Forum for Biotechnology and Food Security

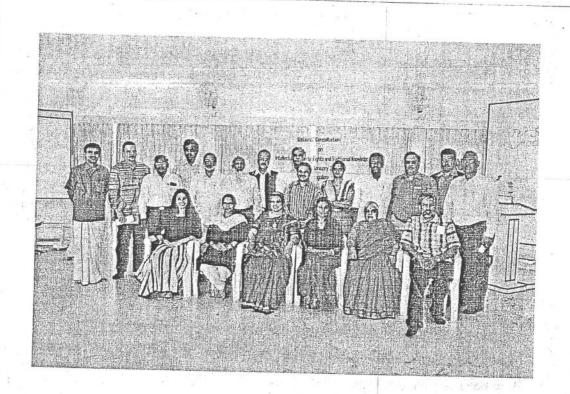




## 1<sup>st</sup> National Consultation on Intellectual Property Rights and Traditional Knowledge

30 - 31 January 2009 School of Ancient Wisdom, Devanahalli, Bangalore

Summary Report



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Global Overview of the political and philosophical TK-IPR frameworks: Need for a common framework

#### Ms. Shalini Bhutani, GRAIN

Ms. Shalini Bhutani began by stating that her presentation would take a closer look at what traditional knowledge 'protection' has come to mean amidst the global politics over genetic resources and related TK, it would also revisit some fundamental concepts, and finally on the premise that there are problems in the existing framework it will

take a view of the 'alternatives'.

Traditional knowledge and IPR (Intellectual Property Rights) belong to inherently different frameworks. So the need is for an 'un'-common framework not one which tries to wed the two. Yet both are being discussed in the same breath in the discussions globally as well as in the domestic space, where the actual implementation is done. Therefore, the difficulties are arising from attempting to reconcile what are two opposites. Given this, there is a need to understand the perception of 'protection' of TK, the fundamental principles of protection, its current framework and its position within the current political economy, and how its has got enmeshed in IPR. The challenge is to develop a framework for TK protection thinking 'outside the box' of IPR.

The purpose of IPR is to privatize, and in according rights and legal entity to the corporation entitling it for economic rights. In this context, the issue of 'rights' within the framework completely ignores the idea of the collective. There is need to examine whether community 'rights' if on IPR lines, are facilitating the collectivism with which the community developed a knowledge system or is it actually breaking up the community and its tangible and intangible components. 'I' and 'Inc.' are touted as the best forms of property in today's times. There needs to be conceptual clarity on whether TK is 'heritage' or 'property' that can be traded. The challenge is to recover spaces for the collective, rather than negotiate for space in the market to participate for an illusory share of 'benefit' from a pro-privatisation policy framework. The discussions and transactions of genetic resources iare being done in the language of sovereign rights. Where governments are not facilitating community sovereignty. States themselves misusing the 'sovereignty principle' are usurping power over natural resources. IPR further takes the sovereign right of decisionmaking on TK and related resources away from local people and into the hands of corporations. The focus on IPR in according 'private' rights is facilitating commodification of TK and its privatization.

Though there is a vision in law on actualization of equity and justice and effecting a balance through a just legal system, in reality traditional knowledge has transited from the framework of communities into the framework of privatization and into the framework of commodification. This is creating new injustices. Subsequently, value added and packaged products have been made using traditional knowledge and are sold back. Local communities who see their knowledge and resources being prospected, documented and collected are



1. Untangling the existing conceptual IPR traps: Search for a new pathway to protect traditional knowledge.

Dr. Devinder Sharma, Forum for Biotechnology & Food Security

Dr. Devinder Sharma initiated the national consultation by stating that despite considerable discussions and debates on IPR and non-IPR over the years, concrete interventions

to protect the traditional knowledge of communities and holders are lacking.

Therefore, the genesis of the national consultation on traditional knowledge and intellectual property rights lies in the need to get varied stakeholders and representations on a common platform and to crystallize various ways to take the issue beyond discussions. The underlying basic interest and concern is to protect the communities, and ensure that their interests are not bartered.

By devising a national level legal mechanism to protect traditional knowledge and its holders, it would be possible to take proactive steps that will go beyond waiting for international acceptance or recognition of traditional knowledge rights. Though a few initiatives have been authored in this direction, there is a heed to arrive at a consensus without reinventing the wheel and to promote better understanding between various stakeholders.

Acknowledging the expertise and experience of the participants, who would discuss divergent issues such as access and benefit sharing, notification of knowledge in the case of traditional knowledge, understanding of the Intellectual Property Rights, the successful models in India, learning from external experiences, and geographical indications of the farmers rights', Dr. Sharma emphasized on the need for togetherness in order to make a difference. He appreciated the support of Thanal in organizing the consultation and shared that the National Biodiversity Authority had indicated its support should there be a subsequent consultation meet in future.

Recalling that the debate on globalization actually began with the IPR issue, Dr. Sharma observed that it does not have the same intensity at present as a national issue as it did in the past. Many believe that the IPR and the National Biodiversity Authority are taking care but there is need to collectively build up the deliberations again, especially as much of the knowledge has already slipped out. It is time to act and react.

...

being told that you give us your TK as is, but for you your TK as is, is not good enough!

Over the years, what was considered natural is now slowly being made illegal through IPR law enforcement. Be it saving seeds, sharing songs, reproducing medicines, copying books. Therefore, the role of law needs to be examined to understand the definition of 'protection' - is it related to the products of traditional knowledge or the knowledge itself or its holders? What and whom is the system actually trying to 'protect'? TK needs protection FROM IPR and not BY IPR! What will a TK law need to be like to be able to 'protect'?

Unregulated access of physical material - the genetic resources, not just in Asia but in several parts of the world, has been systematically going on during colonial rules. Collections have been made through gene banks, botanical gardens, and research institutes. After many countries got independence the plunder continued under the cloak of 'common heritage of humakind'. The CBD principle of sovereignty only saw a transfer in these resources in from countries rich in genetic resources. And now the transfer is being done through IPR.

Orienting frameworks for protection of TK is critical

Where do we begin from? The starting point to orient frameworks for protection of traditional knowledge is critical in determining the future course of action. There can be several references to this benchmarking – for example – dating-back to the origins of traditional knowledge in agricultural history to the more contemporary Indian Patent Act (1970) or the CBD that came into force in 1993. But any endeavour will completely miss the point if it does not begin with the *de facto* knowledge holders and the customary frameworks that facilitated the TK generated thus far by local peoples.

Role of government - reality or myth

The lure of economic benefits upon commercialization of a product and the potential of subsequent social impact entices governments to enter discussions on access and benefit sharing. In addition, with the introduction of intellectual property rights, the governments feel empowered in the process of decision making. However in reality, the industry was facilitating the participation of the governments in the paradigm of privatization so as to make them part of the business of dealing and brokering genetic resources. The wealth redistribution is simply not happening; IPR are creating new poverties and disparities.

Therefore, there is need to understand the definition of 'wealth' - is it only an economic value or overall well-being and continuance of the traditional knowledge systems?

Legal processes

Several countries are in the process of developing legal systems which deal with access in trade, and the processes and procedures where the community could claim certain 'benefits'. Given this development, will new laws on genetic resources and traditional knowledge change either the pre-legal situation or the pre-existing legal situation? Giving examples from 5 South Asian countries she explained that due to external pressure most of these had made changes in

their IPR laws but their biological resources regulation, benefit-sharing rules and conservation mechanisms for knowledge were yet to be put in place.

Industry leveraging to the maximum

The discussion on 'access and benefit sharing' originated within the industry. Its stance was it would not share the benefits of commercialization with the knowledge holder, or the source unless its (the industry's) intellectual property rights on the knowledge is recognized. In other words, unless its economic rights of the 20 years of the term of the patent is recognized, the source will not get the benefits.

Ms. Bhutani also spoke about amendments the Indian Patent Act allowing the patenting of micro-organisms. Thus genetic resources held and used by local communities were bit by bit being fragmented and patented. For example, patenting one gene or one micro-organism of a plant or a forest. This is done because government and countries are not able to totally commit to an overall change in the patent system and level the domestic patent laws into conformity with international standards, therefore bit by bit, the attempt is to slowly move over to all-out patenting. India has already taken a first step towards IPR on plant material by legislating a PVP law.

Given this, since 1993, there has not been any headway internationally except that there are standard material transfer agreements, international transfer agreements, and standard formats being developed. The intent really is to facilitate industry so systems are made standard the world over. Similarly, efforts are to harmonize the intellectual property rights system across the board, and to harmonize the access procedure through a global ABS regime.

At international fora the Indian Government has been pushing disclosure of origin within the access regime to be able to guarantee some kind of trickle-back benefit for knowledge or materials sourced from the country. More recently it is in the lead of a group of countries demanding a 'Biodiversity Amendment' of TRIPS as a way forward. In the 'Biodiversity Amendment' being proposed within the TRIPS Council, developing nations' demanding reconciling TRIPS and CBD, three conditions are being proposed at the time of filing of an application for patent. But these conditionalities don't challenge the IPR system itself!

The kind of IPR policing that is happening through sanctions and the changes that are happening in enforcing point to how IPR infringements are now to be treated not as a civil offence but equivalent to criminal offence.

Way forward

So the long term objective of developing an alternative will need to look at who will control, whether the legal regime will shift control to more local biodiversity managed system and whether 'rights' be reviewed in a completely new frame. A frame that is not 'rights'-based but 'responsibility'-based. A frame that might be

more respectful of people's con complex relationships with booking-sity Disconting, cultural, economic, political and scarious

Ms. Bhutani concluded her presentation by suggesting the following measures to work towards possible alternatives:

1. Redefining benefits, where the benefits mean not only share from the commercialization but first guaranteeing full usage rights.

2. Rolling back privatization from certain resources and working at Government institutions so as to make them willing to revisit their stakes of ownership of resources.

3. Heritage-centred discussion Need for a wisdom culture which we need to nurture rather than allow it to be commodified.

4. 'Sharing' cultures - revitalising and reviving these





In India: TK provisions in Patent Act, Biodiversity Act and Geographical Indication Act

#### Dr. Malathi Lakshmikumaran

Dr. Lakshmikumaran began her presentation by outlining the broad meaning of traditional knowledge. This could include knowledge being rooted in a community specific culture, passed on from one generation to another. The threats to traditional knowledge include misuse by outsiders

commercial motivation. Therefore, the protection of traditional knowledge needs to adopt a two pronged approach of IP sense and preservation, conservation and sustainable use.

The use of intellectual property systems to protect TK includes parameters such as copyright, geographical indications, patents and plant variety protection. The major developing countries are keen to prevent biopiracy, develop international systems and work towards equitable benefit sharing and technology transfer.

Dr. Lakshmikumaran spoke about India successfully revoking the patent granted to WR Grace by EPO. She also took various examples related to efforts to patent neem, turmeric, amla and other plant varieties. The lessons learnt subsequent to these experiences reiterated the need to protect traditional knowledge in any form and evolve systems and laws for adequate protection in India.

Dr. Lakshmikumaran elaborated on the centre of origin of several cereals, fruits and spices and mentioned about various medicinal uses of different parts of the plants or roots. This was in context of potential bioprospecting activities that can optimize the sustainable utilization of biodiversity. For example, in agriculture, bio-insecticides can be derived from plants.

After explaining the relationship between biodiversity and technology, Dr. Lakshmikumaran spoke about a few provisions under TRIPS and the Indian Patent Act, 1970. She also added that there were inventions that were not patentable, and there was opposition to patents and revocation of patents.

Discussing the patentability of genetic resources, Dr. Lakshmikumaran emphasized the need to amend patent laws which included the need to disclose the source of geographical origin and provide proof that consent is acquired from the country from which they were taken.

