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**PROTECTING IPRs OF
SIDDHA PRACTITIONERS THROUGH
PEOPLE'S BIODIVERSITY REGISTER**

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**Gujarat Institute of Development Research
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Abstract

Siddha system of medicine (SSM) is an ancient system that is practiced in Tamil Nadu in India and in other Tamil speaking regions of the world. SSM focuses on addressing the root cause of the disease rather than treating the disease symptoms, and combinations of herbs, medicinal plants, animal and marine resources go on to make the required drugs. In the current scenario where (a) pharmaceutical companies are increasingly turning to bio-prospecting to get useful leads, and (b) side effects caused by the pharmaceuticals are also generating interest to research on the scope for personalized medicine, it is important that the various intellectual property concerning the SSM is protected on an urgent basis. People's Biodiversity Register (PBR) is an ideal solution to the issue of economic and knowledge losses due to bio piracy and lack of protecting the IPRs in SSM. A well documented PBR is an IP registry of a village/region and, therefore, would facilitate in appropriate sharing of the benefits from exploiting the bio-resources of a region.

Keywords : Siddha, traditional knowledge, intellectual property, biodiversity register

JEL Codes : L65, Q57

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Contents

	Page No
Abstract	i
Acknowledgements	i
Contents	ii
List of Tables / Appendix	ii
1. Introduction	1
2. Status of Siddha Medicine in Tamil Nadu	2
2.1 Regulation and Number of Practitioners	3
2.2 Users of Siddha Medicine	5
2.3 Issues surrounding SSM	5
2.3.1 Number of practitioners	5
2.3.2 Use of Natural Materials and their Availability	7
2.3.3 Issues in Standardization	11
3. Protection of Traditional Knowledge through PBR	12
3.1 Use of PBRs	16
3.1.1 Use of IP Database in Estimating the Number of Siddha Practitioners	16
3.2 Local Indigenous Efforts to Conserve TK	19
4. Conclusion	22
References	24

List of Tables / Appendix

1. Number of Siddha Practitioners in Tamil Nadu	4
2. Details of Patients Treated during 2004 and 2010	5
3. Medicinal Plants that are Reportedly Extinct from the Wild	8
4. Names of Plants that are Available in Inadequate Quantities	10
5. Status of Applications Processed by NBA	13
Appendix .1	23

PROTECTING IPRs OF SIDDHA PRACTITIONERS THROUGH PEOPLE'S BIODIVERSITY REGISTER

N. Lalitha

1. Introduction

This paper focuses on protecting the intellectual property rights (IPR) of the knowledge holders of siddha medicine, an Indian systems of medicine practiced mainly in Tamil Nadu and other Tamil speaking regions of the world. In the Siddha system of medicine (SSM) the human is considered as part of the nature and the universe and, therefore, health is a balance between humans and their environment. Siddha and the other codified traditional medical systems such as Ayurveda and Unani cover all basic aspects and branches of medicine including paediatrics, ophthalmology and surgery. Since SSM relies on herbs, medicinal plants, animal and marine resources, protecting this stock of knowledge about the resources itself is the first step in protecting the IPR of SSM.

As SSM depends on natural resources, it can provide a base for cumulative innovations in the biopharmaceutical segment based on rDNA technology. Cumulative innovations based on SSM provide scope for (a) improvements over earlier or existing products and (b) application of basic technologies and enabling technologies such as research tools. As the number of new drug molecules is dwindling and the number of blockbuster drugs is decreasing, pharmaceutical companies are increasingly turning to bio-prospecting to provide useful leads on which further research can be carried out. Further, the side effects caused by the pharmaceuticals are also generating interest to research on the scope for personalized medicine from modern biotechnology. Keeping the fundamental fact that SSM focuses on addressing the root cause of the disease rather than treating the disease symptoms, there is lot of potential that the interest in SSM would be revived not as an alternative system of medicine, but as a research tool for modern biotechnology. The stock of knowledge concerning SSM is not limited to a few text books but is widespread among the practitioners, who, however, are not associated with recognized institutions. Hence, this paper discusses the usefulness of preparing the IP registry of SSM in the lines of People's Biodiversity Register (PBR). PBRs are comprehensive

N. Lalitha (lalithanarayanan@gmail.com) is Professor, Gujarat Institute of Development Research, Ahmedabad.

documentation on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them. It would also provide data on local *vaid*s and practitioners using local biological resources. Further PBRs can also be used to validate the medicinal practices to adapt the useful ones and discard the incorrect ones.

