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RIS Discussion Papers

**Intellectual Property Regime,
Indigenous Knowledge System and Access
and Benefit Sharing: Drawing Lessons
from Kani Case**

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Intellectual Property Regime, Indigenous Knowledge System and Access and Benefit Sharing: Drawing Lessons from Kani Case

Sachin Chaturvedi*

Abstract: Since the Doha Ministerial, the developing countries have been raising issues related to the indigenous knowledge system (IKS) and access and benefit sharing (ABS) in context of conflict between the CBD and the TRIPs. Though the Doha Development Agenda (Paragraph 19) did acknowledge the need of CBD and TRIPs relationship to be looked into, however most of the developed countries rejected ABS on the pretext that the ABS is not a viable proposition and that ABS should be addressed at the national level rather than placing it as part of multilateral regime. The emerging evidence from Kani case in India suggests that a nuanced approach to the benefit sharing regime may help in ensuring equitable distribution of gains through a formal mechanism which may prove out to be sustainable in long run. The study also shows that national regimes are not sufficient to check global misappropriation of IKS.

Keywords: IKS, ABS, TRIPs, CBD, Kani and India.

I. Background

Since the adoption of Doha Declaration, relationship between indigenous knowledge system (IKS) and TRIPs related issues have come at the centre stage as most of the members of WTO have emphasised on delineating

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relationship between CBD and TRIPs. The developing countries have proposed making prior informed consent (PIC) and access and benefit sharing (ABS) as mandatory provisions of the international IPR regime.

Though it is widely acknowledged that under Article 15 of CBD, it is desired to have access and benefit-sharing arrangement on mutually agreed terms, the spirit is not to confine it at the national level alone. With economic liberalisation, opening up of borders and removal of trade restrictions, the ramifications for Genetic Resources (GRs) and indigenous knowledge system (IKS) usage may assume significant proportions, especially in context of their transboundary movements. Many companies acquire GRs or IKS in one country and apply for patent in another country. This would become difficult to manage if only national instruments are used for governing contractual arrangements. Since provisions of CBD do not bind all members of WTO, there are no obligations under any international law to ensure commitment for ABS or PIC. Even if national contractual arrangements have international orientation, lack of framework at international level would adversely affect effective implementation of desired objectives of ABS and PIC.

The story of the Kani access and benefit sharing (ABS) model begins in April, 1987, when a scientist from the All India Coordinated Research Project on Ethnobiology (AICRPE)¹ arrived in the forests of the Agasthyar hills in southern India to seek permission from *Mottu Kani* (head of the Kani tribe) to launch an expedition into the forests.² There is a practice among the Kerala tribes that any outsider is first supposed to meet the tribal chief before entering their settlements. Accordingly, Adichan Kani, the head, deputed a team of three Kanis to accompany the expedition as guides. The full team led by the Chief Coordinator of AICRPE, Dr P. Pushpangadan, arrived in the forests in December, 1987.

Within the first few days, the scientists realised that the Kanis who accompanied the team as guides, did not feel as tired and fatigued as the scientists. On further inquiry the scientists found that the fruits the tribal group members were chewing had imparted this vitality and rejuvenation. After much persuasion the members of the Kani tribe agreed to share details about the plant with the scientists.³ The scientists took samples of the fruit

and other parts of the plant for phytochemical and pharmacological studies at the Regional Research Laboratory (RRL) at Jammu, as the AICRPE project was coordinated through the RRL. The investigations confirmed the presence of certain glycolipids and non-steroidal polysaccharides with immuno-enhancing and anti-fatigue properties. The plant was *Trichopus zeylanicus travancoricus*, which the Kanis describe as *Arogyappacha* (meaning source of evergreen health). Detailed phytochemical and pharmacological investigations pursued at the RRL led to the filing of patents.

In 1990 the Chief Coordinator of AICRPE moved from the RRL to become Director of the Tropical Botanic Garden and Research Institute (TBGRI) in Thiruvananthapuram, Kerala, and the research on *Arogyappacha* also moved to the TBGRI. The Director constituted a team of scientists to focus on this study. Since the TBGRI was not equipped to handle such a comprehensive research project, the services of people from the varied fields of pharmacology, phytochemistry, biochemistry and Ayurveda were hired. As the research progressed, two of the three original Kani guides were included in the team as consultants and paid a consolidated monthly fee from 1993 until 1998.⁴ Eventually, this project led to the development of a product called '*jeevani*' which was ready to market by 1994.

It is pertinent that Kani tribe members were using only the fruits of the plant whereas *jeevani* was developed from its leaves (never used by the Kani tribe members). Only 13 to 15 per cent of the plant was used for the final product, while the remaining ingredients were based on other ayurvedic knowledge and wisdom. In November 1996 the technology was transferred by the TBGRI to M/s. *Arya Vaidya Pharmacy* (AVP), Coimbatore, one of the largest Ayurvedic manufacturing companies in India against a license fee of Rs. 1 million (approximately US \$25,000) and royalties of 2 per cent at ex-factory sale. The TBGRI proposed to share the license fee and royalty with the Kanis on a 1:1 ratio. The Kerala Kani Community (Samudaya) Welfare (Kshema) Trust was registered in November 1997, to regulate and direct the inflow of money.⁵ Though concerns were initially raised about the viability of the Trust,⁶ it is now working well.

However, the ABS arrangement in the Kani case has raised several issues. For instance, whether there was consent by the Kanis for commercialisation of their knowledge and to what extent they were satisfied with their representation on the Trust. Most indigenous communities consider indigenous knowledge as sacred and do not wish to share it with others. This case study delineates the context for some of these issues. Section II follows the introductory discussion and brings in the legal background at the national and international level, while Section III details the major actors in this story. Sections IV and V explain the decision making processes and the ethical issues raised by this case. The last section draws conclusions.

II. Legal Environment

The legal regime in India to protect biological resources and to monitor ABS emanated from national and international discussions as well as international guidelines such as the Convention on Biological Diversity (CBD)⁷, Bonn Guidelines,⁸ etc. The CBD, which came into force on 29 December 1993, aimed at ensuring conservation and the sustainable use of biological diversity in addition to a fair and equitable sharing of the benefits arising from the utilisation of biological resources. India was among the first few countries to sign and ratify the convention in 1994.

As part of the international commitment to produce relevant legal procedures and policies, the Indian government enacted the Biological Diversity Act (BDA) in 2002. This is one of the major instruments available to the government for the protection of indigenous knowledge systems. Apart from this, the other legal provisions dealing with biodiversity are discussed below. The major ones include: the Indian Forest Act (1927), the Wild Life (Protection) Act (1972), and the Forest Conservation Act (1980). The recently announced National Tribal Policy (2006) has set a new legal context for tribal communities.

II.1. National Laws and Implementation

The Biological Diversity Act (BDA) 2002 received the assent of the President on 5th February, 2003. This led to the formulation of the Biological Diversity Rules in 2004.⁹ The Act intended to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing

of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. The Biological Diversity Rules provide the necessary statutory and administrative mechanism at the national level to realise the above objectives. The National Biodiversity Authority (NBA), established at Chennai, was the major institutional arrangement proposed. The NBA has a chairperson, ten ex-officio central government representatives and five non-official specialists and experts. The chairperson is the chief executive of the NBA. The main functions of the Authority are to lay down procedures and guidelines to govern activities such as the granting of permission to foreign companies for obtaining any biological resource and for transferring the results of any research. It advises the government on specific areas such as notifications of threatened species; designation of institutions as repositories for different categories of biological resources; and exemption of certain biological resources, normally traded as commodities. It also encourages the setting up of State Biodiversity Boards.

The ABS Provisions

Article 21 of Chapter V of the BDA suggests mechanisms for the determination of equitable benefit sharing. As part of this, the NBA under section 19 and section 20 demands equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and related knowledge. If any amount of money is ordered by way of benefit sharing, the NBA may direct the amount to be deposited in the National Biodiversity Fund. The Act elaborates the various arrangements under which the benefit sharing could be achieved, as follows:

- (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 utilisation;

- (e) setting up of venture capital fund for aiding the cause of benefit claimers;
- (f) payment of monetary compensation and non monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.¹⁰

Institutional Mechanisms

The BDA provides for the setting up of a National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) in local bodies. The NBA and SBBs are required to consult BMCs in decisions relating to the use of biological resources/related knowledge within their jurisdiction and the BMCs are to promote conservation, sustainable use and documentation of biodiversity. Their main role is to prepare the People's Biodiversity Register (PBR) in consultation with local people, which includes comprehensive information on the availability of local biological resources and the traditional knowledge associated with them.

Foreign and national organisations require prior approval from the NBA for obtaining biological resources and/or associated knowledge for any use. Indian individuals/entities require the approval of the NBA for transferring the results of research with respect to any biological resources to foreign national/organisations (Section 3). Indian industry is required to give prior intimation to the SBBs concerned about obtaining any biological resource for commercial use, and the SBBs may restrict the activity if it is found to violate the objectives of conservation, sustainable use and benefit sharing (Section 4). The provision of mandatory consultation of BMCs by the NBA and SBBs aims to ensure formalisation of prior informed consent (PIC) procedures by the communities and the involvement of BMCs in the decision making process. In cases where specific individuals or a group of individuals are identified, the monetary benefits will be paid directly to them. Otherwise, the amount will be deposited in the National Biodiversity Fund.