Dr. Lakshmikumaran spoke about the Biological Diversity Act, 2002 that aimed to conserve biodiversity, use of biological resources in a sustainable way, and ensure equity in sharing benefits from use of resources. Geographical indications is a collective or community right.

Vis-à-vis traditional knowledge, Dr. Lakshmikumaran opinioned that geographical indications may be better than *sui generis* systems for the protection of that traditional knowledge where it is difficult to assign a specific right holder. GIs are also useful as they allow small local producers to sell directly to final users. At the same time, GI is inadequate to protect traditional knowledge in certain ways.

Dr. Lakshmikumaran ended her presentation by speaking about registered GIs and the protections they enjoy.

## National IPR debate - Community or Commodity?



Importance of Cross cultural understanding for evaluation of IPR Claims

## Dr. M N Balakrishnan Nair / FRLHT, Bangalore

Dr. Nair began his presentation by talking about the two streams of traditional medical knowledge that included codified stream and the folk medicine/ local health traditions.

The codified systems included theory and practices, documented in thousands of medical manuscripts belonging to the Ayurveda, Siddha, Unani and Tibetan schools.

The folk medicine, spread across more than 4,500 ethnic communities had a symbiotic relationship with codified systems. Folk medicine was available, acceptable and affordable and supported by local communities and is contained in more than 50,000 herbal formulations.

The present IPR system is based on the western knowledge systems and market economics while innovations of indigenous non-westernized knowledge systems are not recognized by patent offices.

The Indian traditional knowledge systems have a completely different perspective from modern science with the former believing in the oneness of a living being with all the elements in the world.

Dr. Nair further elaborated on the subject by highlighting the philosophical foundation of Ayurveda and the modern science. While the former deals with shad-darsanas, mainly the samkhya darsana and nyaya vaisesika (knowledge system) the latter is based on logical positivism and Aristotelian logic. While Ayurveda gives importance to direct perception, inference, analogy, logic and verbal testimony, modern science employs empirical methods including perception, induction and deduction. He also elaborated on the differences in the indigenous pharmacology and modern ones. While the former studies the impact of entire plant and/ or its part on parameters which broadly includes taste, qualities, potency after ingestion, post digestion state and biological activity of therapeutic agents, modern pharmacology isolates an active chemical entity from the plant and its parts and studies its in vitro and in vivo effects on the body.

While both have their benefits, the evaluation in indigenous knowledge is systemic while it is atomic or cellular in western medicine.

What may be commonly known knowledge in Ayurveda may be novel for modern medicine. Dr. Nair spoke about the use of Phyllanthus amarus which the folk tradition used for Hepatitis and the same was certified by a Nobel Prize Awardee, Dr. Barooch Blumbera.

In conclusion, Dr. Nair shared that western knowledge systems tend to perceive traditional knowledge systems as an information source that it could refine or innovate upon. However, traditional knowledge systems are profound in their own light and can be appreciated in their own epistemological framework.

Therefore, inter-cultural councils are essential to settle these disputes especially as there are no provisions for involving non-western knowledge systems in resolving patent claim disputes.





#### Prior Informed Consent (PIC) and Access and Benefit Sharing (ABS) in TK-IPR regimes

Dr. K Venkataraman, National Biodiversity Authority

Dr. K Ventakaraman traced the historical systems of utilization when hunters had free access to biodiversity resources, but over a period of time, this access became restricted. He quoted Mahatma Gandhi by stating that the earth has enough for everyone's need but not enough for the greed of even one person.

India is a country rich in biodiversity and about 8% of the world's biodiversity is housed here; however traditional knowledge is required for realizing its potential. Therefore, the issue of access and benefit sharing is of prime importance. In this context, the National Biodiversity Act, which the speaker believed, all Indians are stakeholders in, and which conforms to the Bonn Guidelines, has outlined various safeguards for protecting biodiversity.

A non-registered individual requires prior permission or approval from NBA to access biological resources or knowledge for various reasons including research and commercial purposes. In addition, any biological resources, or the results of research or related knowledge cannot be transferred without permission from NBA. The Patent (Amendments) Act, 2002, required the declaration of source of biological material used in the patent and deposit material in designated national repository.

Dr. Venkataraman said that the NBA takes a decision on approvals based on comprehensive and stringent evaluation measures. This includes the nature of bio-resource, reasons for access, source of access, ownership, permission guidelines and norms of access and benefit sharing. The applications are scrutinized and clarified and is assessed at various levels before a decision is taken. The formats of various applications related to access to bio-resources, transfer of research results, seeking IPR, third party transfer were shown by the speaker.

As of Jan 2009, 21 of 53 applications were approved in access to bioresources, 8 of 10 applications were approved in transfer of research, 250 of 283 applications were approved in Intellectual Property Rights, 16 of 20 applications were approved in third party transfer and 29 of 34 were approved in collaborative research. There are provision of revocation of access that include applications overriding public interest and failure to comply with any of the condition of access granted. The Act imposes restriction on access if the application is likely to, for example, has an adverse impact on the livelihoods of the local people, on the environment and is contrary to national interests.

The money received is deposited in the benefit sharing fund and is given to the identified community. This is the case of monetary benefits. Non-monetary benefits follow the guidelines prescribed. The sources of incoming to the biodiversity fund include the applications fee, compensations, benefit shares, contribution of national and international organizations and grant in aid while the outgoing is towards reimbursement of benefit shares, compensation and supporting conservation. This is at the national, state and local level.

Many issues posed several challenges to NBA. For example, identifying the exact geographical location of the origin of the medicinal plant in the case of purchase from the open market. Or when claimants state that they have cultivated a plant in their garden. In such case, the provisions of biodiversity Act shall not apply to bio-resources. Dr. Venkataraman highlighted the need to be cautious and careful about various issues related to benefit sharing and bio-resources.

## Misappropriation of TK and Traditional Knowledge Digital Libraries

#### Dr. Devinder Sharma

Dr. Devinder Sharma spoke about the way in which an initiative by Thomas Jefferson of US resulted in the country housing the largest gene bank of the world today. The request to US expats to send seeds led to country receiving around 10 million envelopes containing seeds. A separate department was constituted to catalogue the seeds. President Lincoln eventually formalized the body which the world knows as the US Department of Agriculture. Today, this Department is managing the world's agriculture.

Plant species are considered as mankind's heritage and gene banks were constituted for the safe custody of plant varieties in India and the world.

Though germplasm banks for wheat and rice were set up in Mexico and Philippines and other parts of the world, the US cited the need to maintain a copy due to security threats in these parts of the world. This resulted in an air base in Fort Collins in Fort Knox being converted in a gene back that is the only one to house all the germplasm varieties that is housed in various gene banks.

Under the CBD, it was accepted that plant varieties would be a national resource but the US Dept of agriculture is outside the purview of CBD.

Subsequent to possessing the world's largest collection of germplasm, there remained the issue of sourcing knowledge to understand its potential for utilization. This was done by funding projects that engaged personnel from the nation or community to research and document knowledge and make it available to the funder.

The reasons cited for documenting knowledge was that traditional knowledge, like genetic knowledge, is mankind's heritage. Hence, there is need for documentation. However, control of TK is being obtained in a manner similar to that collating germplasm only to from all over the world.

All over the world, the royalty to communities who are the source of traditional knowledge is insignificant. Hence, in the light of creating gene banks and documentation information, the information is being outsourced; benefit sharing is a dead concept. And this mistake of exporting gene species and traditional knowledge is being repeated.

In India, indications signify that many feel that documentation will come in handy to fight the patents in America. CSIR is doing the data base research in which was discovered that of the 4,000 patents which were drawn on plant species in America, 300 were from traditional knowledge from India from just seven species.

Giving an indication of the enormous challenge, Dr. Sharma remarked aseparate ministry has to be constituted to fight patents. Documentation is facilitating bio-piracy and is being used for commodification.

What is adding to the concern is that the Ministry of Commerce is expressing its inability to take the case forward due to lack of finance.

Though it is cited that documenting traditional knowledge is needed to defend and protect the community, several examples indicate that it is the corporations who are the real beneficiaries. The concept of benefit sharing is not defined very clearly.

Traditional Knowledge Digital Library (TKDL) mooted the concept of digital storage of traditional knowledge on CDs for circulation.

Dr. Sharma took an example of where in the symptom of dry eyes, as per the charit samita, was treated with the juice of the leaves of aloe vera. In the application for patent, it was claimed that the leaves of aloe vera are put it in distilled water, regarded as value addition for the cure of dry eyes. It was drafted in a manner which made it sound unique but actually the same traditional knowledge is used. He also added that patent applications run into several hundreds and thousands of pages.

Dr. Sharma said in order to protect traditional knowledge, the onus of responsibility of defending the patent should be on those submitting the application. He felt that if a patent is drawn on something that is traditionally known, the party should be prosecuted.

The onus of responsibility should be on the company which has drawn the patent - to defend the application and establish that this is not traditional. Now the onus is on the community which is taking the entire burden. In the case of Basmati, 50,000 pages were presented as part of the explanation that basmati was known since historical times.



#### Protecting Indigenous Technical Knowledge in Agricultural Practices

Framework for application of IP management in the protection of ITK in agriculture

Dr. P Das, ICAR

Dr. Das spoke about the efforts of ICAR in collection and documentation of 4880 ITKs and among things, the placement of the publication in various libraries (ICAR, agricultural universities and the World Bank). After giving a brief understanding of traditional knowledge, he spoke about the various initiatives for the protection of

indigenous knowledge.

Dr. Das also spoke about the non IPR mechanism of traditional knowledge protection - related to environment, health, trade and development, food and agriculture and the indigenous knowledge resource centres. The legal protection and administration of protection of traditional knowledge includes various measures such as creation of a regional network for the exchange of technical personnel and information.

#### First Day Discussions (pre-lunch) Highlights and summary (On patent, benefit sharing and protection of traditional knowledge and holders)

- Mr. Parveen Raj: The patent offices have people more with a background in chemistry; and are not proficient in Ayurveda or Siddha. As a result, decisions taken are based on the background proficiencies.
- Traditional knowledge should not be patented.
- Dr. Venkataraman there has been no disclosure till date in the access applications got so far that states that traditional knowledge is being accessed for research purpose. Almost all applications indicate benefit sharing.
- Many access bio resources for research purpose, say taxonomical purpose, and accordingly taxonomical applications have been received.
- When applications state that they are for research purpose, the evaluation also does include whether they can be for commercial purpose or not. They may lead to commercial purpose at a later stage. At the time of applying, the applicants have to state if research is for commercial purpose. However, when access is made for research purpose, NBA cannot ask for any benefit sharing. The website also indicates that whatever access made so far has been only for research purpose and that too basic research. There is no charging for access to research. There is no question of benefit sharing.
- NBA is in the process of preparation of guidelines for evaluation. Many Authority members are of the view that we can make our own guidelines and with our own people instead of looking at international support or expertise. However, interactions with United Nations and UNDP are required because of their knowledge and experience. India has pre-CBD cases (examples or experience) on benefit sharing and not on post CBD. Therefore, international authorities are being consulted on this issue as well. A separate committee is being constituted to prepare the guidelines.
- Dr Valsala Kutty raises a query on TK and TKDL regarding the perception of TK and TKDL and its misappropriation.
- Dr Lakshmikumaran replied that the patents granted by the USPTO were all valid ones.
- Dr. Sharma: For the world, the digital library is a remarkable product as it provides access to traditional knowledge.
- Dr. Lakshmikumaran: Most CSIRs have access to TKDL and ever lab is using TKDL to come out with ten or fifteen different patents. So it is that if one is an Indian, it is okay, you will do whatever you want, but if an outsider is using, and then we are questioning why it is being sold outside.
- Dr. Valsala Kutty: The issue is about taking the responsibility to protect something (TK) which is scattered all over India and ensuring that it is put for legitimate use. If this responsibility cannot be taken then it is better to leave it to the community.