In this paper, IPs of the Siddha medicine practitioners is defined to refer to the following: The capacity and ability of the Siddha practitioners to: (1) understand and transcribe the Siddha practices as mentioned in the ancient scripts or palm scripts which are still in the possession of a few of the Siddha practitioners; (2) treat the patients without formal training at a recognized educational institution; (3) identify the herbs and other medicinal plants that are used in the Siddha medicine, their appropriate use, availability and alternatives and (4) conserve these resources and also use them in a sustainable manner.

The organization of the paper is as follows. Following this introduction, the status of SSM in Tamil Nadu and the issues surrounding SSM is provided in Section 2. This is followed by the role and purpose of the PBR and its usefulness in serving the identified issues presented in Section 3. Initiatives already taken to prepare PBR are discussed in the last section.

2. Status of Siddha Medicine in Tamil Nadu

The term Siddha means 'achievements' and eighteen saintly Siddhars were said to have contributed towards the development of this traditional system of medicine. The history of Siddha medicine dates into the pre historic period. The ancient medical literature of Agasthiar and other Siddhars, which exist today, are only compendiums of older treatise that existed before. This system also deals with the concept of salvation and immortality that can be achieved by regulated diet, medicine and processing of mind by yogic or spiritual exercises like meditation and yoga.

The SSM is based on the principle that food is medicine and medicine is food. Siddha system believes that all objects including the human body is made up of the five basic elements, viz., air, water, space, earth and fire. The human body is a physical conglomeration of three humors and seven physical components. Food is considered to be the basic building material of human body which gets processed into humors, tissues and wastes. The

equilibrium of humors, body tissues and wastes is considered as health and any disturbance leads to disease or pathologic state¹. SSM emphasizes that medical treatment is oriented not merely to disease. It identifies the root cause of the problem and thus the medications are towards eradicating the disease from the body. The identification of causative factors is through the examination of pulse, urine, eyes, study of voice, colour of body, tongue and the status of the digestive system. Therefore, the treatment is highly individualistic.

2.1 Regulation and Number of Practitioners

Siddha is governed by the Central Council of Indian Medicine (CCIM) through the Indian Medicine Central Council Act 1970 (IMC, 1970). As per the Government of India instructions, the Government of Tamil Nadu introduced the 'Tamil Nadu Siddha System of Medicine (Development and Registration of Practitioners) Act, 1997 which came in to effect from 29th September 1997. The Tamil Nadu Siddha Medical Council has been formed in GO.MS.NO.70, Health and Family Welfare Department on December 12 1998. This is the statutory registration body for the registration of Siddha practitioners only. For practicing in Tamil Nadu registration with the council is compulsory². The Tamil Nadu government has attached special importance to the growth and development of SSM as it is part of the Tamil culture "The strategy in ISM sector is to restore the credibility and legitimacy of these systems by emphasizing on research, education and product standardization and increasing the outreach of these systems by effectively complementing the efforts of the modern side in making available health services to the common man" (Government of Tamil Nadu, 2005:60).

With this aim in mind, the Government of Tamil Nadu has started providing SSM in its government health care along with the modern allopathy medicine. As of July 2004, Siddha wings were functioning in 26 district headquarters hospitals, 160 taluka headquarters hospitals, 75 non-taluka hospitals, 326 primary health centres and 9 medical college hospitals, besides 32 government Siddha dispensaries in the state.

The Government Siddha Medical College and Hospital in Palayamkottai is

¹ <http://www.tnhealth.org/ims.htm>, accessed on December 10, 2010.

² <http://www.tnhealth.org/imcouncil.htm>, accessed on December 10, 2010.

the oldest institution teaching SSM. In 2005, the National Institute of Siddha was set up in Chennai to impart post graduate education³ in Siddha and to pursue research in SSM. There are a few colleges in the private sector also that offer a five year graduation course.

Within Tamil Nadu, the concentration of Siddha practitioners is found in places such as Madurai, Tirunelveli and Palayamkottai that are close to the biodiversity-rich Western Ghats. A relatively small number is also found in other districts of Tamil Nadu. Table 1 presents the number of Siddha medical practitioners registered with Tamil Nadu Siddha Medical Council.