Other Legal Provisions

The Cabinet has also approved the introduction of the Indian Medicine and Homeopathy Pharmacy Bill, 2005. The Bill proposes to regulate the education and practice of pharmacy in Indian medicine and homeopathy.¹¹ The legislation seeks to set up a Central Pharmacy Council to regulate the

education and practice of pharmacists in *ayurveda*, *siddha*, *unani* and homeopathy. It also seeks to bring uniformity to the standards of pharmacy education in these disciplines. These systems aim to ensure that quality medicines are delivered.

The Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001,¹² is another legal provision which has significant implications for the access and benefit sharing regime. The 'National Gene Fund' proposed under the PPVFR conceptualises contributions by way of benefit sharing for a variety developed from farmers, farming communities and the indigenous knowledge system. The Fund is intended to be used for the benefit of concerned stakeholders, for the conservation and preservation of biological resources, and for the socio-economic development of areas where such biological resources or knowledge come from.

In the pre-British period most of the local rulers had left forests and tribal communities undisturbed by the policies of the State. However, things changed with the Forest Act, 1927,¹³ when the focus of policy became conservation without sufficient acknowledgement of the interests of tribal communities and their livelihood security. As tribal communities were not registered to vote (being mostly nomadic), political parties did not take account of their interests.¹⁴ The Forest Conservation Act 1980 did not improve on the situation even though it included provisions for recording and settlement of the rights of tribal communities.¹⁵ Only in 2006 was legislation promulgated, which took account of the needs of such communities. The legislation is described in the next paragraph.

Report to the People 2004-07

The new United Progressive Alliance (UPA) government has launched fresh legislative and other measures at the federal level to address land ownership and other issues related to tribal communities. The Prime Minister launched a Report on 22 May 2007 that covered all issues related to tribal communities in the period 2004-07.¹⁶ The Government formulated a draft National Tribal Policy on important issues that concern tribal people, such as alienation of tribal land, tribal-forest interface, resettlement and rehabilitation, as well as traditional knowledge.

The Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forests Rights) Act, 2006¹⁷ has been promulgated along with the relevant rules which vests various forest rights in tribes and other traditional forest dwellers who have been living in forests for generations. These include rights over forest land occupied by them; agriculture and ownership of non timber forest produce (NTFPs), including the right to collect, use and dispose of such produce, and certain other traditional and customary rights. The Act will remove the threat of eviction from forest land under their occupation.

II.2. International Initiatives

Among international initiatives, the CBD is the most appropriate for understanding the ABS regime. The CBD was adopted by more than 150 governments at the Rio Earth Summit in 1992 and it came into force in 1993.

One of the three objectives of the CBD is to achieve fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies. Article 15 of the Convention sets out a framework to achieve this objective. It recognises the sovereign rights of respective countries over their natural resources and suggests that national agencies/authorities set the conditionalities for determining access to genetic resources. There is emphatic recognition of the fact that access to genetic resources should be subject to PIC and that national authorities should ensure mechanisms are in place for sharing, in a fair and equitable way, the benefits which arise from the commercial and other utilisation of genetic resources. Article 8(j) encourages national governments to develop mechanisms for equitable benefit sharing:

Each contracting Party shall, as far as possible and as appropriate:
Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the

equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices.¹⁸

Though several years have passed since the CBD was adopted, a model ABS agreement has yet to be developed. The CBD through its Conferences of Parties (CoP) has been discussing various issues related to ABS. Since the adoption of the CBD, eight such conferences have taken place. Part of the rationale for the meetings was to assess user and provider experiences on accessing genetic resources and agreeing benefit sharing so as to identify viable approaches for the involvement of stakeholders. The major achievement of this consultation process has been the adoption of the '*Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation*' (*Bonn Guidelines*).¹⁹

CoP-4 of the CBD, in their IV/8 decision recommended the establishment of a panel of experts appointed by the member governments, composed of representatives from the private and public sectors, as well as representatives of indigenous and local communities. The panel in its first meeting in 1999 reached broad conclusions about PIC on mutually agreed terms, information needs and capacity-building. At CoP-8 at Curitiba, Brazil in 2006, they agreed to establish a group of technical experts to explore and elaborate the possible options for developing an internationally recognised certificate of origin/source/legal provenance and analyse its practicality and feasibility, as well as costs and benefits, with a view to achieving the objectives of Article 15 (Access to Genetic Resources) and 8(j) of the CBD. In the same meeting it was also decided by the CoP that the *Bonn Guidelines* should be used while member governments developed and drafted their legislative, administrative or policy measures on access and benefit-sharing. At the same time, relevant organisations were requested to provide financial and technical assistance to support the implementation of the *Bonn Guidelines* in developing countries, in particular least developed countries, small islands developing states, and countries with economies in transition.

A CBD Working Group on Access and Benefit Sharing is already in place, to work out indicators for assessing access to genetic resources and in particular for the fair and equitable sharing of benefits arising from the

utilisation of genetic resources. The Group will hold its fifth meeting in October 2007 to finalise these indicators. The Group will also look at issues related to a certificate of origin and measures to support PIC requirements, including material transfer agreements.

Apart from the CBD there are other international fora that propose legislation. Benefit sharing has become one of the main issues of contention with regard to the World Trade Organisation's Trade-related Intellectual Property Rights (WTO TRIPS) agreement. In November 2001, a ministerial conference of WTO members agreed the "Doha Mandate" in Qatar. This mandate identifies areas for further negotiations, one of them being the relationship between TRIPS and the CBD's protection of traditional knowledge.²⁰ In a submission to the WTO by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela it was suggested that a benefit sharing check-list ought to be included into TRIPS to bridge the gap between the two agreements.²¹ This suggestion has led to strong opposition by a group of industrialised countries led by the USA. At subsequent meetings of the World Intellectual Property Organisation (WIPO) increased calls have been made by developing countries for the origin of genetic resources and traditional knowledge to be disclosed in patent applications, again with strong opposition by several industrialised countries. The issue remains unresolved and is a main hindrance for realising the objectives of the CBD and fulfilling the Doha Mandate.

WIPO has undertaken work on ABS related issues since 2001, through the Inter-Governmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. It is expected that the final report of the group will be presented by the end of 2007.²² However, the IGC proceedings have so far not identified any point of convergence between the differing views of its members.

III. The Product and Key Actors

The following section will introduce all the players in the Kani benefit sharing case. Some of them played a very important and central role, yet others only had a background role. In order to facilitate understanding of the case, I shall also present more details about the product itself.

III.1. Jeevani

The Jeevani product is a poly herbal drug in a granular form. The members of the Kani tribe were actually chewing fruits of the plant, *Arogyappacha* but since fruits are available in limited numbers, the TBGRI team scientifically validated all parts of the plant including the roots and leaves for possible leads. Eventually they found leaves with the necessary chemical and pharmacological properties. The final product includes three other medicinal plants apart from *Arogyappacha*, *jeevani*, namely *withania somnifera* linn. (*ashwagandha*), *piper longum* linn. and *evolvulus alsinoides* linn. The product was tested for eight months in different Indian cities with over 100 patients from different backgrounds – 70 per cent non-healthy and 30 per cent healthy persons. Apart from modern drug efficacy tests it was also evaluated on the basis of Ayurvedic *dravya guna* and *rasa shastra*. It is classified under the health promoting (*swasthahita*) group of drugs. In Ayurvedic literature, *Arogyappacha* is described as one of the 18 divine herbs.²³ The species *Trichopus zeylanica* can be found in the Malay peninsular, Sri Lanka, Thailand and India.²⁴ In India, it is found distributed in the southern Western Ghats – in the hills of Travancore at Thirunelvely. The Indian species of *Trichopus zeylanica* is different from other Asian specimens and has a subspecies status. It is a small, perennial herb with many slender stems (5 cm to 25 cm long) arising from rhizomes. It usually grows in the shade near the banks of streams and rivulets.²⁵

III.2. Kani Tribes

The Kani tribe is a small previously nomadic but now settled community of almost 25,000 members, based in the Agasthyar Hills in southern India. Under the modern administrative system in India, this tribal group is spread over six gram-panchayats²⁶ across the state of Kerala in southern India. A small number of other members reside in the neighbouring Indian state of Tamil Nadu. Most of the members are engaged in cultivation of mixed crops such as rubber, areca nut, banana, pepper, cashew nut, etc. Almost all the group members have small huts along with a small garden attached to them. The requirements on the tribal communities by the Forest Department have increased over the years and this has adversely affected their own ability to make decisions. For instance, the individual areas which they are

occupying now are on long term lease from the Forest Department. Their choices for cultivation thus depend on the list of NTFPs as issued and amended from time to time by the Forest Department.²⁷