## Some of the views of other speakers in the discussion

 Standards developed in the patent system originated from the western science system and philosophy dating back to 1620. They are not based according to Indian knowledge system and Indian innovations.

- Standards have been formulated by the patent office to look at science from the western perspective. This has led to not being able to appreciate Indian system especially as India does not have the culture of creating private property rights or patenting our tradition. For example, Ayurveda: Though there is protection, it differs from creating a private property based on the philosophy of patent system. Therefore, when confronted with these issues, it makes the patent system weak on the one side and incompetent on the other side to address the challenges.
- There are practical problems in the patent system. The patent decision is taken based on the documents available and the patent examiners understanding of the issue based on his or her training and experience. So a patent examiner uses the documentation and publications available for the purposes of identification of the inventory stamp. Traditional knowledge in effect is looking at it as it is while people use modern technology to document traditional knowledge into private property. Therefore, the decisions of patent systems need to taken by understanding the differing frameworks of two systems.
- Practical science has two types of evaluation of existing knowledge one is evaluation of the knowledge as it is, for the purpose of claiming access and benefit as it is, and two, the evaluation of the benefits arriving out of modification of traditional knowledge. We are talking about IPR being converted into 2% or 4% but it is not mandatory that every research leads to a new product. Are you-charging them for access at that point in time?
- If access to knowledge is for any other commercial purpose, then the person is not accessing it for value addition and selling a product and getting an IPR or whatever that may be. He is simply commercializing on that, what parameters do you use for the purpose of its evaluation? Do you use the modern evaluation methods of IP which has been developed by the West or do you have an independent evaluation policy where the evaluation is substantially different? How do you quantify the value of basmati, the value of neem or the value of anything based on that?
- When talking about the terms and conditions, one is one identifying the community to whom this knowledge belongs; two - is one consulting this community (including tribal communities, traditional medicine practioners) to find out what are the terms and conditions: three - does one take them seriously and accept them as it is.
- Regarding the role of National Biodiversity Authority/ State Biodiversity Boards and the Biodiversity Act in the conservation and sustainable use of biodiversity. The speaker also felt that it is impossible to expect Authorities or the Act regulatory mechanism for protecting something as complex, intricate and diverse as biodiversity and traditional knowledge. The speaker added: "This is an example of how we should not approach our problem of protecting our traditional knowledge as an authority system, as a regulatory clearance mechanism, rather than a conservation oriented mechanism."
- The digital library is the easiest way and an excellent tool to find out if patents could have been avoided. A speaker said that there are about 4,000 and odd patents granted by the USPTO and the digital library could have helped us in finding out if any of them could have been prevented.

#### First Day Presentations (post -lunch)

#### Existing Legal Frameworks



Kerala IPR Policy

#### Mr. Praveen Raj / NIIST

Mr. Raj proposed an IPR policy and not a legal framework. He added that legislations from western countries were adopted without understanding their implications. The Patent Act was not drawn for protecting knowledge, but for protecting inventions and innovations meant for industrial purposes. These inventions relate to application on products and their improvement.

The patent reviewer examines the documents, (he or she does not know whether the information provided is existing knowledge or related to new invention). The issue arises when knowledge is projected as invention.

Mr. Raj also spoke about Traditional Knowledge Digital Library not providing the solution, while at the same time, it was required and useful. He stressed that the interest of the communities be protected through the benefit sharing concept while at the same time, research also should be conducted.

At present, access and benefit sharing was not on knowledge but on biodiversity. There is need for benefit sharing on improvements made on traditional knowledge.

Commodity or knowledge is being traded for monetary value. There is need for *sui generis* IPR legislation. The rights will bring with it responsibility to protect, for which the government has to have a legal framework. This is the concept in the IPR system in Kerala. The solution includes bringing out a comprehensive national legislation for TK.

Mr. Raj made two suggestions to make the Kerala IPR policy operational. This includes having a knowledge custodian and a knowledge subscriber.





Farmer's Rights and PPV&FR Act 2001

#### Mr. Dipal Roy Choudhury, PPV and FRA

Mr. Choudhury began his presentation by speaking about the implementation of the Act. The PPVFR Act (Protection of Plant Varieties and Farmers Rights) says for registration of the new plant varieties, we need to do the field testing, and trans-testing to ascertain whether they are uniform. We hope that we will be able to register some of the farmer's varieties very soon.

The registration of plant varieties has various components and benefits including creation of a gene fund, compensation to farmers, compulsory license and ensuring right price at the right time to the farmers. There is a need to see what the legal framework is and how to protect the farmers.

Various Sections 8(1), 8 (2)c and 8(2) e outline the general functions of the Authority which overall promotes the development of new varieties of plants, protects the rights of farmers and breeders, provides for documentation and cataloguing of farmers varieties, and ensures that seeds of protected varieties are available to the farmers.

In addition, Mr. Choudhury outlined various other acts that defined what is farmer's variety, farmer's rights, the rights of communities, benefits sharing in PPV&FR Act, and the National Gene Fund.

### Best practices from across the globe

#### Ms. Shalini Bhutani /GRAIN

Ms. Bhutani clarified at the outset that since by default the current 'protection' regimes work to the detriment of TK protection and that there seems to be no real evidence of 'benefit-sharing' having happened since CBD, at best what she could present is experience from difference and not 'best practices' as the title suggested. She spoke about countries making efforts towards protect traditional knowledge despite various pulls and pressures. The efforts include drafting new laws and trying to bring the process of sovereigndecision-making as close to the community as possible.

There are attempts to try and accord legal status to collective knowledge and recognize it in its totality, rather than breaking it up in individual components. TK cannot be protected without also recognising full usage rights over the physical resources on which it is based.

In Peru, a national law already exists since 2002 that talks of TK protection. More recently in Jan 2009 while a new executive order favouring community control was being notified in the province of Cusco, the country's national government signed a bilateral trade agreement with the US wherein a new patent law was formulated. This IPR law stated that it did not recognize the collective intellectual property system of Peru. One bilateral agreement with US completely overwrote pre-existing protective provisions for TK in domestic legislation; it is also be seen how a progressive regional administrative order that said 'no' to biopiracy will be able to stay in force in the light of the new developments.

#### Africa

In Africa, the governments and the communities seem to take pride collectively in African culture and knowledge. Here, at least some governments seemed to be working not in competition but in collaboration. The OAU draft model law was one such example.

#### China

The Chinese framework was dealt separately with traditional Chinese medicines and agro biodiversity knowledge. A framework on how to protect traditional knowledge is bring proposed at the national level but this is not yet being made public. The government plans to implement it locally and then upscale.

#### Bangladesh

The draft biodiversity and community knowledge protection Act, written more than 10 years ago, never saw the light of the day because of political pressures, and pressures from the EU. This also includes provisions of signed trade, development and aid related agreements.

In many countries the biodiversity legislation not over and above the patent legislation and if there were to be a conflict, legally and otherwise, because of pressures outside the legal system, it would not be able to give pre-eminence to the law on conservation over the law of trade.

#### Costa Rica

The first pre-CBD benefit-sharing case spoken of is the Merck-INBio deal in Costa Rica. However, bio-prospecting failed as a conservation tool and the benefits did not trickle down to the communities.

Ms. Bhutani then spoke about the post-CBD scenario. A law was made that clearly accorded rights to local communities and indigenous communities to oppose any access to their resources. This was the sovereign principle of the CBD for the community as per Article 66.

Until and unless a system is worked out by which traditional communities, and their knowledge systems and their practices, can be protected, the local communities have the right to say no to access. So they were actually putting at bay, buying time, till an own *sui generis* system is developed. In the meantime, the US signs a free trade agreement with Costa Rica, and the latter is told to remove the option of *sui generis* subsequent to which the agreement will be signed. Under the FTA pressure Costa Rican government is also to provide UPOV 1991 standards of IPR protection for plant varieties, this will be be favour of seed companies. Since 14 January 2009 Costa Rica has become a member of UPOV Treaty.

There are some such good practices and legal provisions but it comes to facing the odds that include trade agreements, then it is a challenge.

#### New Zealand

In 1975, the Waitangi Tribunal was set up, and before that a claim was filed by six Maori tribes (the original inhabitants of New Zealand) and this is by far one of the most comprehensive claims made by indigenous people. The local communities created a linkage with the history of their practices and ways in which they had preserved their knowledge and resources. So the process of staking a claim went far back in history.

This was made possible because of the philosophy based on eco ethics.

Indigenous knowledge is neither a commodity nor a property. The need is for the space to exercise guardianship so that indigenous knowledge can be protected and preserved. And in fact, when the demand for rights is in many ways a disregard for what people have vis-à-vis their natural resources.

There is need to understand if the objective is the protection of the traditional knowledge or is it the protection of the knowledge holder itself. What is the status protection of that knowledge? Tribal communities are being displaced creating more development refugees. It is necessary to get out of this conundrum of rights and get into a holistic and broader usage of rights, creating caveats against monopolies by governments research institutions or private

There is need for a shared cultural heritage that cuts across borders and to introspect if it is time for a new civil disobedience movement against IPR and other forces of extreme privatisation.

#### First Day Discussions (Post-lunch) Highlights and summary

Dr. Vinod: In Germany, thousands of manuscripts from India are stored in underground cellars and being decoded by German Sanskrit scholars. It may come up as German property but the information has been taken away from here (India).

How secure is the information stored in traditional libraries? How does one know that it has not gone out?

The NBA needs to give more attention to the conservation and protection than the utilization of biodiversity.

Dr. Venkataraman: The 5,000 plant varieties and traditional knowledge linked with it is documented over a 15 year old ethno botanic study is right now with a private company in India. Thousands are available with in public domain and therefore, it is difficult to know what is it that we are trying to protect.

Dr. Vanaja: Query about the bio-diversity management committee at the

local level and locally available biodiversity register.

Dr. Venkataraman: A biodiversity register is being made using the national methodology, and being sent for review in order to ensure uniformity in the bio-diversity register.

Legal protection provision is there but its effectiveness depends on how it is developed. It should be fool proof, and should not make the traditional community suffer. India has got the maximum traditional knowledge in the world.

Ms. Usha: India always looks outwards for the solutions to its problem. If we really want to protect traditional knowledge, there is a need to look inwards for that is where the knowledge system developed. We should

look at the system that is already existing.

Ms. Bhutani: If a provision of protection looks at disclosure of origin, then it is not implementable as the resource could have crossed borders. Safeguards need to be implemented at the national space.

 In the US patent legislation, another country's prior art in the oral form in not recognizable. Hence the pressure for documentation.

The financial crisis will teach us to question the conventional wisdom of how the economics have worked. Today, India and China are looking at alternatives. India has leverage and resources, and it has been subsidizing and underwriting the same.

Be it TKDL or physical resources, the focus in conservation today is only on ex situ – everything has to be put in a bank, or in a register or a data base. The trend on ex situ needs to be questioned, and we need to bring back the attention on in situ where everything is on site and nothing is appropriated out of the local area and if at all with the full informed consent of the community.

- Need to examine what is coming in the way of holistic in situ conservation.

 JNU is spending money in accessing academic material data bases, and in the process paying to read its own research (to which it contributed).

The International Treaty on Plant Genetic Resources is also not a non IPR protection of traditional knowledge. When the ITPGR was negotiated under the FAO, the fact that it took so long to come out in black and white, was because of a clause – 12.3 (b) that disallows IPR on material accessed, but only in the form in which the sample is received. This is not a non IPR approach, subsequently in the new intellectual assets policy of the CGIAR which is being finalized and made public, the centre shall not seek IPR, however the centre shall allow third party to seek IP provided the golden rights are distributed free...Is this technology something that we really need or what so it is understanding the nexus between the IPR discussions – if we are hankering for technology transfer, and that same technology is going to erode your biodiversity and your traditional knowledge, is that really desirable? Biotechnology in agriculture and IPR on new agricultural technologies needs to seen in that light.