Table 1: Number of Siddha Practitioners in Tamil Nadu

Class	No. of Practitioners Registered, 2010	No. of Practitioners registered, 2004
BIM & BSMS	3845 (45.05)	2487 (34.00)
LIM, LAM etc	6 (0.07)	6 (0.08)
GCIM	3 (0.03)	3 (0.04)
B class	2245 (26.30)	2245 (31.00)
C class	24 (0.28)	24 (0.33)
Enlistment	2411 (28.25)	2409 (33.00)
Total	8534	7174

Source: Government of Tamil Nadu, *Performance Budget, 2011-12, Health and Family Welfare Department*, p.93, September 2011, available at http://www.tn.gov.in/policynotes/performance_budget/PB_health_fw.pdf (accessed on 23 December, 2011); Government of Tamil Nadu, *Performance Budget, 2004-05, Health and Family Welfare Department*, p.81, July 2004.

Notes: (i) BIM and BSMS stand for Bachelor of Indian Medicine and Bachelor of Siddha Medicine and Surgery; LIM and LAM stand for Licentiate in Integrated Medicine and Ayurvedic Medicine respectively. GCIM denote the Graduate College of Integrated Medicine; B and C refer to those who have been registered based on their experience; enlistment denotes the earlier policy of the Government of Tamil Nadu to register those Siddha practitioners with more than 5 years practice before 1 October 1971 (Sebastia, 2010).

(ii) Figures in parentheses indicate percentages.

³ Post-graduate courses are offered in Gunapadam (pharmacology), Maruthuvam (general medicine), sirappu maruthuvam (special medicine), kuzhanthai maruthuam (paediatrics), noinalad (pathology) and nanju noolum maruthuva neethi noolum (Siddha toxicology and forensic medicine)

2.2 Users of Siddha Medicine

There are a large number of people dependent on SSM in Tamil Nadu as compared to the other Indian systems of medicine (Table 2). The numbers in absolute terms has increased from 2004 to 2010. The newly set up National Institute of Siddha alone treats about 1000 out-patients every day and has facilities for 120 indoor patients. We do not have estimate of the number of people who get treatment from traditional practitioners.

Table 2: Details of Patients Treated during 2004 and 2010

System	Jan-Dec 2004		Jan-Dec 2010	
	Out patients	In patients	Out patients	In patients
Siddha	15475528	199857	20231946	157936
Ayurveda	383977	19128	980916	33419
Unani	187317	20354	224264	15050
Homeopathy	1099756	18261	1595621	19985
Naturopathy and yoga	25153		149215	0
Total	17171731	257600	23181962	226390

Source: *Performance Budget*, Government of Tamil Nadu, 2005-06 and 2010-11.

2.3 Issues surrounding SSM

2.3.1 Number of practitioners

Following the Chopra Committee Report which focused on regulating the medical education and registration of practitioners to weed out the quacks from the system, the practitioners can be classified into three: (1) graduates who have been trained in a recognized institution; (2) non graduates with training under a teacher, classified as B after they had successfully cleared their written and oral examination; (3) *nattu vaidiyars* or non-graduate practitioners classified as C (Sebastia, 2010).

Table 1 informs us that the number of graduates trained in recognized institutions teaching SSM has increased at a rate of nine per cent per year. The numbers reported under B and C type of practitioners could be less since there were practitioners who did not appear for the written and oral examination but had a fixed clientele from specific geographic locations.

For instance, practitioners with knowledge of *varmakalai* (acupressure on vital points on the body) are concentrated in Kanyakumari region. The traditional bone setters (who set the fractured bones without surgery) are popular and are preferred by people from all socio-economic backgrounds for their efficacy and relatively cheaper cost of treatment (*Ibid*). However, we are not sure whether the list of practitioners given by the government covers all these traditional practitioners with particular specialization. The advantage of the hereditary practitioners and those who trained under an *Asan* is that they are exposed to practical aspects of Siddha, starting from reading the pulse to preparation of medicines.

The number of graduates is increasing at a lower rate as studying SSM or any of the Indian system of medicine is taken up only after all the other options of entering professional courses such as medical and engineering is failed⁴. Also it is not uncommon to find that after their BSMS degree, these graduates try to get professional training in an allopathy hospital in the hope of getting absorbed as an assistant doctor in the hospital (*Ibid*) and even practice allopathy medicine as the law of the land enables them to do so if they are registered practitioners⁵. Further, the graduates who are trained in the institutions are exposed only to the knowledge that has been transmitted from the books and do not have practical experience of identifying medicinal plants or in the preparation of the medicine⁶. Concerning toxicology, yoga and varma therapy, these specialties though are inscribed in the syllabus of governmental colleges, they are hardly taught and practiced (*Ibid*).