The community is struggling with poverty at different levels as some of the members are better placed in terms of their economic security. This largely depends on individuals' external linkages for livelihood earnings. Mostly selling of NTFPs (like honey, beeswax, medicinal plants, and python fat, fruits, etc.) is the source of their income. The level of knowledge about the medical properties of plants varies across the settlements and between individual members. Earlier they had experts (called *Plathi*), who knew the medical system of their forests very well. However, over the years this practice has disappeared and members have developed their own practices for managing this knowledge system, for instance several individuals have taken over the art from *plathis*.²⁸

III.3. Tropical Botanic Garden and Research Institute (TBGRI)

The Tropical Botanic Garden and Research Institute (TBGRI) was established at Palode, Thiruvananthapuram in 1979 under the aegis of the Science, Technology and Environment Committee (STEC), Government of Kerala, with the following objectives:

- Conservation and sustainable utilization of plant genetic resources
- Basic and applied botanical, horticultural, biotechnological, phytochemical, ethnomedical and ethnopharmacological research for plant improvement and utilization
- Development of location oriented production technologies that utilize plant resources and human skill
- Dissemination of research and development activities
- Working in collaboration with similar organizations in India and abroad

Since 19th June 2003 the TBGRI has been under the control of the Kerala State Council for Science, Technology and Environment (KSCSTE). The Chief Minister of Kerala is the President of the KSCSTE. Spread over 300 acres, the garden system of the TBGRI is regarded as the biggest conservatory garden in Asia with over 50,000 accessions belonging to about 3,500 species. The overall research and development (R&D) activities of the TBGRI are geared to achieve the most tangible results of conservation

as well as value added and product oriented sustainable utilisation of plant genetic resources of the region. The R&D programmes oriented to accomplish these objectives are therefore integrated and multidisciplinary in nature involving the most pertinent components of exploration, survey, collection, introduction, characterization and evaluation (phytochemical, pharmacological and biotechnological), documentation and conservation.

As part of the initiatives on taxonomy the institute has short-listed a flora of the garden, thereby documenting the native plant wealth. It also covered details about plants introduced from outside Kerala. As part of the biotechnology programme, the TBGRI focused on mass multiplication of plants of commercial importance, especially orchids for cultivation and distribution to the public, which supplemented the major commercial efforts in the state. The Institute has evolved a major work programme under 'Vision 2012'. As part of this programme, the TBGRI envisages becoming the largest botanical garden in Asia. It proposes to establish highly specialised conservatories for specialised groups of plants. There is also a plan to add further modern amenities which are required to make the garden visitor-friendly. The TBGRI is also consolidating its education programmes, including PhD and M.Phil and Diploma courses.

Since its inception the TBGRI has received a total of Rs. 24 billion from the government as grant-in-aid and Rs. 12 billion as financial assistance from various national and international funding agencies for conducting different projects. The total staff strength of the TBGRI is 233, which includes scientists (59), technical staff (34) and non-technical staff (140).²⁹ The Institute has applied for 17 patents including the one on *jeevani*.

III.4. M/s Arya Vaidya Pharmacy Coimbatore

The Arya Vaidya Pharmacy Coimbatore (AVP) is one of the largest Ayurvedic manufacturing companies in India. It was established in 1943 and produces more than 450 varieties of traditional Ayurvedic medicines and more than 15 over-the-counter (OTC) Ayurvedic products.

The AVP has expanded over the years and has launched sister companies with the objective of diversification. One of the subsidiaries called 'Heal'

focuses on common health conditions and distributes its products through select outlets all over India. Another subsidiary company is AVP Marketing and Exports which has been formed specifically to distribute and market the prescription based and OTC Ayurvedic products all over the world.

III.5. Other Actors

In the Kani case story, there are several actors who played a significant role at particular stages of the product development, yet not throughout. The most important of those is the institute which led the expedition to the Agasthyar forests: the RRL, Jammu. All the important scientific validations and verifications of the *Arogyappacha* plant were conducted at the RRL, Jammu. At the TBGRI, the work focused mainly on the formulation of *jeevani* and relevant scientific investigations, including the toxicological and pharmacological evaluations. The two other actors which played a key role, namely the Kerala Forest Department and the Kerala Institute for Research, Training and Development of Schedule Castes and Schedule Tribes, are discussed below.

Kerala Forest Department

The Forest Department assumes importance because of the Forest Act (1927), which makes it responsible for the protection and conservation of forests. It has to regulate the transit of forest produce and the duty leviable on timber and NTFPs. It also issues a list of products which can be classified as minor forest produce. As of now in Kerala 165 such items have been identified but *Arogyappacha* is yet to be included. However, the forest department allows cultivation of *Arogyappacha* within the tribal areas and has also permitted the collection of leaves from outside the core area of the reserve forest.

When the technology was transferred to AVP for commercial production, the company faced a raw material crisis as the Kerala Forest Department refused to allow the tribal community to pluck the leaves of this plant. Their concern was related to the unscientific plucking of leaves which could cause complete extinction of the plant. Later, with the intervention of the TBGRI, cultivation of *T. zeylanicus* was ensured and training was provided to several Kani tribe members under the Integrated Tribal Development

Programme (ITDP) of the Directorate for Tribal Welfare. This programme provided support to fifty Kani families with Rs. 1000 each for cultivation of the plant.³⁰ As part of the new arrangement, the Kerala Forests Department and the TBGRI worked together to develop mechanisms for periodically assessing the production and cultivation practices among the Kani tribes. The Kanis currently have a long term lease from the Forest Department. The proposed New Tribal Policy by the Government of India (2007) and the Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forests Rights) Act, 2006, may help the Kanis to obtain proprietary legal rights to the land on which they have been engaged in cultivation.

The Kerala Institute for Research, Training and Development of Schedule Castes and Schedule Tribes (KIRTADS)

KIRTADS is an independent institution under the Kerala Government's Schedule Caste and Schedule Tribes Development Ministry. At the time of the agreement between the TBGRI and the AVP, KIRTADS was the most vocal critic of the agreement within the government system. KIRTADS suggested that the government should facilitate production of the drug by the tribal community members themselves instead of transferring their knowledge to a private company. Bijoy reports³¹ that in 1995 KIRTADS even drafted a state level bill for protection of the intellectual property of Kani tribe members. However, this was never pursued further.³²

IV. Negotiation and Decision Making

Developing a product based on their research on the *Arogyappacha* plant was the first test case for the TBGRI research team. In fact, the research arm of the TBGRI was almost non-existent until Dr Pushpangadan took over the directorship. He employed the help of several national and international agencies in upgrading the infrastructure and scientific expertise required for carrying out chemical and pharmacological research for different purposes including drug development.³³

Before the details of the negotiation process are outlined, it is important to understand the dynamics behind the Kani case, as it was a voluntary

agreement concluded when there was no legal regime governing the ABS arrangements in India. It is important to realise that it did not happen in isolation. There were initiatives already taking place in India which eventually influenced the decision making process as some of the actors were involved in several of the processes.³⁴ Some of these events occurred far before the CBD came into force. Most of the studies so far have looked at the Kani case from the standpoint of the CBD alone, overlooking the pre-CBD stimulus in the system.³⁵

IV.1. Pre CBD Context

The agreed ABS arrangement was a voluntary initiative, initiated by the scientists as there was no legal obligation laid out in India at the time. However, the scientists did not work in isolation and the context to their decisions is very interesting. The Indian Council of Agricultural Research (ICAR) constituted an inter-organisational panel on food and agriculture which, in a meeting on 21 September 1976, decided that with indiscriminate and unplanned management of tribal areas, India was likely to lose biological resources and the related knowledge systems.³⁶ The recommendation was to form an expert group for working out a roadmap. The responsibility for this was given to a committee headed by Dr T. N. Khoshoo, whose ideas took the form of the AICRPE. Initially launched by the Department of Science and Technology (in 1982) it soon joined the Ministry of Environment and Forests. The precise mandate was to develop several interdisciplinary teams across the country to document the multi-dimensional perspectives of tribal lives; their culture, beliefs and knowledge systems that promote sustainable resource management. The AICRPE coordination unit was located at an equally interesting institute, the RRL, Jammu,³⁷ a constituent National Biological Research Institute under the umbrella of the Council of Scientific and Industrial Research (CSIR).

It was significant that the Head of the AICRPE project was closely involved in the national and global discussions on the protection of the indigenous knowledge system. The very mandate of the AICRPE and the background of the RRL, Jammu had framed his approach in such a way that he was actively involved at international fora for the cause. He provided inputs for the Declaration of Belém, 1988 which eventually led to the

establishment of the International Society of Ethnobiology (ISE). This Declaration explicitly recognised that indigenous peoples have been stewards of 99 per cent of the world's genetic resources and that biological diversity will decrease significantly if knowledge underlying the resource management practices of the world's indigenous peoples depreciates due to the forces of rapid social change in the societies in which this knowledge is repositied.³⁸

As a result, when the first AICRPE expedition reached the Chonampara Tribal settlement, Kootur in the Thiruvananthapuram district of Kerala in 1987, and discovered the source of energy for the Kanis, verbal agreement was made for sharing the proceeds from any gains out of this knowledge. During the stage of intensive research from 1992 until 1998, the TBGRI kept the two guides in the research loop as ethno-medical experts with a standard payment on a monthly basis for their two visits a week to the TBGRI.³⁹

IV.2. The Negotiation Phase

The negotiation process at the TBGRI has been intense and very interesting. Initially, Kanis participated in an informal manner, more as bystanders, but they entered the process in a formal way in the second phase in 2004. However, the negotiations within the TBGRI reveal more about how the actual ABS regime emerged.

