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Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report

The report was prepared through a consultative process including various stakeholders in the government and non-government sectors. These interalia included: experts, academicians, NGOs. Their inputs were specifically sought on the following issues:

- Intellectual property and traditional knowledge related to genetic resources; and
- Intellectual property rights and access and benefit sharing agreements.

In addition, interactive sessions were held with the Thematic Working Group on Access and Benefit Sharing under the National Biodiversity Strategy and Action plan (NBSAP) project. Some other material which was used for preparation of this report interalia include:

(i) 'The role of IPRs in the sharing of benefits arising from the use of biological resources and associated traditional knowledge – Selected case studies.' (Case study : India by Prof. Anil Gupta).

A joint submission by WIPO and UNEP.

(ii) 'Sharing with Kanis : A case study from Kerala' by Anuradha, R.V. 1998.

(iii) 'Rewarding traditional knowledge and contemporary grassroots creativity : The role of IPRs' by Prof. Anil Gupta. 2000.

(iv) 'National Policy and Macrolevel Action Strategy on Biodiversity : India'. 1999.

(v) 'Recognising and rewarding common pool knowledge resources'. Madhav Gadgil. 2000.

I. **Please provide the views of your country on the following issues:**

Intellectual property and traditional knowledge related to genetic resources

(a) *How to define relevant terms including subject matter of traditional knowledge and scope of existing rights;*

Traditional knowledge is understood as knowledge derived and transmitted outside the boundaries of formal scientific/technical discourse. It is based on practical experience and experimentation involving trial and error, codified to varying degrees. Traditional knowledge is often governed by customs and social conventions, making it very widely available. It is not protected today by any legally defined rights.

(b) *Whether existing intellectual property rights regimes can be used to protect traditional knowledge*;

No. Protection of knowledge, innovations and practices associated with biological resources, these do not seem to meet the conditions required for grant of patents or other IPRs (e.g. copyrights, trademark, etc.) under the prevalent IPR regimes, i.e. novelty, inventiveness and industrial applicability. These conventional forms of IPRs are inadequate to protect indigenous knowledge essentially because they are based on protection of individual property rights whereas traditional knowledge is by and large collective. Further, the informal knowledge presents other difficulties in being recognised for the purpose of IP protection, such as :

- Knowledge is developed over a period of time and may either be codified in texts or retained in oral traditions over generations. The conditions of novelty and innovative step necessary for grant of patent are therefore not satisfied.

- Knowledge is quite often held parallely by communities.

(c) *Options for the development of sui generis protection of traditional knowledge rights*.

Various suggestions have been advanced to extend protection to knowledge, innovations and practices. These interalia include: (I) documentation of TK; (ii) registration and innovation patent system; and (iii) development of a new legal framework outside the existing patent system. Documentation of TK serves only a defensive purpose, namely that of preventing patenting of TK in the form in which it exists, but by itself, documentation will not facilitate benefit sharing with the holders of TK. Many of the grassroot innovators, however, do not have the capacity for value addition. Thus, there is a need for providing institutional support in scouting, spanning, sustaining and scaling up of grassroots innovations and to enhance technical competence and self reliance of these innovators, through establishment of green venture promotion funds and incubators. In India, a National Innovation Foundation (NIF) has been established to build a national register of innovations, mobilize intellectual property protection, set up incubators for coverting innovations into viable business opportunities and help in dissemination across the country. The NIF solicits entries about technological grassroots innovations attempted by individuals engaged in small and cottage industries, workshops, farming, craft, fishing and livestock rearing, herbal medicines and other biodiversity uses, household and workplace technologies used by women etc. Entries are also solicited from farmers, slum dwellers, local communities in managing natural resources, construction of low cost environmentally benign houses or small machines, products or any other technological aspects of survival in urban and rural areas.

(d) *The relationship between customary laws governing custodianship, use and transmission of traditional knowledge, on the one hand, and the formal intellectual property system, on the other;*

Customary laws are very variable and there is no simple relationship with formal IPR systems.This is also reflected in the information given against (b) and (c) above.