One of the private colleges teaching Siddha medicine reported of inviting such practitioners to demonstrate that knowledge goes beyond the text

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- ⁴ Personal interaction with faculty at Chennai, Muncirai (Kanyakumari district) and practitioners.
 - ⁵ In a sensational case in Tamil Nadu, Tamil Nadu police had arrested a few Siddha practitioners who were practicing allopathy medicine, claiming them as quacks. However, the Madras High Court, citing a government order issued by the Department of Health and Family Welfare, has said that the registered practitioners of Indian system of medicine could practice allopathy medicine along with Indian system of medicine. <http://www.hindu.com/2010/07/31/stories/2010073163460400.htm>, <http://www.hindu.com/2010/11/13/stories/2010111351380500.htm> (both accessed on December 20, 2010).
 - ⁶ Personal interaction with faculty at Chennai and practitioners at Madurai and Nagarkovil.

books⁷ and also offers electives such as snake venom and varma therapy, which are well known in this region (*Ibid*). A few such practitioners also train some of the post graduate students of Siddha medicine, who, in their own interest, approach these practitioners to get trained in: (a) the identification of herbals, and (b) the process of making herbal preparations. But this kind of dissemination of knowledge is limited and would disappear if timely intervention is not made.

2.3.2 Use of Natural Materials and their Availability

There are 7483 units producing medicines in the ISM sector (GOI Taskforce on Medicinal Plants, 2000), which comprise of both organized and unorganized sectors. There are only approximate figures about the demand for herbal and other resources by these units. According to the Taskforce on Medicinal Plants (2000) India requires a total of 31,780 tons of herbal raw materials for the pharmaceutical industries. Of this 7180 tons (22 per cent) are imported from Bangladesh, Nepal, Bhutan, Afghanistan, Pakistan, Singapore etc. The rest are procured from different parts of India. It is reported that over 90 per cent of the medicinal plants used by the ISM sector is collected from wild and natural sources. Less than 20 plant species are under commercial cultivation. The raw materials are procured from drug dealers operating in Chennai, Hyderabad, Delhi, Calcutta and other places in the country. These drug dealers procure the raw material from different parts of the country (which are often kept as secret as it forms part of their trade secret), often collected by unskilled persons for a nominal price. The supply chain extends to 3-4 tiers but with price rise at each stage (GOI, 2000). This source further states that, "the plant parts are collected without paying attention to the state of maturity, dried haphazardly, and stored for long periods at unsustainable conditions. The unsustainable collection is rapidly depleting the resource base and many species are under threat" (p.135).

Siddha medicine uses plant, animal, and marine resources and minerals and metals. The efficacy of the medicine depends on appropriate use of genuine raw materials produced in the prescribed manner. However, over the years either because of unsustainable method of harvesting the medicinal plants or due to the fact that implementation of the forest laws is stricter than

⁷ Interaction with the management of the college at Municirai.

before, some of the resources are not available and, therefore, can not be used in the preparation of Siddha medicine. For instance, animal resources such as *punugu* (Civet Cat or *Viverricula Indica*) and *kasthuri* (musk deer), which are claimed to be effective in curing asthma, epilepsy and act as a general stimulant to heart, are no more allowed to be collected from the forests because they fall in the endangered species list. Further, some of the plants have already become extinct and the number of entries in the forest red book is increasing by the year. (See Table 3 for the list of medicinal plants that have reportedly become extinct). In such cases, the practitioners and the manufacturers mentioned that they do not produce such medicines for want of the original materials and the consumers have to shift to modern system of medicine.

