be less than one year but which may extend to	hree years and with fine which shall not be less than one lakh rupees but which may extend to two lakh rupees:

Provided that the Court may, for adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term less than one year or a fine of less than one lakh rupees.

25. Offences by companies

If the person committing an offence under this Bill is a company, the company as well as every person in-charge of, and responsible to, the company for the conduct of its business at the time of the commission of the offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punishable accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Bill has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or that the commission of the offence is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation:- For the purpose of this section-
(a) “company” means any body corporate and includes a firm or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm

26. Jurisdiction of the Court

(1) No court inferior to that District Court shall try an offence under this Bill.

(2) The offences under this Bill shall be cognizable.

(3) In all matters arising under this Bill the burden of proof shall lie on the third party.

CHAPTER X
MISCELLANEOUS

27. Application of existing laws

Notwithstanding anything contained in any other law in force, all matters connected with the protection of traditional knowledge and associated resources shall be exclusively governed by the provisions of this law.