(e) *Means by which holders of traditional knowledge, including indigenous peoples, may test means of protection of traditional knowledge based on existing intellectual property rights, sui generis possibilities, and customary laws;*

Sui generis systems as outlined under (c) above are needed to protect traditional knowledge. It is not possible to do so either using existing IPR systems or the extremely variable customary laws.

(f) *How to make provision for the exploitation and use of intellectual property rights to include joint research, obligation to work any right on inventions obtained or provide licenses*;

IPRs contribute to value addition of the resources. By incorporating appropriate conditions in the IPR laws for sharing of benefits through terms and conditions, IPRs could contribute to sharing of benefits also.

(g) *How to take into account the possibility of joint ownership of intellectual property rights*.

This can be done by incorporating appropriate provisions in the national legislation.For example, India's proposed biodiversity legislation, while granting access to biological resources and associated traditional knowledge, the National Biodiversity Authority (NBA) will impose terms and conditions to secure equitable sharing of benefits. These interalia include:

a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
b) transfer of technology;
c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
e) setting up of venture capital fund for aiding the cause of benefit claimers;
f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

In addition, one of the conditions in India's proposed biodiversity legislation is prior approval of the NBA before seeking any form of IPRs for an invention based on research or information on a biological resource obtained from India. The NBA while granting approval will impose conditions for sharing of benefits. The joint ownership of IPRs can thus be taken into account.

CASE STUDY ON BENEFIT SHARING ARRANGEMENTS

1. Overview

This case study relates to benefit sharing arrangements arrived at between Tropical Botanical Garden and Research Institute (TBGRI) and the Kani tribals of Kerala for the development of a drug called 'Jeevani' based on the knowledge of the Kani tribe. 'Jeevani' is a restorative, immuno-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant *arogyapaacha*, used by the Kani tribals in their traditional medicine. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribals healers, known as *Plathis*. The knowledge was divulged by three Kani tribal members to the scientists of TBGRI who isolated 12 active compounds from *arogyappacha* (*Trichopus zeylanicus*), and developed the drug 'Jeevani'. The technology was then licensed to the Arya Vaidya Pharmacy Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations. A Trust Fund was established to share the benefits arising from the commercialization of the TK-based drug 'Jeevani'. The operations of the Fund with the involvement of all relevant stakeholders, as well as the sustainable harvesting of the *arogyappacha* plant, have posed certain problems which offer lessons on benefit sharing over genetic resources and associated traditional knowledge. This experience has provided insight for developing benefit sharing provisions in the National Biodiversity Policy and Macrolevel Action Strategy as well as the legislation on biodiversity.

A brief description of the geographical setting, the discovery of medicinal properties of arogyapacha, efforts made towards preparation of the herbal drug 'Jeevani', and the benefit sharing arrangements worked out, are described in the following paragraphs. The principles pertaining to benefit sharing in the National Biodiversity Policy and Macrolevel Action Strategy and provisions relating to access and benefit sharing in the proposed biodiversity legislation are also described.

2. Description of the context

The key players in this case study are: a tribal community called Kani tribe, a research institute called Tropical Botanic Garden and Research

Institute (TBGRI) and a pharmaceutical company called Arya Vaidya Pharmacy.

(i)**Kani tribe**

The Agastyamalai tropical rain forests of Western Ghats is designated as a reserved forest area. Kani is a tribal community inhabiting the Agastyamalai forests. Their current population is approximately 17,000. Their settlement system is such that a few families live in a cluster interspersed with the forest. The terrain is undulated. Kanis maintain small gardens around their huts for growing plants of rubber, palms, fruits and flowers. They also do limited cultivation of tapioca, banana, millets and cash crops such as pepper, coconut, rubber, arecanut and cashewnut etc., in small plots of land given by the Forest Department. They derive most of their livelihood from crafts, and gathering and selling of various permitted forest produce. Though traditionally a nomadic community, most of the Kanis are now well settled for a long time.