Table 3: Medicinal Plants that are Reportedly Extinct from the Wild

<i>Sageraea grandiflora</i>	<i>Paphiopedilum dr urgi</i>
<i>Pimpinella polynesiensis</i>	<i>Vanda wightii</i>
<i>Gonium nothum</i>	<i>Eriochrysis rangachari</i>
<i>Vernonia recurva</i>	<i>Ophiorrhiza barnesii</i>
<i>Eronymus serratifolius</i>	<i>Ophiorrhiza brunonis</i>
<i>Salacia malabarica</i>	<i>Ophiorrhiza caudate</i>
<i>Dipcadi canenense</i>	<i>Ophiorrhiza pykarensis</i>
<i>Eugenia argentea</i>	<i>Wendlandia angustifolia</i>
<i>Eugenia singumpathiana</i>	<i>Ophiorrhiza radicans</i>
<i>Syzygium bourdillonii</i>	<i>Neuracanthus neesianus</i>
<i>Syzygium palyhense</i>	<i>Ceropegia mawlata</i>
<i>Anoectochilus rotundifolius</i>	<i>Carex christii</i>

Source: Private communication from Deputy Conservator of Forests, Vandalur, Chennai, August 2007.

While it would be ideal to find alternatives for those restricted resources, it nevertheless calls for large research funding to conduct the pre-clinical and clinical studies with alternatives that have been found. Almost all the state governments' budgets are urban centric and focused on modern medicine. Indian System of Medicine in Tamil Nadu gets around 3.7 per cent or around Rs. 50 crore of the Rs.1300 crore or so that is allocated for health annually (Lalitha, 2007). As with any other programme, 70 per cent

of it would go for administration and salaries. Hence, the actual amount that is going towards research and development, strengthening regulation, training etc. has to be increased in a significant manner, if the system has to survive.

The other alternative is to undertake cultivation of medicinal plants in places other than its original habitat. However, our respondents, particularly, Tamil Nadu Medicinal Products Company Limited (TAMPCOL), and Indian Medical Co-operative Pharmacy and Stores (IMPCOPS), who supply to the Government health care facilities in Tamil Nadu and the officials from forest department reveal that cultivation of medicinal plants in places other than their natural habitat has several hurdles⁸. First, farmers are more often reluctant to grow medicinal plants for the following reasons: (1) they are not aware of the exact demand for their products and whether they can supply these resources on a sustainable basis; (2) the price offered is not attractive; (3) the farmers are not aware of the appropriate cultivation practices like the importance of not spraying pesticides or the post harvesting practices to be adopted to get higher market value. Some of the herbals, if they remain unattended after harvest, lose their weight and their therapeutic value, which reduces the price that the farmers would get.

For example, *Kilza nelli* or *Phyllanthus amarus* has been certified by the World Health Organisation (WHO) for its medicinal properties particularly in curing hepatitis. This plant has to be dried in shade after the harvest. If it is dried beyond a certain point, then the product is useless. The other problem observed by the manufacturers is that *Kilza nelli* grown in three different districts differs in quality. Also, plants grown in sandy areas have their limitations of quality. These are the kinds of information rich in Intellectual Property (IP) content that would serve as a valuable reference for Siddha drug manufacturers. However, once the catalogue of creative knowledge remembered by the traditional healers is lost, several of the medicinal plants would become weeds (Gupta, 2007).

It emerges from the current procurement practices adopted by TAMPCOL and IMPCOPS that these agencies procure the raw materials through tender *process specifying certain standards. These raw materials are procured from*

⁸ TAMPCOL has signed a memorandum with the Council of Scientific and Industrial Research for various activities including screening of siddha medicines for bio-activity (See Appendix 1).

various places in India and some items are also imported. But because the raw materials are procured from different agencies, adequate attention is not paid presently to (a) sustainable aspects of the raw materials; and (b) the benefit sharing practices by these agencies. If the procuring agencies are not adequately sensitized, particularly, about the sustainability aspects of harvesting the herbals and the medicinal plants, many of these resources would be added to the extinct list. This is bound to impact the production of the medicines as well in due course.

Sources within TAMPCOL point out that they face shortages of some of the herbal products for their medicinal preparations (Table 4). In cases where alternatives are available in satisfactory standards and quantities, the agency continues with the production of such products. If alternatives are not available, production of such products are discontinued and resumed only when they are available. It follows from this that non availability of such drugs will force the consumers to shift from SSM to other methods of treatment. Here again, if the data base throws light on the availability of a particular resource during the past and the present, appropriate measures could be initiated to arrest the decline of such resources.