Dr. Venkataraman: Six monthly reports are being required on the access material and the results. The results are with us. We have approached the customs department for enforcement of the biodiversity Act. However, NBA approaches government and they approached customs, they said that we give everything to the central government. If they are not ready, then this Act cannot be enforced. NBA has approached forest department range officers. Now the officers in the NBA and officers in the state biodiversity boards and regional officers of Ministry of Environment and Fisheries etc. Now any misappropriation can be identified immediately.

Dr. Sharma: When a patent is drawn, in a way it is intellectual dishonesty. For when a patent is drawn, it actually blocks knowledge from public domain for 20 years. There is something fundamentally wrong in our approach. Those who say that traditional knowledge should be documented should be the ones to say that there should be no patents. The argument is that traditional knowledge should be in the public domain. This is politicization of patenting. The IPGRI — which is the custodian of the entire plant accessions in the world - has actually gone on record in the committee that I sit, by saying that we do not know that where the genetic resources are coming from, (the six lakhs plant accessions that they have). It says how do you know that the plant

accessions are coming from a particular country because they have no such classification and if this what IPGRI is saying, then the disclosure aspect that we are looking for has already become redundant. There are no databases to establish origins. There is a need to understand the politics behind us that all these are measures to just to engage organizations and persons in a dialogue or discussions.

## Some of the views of other speakers in the discussion

- The follow up on patent applications is intense.
- There are some fundamental flaws in the act Section 03 debates the citizens and non-citizens of India.
- The patent office looks at it very technically, they don't look at the far reaching implications or the protection of the community, or issues of access. Need to develop that linkage with the community.
- On benefits sharing to get research outcomes as part of the benefit sharing and to have upstream research.
- Let us not think negatively. Let us see if it is possible to retrieve what we are trying to protect. We are going to make biodiversity register. The biodiversity register should have been made much earlier so that it could be monitored. The traditional knowledge should be recorded but not misused; it should not die but should be made use of.
- It is important to avoid misuse during discussions in Kerala, many believed that even if the knowledge dies with the holder, they were fine with it but they did not want a multi-national to misuse it. Now again, the decision information is already into public domain but don't want the the period actual knowledge holder to be denied of the benefit. It is required to share the benefits with the communities.
  - Let\_the knowledge\_not be given to multi-nationals, let it-be-developed atthe district level. The community should be protected. The speaker said that he is against multi-national and also against losing the knowledge.
  - This is about the patent of IPR and the norms being developed on the patent and our relationship with the knowledge. Our knowledge should act as a base for use with the new technology, the loss in the knowledge means potential of thousands of patent is lost.
  - Politics of patent there is need for raw material to build a base upon from the bio-technology point of view. This raw material is the genetic material and the knowledge associated with genetic material. If the knowledge is lost, then genetic material is also lost because genetic material has no value without the knowledge associated with that.
  - The answer is creating a legal framework.
  - Documentation is not easy. Even if documentation is done, is it possible to sustain it? The way out is to invest time, develop legal systems, invest money, and review administrative processes.
  - We do value traditional knowledge and that is why we want to protect it, whereas as the same time, it is dying. If we really value it, we have to see that the future generations sustain it, we have to see how to make it remunerative and building livelihoods. A complete social engineering is
  - Traditional knowledge is not very static, it is dynamic. It can interact with modern or formalized knowledge systems.

## Post presentation discussion (Dr. Sharma)

Seeds of protected varieties have to be made available to the farmers. Is it something that is being done or that needs to be done - Bt Cotton has ensured that all the other cotton varieties are out of the market.

The experience of IPR Kerala indicates that it needs many more inputs. Though there are political compulsions, there is need to take the best of it and take

There is need to realize the positive strengths of the models, and create benchmarks for policies. A defeatist mentality should not be adopted. The speaker took the example of the member countries of the WTO where in they and the civil society resisted. We need to continue with the same kind of

Another speaker spoke about the patenting of 15 yoga postures in the US.

Day Two Existing Legal Frameworks



## Sui Generis Protection for TK - Policy Concerns

## Prof N S Gopalakrishnan, Cochin University of Science and Technology

Prof Gopalakrishnan began his presentation by putting in context the current protection of traditional knowledge in India, the policy issues in developing a Sui Generis Law and its basic principles.

The context took into account the evolving dynamics of traditional knowledge, including use of technology.

India is demanding for an international treaty on sui generis protection of traditional knowledge. WIPO is attempting to develop different models to protect traditional knowledge, which includes methods to separate traditional cultural expressions from traditional knowledge and follow different approaches for the two. There were objections from developed countries towards a sui generis

The countries rich in traditional knowledge lacked models to find solutions to various problematic areas including definition and ownership and benefit

India's stance was defined by Prof. Gopalakrishnan through various Acts and systems. He also highlighted that the Indian viewpoint approached from the perspective of exploiters of traditional knowledge and not its holders. There was

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The experience of IPR Kerala indicates that it needs many more inputs. Though there are political compulsions, there is need to take the best of it and take adequaté precautions.

There is need to realize the positive strengths of the models, and create benchmarks for policies. A defeatist mentality should not be adopted. The speaker took the example of the member countries of the WTO where in they and the civil society resisted. We need to continue with the same kind of resistance and not get disheartened.

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Day Two **Existing Legal Frameworks** 



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The countries rich in traditional knowledge lacked models to find solutions to various problematic areas including definition and ownership and benefit sharing.

India's stance was defined by Prof. Gopalakrishnan through various Acts and systems. He also highlighted that the Indian viewpoint approached from the perspective of exploiters of traditional knowledge and not its holders. There was lack of clarity and procedures were made more complex for the holders as far as realizing benefits were concerned.

Therefore, the policy issues need to examine identify the objectives of protection of traditional knowledge, identify the perspective of protection – (holders, commercial exploitators, institutions and individuals other than holders wanting to preserve).

The policy issues also needs to look at the scope of protection of traditional knowledge – at regularization of all forms including commercial, non-commercial and research and regulate the user – holders of traditional knowledge, Indian citizens and foreigners. The policy issues should also examine the nature of protection and its content.

The management of traditional knowledge and addressing that which is already in use also was discussed in the policy issues. This included centralization, participatory and democratic and conditional permission to use.

In his concluding remarks, Prof Gopalakrishnan spoke about various basic principles of sui generis law. These advocated recognizing traditional knowledge and regulate use for those other than the holders as it was used for existence.

The management of traditional knowledge should be decentralized and adopt a democratic, participatory approach that facilitates interaction between traditional knowledge and modern scientific developments.





ARCHOC.

Legal Protection of IPR & TK
Ms. Sunita Sreedharan, SKS Associates

Though India is a very ancient culture, the independent thinking processes have developed recently and cannot compete with the US or any other country. India is unique in many ways and this comes to light especially when Indians travel abroad. Indians realize that they are positioned beautifully (appropriately) with regards to the culture and wisdom, large manpower, scientific

research, and the ability to speak English which gives an advantage during communication and interaction with the international community.

It is a challenge to identify a starting point in traditional knowledge which is so vast. Traditional knowledge includes arts, crafts, handicrafts, but also the existence of traditional people in a manner that leads to their sustainable development. There is a symbiotic relationship between traditional communities and the environment. Hence, discussions on access and sharing are confusing as TK entails folklore, folk music and much more.

Therefore, there is need to precisely define and understand what exactly is traditional knowledge - to understand its perspective. Is it being viewed from

the point of view of legislation, or is one protecting it from foreign entities or from one selves?

The rapid movement technology makes it outdated very fast and this can have a positive and negative, usually negative impact on our systems. Hence, once again, it is important to define the aspects of traditional knowledge.

For example, folk music or folk art or folklore -could have a copyright implication and not necessarily implications of patent. We also need to identify what and whom to protect and study the related legislative aspects.

Ms. Sreedharan took the example of the Pashmina craft of Kashmir and the Crafts Development Institute in Srinagar to whom she is an advisor. She explained that many craft and art forms have geographic indications as well and this too needs to be taken into account as they (the arts and crafts) are not only the creation of the people there but it is sustenance and livelihood for the people. The arts are in tandem with the environment, with the eco-system in which they live. Therefore, there is a need to make communities proud of what they are doing, and to ensure that the younger generation does not leave and move on to greener pastures, given the overriding importance to money.

Ms. Sreedharan added that once traditional knowledge enters public domain, nothing can be done to retrieve it. However, one of the things that could make a difference is for efforts of retrieving it to be overwhelming enough (information or sensitization campaign of a large magnitude) for people to understand this is what it is. That aspect goes beyond legislation, it comes to the point of branding and commercializing. In a sense, it is not about big money but about telling people that this particular knowledge is Indian's traditional knowledge. In this context, creating awareness, continuous discussions, and communication in a rationale way at various forums is very important. This way, the viewpoint becomes more highlighted and carried forward.

## Summary of discussion (Day Two)

- Access to traditional knowledge is important not just for research, commercialization and economic purpose but also for future generation.
- Ethnic lifestyles, including Indian cuisine and food habits, is giving way to exotic and foreign cuisines on the table.
- Everything is being measured and translated at the physical and materialistic level. There is commodification everywhere. This is affecting the traditional practioners. The commercialization of Ayurveda is making it difficult to practice it especially as raw materials are being exported. India needs resources for its own use and then export. Instead, the best is being exported and Indians are using second or third or fourth quality of everything.

#### Annexure

Draft Policy Framework for Traditional Knowledge Systems in India

Vision: The Conservation of Traditional Knowledge, Wisdom and Practices in their bio-diverse contexts.

Background: Traditional knowledge and natural resources of the country are being increasingly exploited and the existing regulatory regimes have not only failed to contain commercialisation, but are facilitating more IPRs and monopolies to the detriment of local knowledge holders. In the current paradigm, privatisation neither offers any possibility of solutions to protection of traditional knowledge and its biodiversity base, nor the well being of communities that have collectively nurtured the knowledge for generations. Traditional knowledge is also at risk of dilution and death, and mere documentation and centralised holding of knowledge in a de-contextualised format is both deeply disrespectful and disempowering. The present system therefore not only devalues the knowledge and the holders but also prevents its continuance, thus undermining their stewardship role in offering solutions for their-lives and-livelihood and the several crisis that the world faces today. Moreover, this system stifles true innovations on the ground, and instead promotes only corporate-sponsored market-oriented research. On the contrary, any incentive that the system itself provides is only illusionary and leads to further exploitation.

Therefore, there is a need for rewriting the existing regime and formulating a culturally appropriate, ecologically benign, socially sensitive people's policy based on the premises of conservation of traditional knowledge and practices within its cultural and biodiversity context.

#### Objectives

- Recognising and respecting the intrinsic value and diversity of knowledge, wisdom and practices
- Ensuring the conservation and continuum of knowledge and its practice where it is rooted
- Sustaining the lives and livelihoods of traditional practitioners and resourcedependent communities
- 4. Nurturing biodiversity and respecting the sanctity of all life forms
- Ensuring a non-centralised system, with community decision making / autonomy

#### Approach

The policy and process to be developed:

 must recognise the unique epistemological foundation of the traditional knowledge systems, with its basis on the culture of sharing of knowledge, nurturing biodiversity, social, economic and cultural services, practices and heritage.