The Kani community structure has traditionally been that of a highly coordinated unit under the control of a tribal chief called the Moottukani who combined the roles of law-giver, protector and dispenser of justice, physician and priest. However, over the years, this traditional system of governance has been eroded and the role of the Moottukani is now only a token one. The Kanis occupy several tribal hamlets, each consisting of 10 to 20 families dispersed in and around the forest areas of Thiruvananthapuram district.

Tribal physicians among the Kanis are known as ‘Plathi’ – who is a repository of tribal medical wisdom. They cure ailments through their traditional healing art which includes administration of various drugs or some magico-religious cures like mantras and rituals.

(ii)**Tropical Botanic Garden and Research Institute (TBGRI**)

TBGRI is an autonomous body established by the Government of Kerala in 1979. It has been accorded the status of a Center of Excellence in conservation and sustainable utilisation of tropical plant diversity by the Ministry of Environment and Forests, Government of India.

Spread over 300 acres, the Garden System of TBGRI has over 50,000 accessions belonging to 7000 tropical plant species. The garden system includes an Arboretum, Bamboosetum, Palmetum, Orchidarium and field collections of medicinal plants, wild ornamentals and lesser known wild edibles. In addition to these, there are special conservatories for rare, threatened and endemic plants, special assorted collections of Ficus, Cycads, Ferns, Cacti and Succulents, Aquatic plants etc. The medicinal plant collection includes wild lesser known plants used by the indigenous communities. As one of the National Gene Bank for Medicinal and Aromatic Plants established under the aegis of the G-15 countries, TBGRI has established a field gene bank, seed bank, tissue repository and cryobank of rare and endangered medicinal and aromatic plants of tropical India.

The R&D activities of TBGRI are integrated and multidisciplinary in nature and are geared to achieve the most tangible results of conservation as well as of value added and product oriented sustainable utilization of plant genetic resources of the region.

(iii)**All India Coordinated Research Project on Ethnobiology (AICRPE**)

The Ministry of Environment and Forests, Government of India had launched an All India Coordinated Research Project on Ethnobiology (AICRPE) in 1982, with the broad objective of preserving the knowledge system of our tribal communities. The TBGRI was the Coordinating Centre of this multi-institutional, multi-disciplinary action oriented research programme.

(iv)**Arya Vaidya Pharmacy (AVP**)

Arya Vaidya Pharmacy, a Coimbatore based company has been manufacturing Ayurvedic drugs since 1948. AVP is pursuing the commercialization of Ayurvedic and herbal formulations in a highly value based manner, upholding high quality standards.

3. Discovery and development of the drug

In December 1987, under the All India Coordinated Research Project on Ethnobiology, a team of scientists undertook a botanical expedition into the Agastyamalai forests. They were accompanied by members of the Kani tribe as guides.

During the expedition, the scientist team observed that the Kani guides frequently ate black fruits of some plants which kept them energetic and agile. They offered a fruit to the exhausted scientists during the trip. Upon eating the fruits, the team felt immediately charged and full of energy and vitality. The tribals were initially reluctant to reveal the identity of the fruit and pleaded that it was a time-honored tribal secret and a sacred one.It was only after much persuasion, they showed the scientists the plant from which the fruit was obtained. Kanis call the plant in their language as 'Arogyapacha'. The plant specimens were collected for study, and the plant was identified as *Trichopus zeylanicus*. Detailed scientific investigation of the plant was subsequently carried out, including chemical screening to isolate the active principles, and pharmacological screening. The fruit of the plant contained anti-fatigue properties that the Kanis had identified. Studies on the leaves showed the presence of certain glycolipids and non-steroidal compounds which possessed anti-stress, anti-hepatotoxic and immunodulatory/ immunorestorative properties. The TBGRI scientists developed a drug 'Jeevani' by adding three other medicinal plants as ingredients.