When the product was developed, the TBGRI invited companies to bid for the product's commercial production. The AVP was short listed for production of the drug after they agreed to establish a GMP (Good Manufacturing Process) facility according to WHO standards. It was decided to sign the agreement in the presence of the Chairman, Governing Body of the TBGRI (who is the Chief Minister (CM) of Kerala State) on 22 July 1995. However, the CM did not witness the signature on that day as a letter written to him by the then leader of the Opposition, Mr. V.S. Achuthanandan, (the current CM) argued that the lump sum amount offered by the private company was inadequate and that public limited companies owned by the Government should be given priority over private companies.⁴⁰ Accordingly, the TBGRI appointed a committee of scientists to look into both points. The TBGRI Scientists' Committee

found that there were no GMP standard production and marketing capacities in the Kerala State Drugs and Pharmaceuticals, Alappuzha and Pharmaceutical Corporation of Indigenous Medicine (*Oushudhi*), Trichur, etc. the two major public sector organizations. Both agencies were neither producing nor marketing herbal drugs. With regard to the point on a lump sum license fee of Rs 1 million (approximately \$25,000) it was noted that no institute had earned any better amount on any herbal product. It was pointed out that the Central Drug Research Institute, Lucknow, an institute under the CSIR, had earned only Rs. 0.5 million through its memory enhancing drug *Bacopa Moneri* (*Brahmi*). In the subsequent meeting on 20 October 1995 the agreement with the AVP was cleared by the Governing Body.⁴¹ The Agreement left all the rights with the TBGRI (see Annex 1 for the text of the Agreement). It suggested that after seven years AVP would have no right over the drug and that the TBGRI would be free to negotiate with any other company. As mentioned earlier, in this phase the Kanis had no formal presence in the process, though informally the two ‘consultants’ remained involved.

Once the transfer of technology and production were finalised other issues related to the modalities for transfer emerged. The Director proposed that the proceeds be shared with the tribal community, which at that time was an alien concept for the Executive Committee of the TBGRI, which had no precedent. The Executive Committee decided to follow the CSIR model of benefit sharing. In this, 60 per cent goes to the scientists and 40 per cent to the institutions. In the Executive Committee Meeting of the TBGRI in September 1995, it was decided that the proceeds would be shared on a 50–50 per cent basis. The scientists decided to forego their share in favour of the tribal community. The fact that by then, India had signed the CBD and Articles 8(j) and Article 15.7 were directly applicable, helped the Director to pursue this case with the Executive Committee. As a result, the arrangement was worked out at 1:1 that is 50 per cent to the tribal community and 50 per cent for the Institute. After the TBGRI decision was made, the Institute approached the community and discussed the plan. Apart from the three guides, ten further members of the community were invited to be present.

The Executive Committee suggested transferring the money to the Tribal Department (the Schedule Castes and Schedule Tribes (SC/ST) Department in Kerala). The Kanis vehemently opposed the idea. However, the TBGRI was reluctant to transfer the money directly into their hands, due to serious levels of alcohol misuse in the community. At that stage the Director of the TBGRI got in touch with the leading experts in traditional knowledge. Some of them, including Prof Anil Gupta, proposed the idea of a Trust for the tribal community.⁴² The TBGRI also used the expertise of other individuals and social workers for educating the Kani people in organizing themselves to form a society or trust.⁴³ Eventually, the TBGRI took the services of Advocate Mr. Kariyam B. Vijayakumar, who developed the Trust Deed.

The Secretary of the SC/ST Department was emphatic in ensuring that the Trust should be representative in nature. He called a meeting of all the factions of the Kani tribes on 21 January 1999 at Kottur. All Kani members present suggested to the Secretary to transfer the money to the Trust. Accordingly, an amount of Rs. 5, 19,062 (50 per cent license fee and 50 per cent royalties) was transferred to the registered Trust (No. 109/97) on 22 February, 1999. The Kerala Kani Community (Samudaya) Welfare (Kshema) Trust had been registered on 12 November 1997.⁴⁴

According to the Indian Societies Act,⁴⁵ there could be six or nine members in a trust. In this case the Advocate suggested nine members. The two guides were kept as permanent life members while the rest of the positions were kept open to election. There is a provision for elections every third year. Within one year, the first funds were scheduled to arrive. In February 1999 the bank account was opened for the Trust at the Union Bank of India, Kuttichal, the nearest town for the tribal settlement, exclusively under the control of the office bearers of the Trust.

After transfer of the technology for manufacturing *Jeevani* to the AVP, in 1996, the TBGRI earned US\$50,000. Fifty per cent of the license fee as well as fifty per cent of royalties from sale were given to the Kani tribes. It is interesting to note that following the transfer of money to the Trust, the

Table 1: Comparison of the First and Second ABS Agreements between Stakeholders

First Agreement, 1996	Second Agreement, 2006
Parties were the TBGRI and the AVP	Parties included Kanis, the TBGRI and the AVP
Entered into force on November 10, 1996	Yet to be implemented
Valid for a period of 7 Years	Would be valid for a period of 7 Years
License fee of Rs. 10,000,00	License Fee 20,000,00
Royalty to be paid at 2 % for 10 years	Royalty to be paid at 4 % for 10 years

first meeting of the Trust was not held until 19 March, 1999. At the meeting, it was decided that the three Kanis who had passed on the information to the scientists would be rewarded with cash prizes.⁴⁶

As is clear from Table 1, in the Second Phase of the ABS agreement, the TBGRI rendered the process more democratic and transparent in nature. This phase also formalized the presence of the Trust representatives in the new negotiation process. In 2004, the new Director at the TBGRI constituted a Business Management Committee (BMC), with a membership of seven persons, two from its faculty, three outside experts and two representatives of the Kani Trust. The role of the BMC was to negotiate fresh bids with companies interested in the commercial production of the drug. The BMC placed advertisements in leading newspapers, on the basis of which they received a number of proposals. As the Table shows the BMC decided to set minimum conditions for the ABS arrangement. It suggested the license fee be doubled to Rs. 2.1 million and that the royalty payment also be doubled to 4 per cent.⁴⁷

IV.3. Patents and Trademark

There are five patents which emanated from the research work at RRL, Jammu and the TBGRI. The first patent was awarded to the RRL based research team in 1994 (File No: 88/Del/1994) on the process for isolation of glycolipid in the *Arogyappacha* plant. After the research moved to the

TBGRI four patents were applied for. Among them one was on the process for *jeevani* titled as, ‘A process for the preparation of a novel immuno enhancing, anti-fatigue, anti-stress and hepatoprotective herbal drug (*Jeevani*)’. This was received in 1996 (File No: 959/MAS/1996). The team also received a patent on an anti-diabetic herbal drug developed at the TBGRI in 1996 (File No: 957/MAS/1996). Similarly, a herbal sports medicine was developed called ‘*Vaji*’ for which a patent was received (File No: 958/MAS/1996). The TBGRI also received a patent for herbal medicinal compositions for cancer treatment from *Janakia arayalpathra* root and *Trichopus zeylanicus* leaf (Patent No. 193609).

In 2000, NutriScience Innovations LLC, a US based supplier of nutritional and functional food ingredients raised a storm by acquiring a trademark on *jeevani* (Serial No. 75692281). The company was importing the drug from the AVP and without informing the TBGRI or the AVP registered *jeevani* under the US trademarks rule and sold the product at much higher prices than originally charged by the AVP.⁴⁸

The following is a chronology of developments in the Kani case, leading up to the present. Thereafter some of the ethical issues arising during the negotiations, such as PIC, representation, the nature of benefits and beneficiaries and factors influencing the vulnerability of the Kani are discussed.

V. Ethical Issues

The Kani case has raised several ethical concerns. The Kani are amongst the poorest communities of the world and the monetary benefits realised under the present benefit sharing arrangement are not seen as adequate compensation for their knowledge. Moreover, issues related to the nature of PIC have been raised which lead us to consider approaches for making benefit sharing equitable, as is required by the CBD. In this section we look into some of these issues. It is correct that the earnings from the raw material for *Jeevani* and the Kani Trust have helped alleviate poverty in the Agasthyar Hills, but at this stage the beneficiaries are still limited to a very small number of this community.