- must recognise that the understanding of the term "benefits" goes beyond
  the limited paradigm offered by monetary-based systems and has such nonmonetary values that are ecological, social, cultural and/ or spiritual.
- must respect and recognise that this traditional system evolved, transferred, nurtured and changed through generations is holistic and diverse and continues to undergo the evolutionary process within the context of the
- must respect and incorporate the concept of community/ collective intellectual heritage.
- must guarantee the territorial security and entitlement of collective management of traditional knowledge and resources so as to ensure sustainable livelihoods and conservation of knowledge and practices.
- 6. must establish a system of incentives including social, economic, legal, etc. to ensure local peoples continuing their practice and sustaining the knowledge system including their lives, livelihoods and culture and most essentially to re-establish dignity of their lives and practice.
  - must ensure that such social, economic, resource access and legal conditions conducive for continuing the practice is available and not infringed upon nor appropriated.
  - must ensure that mechanisms for resolving conflicts between the value systems be established within the system itself.
  - must ensure that a process of recovering, revitalising and re-establishing the lost/ diluted knowledge systems back into the cultures be established.
  - 10. must also ensure that the degraded resource base, including biodiversity be also restored and revitalised for use by the TK practitioners.
  - 11. must ensure that there should not be any introduction of practices / technologies that could cause harm to the traditional knowledge base and associated resources e.g. pesticides, genetically modified organisms(GMOs), industrialisation of traditional health practices, etc.
- 12. must ensure that the corporate-driven market systems do not exploit, corrupt, contaminate and dilute the traditional systems by way of appropriation of resource and knowledge through (Intellectual Property Rights) IPRs, or otherwise, by way of monopolies or concentration.
- 13. must ensure that a non-centralised, people-centric, culturally appropriate, ecologically benign, socially sensitive mechanism be established.

#### Agenda

			Evidou 20.04.00
		9.30 – 9.50 AM 9.50 – 10.30 10.30 – 11.00 AM	Geographical Indication Act  Dr. Malathi Lakshmikumaran (Lakshmi Kumaran and Sridharan)
		11.30 AM – 1.30 PM	National IPR debate – Community or Commodity? Chair: Dr. Vijayan/ Kerala State Biodiversity Board Importance of Cross Cultural Understanding for Evaluation of IPR Claims
of Transition		Windows Des	<ul> <li>Dr. Balakrishnan Nair/ FRLHT (20 min)</li> <li>Prior Informed Consent (PIC) and Access and Benefit Sharing (ABS) in TK-IPR regimes</li></ul>
	3 3 11 <sup>8</sup> 3 10 11		Framework for application of IP management in the protection of ITK in agriculture     Dr. P. Das/ ICAR (20 min)  Discussion (40 min)
The second	-	1.30 - 2.30 PM	Lunch
		2.30 – 4.30 PM	Existing legal frameworks Chair: Ms Vanaja Ramprasad/ Green Foundation  Kerala IPR Policy Mr. Praveen Raj/ NIIST (20 min)  Farmers' rights in PVPFR Mr. Dipal Roy Choudhury/ PVPFRA (20 min)  Some Best/ Good Practice from across the Globe Ms. Shalini Bhutani/ GRAIN (20 min)  Discussion (60 min)
	-	4.30 – 4.45 PM	Tea
		4.45 – 6.00 PM	Summary of discussion: pillars/ benchmarks for paradigm/ legislation Chair: Ms. Valsala Kutty

is Think

		Saturday, 31.01.09
	9.30 – 11.00 AM	Panel Discussion: How to integrate the identified pillars/benchmarks into a legal framework? Chair: Prof. Gopakumar Keynote: Prof. Gopalakrishnan: "Sui Generis Protection for TK: Policy Concerns" (20 mins.) Discussants:  1• Dr. K Venkataraman (NBA) 10 mins 2• Dr. Vinod (Ayurvedic Physician) 10 mins 3• Ms. Sunita Sreedharan (SKS Associates) 10 mins 4• Ms. S. Usha (Thanal) 10 mins 5• Dr. Udayakumar (Ayurveda Medical Practitioners) 10 mins 6• Dr. Raghavan Pyyanad (Centre for Folklore Study) 10 mins
	11.00 – 11.30 AM	Tea
	11.30 – 1.00 PM	Discussion continued .
Or. (	1.00 – 2.00 PM	Lunch
	2.00 - 3.00 PM	Drafting a policy document Facilitator: Dr. Devinder Sharma
	3.00 – 4.00 PM	Next steps, set-up of core group for fine-tuning and legislation blueprint



Yoga lakshmi <yogarajasekar@gmail.com>

#### FW: \*India's IPR policy: Being egalitarian or foolhardy?\* 2 messages

NBA Secretary <secretary@nbaindia.in>

To: yogarajasekar@gmail.com

Cc: tech@nbaindia.in

Wed, Nov 4, 2009 at 7:44 PM

Please go trough for discussions

Secy/nba

From: NBA Chairman [mailto:chairman@nbaindia.in] Sent: Wednesday, November 04, 2009 6:38 PM

To: 'NBA Secretary'

Subject: FW: \*India's IPR policy: Being egalitarian or foolhardy?\*

Plz discuss.

From: Kanchi Kohli [mailto:kanchikohli@gmail.com]

Sent: 22 October 2009 22:10

To: Yogesh Gokhale

Cc: nathistory-india@princeton.edu; Raghunandan Velankar; indrani.barpujari@teri.res.in; Unnikrishnan Payyappalli; yogeshg@teri.res.in; Ashish Kothari; GRAIN - Shalini Bhutani; Satheesh Periyapatna; Manju

Menon; Madhav Gadgil; yshenoy@gmail.com; Sujata Arora; shrutisrai@rediffmail.com

Subject: Re: \*India's IPR policy: Being egalitarian or foolhardy?\*

Dear Yogesh,

Thanks for your detailed response. Unfortunately, I tend to differ on almost all the points you mention in your mail. What you might refer to my misunderstanding might be a conclusion arrived through research and analysis located within a ideological frame slightly different from yours. Therefore, I don't think this is something that can be resolved over email...and lets wait for a face to face interaction on it.

best wishes Kanchi

2009/10/22 Yogesh Gokhale <ssopan@gmail.com>

Dear Kanchi and Shalini,

http://mail.google.com/mail/?ui=2&ik=69e374fe2f&view=pt&search=inbox&th=124bf8...

28

Sorry for late reply and am happy that you have put forth various aspects of concern regarding TK, etc. I do have my observations on your points and I have tried to mention below -

I do not find any conflict in having myriad forms for documenting the local knowledge. Databases require defined structures (which also could be made in evolving nature as per the requirements). So my experience with the documentation knowledge suggests that there is no need to follow only one structure of format for documentation of the knowledge. Ultimately while you organise that knowledge in form of database requires structured approach but it does not have to do anything with the efforts of documentation. So technically speaking based on my experience there is no conflict in following multiple format model as long as database structure is made as inclusive as possible. So there is no reason why it should not work for GoI.

Your second point of defensive nature of database certainly needs to be seen in light of some o fthe ongoing experiemnets of providing use value to the local knowledge. In this context I would like to quote the example of few products developed by National Innovation Foundation such as Herbavate. I would urge you to have a look at - http://www.herbavate.com/herbavate.htm

The genesis of herbavate is an excellent example to put to use the local knowledge and also share the benefits with the knowledge holders. The website does not have details of benefits shared by NIF could provide further info on it. The documentation done as per teh BD Act is certainly not a defensive approach in that sense but an opportunity to benefit the local communities by developing products and securing the IPR on it. Such database would also provide an excellent opportunity for mapping the knowledge and also indentifying the overlapping nature of knowledge all over the country. This understanding will help in avoiding the Kani type of situation where the Kanis from Tamilnadu also had to struggle to get their claim over the Arogyapacha. So I feel that documentation of knowledge for the purpose of database of Biodiversity lnformation System is one of the positive and proactive approaches for conserving the traditional knowledge and the biodiversity.

Your point of US not recognizing the oral knowledge as prior art needs a separate communication which I would try in coming week. But I see compulsory disclosure of source/provenance of knowledge or biodiversity material which is getting negotiated as a part of International Regime on ABS supported by the official documentation maintained by nation states would form a strong case against such misuse.

Your claim of shift of custodianship due to documentation and digitisation is again a misunderstanding. The custodianship will only get diluted when the knowledge is brought in the public domain. The IBIS kind of efforts can be designed to record the knowledge and not for publication. NIF has been doing it for past several years now without any breach of trust reported so far. In fact publishing the ethnobotanical accounts dilutes the custodianship of the knowledge where the commercial utilisation of the knowledge could be done by anyone and the profits need not be shared with the knowledgeholders. Many of us working on ethnobotany, etc. have been committing this mistake most of the times unknowingly. I would be happy to

So in conclusion I would say that the provisions in the BD Act are certainly suggesting out of box approach but the inadequate approaches and limited capacities for implementing the provisions of BD Act has added to the confusion about the ABS debate in India and more or less in most of the developing country.

Thanks for marking mails to other friends also. And I would thankful to have their views heard on this aspect.

On Tue, Oct 20, 2009 at 2:23 PM, Kanchi Kohli <a href="mailto:kanchikohli@gmail.com">kanchikohli@gmail.com</a> wrote:

Dear Yogesh,

thanks for your response and feedback on the article.

Since you have stated upfront your position on TKDL, am taking the opportunity to clarify mine.

I think there are three points to contend with here. First, I think there is a distinct difference between

digitizing/databasing knowledge and resources in contrast to documenting it. TKDL, Indian Biodiversity information System (IBIS) under the Biodiversity Act and other such approaches, for me fall within the bracket of databasing, where there are clear formats to follow and models within which knowledge will be recorded. Documentation for local level conservation can take myriad forms those that can be both creative and locally applicable, as you are well aware of

For Gol, obviously multiple formats and local level documentation will not work; if the purpose of preparing databases is to determine 'prior art'. This is my second point, where TKDL, IBIS etc are defensive approaches rather than an offensive against allowing for IPRs on traditional knowledge. It is because countries like the USA don't recognise oral knowledge as 'prior art' against patents, that we need to record traditional knowledge and biodiversity alone.

Third, is the level at which controls lie. This point is linked to the first two above. While traditional knowledge is created and has existed for years at a community levels, digitising (and I emphasise this being different from statement to understand.

Therefore, TKDL kind of databasing is not outside of the IPR system, which is what the MoEF hints at achieving in the State of Environment report. Our article is an attempt to point to this very basic contradiction. It do agree with you that TKDL is a well thought out by the GoI, but it does not think outside the box, the keys to which are controlled perhaps in patent offices and global negotiations.

Marking to some others who might be interested in this exchange, other than Shalini to whom this mail was addressed but not marked.

With you on the objective for conservation of biodiversity and traditional knowledge.

best regards Kanchi

Yogesh Gokhale wrote:

Dear Kanchi and Shalini,

Your article talks about TKDL initiative. In this aspect I would like to put forward some facts. The purpose of TKDL is to provide information on traditional knowledge existing in the country, in languages and format understandable by patent examiners at International Patent Offices (IPOs), so as to prevent the grant of wrong patents. This process of preventing wrong patents is extremely important in light of increasing number of patents being granted by USPTO (United States Patent Office), EPO (European Patent Office), UKPO (United Kingdom Patent Office) based on Indian traditional knowledge (5000 patents were granted in year 2000 and in year initiative to monitor the patents being granted based on the Indian traditional knowledge in light of availability of TKDL info to the patent offices.

Apparently, based on the experience of reverting the patent on the properties of turmeric based on the Indian traditional knowledge it is suggested that having a searchable database like TKDL would be more cost effective to revert such wrong patents. Also organising such information would certainly help further in validation of the knowledge and making its use for useful products.

In the context of your point regarding 'Access', all the books of the organized knowledge systems on

edicines like Ayurveda, Siddha and Unani in the local Indian languages along with authentic english translations are publicaly available all over India. In that sense this knowledge is freely accessible for those who want to use or misuse it.