4. Benefit Sharing arrangements between Kani tribe and TBGRI

The Governing Body of the TBGRI authorised the TBGRI Director to transfer technology for the manufacture of Jeevani to interested parties on payment of an appropriate licence fee. Negotiations for the same were conducted by a committee constituted for this purpose headed by the Chairman of the TBGRI Executive Committee who is also Chairman of the State Committee on Science, Technology and Environment, Government of Kerala. This committee recommended a transfer of the right to manufacture Jeevani to Arya Vaidya Pharmacy (Coimbatore) Ltd. for a period of seven years at a licence fee of Rs. 10 lakh (one million rupees, approximately $25,000).

TBGRI was also to receive two per cent royalty on any future drug sales. This was done as per the guidelines of Council of Scientific and Industrial Research. According to TBGRI, it was the best bargain that could be arrived at by their selection committee. They emphasise that the license period is only for the purpose of a promotional venture and that once the drug is able to establish a market for itself within the license period of seven years, the license fee could be suitably enhanced and that it could be licensed to another company if that is more beneficial.

In a separate resolution approved by both the Governing Body and the Executive Committee of the TBGRI, it was decided that the Kani tribals would receive 50 per cent of the licence fee, as well as 50 per cent of the royalties obtained by the TBGRI on sale of the drug, as part of the benefit sharing arrangement for divulging the information.

In November 1997 with the assistance of TBGRI, a trust was registered, named the Kerala Kani Samudaya Kshema Trust. All the nine registered members of the Trust are Kani tribals. The president and vice-president of the Trust are the two Kanis who imparted the traditional knowledge to TBGRI regarding arogyapacha. The objectives of the Trust are:

- Welfare and development activities for Kanis in Kerala,
- Preparation of a biodiversity register to document the knowledge base of the Kanis,
- Evolving and supporting methods to promote sustainable use and conservation of biological resources.

The first tranche of Rupees 5 lakh and royalties of Rupees 19,000 of the benefit sharing formula were deposited in the account of Kani Samudaya Kshema Trust at Kuttichal Union Bank. The first meeting of the Trust after the transfer was held at the Kallar Mattammodhu Kani tribal settlement on March 19, 1999. In the meeting it was decided to grant as special incentives, Rs. 20,000 to Mallan Kani, Rs. 20,000 to Kuthy Mathan Kani and Rs. 10,000 to Eachen Kani, who passed on the information to the scientists.

The Trust is currently working out a scheme to utilise the funds. A tentative project is being worked out to set up a telephone booth, an insurance scheme for pregnant women and to cover accidental deaths.

5. Impact on conservation and sustainable extraction of the plant

During the harvest of leaves, some people uprooted the whole plant from their gardens and some others took the wild herb from the forest. This alerted the Forest Department against possible large scale 'smuggling' of the herb. Scientists at TBGRI also felt that this should not be done since sustainable collection of the leaves of the plant is possible. They emphasised that only the leaves of the plant are required for the production of Jeevani.

A pilot phase for cultivation of the plant was undertaken in certain Kani settlements, in areas adjoining the Reserved Forest, during the period 1994-96. It was supported by the Integrated Tribal Development Programme (ITDP) initiated by the Directorate for Tribal Welfare, Government of Kerala. Fifty families were given Rs. 1,000 (approximately $40) each by the ITDP to cultivate the plant. Under the scheme, the TBGRI agreed to buy the harvested leaves from the families which were then supplied to AVP for pilot phase production of Jeevani.

However, there has been no further cultivation of the plant. This is because *Trichopus zeylanicus* is not included in the Forest Department's notified list of minor forest produce. The Forest Department has hesitated in granting permission to the tribals to grow and harvest the leaves of *Trichopus zeylanicus*, largely due to earlier attempts by private concerns to smuggle the plant out of the Reserved Forest area. In one incident, the Forest Department seized 10,500 plants (loaded in two trucks) collected by tribals for sale to a private nursery near Thiruvananthapuram. The Chief Conservator of Forests (Vigilance) is of the opinion that though there may be no harm in the Kanis collecting the leaves of this plant for personal use, pressures from outside commercial interests may cause the rapid depletion of the plant from the area.