Table 2: Evolution of Kani Case: A Chronological Exposé

The ICAR floated the idea for documentation of ethno-biology for conservation of IKS of the tribal communities of India	21 September 1976
The Department of Science and Technology launches the AICRPE under the 'Man and Biosphere Programme'	July 1982
Ministry of Environment and Forests takes over the AICRPE	September 1983
Coordination Unit for the AICRPE established at the RRL, Jammu, under Dr Pushpangadan	18 September 1983
First Group of AICRPE led by Dr S Rajasekharan meets the Moottu Kani (tribal head) and gets permission for the expedition	June 1987
Full AICRPE Group led by Dr Pushpangadan in the Agasthyar hills, accompanied by Mottu Kani's Representatives	December 1987
First scientific paper on <i>Arogyappacha</i> in <i>Ancient Science of Life</i>	July 1988
Two Kanis join the TBGRI as consultants on monthly salary of Rs. 3000/- (they remain there till 1999)	January 1993
First Patent on <i>Arogyappacha</i> (Application No. 8/DEL/94)	8 December 1994
Original proposed date for signing of an agreement between the TBGRI and the AVP	22 July 1995
Executive Committee reconsidered the matter	16 October 1995
Final approval to transfer the technology to the AVP	20 October 1995
Agreement for Transfer of Technology signed	10 November 1995
Direction by the Executive Committee to consult the SC/ST Department for working out the modalities	30 September 1996

Table 2 continued

<i>Table 2 continued</i>	
Filing of Jeevani Patent (Application No 959/MAS/96)	4 June 1996
Transfer of technology to the AVP	September 1996
Execution of the Trust Deed	12 September 1997
Approval for transfer of funds to the Trust	9 October 1998
All Segment Meeting of the Kani Tribes organised by the Secretary, Kerala SC/ST Department at Chonam para, Tribal Settlement	21 January 1999
Funds transferred to the Trust	22 February, 1999
First election at the Kani Trust	9 September 2001
TBGRI agreement with the AVP comes to an end	2003
The TBGRI gives a year long extension until 2004	2003
Business Management Committee with Kanis formed at TBGRI. Minimum license fee is decided at Rs 2 million and 4 per cent royalty	2004
Fresh advertisement for production of Jeevani	2006

Although the Trust is open to all (initially started with 50 families, it now has 3000 members) the membership has not expanded in the way one would have expected for achieving a 'fair' and 'equitable' sharing of benefits. Limited efforts from the SC/ST Department for making the Trust more representative at the initial stage are acknowledged in this paper. However, it seems that more comprehensive ways and means could be thought of to enable the current ABS arrangement to foster opportunities and empowerment for all.

V.1. Prior Informed Consent

The process for obtaining PIC should ideally have a standard procedure.⁴⁹ PIC should precede ABS negotiations. In the Kani case this is an area of concern, which was not adequately addressed if one looks at it from the standpoint of the CBD. However, it is important to note that the knowledge was shared way back in 1987 (before either the CBD or any national guidelines were in place) and the product was released in 1994 (when the CBD had just entered into force). This fact is often overlooked.⁵⁰ Nevertheless, it has also emerged in the literature that there is an urgent need to establish a mechanism for ensuring effective communication for acquiring PIC from indigenous people, local communities and others involved.⁵¹ The Kani case clearly shows that in the initial phase it lacked a clear and transparent process of acquiring consent. Since there were very few members of the larger community involved, the ones outside the privileged few completely rejected the mechanism. It was felt that those who divulged the IKS secret had no legitimation from the rest of the community and yet they were the ones most rewarded by the TBGRI arrangement.⁵² The state-based heritage protection schemes complicate the system further.⁵³ Some observers have discussed the lack of awareness among several Kanis which led to their exploitation and adversely affected their interests.⁵⁴ However, as discussed previously, these early drawbacks have been addressed in the later stages of ABS.

V.2. Nature of Benefits

With the help of funds from the Trust, the community constructed a reasonably sized covered meeting place, along with a one room school for children. They also bought a vehicle to transport NTFPs to the nearest

market place and built a reasonably levelled road. The TBGRI linkage ensured human capital formation for cultivation training programmes through the SC/ST Department under their various programmes. The cultivation of plants required initial training but has equipped Kani members for daily earning in specific seasons when the leaves are available. The AVP purchases leaves at Rs. 150 per kilogram. In the period 1999-2005 the royalties payment to the Trust was Rs. 0.25 million, plus a license fee of Rs. 1 million.

Apart from monetary returns for the sharing of knowledge, it is also important to mention non-monetary aspects. For instance, in the Kani case it has come to the fore that PIC would have been more effective had there been some prior effort for capacity building and awareness creation. More focused attention on addressing information gaps may also facilitate confidence building and make the process more transparent. The fact that Kanis could oppose the transfer of money to the tribal community department and the blockade by the Forest Department to stop the picking of *Arogyappacha* leaves shows that awareness about rights has been raised in a community which was previously largely passive.

In the Kani case the role of IPR has emerged as a crucial impediment.⁵⁵ The fact that the TBGRI never thought of protecting *jeevani* as a trademark⁵⁶ and did not include the tribal informants as co-inventors in the patent application is largely seen as a gross violation of ethical norms. However, Gupta elaborates that many of these observers overlook the fact that the patent applications from the TBGRI were only for the process of making drugs, because Indian patent law did not permit product patents at that point.⁵⁷ The patent just protected the TBGRI formulation. Thus it did not affect adversely anybody's right, as whatever was in the public domain remained so even after such patents were granted. This problem may be removed with the Second Patents Amendment Bill wherein disclosure of PIC and IKS related details is mandatory.

V.3. Identification of Beneficiaries

There are discussions about the unheard voices of major tribal group members which suggest that the decisions taken were not representative.⁵⁸

Grievances of several Kanis about their lack of awareness not only about the Trust but also about the medicine developed with their knowledge and the programmes undertaken for their development have been raised.⁵⁹ However, the efforts made by the Kerala government and the TBGRI, particularly the meeting of Kani tribes at Kottur settlement on 21 February, 1999 which was convened by the Secretary of the SC/ST Department of the Kerala government, suggests that the aim was to broaden the coverage of beneficiaries.

KIRTADS have suggested that the TBGRI should amend the terms and conditions of the agreement in such a way that the Kani tribes get access to technical know-how and are able to manufacture *jeevani* on their own terms and conditions.⁶⁰ This also seems to be the inclination of three panchayats based in Vithura, Amburi and Perinyamala.⁶¹ This could have been discussed with the community, bringing in other government agencies responsible for the welfare of schedule tribes like KIRTADS itself.

At this stage the Trust membership has already expanded to nearly 3000 families. More efforts in different hamlets may be intensified to improve the representation of remaining Kani families. This process may require allaying the fears, apprehensions and reservations if any, of all those who are out of the ambit.

V.4. Vulnerability

Whether Kanis have become more vulnerable to external pressures after the ABS, is the question that bothers many. There can be no easy answer to this as the process is very complicated. Their vulnerability is exemplified through the ongoing conflict between the culture of a nomadic tribe and one with a settled life style. Since their movements within forests have been restricted over the years, the Kanis had no choice but to adopt a settled style of living. As a result, they had to earn from what was available there. The shift to a settled life also increased their proximity to external cultural and social influences. The urge to acquire livelihood security coupled with the growing influence of the Forest Department, catalysed the process of breaking down the social fabric within the community. In the process they lost the unity of

the tribal group. This paved the way for an alien culture of individualism. Thus, under two different cultural systems the vulnerability multiplied.

It has been documented very clearly that narrow and conflicting institutional interests make the tribal community even more vulnerable.⁶² When the TBGRI and KIRTADS took counter positions on the ABS issue – the Kanis ended up being the instruments for carrying out institutional arguments. The TBGRI scientists accused KIRTADS of trying to torpedo the *Arogyappacha* project. It also emerged that these institutions had two different groups of Kanis to back their respective positions but the institutions never made any effort to resolve the issue. The Director of KIRTADS also complained about the fact that intellectual property rights were not being sought by local tribe members and instead rights were granted to private entities. It has been observed that “the story of *Arogyappacha* also illustrates how various government institutions try to push their own agenda in the name of an ethnic community”.⁶³ It was much later that the Government of Kerala intervened and sorted out the matter between the two institutions.

Another area of concern is that as proposed initially in the benefit sharing arrangement, the conservation of raw materials was not included in the main text of the agreement. Once this issue arose with the entry of the Forest Department, arrangements were made to ensure a sustainable supply of *Arogyappacha* leaves and a mechanism was evolved for the cultivation of the plants. The total amount of money to be shared as benefit money then had to be re-apportioned to meet the additional cost of plantation. It has been pointed out that in most ABS arrangements sustainability is not viewed as part of the main objective but is overlooked at the time of arrangement.⁶⁴ This is despite the fact that the CBD strongly recommends inclusion of conservation related aspects.

VI. Conclusions

The Kani case has offered lessons to be learnt at various levels. It also illustrates the growing interplay between collective rights, as evident from the common goods approach and individual rights, as evident from the upcoming intellectual property regime. With the expansion of economic growth across developing countries, it is this common goods approach which

is facing the maximum pressure from those who wish to tap natural resources for personal profits. The recent policy initiatives from the Government of India may help in correcting the continuous pressure from outside the tribal areas. The proposed New Tribal Policy (2006)⁶⁵ has legal provisions to safeguard against exploitation. The introduction of PIC and ABS as part of the TRIPs regime may help in addressing concerns related to the protection of intellectual property of indigenous knowledge systems.