So I feel that the Indian policy on IPR if its only been judged on the basis of TKDL kind of initiatives as ficussed in your artcile seems a well thought approach with good intentions of preventing the misuse of the Indian traditional knowledge. There are no efforts by government as of my knowledge to share any local knowledge being practised all over India and for which your arguments carry lot of importance. But there is a need to track the use of the public domain traditional knowledge available in print form and TKDL kind of initiative is a welcome step towards it in the context of Ayurveda, Siddha and Unani and lot remains to be done about huge literature on ethnobotany which has been getting published over the period possibly without the consent and knowledge of the owners of the knowledge.

thanks, Yogesh Gokhale

On 10/15/09, Kanchi Kohli <a href="mailto:kanchikohli@gmail.com">kanchi kohli <a href="mailto:kanchikohli@gmail.com">kanchikohli@gmail.com</a>> wrote:

**DECCAN HERALD** 13th October 2009\*

\*India's IPR policy: Being egalitarian or foolhardy?\*

\*Kanchi Kohli and Shalini Bhutani\*

/The world is full of contradictions and so its governance also reflects that./

If one takes this reality as a given, especially in the Indian context, then the dilemmas of govern-'mentality' might not come as a surprise anymore. Here is a closer look at the much controversial Intellectual Property Rights (IPRs), and some recent official articulations on it.

IPRs like patents, trademarks or copyrights, supposedly protect new and innovative products giving the inventor private rights over their sale, import, export and distribution. Any commercial use of the product cannot be without due permissions and royalties to the 'original' inventor.

This is what large seed corporations and agriculture research giants are trying to cash in on. IPRs today are a mainstay of profit generation of many corporate and research bodies, be it agriculture, software, art, or medicine. Envisioning a world as it indeed was before — without IPRs, is considered to be a foolhardy dream. Ironically, many of the real innovators in traditional systems of medicine and small farm agriculture continue to situate themselves within a non-IPR world.

So, is Government of India indecisive or confused about which world it wants to belong to and protect? On the side of private profit or on encouraging common heritage and growth of shared knowledge and collective

In August 2009, after a long hiatus the ministry of environment and forests (MoEF) released its latest state of environment report (SOE) 2009 for India. It has reference and makes use of text from page 25 of a 2002

http://mail.google.com/mail/?ui=2&ik=69e374fe2f&view=pt&search=inbox&th=124bf8... 11/12/2009

riefing put out by two NGOs, Grain and Kalpavriksh titled 'Traditional Knowledge of Biodiversity in Asia-Pacific — Problems of Piracy & Protection.' The SOE deeply questions the role of IPRs and states that IPRs as prescribed through international treaties are being used by commercial interests to gain ownership and control over traditional knowledge. The increased support of the government in facilitating this exercise is also acknowledged and also the fact that communities are struggling to sustain traditional practices in adverse

On the same page of the SOE is a set of recommendations on traditional knowledge protection. Therein is a very refreshing mention, that one of the ways forward is actually examining and highlighting alternatives to IPRs to be able to protect traditional knowledge. It also states that there is a need to strengthen a unified demand to amend and review the World Trade Organisation's TRIPs agreement, of which India is a signatory. Since the report is signed and endorsed by Jairam Ramesh, Union minister of state (environment and forests) and Vijay Sharma, the current secretary, MoEF, one has good reason to believe that the MoEF truly agrees to this non-IPR position.

But actions and other statements from the same ministry stand in contrast. The MoEF, its biodiversity regulations, the National Biodiversity Authority under it, all convey that documentation of traditional knowledge (TK) into digital libraries and databases is the first step in the protection of TK. The next step is to grant access of these databases to international patent offices so that they can check any existence of 'prior art' before granting of patent rights to the applicant!

This can certainly not be classified as a 'non-IPR approach.' A memorandum of understanding (MoU) has already been signed with the European Patent Office in February 2009 granting the EPO access to our Traditional Knowledge Digital Library (TKDL) and another like MoU is due to be signed with the US Patent Office anytime now. This has been reported by the minister, MoEF in the press coverage of what he said during the inauguration of the new office of the National Biodiversity Authority (NBA) in Chennai.

But are the European (EPO) and US (USPTO) patent offices interested in the TKDL for verification of any infrignments? Or would the access to this centralised database be to delve deeper to create new 'innovations' based on the knowledge contained therein? The TKDL currently contains transcriptions of over 2 lakh medicinal formulations from 148 books and 230 volumes of Unani, Ayurveda, Siddha besides 500 postures of

Quite interestingly, the ministry of human resource development (MHRD) as early as 2006 had written to the prime minister that access to International Patent Offices should not be granted before a national access policy is finalised, and if access is granted then it will be a violation of India's commitment to the Convention on Biological Diversity (CBD). The CBD mandates the principles of prior informed consent and disclosure of origin of the access before an IPR can be sought. The CSIR and the ministry of commerce's department of industrial policy believed that since the knowledge in the TKDL is all public domain knowledge, the CBD policies don't apply to it.

These arguments were 'duly' considered before access was granted to the EPO. It may be noted that India's sui generis system for protection of traditional knowledge to be elaborated under the Biological Diversity Act, 2002 (as a follow up to CBD) is still to be worked out.

Yet, we continue to be keen to create new databases and grant access to international IPR offices as Gol ironically sees it as a means of protection of traditional knowledge. How about seeking real alternatives to the IPR system as stated in the new SOE report by the MoEF?

Source: http://www.deccanherald.com/content/30221/indias-ipr-policy-being-egalitarian.html

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NBA/BDA/TK/01

# THE PROTECTION, CONSERVATION AND EFFECTIVE MANAGEMENT OF TRADITIONAL KNOWLEDGE – Draft Rules

# Document for discussion



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# THE PROTECTION, CONSERVATION AND EFFECTIVE MANAGEMENT OF TRADITIONAL KNOWLEDGE RELATING TO BIOLOGICAL DIVERSITY RULES, 2009

In exercise of the powers conferred under sections 36(5) and 62 of the Biological Diversity Act, 2002 and on the recommendations of the National Biodiversity Authority, the Central Government, hereby, makes the following rules, namely:--

### 1. Short Title and Commencement.--

- (1) These rules may be called the Rules for Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity, 2009.
- (2) They shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.
- 2. Definitions. —In these rules, unless the context otherwise requires, --
  - (a) "Abuse" means use or application of the traditional knowledge or one or more of its components, by any person, including a member of the traditional community or a traditional practitioner, in a manner that is in contravention of their traditional beliefs and practices, or which is against public order and morality, or against the interests of the traditional communities or, any action in contravention to these Rules:
  - (b) "Accessor" means a person who accesses traditional knowledge for commercial gain and /or for research, and includes members of traditional communities who access traditional knowledge of any other community for commercial gain and /or research;
  - (c) "Act" means the Biological Diversity Act, 2002 (18 of 2003)
  - (d) "Authority" means the National Biodiversity Authority established under subsection (1) of section 8 of the Act:
  - (e) "Benefit" means gains that can be monetary, non-monetary, welfare-based and any other form that comes out of an agreement between the accessor and the traditional community and / or National Biodiversity Authority, as the case may be, upon access of traditional knowledge or a component thereof and shall include
    - i. access fee determined by the National Biodiversity Authority or the State Biodiversity Board as the case may be, in consultation with the

traditional community at the time of accessing the traditional knowledge;

- ii. benefits as described under section 27(2) of the Act; and
- iii. milestone payments where applicable.
- (f) "Biodiversity Management Committee" means a Biodiversity Management Committee established by a local body under sub-section (1) of section 41 of the
- (g) "Chairperson" means the chairperson of the National Biodiversity Authority;
- (h) "Collective rights" mean the rights which the traditional community as a group has been enjoying over the particular traditional knowledge for generations;
- (i) "Commercial gain" means commercialization of a component or components of traditional knowledge or derivatives thereof, in a way that is not being practised by the community which owns the said knowledge;
- (j) "Fee" means any fee stipulated in the Schedule;
- (k) "Informed consent" means consent to be obtained from the traditional community or the National Biodiversity Authority, as the case may be, in case where the traditional knowledge is already under access and use before the notification of this Act;
- (l) "Intellectual Property Rights" mean intellectual property rights including, copyrights, designs, geographical indications, patents and trademarks;
- (m)"License of Use" means the permission granted to the applicant by the National Biodiversity Authority for accessing the traditional knowledge;
- (n) "Livelihood" means the financial and/or other traditional / customary means for
- (o) "Milestone payments" means periodic payments made to the traditional knowledge fund by the accessor which shall not be less than 10% of the gross revenue realized from the commercialization of products using traditional knowledge or derivatives thereof;
- (p) "Misappropriation of traditional knowledge" means any form of appropriation, monopolisation, including claims of private ownership and/or intellectual property rights, and such other acts which deprive the traditional community whose traditional knowledge it is, from using, conserving and protecting the said knowledge, and from equitable benefit sharing arising out of any commercial utilization of said traditional knowledge and /or derivatives thereof, and also unsustainable utilisation of the genetic resources relating to that traditional

- (q) "Misuse of traditional knowledge" means access to and/or use of traditional knowledge by persons not belonging to the traditional community whose traditional knowledge it is, without License to Use or against the terms and conditions of License to Use;
- (r) "National Standing Committee" means a committee set up by the Authority to examine and advise the Authority on applications for access to traditional knowledge;
- (s) "Prior-informed Consent" means a written authorisation given by the traditional community to an applicant in the prescribed manner, in consultation with the Biodiversity Management Committee and facilitated by the State Biodiversity Board, for the conduct of a particular activity that entails access to and use of the said traditional knowledge, based on an access application submitted in the prescribed manner containing complete and accurate access information on the purposes, risk, implications and environmental impact of the said activity, including any use that might be made of the said knowledge, and, wherever applicable, on its commercial value;
- (t) "State Standing Committee" means a committee set up by the State Biodiversity Board to examine and advise the Board on applications for access to traditional knowledge;
- (u) "Traditional community" means a community holding traditional knowledge including families, people belonging to Scheduled Tribes as per Article 342 of the Constitution of India, and other notified tribal groups including nomadic tribes, and shall be represented by their representative bodies;
- (v) "Traditional Knowledge" means the collective knowledge of a traditional community including of a group of families, on a particular subject or a skill and passed down from generation to generation, either orally or in written form, relating to properties, uses and characteristics of plant and animal genetic resources; agricultural and healthcare practices, food preservation and processing techniques and devices developed from traditional materials; cultural expressions, products and practices such as weaving patterns, colors, dyes, pottery, painting, poetry, folklore, dance and music; and all other products or processes discovered through a community process including by a member of the community individually but for the common use of the community; and
- (w) "Traditional Practitioner" means person(s) who are members of a traditional community and have been practising traditional knowledge including healing

and/or rendering medical service based on traditional knowledge and customary practice.

- 3. Measures to be taken by National Biodiversity Authority for protection and promotion of traditional knowledge.--
- (1) The National Biodiversity Authority shall recognize existing traditional forms of representative organizations of the traditional community, including family / community based organisations;

Provided that, where there are no representative bodies representing the said traditional community, the National Biodiversity Authority shall, through State Biodiversity Boards and Biodiversity Management Committee enable traditional communities to set up representative bodies keeping in view their customary practices and traditional forms of organization;

Provided also that where there is more than one representative organization representing a traditional community, the National Biodiversity Authority shall refer the matter to the Biodiversity Management Committee through the State Biodiversity Board for identifying the representative organization(s).