In October 1996, AVP wrote to the Kerala Forest Department and the Tribal Welfare Department proposing a plan for the cultivation of Arogyapacha whereby it would pay the Kanis initial seed money for cultivation of the plant, and enter into an arrangement with the tribals to buy leaves harvested from those plants. The letter stated that AVP was prepared to buy five tonnes of leaves a month and that at least 500 to 1,000 Kani families would be employed under such a scheme. The company assured the State Departments that no private parties would be involved in cultivation of the plant. The Forest Department, in its letter of October 1996, rejected

AVP's proposal saying that the plant was endemic and its collection could not be permitted. A recent report, however, states that the Forest Department has agreed to consider including *Trichopus zeylanicus* in its list of minor forest produce, and evolving a mechanism whereby AVP could buy the leaves directly from the Kanis.

6. Lessons learned

- This case study brings to light the need for multi-stakeholder framework for discussing the scope of access, value addition and benefit sharing.
- The case also illustrates that while intellectual property rights play a crucial role in generating benefits from biological resources and traditional knowledge, their role should be balanced with the conservation objective.
- The increase in demand could have led to excessive extraction of the biological resources, if the following measures were not taken:

- Raising adequate awareness among all stakeholders,
- Supporting and creating local institutions for sustainable extraction, and
- Legitimising the property rights of communities over the use of biological resources and associated knowledge which were negotiated and defined at local level.

- In the early stages of the case when many people started buying this plant at the rate of Rs. 100 per kilogram, the Forest Department had to impose restriction when they confiscated illegally collected leaves and whole plants. The offer of the Arya Vaidya Pharmacy of giving a buy back guarantee to the Kanis alongwith the technology to cultivate and extract leaves in a sustainable manner was a solution to this problem.

- The effective protection of intellectual property is a necessary condition for generating benefits, but it is not a sufficient condition for benefit sharing. Several additional measures are needed to supplement the role of intellectual property rights in benefit sharing over biological resources and traditional knowledge.

- The degree of involvement of various tribal settlements and groups could have been increased. The rights of informants vis-à-vis the communities requires more discussion among the communities themselves.

- The non-material contribution of benefits by way of empowerment of local communities deserves to be noted, but several more such benefits could have been considered. For instance health check-ups for the local communities were urgently needed given the very poor health condition of many women, children and also some male adults.

- The Forest Department had not permitted the cultivation and collection of the arogyapacha plant. This was so in spite of the fact that the plant could be easily cultivated and many tribals had actually done so. If the Forest Department had been involved from the beginning of this value chain, perhaps their attitude might have been different.

- The objective of the Kani Samudaya Kshema Trust to establish a biodiversity register to document the knowledge base of the Kanis must be pursued with the intellectual property implications of such a register in mind. Intellectual property questions to be resolved for the creation of such a register include who operates the register, who provides access to its contents to which parties on which terms, who conducts documentation of the knowledge, who has the right to authorise documentation on behalf of the tribes, which knowledge elements will be documented in which format, how to deal with local language documentation in relation to national and international use of the register etc.

- In order to meet the demand of regular supply of plant to the manufacturing unit, it needs to be grown in large quantities. Since, it is a shade loving plant, it has to be cultivated as an understorey vegetation of trees in the forests. Local tribals have been encouraged to take up cultivation of “Arogyapacha” with the active cooperation of Integrated Rural Development Programme (IRDP) and Forest Department. Cultivation of these plants provides protection to the associated tree species, in addition to securing economic uplift of the tribal people in terms of employment and additional income. Thus modern economic working of the local knowledge and use of plants leads to conservation of the plant species as well as its associates. This case study clearly

establishes that conservation and sustainable utilization are dependent on long-term benefits. It illustrates the point that sharing of benefits leads to conservation and sustainable utilization of biological resources.

7. Implications on the development of policy, legislative and administrative measures

The Kani-TBGRI experience has provided insights for formulating policy and legislative measures for benefit sharing arrangements in India. The relevant goals and principles of the national policy and the relevant provisions of the national legislation on biodiversity are described below.