Table 4: Names of Plants that are Available in Inadequate Quantities

Indian name	Botanical name
<i>Aswagandha seemai</i>	<i>Withania somnifara</i>
<i>Aswagandha naadu</i>	*
<i>Malai nannari</i>	*
<i>Kilza nelli</i>	<i>Phyllanthus Amarus</i>
<i>Saranganshivin</i>	*
<i>Maramanjai</i>	*
<i>Punugu</i>	<i>Animal product</i>
<i>Kadi pavalam/coral reef</i>	<i>Animal product</i>
<i>Mamparuppu</i>	*
<i>Sada manjai</i>	*
<i>Arisi thippili</i>	<i>Piper longum</i>

Source: Private communication from TAMPCOL, 2007.

Note: * Could not ascertain the botanical name.

2.3.3 Issues in Standardization

There are two types of regulations governing manufacturing of Siddha medicine. One set governs the manufacturing practices in the form of set procedures called Good Manufacturing Practices (GMP). The second type of regulation is in terms of bringing out pharmacopoeias and formularies for producing standard Siddha drugs. One of the basic problems in Siddha and Ayurveda is that each medicine comprises of minimum 20 materials. Non availability of a few materials in the composition adds to the problem. Hence, matching and maintaining the uniqueness of each of the material to bring out their combined effect in the final product at the same time maintaining their standards become the Herculean task for the units⁹.

Regulations of manufacturing Siddha medicines come under the Drugs and Cosmetics Act of 1940 and Drugs and Cosmetics Rules of 1945. As part of the regulation, like the chemical pharmaceutical units, Siddha manufacturing units should also adhere to GMP, which ensures the users that the medicines are manufactured adhering to standard manufacturing practices. However, there is a sufficiently large unorganized manufacturing of Siddha medicine takes place, which is difficult to be brought under any regulation. The GMP practices not only cover manufacturing practices but also set standards for procurement of raw materials. These requirements in short are called as Schedule T requirements. Units were given time till June 2003 initially and then later extended to June 2005 to adhere to the GMP measures. After this stipulated deadline, the units that could not adhere to such practices were closed down and their licenses cancelled.

The purpose of the broad GMP measures are to assure the public that the medicines produced are safe; raw materials used in the manufacture of drugs are authentic and of prescribed quality and are free from contamination; the manufacturing process has been prescribed to maintain standards; adequate quality control measures are adopted; and the manufactured drug

⁹ In order to standardize the preparations in Ayurveda, the government, has chosen 10-15 laboratories all over and have given them a few products and also conduct shelf life studies. These laboratories will have to produce these products as provided in the text following the Standard Operating Procedures and also provide the procedures for scaling up/ or when it is produced on a commercial scale. They will have to procure raw materials from standard places according to the standards set in the pharmacopoeia (*Pharmabiz*, sources from IMPCOPS and TAMPCOL).

released for sale is of acceptable quality. To achieve the objectives listed above, GMP measures require that each manufacturer evolves methodology and procedures for following the prescribed process of manufacture of drugs, which should be documented as a manual and kept for reference and inspection. However, teaching institutions and registered qualified *vaidyas*, *siddhas* and *hakeems*, who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of GMP.

In issues relating to standardization and adopting GMP practices, particularly, for accessing standard raw materials in the preparation of the medicines, preparation of the People's Biodiversity Register would offer some solution which is discussed below.

3. Protection of Traditional Knowledge through PBR

Convention on Biological Diversity (1992) was the first international legal binding instrument (particularly through Article 8j) that explicitly refers to the protection of traditional knowledge (TK). India is party to the Convention of Biodiversity Act that came into force in 2002 (herein referred to as BDA, 2002). The main objectives of the BDA are: (a) conservation of biological diversity; (2) sustainable use of the components of biodiversity; and (3) fair and equitable sharing of benefits arising out of the use of genetic resources. In order to effectively implement the BDA 2002, three layers of institutions have been proposed. These are the National Biodiversity Authority (NBA) at the central level, State Biodiversity Boards (SBB) at the state level, and the Biodiversity Management Committees (BMC) at the level of local state governments.

NBA was set up in 2003 and is located in Chennai. It deals with matters relating to requests for access to biological resources by foreign individuals, institutions or companies. All matters relating to transfer of results of research to any foreigner will also be dealt with by the NBA. As Table 5 shows, applications claiming IPR through the use of biological resources are higher than the other categories indicating the interest in this area.