- (2) A traditional community shall, for the implementation of these Rules, be represented by its traditional representative body and that body shall be the authorised body for all matters pertaining to the implementation of these rules with reference to that community.
- (3) National Biodiversity Authority shall facilitate the traditional communities to exercise their collective rights to their own access and use, and to regulate access by others including fair and equitable benefit sharing for such access and relief on abuse and/or misuse and/or misappropriation and/or infringement of the traditional knowledge.
- (4) National Biodiversity Authority shall ensure that members of any traditional community shall be allowed to access or practice the traditional knowledge of another traditional community for the purpose of earning their livelihood and not for commercial gain.
- (5) The National Biodiversity Authority shall take steps to prevent abuse and/or misuse and/or misappropriation of traditional knowledge; and where such abuse, misuse

or misappropriation has taken place, the NBA shall institute proceedings in the appropriate forum.

- (6) The National Biodiversity Authority shall ensure that the traditional communities make sustainable use of the resources on which their traditional knowledge is based; and that the traditional community shall protect, conserve and practice the traditional knowledge for the continued good of the traditional community.
- (7) The National Biodiversity Authority shall set up a fund called the Traditional Knowledge Fund under Section 27 of the Act and there shall be credited thereto all charges, fees, royalties and all sums received by the National Biodiversity Authority in the administration of these Rules.
- (8) The said Fund shall be applied for the benefit of the traditional communities and in the protection, conservation and continued practice of traditional knowledge, by way of monetary and non-monetary as well as welfare based measures that shall include but not be restricted to incentives for continuing use and public service, direct income supports, registration and accreditation of such practices, etc.
- (9) The National Biodiversity Authority shall take initiatives to introduce traditional knowledge education including local traditional knowledge in the formal and non-formal systems of education and shall involve knowledgeable members of traditional community for the same.
- (10) The National Biodiversity Authority shall maintain a Traditional Knowledge Register to register Traditional Knowledge as described in these rules.

# 4. Traditional Knowledge Register .--

(1) There shall be kept at the National Biodiversity Authority, a Traditional Knowledge Register wherein shall be entered the name, location, description of the traditional knowledge, as is revealed by the traditional community, or in the already documented system, along with the names of the practising traditional community(ies) in the prescribed format, as and when such information regarding the concerned TK is intimated to the National Biodiversity Authority by the traditional community or by the suo motu efforts of the Authority or any of the State Biodiversity Boards or the Biodiversity Management Committee upon an application for access;

Provided that the traditional community concerned has permitted the documentation and the form of documentation of the said traditional knowledge; Provided also that such permission is not needed in case of traditional knowledge that is already in the public domain and/ or the traditional community concerned is not identifiable.

- (2) On registering the traditional knowledge, the National Biodiversity Authority shall mark such knowledge as either "PUBLIC" or "CONFIDENTIAL," depending on whether the components of traditional knowledge are of confidential nature and are so indicated by the traditional community that applies for registration, or if the National Biodiversity Authority deems so.
- (3) The name and address of the accessor, if any, accessing the said traditional knowledge, along with the nature of use of the accessed traditional knowledge and benefit sharing mechanism, and of amendments, extension and revocation of access shall also be entered in the said Register.
- (4) The Traditional Knowledge Register shall be maintained in electronic or paper form or in any other form that captures the essence of the traditional knowledge.
- (5) All existing and future databases pertaining to traditional knowledge relating to genetic resources under the control of the Central or State governments, including the Traditional Knowledge Digital Library and the People's Biodiversity Register(s) shall form part of the Traditional Knowledge Register.
- (6) Subject to the superintendence and direction of the Central Government the Register shall be kept under the control and management of the Chairperson.
- (7) The contents of the Traditional Knowledge Register shall not be disclosed without authorisation of the Chairperson.
- (8) No application for access of any Traditional Knowledge shall be allowed if the said traditional knowledge is not registered in the Traditional Knowledge Register;

*Provided* that where traditional knowledge has already been accessed without obtaining prior informed consent the accessor shall approach the appropriate forum under Rule 5.

- Regulation of access to traditional knowledge and informed consent.--5. (1)
- Any person desirous of accessing traditional knowledge or any component thereof shall apply to the National Biodiversity Authority in the prescribed form with the
- On receiving the application for access, the National Biodiversity Authority shall examine the application for compliance of formalities and refer the same to the National Standing Committee; whereupon said committee shall examine the application to check for registration of the traditional knowledge in the Traditional Knowledge Register.
- Where the traditional knowledge is found to be registered in the Traditional (3)Knowledge Register, then the National Standing Committee shall refer the said application to the appropriate State Biodiversity Board (s);

Provided that if the traditional knowledge is registered in the name of one more traditional communities from at least three different states, then the process for obtaining informed consent and negotiation shall be initiated by the National Biodiversity Authority, in consultations with all the State biodiversity Boards concerned.

Where there are no State Biodiversity Boards and / or Biodiversity Management (4) Committee, the National Biodiversity Authority shall direct the State(s) concerned to set up the State Biodiversity Board(s) and / or Biodiversity Management Committee(s) within 6 months from the date of such direction;

Provided that where the state fails to comply within the stipulated time, the State may request an additional time of a period no greater than 6 months to set up the State Biodiversity Committee and / or the Biodiversity Management Committee; Provided further that where the State fails to comply altogether, the National Standing Committee shall facilitate the consultation between the traditional community(ies) and the applicant for issuance of the prior informed consent and negotiations for the access and benefit sharing agreement.

On receiving the application, the State Biodiversity Boards shall refer the said (5)application to the appropriate Biodiversity Management Committees and traditional communities.

- (6) On receiving the application the traditional communities shall inform the State Biodiversity Board of their willingness or unwillingness to participate in consultation on prior informed consent.
- (7) Where the traditional communities communicates their unwillingness to participate in consultation on prior informed consent to the State Biodiversity Board the said Board shall communicate the same to the National Biodiversity Authority through the NSC; whereupon the NBA shall communicate denial of access to the applicant.
- (8) Where the traditional communities communicates their willingness to participate in consultation on prior informed consent to the State Biodiversity Boards, the State Biodiversity Board concerned shall refer the application to the State Standing Committee.
- (9) The State Standing Committee shall in consultation with the said traditional community and the Biodiversity Management Committee, conduct a comprehensive assessment including assessment on sustainability of the resources, social and environmental implications and potential value of the traditional knowledge, and produce a report along with recommendations and a resource management plan;

*Provided* that where the State Standing Committee requires any further information, it may require the applicant to provide further details regarding the proposed use of the traditional knowledge.

- (10) On receiving the comprehensive assessment report of the State Standing Committee, the State Biodiversity Board shall facilitate consultation(s) among the applicant, the traditional community(ies) and the Biodiversity Management Committee(s) at the location(s).
- (11) Where there is no agreement on granting access to the applicant, the same shall be communicated by State Biodiversity Board to the National Biodiversity Authority through the National Standing Committee, who shall then communicate the denial of the access to the applicant.
- (12) Where there is a consensus on the granting of access to TK(s), the SBB shall initiate the process for negotiating the terms and conditions of the access, use and benefit sharing of the TK(s), taking into account the recommendations of the State Standing Committee:

Provided that if there are more than one State Biodiversity Board, the same shall be communicated to the National Biodiversity Authority through the National Standing Committee, and the process for negotiating shall be initiated by the National Biodiversity Authority.

- (13) On agreement between the applicant and the traditional community, the latter shall affix their signatures on the prior informed consent form, and thereafter both parties shall affix their signatures on the agreement for access and benefit sharing.
- (14) Copies of the prior informed consent, agreement on access and benefit sharing and the Report of the State Standing Committee shall be submitted to the National Standing Committee by the State Biodiversity Board.
- (15) On receiving the prior informed consent, the access and benefit sharing agreement and the report of the State Standing Committee, if any, the National Standing Committee shall refer the same to the National Biodiversity Authority with appropriate recommendations for issuance of the "licence of use" incorporating the prior informed consent and the terms and conditions of the access and benefit sharing agreement.
- (16) The Authority shall issue the "License of Use" after being satisfied that due processes under the law have been complied with, and the issuance of said "License of Use" shall not be against the national interest.
- 6. Regulation of access to traditional knowledge in the public domain not owned by any specific traditional community or owned by traditional community(ies) in more than three states.
- (1) Where the traditional knowledge is already in the public domain and is not specifically owned by any particular traditional community or if the traditional community(ies) is/are spread in more than three states, then the willingness to issue a prior informed consent and negotiating an access and benefit sharing agreement shall be done by the National Standing committee in consultation with the respective State Biodiversity Boards, Biodiversity Management Committees and traditional communities, wherever possible and recommendations made to the National Biodiversity Authority.
- (2) The National Standing Committee shall, in consultation with the respective State Biodiversity Boards, Biodiversity Management Committees and traditional communities,

wherever possible, conduct a comprehensive assessment including assessment on sustainability of the resources, social and environmental implications and potential value of the traditional knowledge, and produce a report along with recommendations, resource management plan along with an access and benefit sharing plan:

Provided that where the National Standing Committee requires any further information, it may require the applicant to provide further details regarding the proposed use of the traditional knowledge.

- (3) The National Biodiversity Authority shall exercise its discretionary powers with regard to the allowance of access to particular traditional knowledge on the basis of report(s) submitted by the National Standing Committee.
- (4) Where allowance of access to said traditional knowledge is granted by the National Biodiversity Authority, the prior informed consent along with access and benefit sharing agreement shall be signed between the National Biodiversity Authority and the applicant; whereupon the National Biodiversity Authority shall issue the license of use.
- (5) Where allowance of access to said traditional knowledge is refused by the National Biodiversity Authority, the same shall be communicated to the applicant within reasonable time.

# Regulation of access to non-registered traditional knowledge.

- (1) Where an application is received under rule 5(2), and the traditional knowledge is not registered, the National Standing Committee shall evaluate the traditional knowledge for its availability in public domain.
- (2) Where the said traditional knowledge is found to be in public domain, the National Standing Committee shall conduct an assessment of the said traditional knowledge including sustainability of the resources, social and environmental implications and the current and potential value of the traditional knowledge, and recommend the said traditional knowledge to the National Biodiversity Authority for registration in the Traditional Knowledge Register as PUBLIC traditional knowledge, along with the said assessment report:

Provided that if the said traditional knowledge is not in public domain, the National Standing Committee shall refer the application to all / relevant State Biodiversity Board(s).

- (3) On receiving the recommendation for registration of traditional knowledge in public domain and the assessment report under Rule 7(2), the National Biodiversity Authority shall register the said traditional knowledge in the Traditional Knowledge Register and commence negotiations as specified in Rule 6.
- (4) On receiving the referral from the National Standing Committee under Rule 7(2), the State Biodiversity Board(s) shall identify the appropriate traditional community(ies) practising the said traditional knowledge through the Biodiversity Management Committee(s) and communicate the same to the National Standing Committee for registration of the traditional knowledge as either "PUBLIC" or "CONFIDENTIAL";

Provided that such information shall be registered only with the consent of the traditional community.

(5) Where the traditional knowledge is PUBLIC and is identified with one or more traditional community(ies) of more than three states, the National Standing Committee shall conduct an assessment as stated in rule 7(2) and refer the application to the National Biodiversity Authority along with the assessment report, whereupon the National Biodiversity Authority shall start proceedings as in rule 6(2):

Provided that where the traditional knowledge is CONFIDENTIAL, the National Standing Committee shall recommend to the National Biodiversity Authority to register the said traditional knowledge as CONFIDENTAL in the Traditional Knowledge Register, and shall refer the application back to the concerned State Biodiversity Board for obtaining prior informed consent and access and benefit sharing agreement under Rule 6(4).