The Biodiversity Conservation Act stipulated the establishment of the National Biodiversity Authority (NBA) which has been in place in the southern Indian city of Chennai since 2002. However, so far it has not released any formal documents or a model guideline for ABS. As a result, there is no certainty about how PIC is being ensured and implemented, even in the subsequent products which the TBGRI or other institutions are developing.

The Kani case provided an important policy lesson for the TBGRI regarding the involvement of other concerned agencies in the Agreement. The first ABS Agreement was only concluded between the TBGRI and the AVP. At the time of the second agreement (renewal) the TBGRI established a business management committee on which the Kani Trust was represented. However, in no way was the Forest Department represented. Initially, it was the Forest Department which had checked the collection of *Arogyappacha* leaves on the pretext of preventing depletion of the plant. Had the Forest Department been on the Board, they could have been taken into confidence right from the beginning. It is advisable that there is full cooperation between researchers, tribal communities and forest and tribal welfare departments in the bulk procurement and supply of raw materials, without which no commercial endeavour based on biodiversity is possible.⁶⁶ Similarly, had the Kanis been part of the agreement, PIC related issues could have been addressed in a more effective manner. Though the new policy regime for tribal communities may address issues related to tenurial rights, sustainable cultivation of the plant would be an important consideration for both the TBGRI and the AVP. In fact, limited supply of the drug may help in driving a better market price.

There is also a need to establish linkages between various ABS arrangements so that inferences may be drawn for specific settings. Following

the COP VI decision, a database on capacity-building projects for ABS was established to facilitate information exchange on ongoing capacity building activities⁶⁷ related to access to genetic resources and benefit sharing.

The Kani case has demonstrated that national level benefit sharing arrangements are not sufficient for deriving actual benefits. These need to be supplemented with international arrangements.⁶⁸ The debate about the Kani experience assumes significance as ABS has emerged as an important stumbling block at the TRIPs committee of WTO and also at WIPO. The fact that NutriScience could get a trademark in the US and could market the drug at a price eleven times more than what the Kani tribe was getting from the local pharmacy is itself suggestive of such a need. That the seventh CoP of the CBD in the decision VII/19 recommended an ad hoc open ended working group for evolving such a mechanism is an important step.⁶⁹ One of the strong recommendations of the CBD is to ensure technology transfer and capacity building, with the community facilitating access to genetic resources.⁷⁰

In the light of this case study, it is also important to look into the wider processes launched by India after successfully blocking a US company from patenting the use of turmeric.⁷¹ CSIR launched a 30 million page project known as the *Traditional Knowledge Digital Library* incorporating 120,000 remedies contained in the country's ancient written medical literature of Ayurveda, Siddha and Unani.

Annex 1

AGREEMENT FOR LICENSING OF KNOW-HOW

A.1 THE AGREEMENT

A.1.1 THIS AGREEMENT made and entered into this Tenth day of November One Thousand Nine Hundred and Ninety Five between Tropical Botanic Garden & Research Institute, a Society registered under the Travancore Cochin Literary, Scientific and Charitable Societies Registration Act 1955, having its registered office at Tropical Botanic Garden and Research Institute, Karimancode, P.O. Pacha-Palode, Thiruvananthapuram - 695 562 (hereinafter called TBGRI which expression shall where the context so admits, include its successors and permitted assigns) of the one part

AND

A.1.2 The Arya Vaidya Pharmacy (Coimbatore) Ltd., a COMPANY incorporated in India under the Indian Companies Act 1913 (No.61 of 1947 - 48) and having its registered office at 1381 & 1382, Trichy Road, Coimbatore - 641 018 (hereinafter called the PARTY which expression shall where the context so admits include its successors and permitted assigns) of the other part.

A.2 PREAMBLE

A.2.1 WHEREAS TBGRI has developed and is in full possession of and has full intellectual property rights to manufacture herbal formulation based on "Arogyapacha" and a few other herbal drugs (Jeevani) as detailed in Annexure I (hereinafter called the KNOWHOW) for making Herbal Formulation based on "Arogyapacha" and a few other herbal drugs (Jeevani) as per specifications laid down in Annexure II (hereinafter called the PRODUCT).

A.2.2 And whereas TBGRI at the request of the PARTY has agreed to grant licence to the PARTY for utilising the KNOWHOW on terms and conditions hereinafter contained.

A.3 SCOPE OF AGREEMENT

This agreement details the modalities and the terms and conditions for the grant of licence by TBGRI to the PARTY for utilising the said KNOWHOW, the rights and obligations of either party thereto and the financial arrangements between the parties.

A.4 GRANT OF LICENCE

A.4.1 In consideration of the payment as provided for in Clause 5.1 and performance by PARTY of the covenants herein contained, TBGRI hereby grants to the PARTY the licence to utilise the KNOWHOW to make and sell the PRODUCT directly or through any marketing agency authorised by The Arya Vaidya Pharmacy (Coimbatore) Ltd.

A.4.2 The license hereby granted to the PARTY by TBGRI is for utilisation of KNOWHOW for a period of seven years on exclusive basis commencing from the date of transfer of KNOWHOW provided that the KNOWHOW is effectively utilised within 4 years from the date of transfer of KNOWHOW.

A.4.3 The license shall come into force from Tenth day of November One Thousand Nine Hundred and Ninety Five (hereinafter called the EFFECTIVE DATE) and shall remain valid for a period of seven years thereafter.

A.4.4 The PARTY will produce and market the PRODUCT within 4 years from the date of transfer of KNOWHOW. If PARTY fails to do so TBGRI will have the right to cancel the licence granted to PARTY and the PARTY in turn should surrender the KNOWHOW. In such a circumstance the PARTY will not have any right to claim licence fee already paid to TBGRI.

A.5 FINANCIAL ARRANGEMENTS

A.5.1 In consideration of the licence hereby granted and the transfer of KNOWHOW by TBGRI to the PARTY, the PARTY shall pay to TBGRI as hereunder:

Licence Fee

i. Lump sum

Rs. 5 Lakhs on signing of the agreement, and

Rs. 5 Lakhs on the day of transfer of KNOWHOW by TBGRI

and

ii. Royalty

Royalty at the rate of 2% of the ex-factory sale price of the PRODUCT made by the PARTY for a period of 10 years, computed from the date of commercial production. The terms and conditions governing the payment of royalty shall be as in Annexure III.

A.6 RESPONSIBILITIES OF TBGRI

A.6.1 Transfer of KNOWHOW

i. Transfer of KNOWHOW Documents

TBGRI shall within 180 days of the EFFECTIVE DATE hand over to the PARTY Technology Transfer Documents (TTD) consisting of specifications of product, process details, quality control procedures and user manuals.

ii. Demonstration

TBGRI shall demonstrate the KNOWHOW at TBGRI, Palode to the authorised representative of the PARTY within 6 months from the EFFECTIVE DATE for which the PARTY shall pay separately. On completion of the demonstration both parties shall sign a certificate to this effect.

iii. Training

TBGRI shall arrange for the training of Two or Three of PARTY's personnel having the requisite qualifications for a maximum of 2 months for which the PARTY shall provide inputs/pay separately. The training shall be availed of by the PARTY within a period of 3 months from the date of transfer of KNOWHOW.

A.6.2 The transfer of KNOWHOW shall be deemed as completed on performance by TBGRI the tasks stipulated in clause A.6.1.

A.6.3 Assistance

TBGRI may at the request of the PARTY and on its paying charges as specified by TBGRI, depute qualified personnel to render assistance in KNOWHOW implementation. This assistance would be available up to a period of 4 years from the EFFECTIVE DATE.

A.7 RESPONSIBILITIES OF PARTY

A.7.1 The PARTY shall employ its best endeavour to work the KNOWHOW and sell the PRODUCT on a commercial scale. The PARTY shall commercialise the KNOWHOW within a period of 48 months from the date of transfer of KNOWHOW as defined in clause A.6.2.

A.7.2 Fulfilment of all procedural, legal, operational requirements for the commercial implementation of the KNOWHOW shall be the responsibility of the PARTY.

A.7.3 The PARTY acknowledges the absolute ownership of KNOWHOW by TBGRI and shall not dispute the legality, validity or enforceability of the licence granted.

A.7.4 It shall not be open to the PARTY to claim the KNOWHOW in their name on the plea of having effected any improvements/modifications upon the KNOWHOW or upon the PRODUCT. All PRODUCTS manufactured by the PARTY shall be deemed to have been manufactured under the licence hereby granted.

A.7.5 The PARTY shall permit the personnel of TBGRI or its attorneys or duly authorised agents, at all convenient time to enter into and upon any premises of PARTY where PRODUCTS under this licence are manufactured/stocked/sold/used for the purpose of inspecting the same and the manufacture thereof, generally to ascertain that the provisions of this licence are being complied with and quality of the PRODUCT maintained.

A.7.6 The PARTY shall not, at any time, assign, mortgage, charge, grant sub-licence or otherwise deal with possession or control of the licence hereby granted.