Table 5: Status of Applications Processed by NBA

Year 2006-07 to 2011-12	Access to bioresources for research and commercial purposes	Transfer of research results	IPR	Third party transfer	Total
Agreement signed by the applicant with NBA	16	10	49	16	91
Applications cleared	26	14	288	19	347
Applications under processing	48	23	133	16	220
Closed applications	22	0	17	5	57*

Source: www.nbaindia.org (accessed on December 23, 2011).

Note: * Inclusive of 13 applications that were not applied in prescribed form and fee. State Biodiversity Boards (SBBs) look after the applications for the access to the bioresources by Indians, Indian companies and institutions. SBBs also have the power to restrain any activity that violates the objectives of conservation¹⁰.

At the next level, state governments with the help of local government bodies will have to set up the Biodiversity Management Committees (BMCs) in their jurisdiction for the conservation, sustainable use and documenting the knowledge relating to biodiversity. Its crucial function is to prepare the PBRs which provide comprehensive documentation on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them. It would also provide data on local *vaid*s and practitioners using local biological resources.

BMCs play a very crucial role in the protection of biodiversity. Both NBA

¹⁰ Though most of the states have notified the setting up of SBBs, they are yet to become fully operational. Even Tamil Nadu has notified the setting up of the Tamil Nadu Biodiversity Board only in May 2008.

and SBBs shall consult the BMCs while taking any decision relating to the use of biological resources and knowledge associated with such resources occurring within the territorial jurisdiction of the BMCs (NBA, 2007; Gadgil, 2006)¹¹. Hence, for any fundamental action to protect the traditional knowledge and biological resources, the PBRs will have to be in place. The NBA provides a detailed template for collecting information through PBRs, which is available on their website. For instance, on medicinal plants and wild plants of medicinal importance, the information sought include the following: the plant variety, local name, scientific name, variety, habitat/landscape, source of seeds/plant, local availability status of the plant in the past and present, uses, plant part used, associated TK, other details such as used for market or own use, community/knowledge holders.

Thus, PBR is expected to serve as a tool to (a) document, monitor¹² and provide information for sustainable management of local biodiversity resources; (b) promote biodiversity-friendly development in the emerging process of decentralized management of natural resources; (c) establish claims of individuals and local communities over knowledge of uses of biodiversity resources and to bring to them an equitable share of benefits flowing from the use of such knowledge and such resources; (d) teach environment and biology; and (e) to perpetuate and promote the development of practical ecological knowledge of local communities and of traditional 'slow' sciences such as Ayurveda and Unani medicine (Gadgil et al., 1996).

Biodiversity register, in other words, is an atlas of mapping of the local resources as well as knowledge and is highly location and time specific. In the context of the IP it is an extremely valuable database. Since these are time specific information, it has also been proposed to update this data base at a timely interval. NBA has also proposed that the collected information would be validated in consultation with an expert technical committee. However, it is a very complex process as the task is not only to identify the

¹¹ As of December 2011 among the several states that have set up BMCs, Karnataka ranks the highest with 3592 BMCs, followed by 948 BMCs in Kerala (www.nbindia.org).

¹² Thanks to Y. Gokhale for highlighting the point that monitoring happens when the exercise is repeated. So even though the PBR is visualised as a mechanism for monitoring, the iteration of the process has hardly been thought about.

knowledge holders, but to document their knowledge about the practices, resources used, availability of the resources etc. But such documentation will take place only if the knowledge holders are convinced about the purpose for which such information is collected. Nevertheless, once the more complicated validation of the data is also done, it would be a valuable intellectual property of that region giving all information and an important step in preventing both 'knowledge and bio piracy'. This will also prove to be an important document, which will show the 'bargaining power of the communities' in terms of the resources that are under their control and in deciding the benefit sharing strategy. If we vest the communities, who possess the categories of traditional knowledge in the sense of ethno botanical knowledge, with the right to control physically their territories, then it would help them to impose limitations on users for the usage of biological resources within their territories which is the crux of achieving such community based conservation (Gehl, 2003: 36). This has been happening in a few places in India where people have been effectively using Forest Rights Act provisions to exercise control over resources in the form of community rights (e.g. Mendha-Lekha village, Gadchiroli, Maharashtra). We have enough of policy and legal instruments to actually evolve effective community based conservation and safeguarding of resources¹³.