(6) Any third party including a civil rights group may approach the chairperson with information of a traditional knowledge or a component thereof which may include information about its abuse and /or misuse and /or misappropriation, whereupon the Chairperson shall refer the matter to the National Standing Committee to investigate the accuracy of such information, evaluate the so identified traditional knowledge and register the same, after obtaining the required consent from the traditional community concerned if so identifiable, and after appropriate classification as "PUBLIC", "CONFIDENTIAL and/or recommend action in case of abuse and/or misuse and/

#### 8. Licence to Use.--

- (1) The National biodiversity Authority may issue a non assignable and non-transferable licence to use to an applicant, in response to a written application only and after following the prescribed procedures, to access a specified traditional knowledge, subject to the conditions stipulated in the said licence for a period not less than I year and not greater than 3 years, the said licence may be renewed for a further period not exceeding 3 years.
- (2) The Licence to Use issued to an accessor shall be published in the Official Journal and along with the supporting documents, including the prior informed consent, various assessment reports and the agreement between the parties concerned shall be published on the website of the National Biodiversity Authority as soon as possible.
- (3) Any person who has an interest in the traditional knowledge concerned may, within six months of the publication of the agreement on the website of the National Biodiversity Authority, make an application for opposition or revocation of the agreement and the licence to use, to the National Biodiversity Authority in the prescribed manner.
- (4) On receipt of such notice of opposition / revocation, the National Biodiversity Authority shall refer the matter to the National Standing Committee for re-examination of the Agreement and the grant of licence.
- (5) The National Standing Committee shall re-examine the agreement taking into consideration all information made available to it by both parties, in writing and orally, and after detailed hearing of both parties, submit a report with recommendations to the National Biodiversity Authority.
- (6) On receipt of the re-examination report of the National Standing Committee and after giving the accessor and the opponent an opportunity of being heard, the Chairperson shall pass an order to maintain or amend or revoke the agreement and or the licence to use.
- (7) The accessor has the responsibility to inform the National Biodiversity Authority of any change in address and/or in his legal status, if any, within two weeks of such an event.

(8) In case of misuse of Traditional Knowledge, the Licence to Use shall be revoked by the Authority and the accessor shall be liable under Rule 18 herein.

#### 9. Sharing of Benefits.--

- (1) Sharing of all benefits arising out of the access to the traditional knowledge and /or its consequential commercial use shall be as negotiated between the traditional community and the applicant and facilitated by the State Biodiversity Board through the Biodiversity Management Committee(s).
- (2) All benefit share shall directly be paid to the traditional community by the applicant and shall be reported annually to the State Biodiversity Board, concerned and the National Biodiversity Authority by both the applicant and the traditional community;

Provided such benefits that arise from an agreement between the National Biodiversity Authority and the applicant shall accrue to the Traditional Knowledge Fund.

(3) Details of all the reported benefits shall be published in the website of the National Biodiversity Authority as soon as possible.

#### 10. Access Fee.--

- (1) The National Biodiversity Authority shall, at the time of approving the license to use, impose an access fee based on the negotiations between the traditional community and the accessor.
- (2) The access fee shall be deposited by the accessor at the Traditional Knowledge Fund established under rule 11.

# 11. Constitution of Traditional Knowledge Fund.--

- (1) There shall be constituted a fund to be called the Traditional Knowledge Fund and there shall be credited thereto
  - (a) any grants and loans made to the National Biodiversity Authority for specific needs of the implementation of the Rules;
  - (b) all charges and access fees received by the National Biodiversity Authority;

- (c) all monetary benefits that accrue to the National Biodiversity Authority upon an agreement signed for access between National Biodiversity Authority and the applicant; and
- (d) all sums received by the National Biodiversity Authority from such other sources as may be decided upon by the Central Government.
- (2) The Fund shall be used for the protection, conservation and development of traditional knowledge and the traditional communities which shall include
  - (a) channeling benefits to the benefit claimers;
  - (b) conservation and sustainability of traditional resources, welfare and livelihood support for traditional communities and traditional practitioners;
  - (c) ecological and cultural restoration programmes specifically related to traditional knowledge practices and such regions / sectors such as traditional medicine, health and educational practices, farming and other traditional livelihoods; and
  - (d) socio-economic, ecological and cultural development of areas referred to in subrule (b) in consultation with the State Biodiversity Board(s), Biodiversity Management Committee(s) and traditional community (ies) concerned;
  - (e) recognition and accreditation of traditional practitioners;
  - (f) promoting the use and practice of common public domain traditional knowledge such as home remedies, customary healing and agricultural practices etc especially in formal and non-formal educational systems and among traditional communities.

# 12. National Strategies, Plans, etc., for Conservation, Development, etc., of Traditional Knowledge and Resources.--

- (1) The National Biodiversity Authority shall develop national strategies, plans, programmes for the conservation, development and sustainable use of traditional knowledge including (a) measures for identification and monitoring of areas rich in traditional knowledge, (b) incentives and support systems for traditional communities and traditional practitioners, and (c) incentives for training and public education to increase awareness with respect to traditional knowledge.
- (2) Where the National Biodiversity Authority has reason to believe that any area or traditional community rich in traditional knowledge and resources is being threatened by overuse, abuse or neglect, it shall issue directives to the State Government concerned to

take immediate ameliorative measures and also offer the State Government concerned technical and other assistance that is possible to be provided.

- (3) The National Biodiversity Authority shall recommend, as far as practicable wherever it deems appropriate, the integration, conservation, promotion and sustainable use of traditional knowledge and resources into relevant sectoral or cross-sectoral plans, programmes and policies.
- (4) The National Biodiversity Authority shall undertake measures wherever necessary,
  - (a) for assessment of socio-cultural, economic and environmental impact of that project which is likely to impact or have adverse effect on traditional knowledge, traditional practices and biological diversity, with a view to avoiding or minimizing such effects and provide for public participation in such assessment; and
  - (b) to prevent the risks associated with the use of any technology or process or introduction of alien species that is likely to impact the conservation and continuum of the use and practice of traditional knowledge and/or its related biotic and abiotic resources.

### 13. Traditional Knowledge Facing Extinction.--

- (1) Without prejudice to the provisions of any other law for the time being in force, the National Biodiversity Authority, in consultation with the State Biodiversity Board concerned, may from time to time notify any traditional knowledge or resource which is on the verge of extinction or likely to become extinct in the near future on account of (a) depletion of resources to sustain the traditional knowledge, (b) unwillingness of the traditional community to practise the traditional knowledge due to lack of opportunities, and (c) usurpation of the traditional knowledge for commercial gains, and prohibit or regulate access thereto for any purpose and take appropriate steps to preserve and ensure continuum of the same
- (2) The National Biodiversity Authority shall facilitate development of plans in consultation with traditional communities to protect, regenerate and propagate the traditional knowledge facing extinction, along with detailed conservation measures for the biological resources. The National Biodiversity Authority will also earmark dedicated funds to ensure that the continued practice of the traditional knowledge facing extinction.

#### 14. Traditional Knowledge Heritage Zones.--

- (1) Without prejudice to any other law for the time being in force, the National Biodiversity Authority, in consultation with the State Biodiversity Board concerned, and on application from a Biodiversity Management Committee, notify in the Official Gazette, areas of importance as traditional knowledge heritage zones under the Act.
- (2) The National Biodiversity Authority, in consultation with the State Biodiversity Board concerned, shall prescribe regulations and guidelines for the management and conservation of all the traditional knowledge heritage zones.

#### 15. Standing Committees.--

- (1) The National Biodiversity Authority shall constitute a National Standing Committee with a Presiding Member and not more than six other members of whom, one shall be a member from a civil society who is knowledgeable and experienced in matters of traditional knowledge practices and conservation, and at least three shall be representatives of traditional communities of India, provided that women shall constitute at least 30% of the total members.
- (2) The State Biodiversity Board shall set up a State Standing Committee with a Presiding Member and not more than six other members of whom, one shall be a member from a civil society who is knowledgeable and experienced in matters of traditional knowledge practices and conservation of the State, and at least three shall be representatives of traditional communities of the State concerned, provided that women shall constitute at least 30% of the total members.
- (3) The meetings of the National Standing Committee and the State Standing Committees shall be convened by the respective Presiding Member.
- (4) The duties and functions of the National Standing Committee and the State Standing Committees shall be as specified in these rules and as assigned by the National Biodiversity Authority or the State Biodiversity Board, as the case may be.
- (5) All decisions of the National Standing Committee and the State Standing Committees shall be taken by a majority of the membership.

(6) The expenditure of the National Standing Committee shall be debitable to the same budget head to which the expenditure of the National Biodiversity Authority is debited and that of each State Standing Committee to the same budget head to which the expenditure of the State Biodiversity Board concerned is debitable.

# 16. Budget, Accounts and Audit .--

The National Biodiversity Authority shall prepare a separate budget, maintain proper accounts and other relevant records, including the accounts and other relevant records of the Traditional Knowledge Fund, and prepare an annual statement of account in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India

# 17. Documents open to public inspection.--

- (1) The following documents, subject to such conditions as may be prescribed, shall be open to public inspection at the National Biodiversity Authority, namely:-
  - (a) the register and any document upon which a public entry in the register is based;
    - provided, the entries marked in the Register as "CONFIDENTIAL" shall not be made available to the public;
  - (b) all documents pertaining to an application for access, the reports of the National Standing Committee, State Biodiversity Boards and State Standing Committees and the prior informed consents, agreements, and Licences to Use;
  - (c) every notice of opposition to the registration of a traditional knowledge, application for rectification before the chairperson, counterstatement thereto, and any affidavit or document filed by the parties in any proceedings before the chairperson; and
  - (d) such other documents as the Central Government may, by notification in the Official Gazette, specify.
- (2) Any person may, subject to such conditions as may be prescribed, on an application to the Chairperson and on payment of such fee as may be prescribed, obtain a certified copy of any entry in the register or any document referred to in sub-rule (1).

#### 18. Offences and Penalties:-

- (1) Whoever contravenes or attempts to contravene or abets the contravention of any of the provisions of these Rules, shall be deemed to have committed an offence and shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both.
- (2) Notwithstanding anything contained in Rule 18(1) whoever misappropriates and/or misuses and/or abuses traditional knowledge shall be deemed to have committed an offence and shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both.
- (3) Protection of action taken in good faith: No suit, prosecution or other legal proceedings shall lie against any Authority in respect of anything which is in good faith done or intended to be done under this Act or the rules or regulations made there under.
- (4) Cognizance of offences: No Court shall take cognizance of any offence under this Act except on a complaint made by
  - (a) the Central Government or any authority or officer authorized in this behalf by that Government; or
  - (b) any benefit claimer who has given notice of not less than thirty days in the prescribed manner, of such offence and of his intention to make a complaint, to the Central Government or the authority or officer authorized as aforesaid.

#### 19. Appeal .--

Any person, aggrieved by any proceeding or order of the National Biodiversity Authority under these Rules, may file an appeal in the Supreme Court within thirty days from the date of communication to him, of the proceeding or order of the National Biodiversity Authority, as the case may be;

Provided that the Supreme Court may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the said period, allow it to be filed within a further period not exceeding sixty days.

#### 20. Execution of Proceeding or Order.--

Every proceeding or order made by the National Biodiversity Authority as per these Rules shall, on a certificate issued by any officer of the National Biodiversity Authority in the same manner as a decree of a court.

#### 21. Annual Report of National Biodiversity Authority .--

- (1) The National Biodiversity Authority shall prepare, in such form and at such time each financial year as may be prescribed, its annual report, giving a full account of its activities relating to the traditional knowledge during the previous financial year and furnish, to the Central Government, before such date as may be prescribed, its audited copy of accounts together with auditors' report thereon.
- (2) The Central Government shall cause the annual report and auditor's report to be laid, as soon as may be after they are received, before each House of Parliament.

#### 22. Power to make regulations.--

The National Biodiversity Authority may, with the previous approval of the Central Government, by notification in the Official Gazette, make regulations for implementing these Rules.

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