(i) National Policy and Macrolevel Action Strategy on Biodiversity

India has enunciated its National Policy and Macrolevel Action Strategy on Biodiversity in 1999. One of the goals of the National Policy is:

(i) Ensure benefits to India as country of origin of biological resources and to local communities and people as conservers of biodiversity, creators and holders of indigenous knowledge systems, innovations and practices.

The relevant principles governing this goal are:

(i) India has sovereign rights over its own biological resources. Access and utilisation of the biological diversity occurring in India would be in accordance with the administrative and legislative measures of the State, including with the prior approval of the Central Government or the State Governments as the case may be.

(ii) Local communities and people have over the years developed lifestyles, innovations and practices conducive to conservation and sustainable use of biodiversity. They have developed a body of knowledge regarding the use of these resources for food, medicines, pesticides etc. Considering the dependence of the lifestyles of communities and local people on biological diversity, practices of utilisation conducive to conservation would be encouraged. Such practices, innovations and knowledge would be protected and propagated for wider use

subject to ensuring benefits to these communities/people for utilising such knowledge and practices. Any commercial use of such knowledge, innovations and practices would be permissible only after ensuring a due share of the community in the benefits realised from such knowledge, innovations and practices.

(ii) National legislation on biodiversity

India has been in the process of formulating a legislation on biodiversity since 1994, when India became a Party to the Convention. Extensive, transparent and participative consultations were held with eminent experts, NGOs, different departments of Central Government and State Governments. The biological diversity legislation introduced in the Parliament is an outcome of extensive and intensive consultation process involving all stakeholders.

Salient features of the biodiversity legislation are as follows:

- The legislation primarily addresses the issue concerning access to genetic resources and associated knowledge by individuals, institutions or companies, and equitable sharing of benefit arising out of the use of these resources and knowledge to the country and the people.

- The legislation provides for setting up of a three tiered structure at national, state and local levels.

a) The National Biodiversity Authority will deal with matters relating to requests for access by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner; imposition of terms and conditions to secure equitable sharing of benefits and approval for seeking any form of Intellectual Property Rights (IPRs) in or outside India for an invention based on research or information pertaining to a biological resource obtained from India.

b) State Biodiversity Boards will deal with matters relating to access by Indians for commercial purposes and restrict any activity which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

c) Biodiversity Management Committees will be set up by institutions of self-government in their respective areas for conservation, sustainable use, documentation of biodiversity and chronicling of knowledge relating to biodiversity. Biodiversity Management Committees shall be consulted by the National Biodiversity Authority and State Biodiversity Boards on matters related to use of biological resources and associated knowledge within their jurisdiction.

- All foreign nationals/organisations require prior approval of NBA for obtaining biological resources and/or associated knowledge for any use. Indian individuals/entities require approval of NBA for transferring results of research with respect to any biological resource to foreign nationals/organisations. Indian citizens and organisations are required to give prior intimation to the concerned SBB about obtaining any biological resource for commercial use, and the SBB may prohibit or restrict the activity if found to violate the objectives of conservation, sustainable use and benefit sharing. However, local people and communities of the area, including vaids and hakims to have free access to use biological resources within the country. While granting approvals for access, NBA will impose terms and conditions so as to secure equitable sharing of benefits. These benefits interalia include:

a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
b) transfer of technology;
c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
e) setting up of venture capital fund for aiding the cause of benefit claimers;
f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

- The legislation provides for setting up of biodiversity funds at central, state and local levels. Benefits will be given directly to individuals or group of individuals only in cases where biological resources or knowledge are accessed directly from them. In all other cases, monetary benefits will be deposited in the Biodiversity Fund which in turn is used for the conservation

and development of biological resources and socio-economic development of areas from where resources have been accessed.

- Before applying for any form of IPRs in or outside India for an invention based on research or information on a biological resource obtained from India, prior approval of NBA will be required. The NBA while granting the approval impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.