A.7.7 The PARTY shall not directly or indirectly and either by itself or by its agents use the KNOWHOW otherwise than in accordance with these presents.

A.7.8 The PARTY shall not file any application for seeking intellectual property rights in its own name or in the name of other person(s) on any matter relating to the information disclosed to it by TBGRI under this agreement, save with the written prior approval of TBGRI.

A.7.9 The PARTY shall not oppose or direct or cause any persons to oppose any application seeking intellectual property rights relating to the PRODUCT and/or KNOWHOW filed by TBGRI.

A.7.10 The PARTY shall treat as strictly confidential all information/knowledge obtained from TBGRI, in connection with or relating to the licence hereby granted.

A.8 GENERAL PROVISIONS

A.8.1 During the currency of the agreement both parties shall promptly disclose to each other in writing, all or any improvements or modifications made on the KNOWHOW / PRODUCT. All such improvements/modifications shall then form an integral part of the KNOWHOW.

A.8.2 These presents shall not be construed as a warranty by TBGRI of the novelty, utility, saleability and workability of the KNOWHOW/PRODUCT.

A.8.3 This agreement shall be the sole repository of the terms and conditions agreed to herein by and between TBGRI and the PARTY and no amendment thereof shall take effect and be binding on either of them except provided for in clause A.16. hereunder.

A.9 ACKNOWLEDGEMENT

A.9.1 The PARTY shall affix in a conspicuous manner upon every PRODUCT and a label or plate bearing the inscription “TBGRI KNOWHOW” in letters of size not less than half the nominal size of the largest size of letter _____ name of the party or its brand name or trademark for the PRODUCT. The PARTY shall not sell [PRODUCT and/or any box or Package containing the PRODUCT] without such label or plate being affixed thereon. Similarly every advertisement, boarding, technical literature, publicity and the like material in respect of or relative to the PRODUCT issued by the PARTY shall include the same inscription as aforesaid in a prominent manner.

A.10 FORCE MAJEURE

Neither party shall be held responsible for non-fulfilment of their respective obligations under this agreement due to the exigency of one or more of the force majeure events such as but not limited to acts of God, War, Flood, Earthquakes, Strikes, Lockouts, Epidemics, Riots, Civil Commotions etc., provided on the occurrence and cessation of any such event the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond six months, the parties shall jointly decide about the future course of action.

A.11 INDEMNITY

TBGRI hereby agrees to authorise and to empower the PARTY to institute and prosecute such suits or proceedings as the PARTY may deem expedient, to protect the rights hereby conferred and for the recoveries of damages and penalties for the infringement of such rights and to secure to the PARTY full benefits of this licence and for any such purpose to use the name of TBGRI. The PARTY in its turn shall indemnify TBGRI against damages, costs and expenses occasioned by such proceedings, and TBGRI shall in any such proceedings, at the expense of the PARTY afford to the PARTY all proper and or reasonable assistance in proving and defending its title to the grant of the rights hereby conferred.

A.12 TERMINATION OF AGREEMENT

A.12.1 This agreement may be terminated by either of the parties forthwith if the other party commits breach of any of the terms hereof and

shall have failed to rectify such breach within sixty days of the notice in this behalf having been served on it by the other party.

A.12.2 In addition to the reasons for termination as set forth above, this agreement may be terminated forthwith if either of the parties voluntarily or involuntarily enters into composition, bankruptcy or similar reorganisation proceedings or if applications invoking such proceedings have been filed.

A.13 SETTLEMENTS

Upon termination of the agreement:

A.13.1 All rights granted to and the obligations undertaken by the parties hereto shall cease to exist forthwith except the obligation of the PARTY to keep KNOWHOW in confidence vide clause A.7.10 herein and pay royalty as per clause A.5.1. (ii) above accrued on or prior to the date of such termination, make written reports and keep records, files and books vide para 6 of Annexure III hereto and the right of TBGRI to inspect the same.

A.13.2 The PARTY or its assigns will not utilise the KNOWHOW to manufacture the PRODUCT and the PARTY shall immediately deposit with TBGRI the original and all copies of TTD, and other documents data related to this licence received from TBGRI.

A.13.3 The PARTY shall immediately pay to TBGRI all amounts of money due from it upto the date of termination. Also all sums of money hereto paid by the PARTY under the terms of this licence shall be forfeited to TBGRI, and the PARTY shall not be entitled to any credit or allowance in respect thereof.

A.13.4 The PARTY will not be debarred from disposing off the PRODUCTS which are already manufactured or in the process thereof by sale or otherwise. Such disposal will however, not be effected unless and until the PARTY remits to TBGRI the entire amount of royalty due, in accordance with Clause 5 above including the PRODUCTS sought to be disposed off.

A.14 NOTICES

A.14 All notices and other communications required to be served on the PARTY under the terms of this agreement, shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to PARTY at its last known address of business. Similarly, any notice to be given to TBGRI shall be considered as duly served if the same shall have been delivered to, left or posted by registered mail to TBGIR at its registered address in Pacha-Palode, Thiruvananthapuram.

A.15 AMENDMENTS TO THE AGREEMENT

A.15.1 No amendment or modification of this agreement shall be allowed. The request for the same is made in writing by both the parties or their authorised representatives and specifically stating the same to be an amendment of this agreement. The modifications/changes shall be effective from the date on which they are made/executed unless otherwise agreed to.

A.16 ASSIGNMENT OF THE AGREEMENT

A.16.1 The rights and/or liabilities arising to any PARTY to this agreement shall not be assigned except with the written consent of the PARTY and subject to such terms and conditions as may be mutually agreed upon.

A.17 ARBITRATION

Applicable to agreements with private parties in India

A.17.1 Except as hereinbefore provided, any dispute arising out of this Agreement, the same shall be referred to the arbitration of two arbitrators, one to be appointed by each party to the dispute, and in case of difference of opinion between them to an umpire appointed by the said two arbitrators before entering on the reference, and the decision of such arbitrators or umpire, as the case may be, shall be final and binding on both parties. The venue of arbitration shall be at such place as may be fixed by such arbitrators or umpire and the arbitration proceedings shall take place under the Indian Arbitration Act, 1940.

A.17.2 Any legal appeal over the arbitrators' award arising out of or in any way connected with this agreement shall be deemed to have arisen in Thiruvananthapuram and only the courts in Kerala shall have the first jurisdiction to determine such matters.

SEAL OF PARTIES

This agreement has been executed in two originals one of these has been retained by TBGRI and the other by the PARTY.

In witness whereof the parties hereto have signed this agreement the Tenth day of November One Thousand Nine Hundred and Ninety Five mentioned hereinbefore.

For and on behalf of TBGRI

For and on behalf of PARTY

ANNEXURE - I

KNOWHOW

The KNOWHOW shall mean [please specify the type of knowhow/ scale of development/ parameters, specifications of its operation / use etc.]

ANNEXURE - II

PRODUCT

The PRODUCT shall meet/conform to the following [specifications / parameters etc.]

ANNEXURE - III

TERMS & CONDITIONS FOR PAYMENT OF ROYALTY

The royalty shall be payable on net ex-factory sale price of all the PRODUCT manufactures sold and used for as such or to make any other product therefrom, exclusive of all duties and taxes payable to the Government. The ex-factory sale price for the basis of payment of royalty on the PRODUCT used for shall be (i) the highest ex-factory sale price of the PRODUCT sold; (ii) or if no merchant sales have taken place, the price such a PRODUCT would fetch if sold in the market as determined by the DIRECTOR TBGRI.

The period 10 years for the payment of royalty shall be computed from the date of the start of the commercial manufacture of the PRODUCT authorised by the PARTY to any agency of the Central or State Government or in the PARTY's Annual Reports and shall survive the period of licence hereinbefore mentioned.

The royalty shall become due for payment on the 31st March and on 30th September in every year and shall be paid by the PARTY on / or before the expiry of 60 days from the above two stipulated dates. In the event of default in the payment of royalty amount as above the PARTY

shall pay interest on amount in default at the rate of 18% per annum.

The PARTY shall within 60 days of the stipulated dates deliver to TBGRI in a prescribed form, a true and complete statement in writing of PRODUCT manufactured, sold and / or used by PARTY during the preceding half year and all the royalty payable to TBGRI under this agreement.

PARTY shall be liable for the payment of royalty on all PRODUCT irrespective of any plea whether the same have been manufactured as per the KNOWHOW licensed by TBGRI or otherwise. All PRODUCT manufactured by the PARTY shall be deemed to have been manufactured under KNOWHOW licensed TBGRI. It will not be open to PARTY to claim any exemption or reduction in the payment or amount of royalty accruing under this agreement on the plea of having used KNOWHOW other than that of TBGRI or having effected any improvements/modifications in the intellectual property licensed by TBGRI.

PARTY shall at its place of business, keep accurate records in sufficient details to enable the calculation and determination of royalty payable hereunder and upon TBGRI's request shall permit an authorised representative of TBGRI to have access during its business hours to examine relevant records as may be necessary to (a) determine in respect of any half year as specified above, ending not more than one year prior to the date of such request, the correctness of any report and / or payment under this agreement and (b) obtain information as to the royalty payable for any such period in case of failure to comply with the terms of the agreement.

Endnotes

- ¹ Details of AICRPE are discussed in Section IV.1
- ² The project coordinator Dr S. Rajasekharan met the Mottu Kani from the Chonampara Tribal settlement, Kootur Thiruvananthapuram District in April 1987 (based on personal communication with Dr S Rajsekharan).
- ³ Members of the Kani tribe considered this as a sacred knowledge and did not want to disclose it to others.
- ⁴ They were supposed to be at the TBGRI for 2 days a week. The fee was Rs. 3000 (based on personal communication from Dr S Rajsekharan).
- ⁵ 'The Innovative Partnership Awards for Sustainable Development in Tropical Ecosystems'. Equator Prize Announcement, New York: UNDP. Equator Initiative (2002).
- ⁶ For instance, see comment by Dan Janzen who called this arrangement of ABS a "publicity and political move by the participants, the benefits of which would disappear within few years." Janzen, Dan, 'Bioprospecting: Model Indian Deal Generates Payments,' *Science* 283, March 1999.
- ⁷ Conference of the Parties, Convention on Biological Diversity, 1992 <http://www.biodiv.org/convention/articles.asp>
- ⁸ Conference of the Parties, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, 2002 <http://www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf>
- ⁹ The Biological Diversity Act, 2002 and Biological Diversity Rules, 2004 <http://www.nbaindia.org/publications.htm>
- ¹⁰ The Biological Diversity Act, 2002, Article 21, Chapter V.
- ¹¹ 'Cabinet Okays Bill on Alternative Medicines,' *The Hindu Business Line*, June 24, 2005.
- ¹² The Protection of Plant Varieties and Farmers' Rights Act, 2001 available at <http://www.plantauthority.in/>
- ¹³ The Indian Forest Act, 1927 available at <http://envfor.nic.in/legis/forest/forest4.html>
- ¹⁴ Bijoy, C. R., 'Access and Benefit Sharing from the Indigenous Peoples' Perspective: The TBGRI-Kani Model,' *Law, Environment and Development Journal*, 3 (1) (2007): 1-19.
- ¹⁵ *ibid.*
- ¹⁶ Report to the People 2004-07: Ministry of Tribal Affairs, Press information Bureau (PIB), New Delhi, Friday, June 01, 2007.
- ¹⁷ The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forests Rights) Act, 2006, available at <http://www.elaw.org/resources/text.asp?id=2790>
- ¹⁸ Convention on Biological Diversity.
- ¹⁹ Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, Conference of the Parties to the Convention on Biological Diversity, 2002, available at <http://www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf>
- ²⁰ World Trade Organisation (2002), 'The Doha Declaration Explained', available at: http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips, accessed: 14 August 2007.

21 World Trade Organisation (2003), 'The Relationship between the Trips Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge - Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela,' available at: <http://docsonline.wto.org/DDFDocuments/t/IP/C/W403.doc>, accessed: 3 June 2005.

22 WIPO, 'IGC Addresses Core Issues for the Protection of Traditional Knowledge and Traditional Cultural Expressions,' Press Release 470, Geneva, December 12, 2006.

23 As mentioned in the Charak Samhita and Surutha Samhita, both written before 3000 B.C. and published in 1931.

24 Pushpangadan P., Rajasekharan S. and George V. et.al, 'Benefit Sharing with the Kani Tribe: A Model Experimented by the Tropical Botanic Garden and Research Institute (TBGRI)'; in Medicinal Plants: A Global Heritage. Proceedings of the International Conference on Medicinal Plants for Survival, 16-18 February 1998, Bangalore organised by IDRC.

25 *ibid.*

26 They are Amboori, Kuttichal, Vithura, Peringamala, Kulathupuzha, Aryankavu.

27 Gupta, Anil K. WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge. Study No. 4. 2004, WIPO and UNEP, Geneva.

28 Personal communication with Malan Kani.

29 *ibid.*

30 Gupta.

31 Bijoy.

32 *ibid.*

33 However, it is important to note that the project was entirely funded and managed with the indigenous efforts of the Indian institutions. Danida and the National University of Singapore were involved in other on-going programmes of TBGRI but had nothing to do with the Arogyappacha project.

34 It was largely Dr. Pushpangadan who was a link between these 'processes' at the national level and the ABS at TBGRI.

35 Anuradha R., 'Sharing with the Kanis: A Case Study from Kerela, India,' in Dhar, B., Sachin Chaturvedi and R.V. Anuradha (eds.), *Regime of the Intellectual Property Protection for Biodiversity: A Developing Country Perspective*, (New Delhi: RIS and IUCN, 1998): also see Gupta; Bijoy.

36 Ministry of Environment and Forests, Report of the All India Coordinated Project on Ethnobiology, Undated.

37 RRL was initially called a Drug Research Laboratory. It was established in November 1941 by Col. Sir Ram Nath Chopra to gainfully exploit the biodiversity of the Himalayas. CSIR took it over in 1957 and made it part of the network of regional labs and it became RRL. In December 2006, CSIR renamed RRL Jammu as the Indian Institute of Integrative Medicine, IIIM. <http://ise.arts.ubc.ca/about.html>

38 <http://ise.arts.ubc.ca/about.html>

39 Personal communication with Dr S. Rajasekharan.

40 *The Hindu*, 'TBGRI Pact with Private Firms Put Off', July 25, 1995.

41 *ibid.*

42 Gupta.

43 Mr. P. R. J. Pardeep was one of the leading figures in this group.

44 Equator Initiative.

45 The Indian Societies Registration Act of 1860 <http://www.laghuvit.net/LegalFrameWork/Acts/societiesregistrationact1860.pdf>

46 Khwaja, R. H., Report to CoP-MoP 4 from National Focal Point (Ministry of Environment and Forests, Government of India, New Delhi, 2001).

47 *The Hindu*, 'Tribals to Benefit from Renewal of Licence from Herbal Drug', March 28, 2006.

48 Varshney, Vibha, 'Tribals Lose Out as Herbal Drug is Stuck in IPR Jam,' *Down to Earth*, 12 (21), March 18, 2004.

49 Henne, Gudrum, Klaus Liebig, Andreas Drews, Thomas Plan, 'Access and Benefit Sharing: An Instrument for Poverty Alleviation,' (German Development Institute, Bonn, November 2003), p45.

50 See for instance John J. and Sindhu Menon, 'Kerala Tribe Accuses Indian Biologists of Stealing Knowledge,' PANOS-Biopiracy (IOPIRACY/1, London, August 4, 1998): and Anuradha.

51 Anuradha; Gupta; Frein, Michael and Hartmut Meyer, 'The Concept of Benefit-Sharing: A Step Forward or Backward,' in Beth Burrows (ed.) *The Catch; Perspectives in Benefit Sharing* (The Edmonds Institute: USA, 2005); Reddy, Sita, 'Making Heritage Legible: Who Owns Traditional Medical Knowledge?' *International Journal of Cultural Property* (2006): 13:161-188: RIS, *World Trade and Development Report*, (Oxford University Press, Research and Information Systems (RIS), New Delhi 2007.).

52 Bijoy.

53 Reddy.

54 John and Sindhu.

55 Reddy; Gupta.

56 Varshney.

57 Gupta.

58 Reddy; Bijoy.

59 Anuradha.

60 Gupta.

61 Anuradha.

62 Martin, Max, 'How to Sell a Wonder Herb,' *Down to Earth*, 7 (12), November 15, 1998 (Centre for Science and Environment, New Delhi).

63 *ibid.*

64 Peria, Elpidio V. 'Benefit Sharing from the Use of Genetic Resources: Real Myths or Mythical Realities,' in Beth Burrows (ed.) *The Catch; Perspectives in Benefit Sharing* (The Edmonds Institute, USA, 2005).

65 "National Tribal Policy (A Policy for the Scheduled Tribes of India)," Revised Draft, Ministry of Tribal Affairs, 2006. <http://tribal.nic.in/index1.html>

66 Pushpangadan et al., 'Benefit Sharing with the Kani Tribe.

67 This is available at <http://www.biodiv.org/programmes/socio-eco/benefit/projects.aspx>.

68 RIS, *World Trade and Development Report*.

69 CBD (2005). Analysis of Existing National, Regional and International Legal Instruments Relating to Access and Benefit-Sharing and Experience Gained in their

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- ⁷⁰ WTO. 'Protection of Biodiversity and Traditional Knowledge-The Indian Experience'. Submission at WTO by India. WT/CTE/W/156, IP/C/W/198, July 14, 2000. WTO. Minutes of Meeting, Held in the Centre William Rappard, 8-9 and 31 March 2005. Submission at WTO by Kenya. IP/C/M/47, June 3, 2005. (World Trade Organization, Geneva, 2005).
- ⁷¹ Voigt, Kevin, 'Society Modern Medicine? New Life for Old Cures.' *Wall Street Journal*, May 12-14, 2006.

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