Preparation of PBR, however, is a multidisciplinary task and it involves huge financial and human resources. First and foremost, people need to be sensitized as to the need and the purpose such register would serve. On the PBR exercise of documenting knowledge, Gadgil et al. (1996) note that "a few tend to be especially knowledgeable, perhaps five to six in a community of a few hundred to a few thousand people. These are mostly men, mostly over 40, suggesting an ongoing erosion of such knowledge as younger people become alienated from the natural world. Many of the specialists use their knowledge to earn a supplementary income, often as medicine men. They are often apprehensive of misuse of their knowledge; but many were supportive of a PBR kind of exercise as a tool for preventing misuse". As of December 2011, a total of 932 PBRs have been documented with the highest of 480 from Madhya Pradesh according to the NBP. Individually the Kerala Sastra Sahitya Parishad and M.S.Swaminathan Research foundation have prepared the PBRs for all the 85 gram panchayats of the districts Ernakulam and Wynad in Kerala respectively. Under the co-ordinated network

¹³ Thanks to Y. Gokhale for bringing in this point.

programme of Indian Institute of Science, PBRs in 52 sites in 7 states was undertaken in a systematic manner (Gadgil, 2006).

3.1 Use of PBRs

Citing evidences from different geographical locations of India, Gadgil (2006) notes that PBRs have a significant role in (1) providing authority to the communities to regulator access to harvest bioresources on a sustainable manner; (2) promoting knowledge based sustainable management of agriculture, livestock, fish, forest and public health to improve the quality of life of the communities; (3) creating opportunities to generate resources through collection fees for access to bio-resources and knowledge; and (4) conserving and increasing the value addition to the bioresources of a region. In the context of some of the issues highlighted in Section 2, SSM would benefit in the following specific aspects, if efforts are taken at the earliest to organize documentation of TK related to Siddha through the PBR.

3.1.1 Use of IP Database in Estimating the Number of Siddha Practitioners

Table 1 discussed earlier gives an estimate of number of traditional Siddha practitioners, of which a larger percentage belonged to those practitioners who had received training in the SSM in the traditional way. During our field work, a few of the practitioners said that these figures are grossly underestimated and there are a number of hereditary practitioners, who have not been listed. Though there are associations for such kinds of practitioners, the list is incomplete.

If a PBR is in place, it would provide information on the number of people with traditional medicinal knowledge in a particular geographic location with an idea of knowledge of specialization. This would serve many purposes: (1) these traditional practitioners would be highly resourceful in imparting practical knowledge in institutions, which rely mainly on the text books, for instance, on identification of plants, toxicology, yoga and Varmakkalai. Though these are part of the syllabus, they are hardly taught in the colleges. During the field work, from the interaction with a traditional Siddha practitioner, who has set up a college in Municirai¹⁴, we learnt that

¹⁴ Kanyakumari district in Tamil Nadu.

this particular college brings in hereditary practitioners with specific expertise to teach the students. We were also given an example of the small number of people with the ability to read the palm scripts or *olaichuvati*. "The *ôlaicuvâti* constitute an important part of the knowledge of traditional practitioners, but nowadays, they are scarcely used because rare are the practitioners capable to read and understand them; they prepare medicines from formulas which were rewritten from manuscripts in notebooks by their parents" (Sebastia, 2010: 12). Such knowledge would be of tremendous resource for preparing the Traditional Knowledge Digital Library (TKDL) of Siddha.

- (2) In the case of benefit sharing that arises from the use of TK, PBR will give us an idea, for instance, as to how many practitioners in a specific area would receive benefits in the commercial use of the knowledge. PBRs would play an important role in material transfer agreements when bioresources of a region are transferred outside the country. Importantly, in determining the economic value associated with a resource and knowledge, PBR would play a significant role.
- (3) The other use of PBR is on understanding or stocktaking of available different types of natural resources such as herbs, medicinal plants and animal resources that are used in the SSM. "Supplies of 700 out of 776 Indian plant species used commercially for preparation of medicines still come from natural populations. There is no proper information on their current status and possible levels of over-exploitation with either Governmental agencies or pharmaceutical industry. The only reliable information on these issues, albeit limited to their own localities, resides with local forest produce collectors who are employed by agents of pharmaceutical companies, or with folk practitioners of herbal remedies." (Gadgil et al., 1996). As mentioned elsewhere, if the knowledge regarding these resources is not documented, many of the medicinal plants would be considered as weeds.
- (4) Controversies around patenting well known TKs relating to neem and turmeric resulted in making it mandatory on the part of the IPR applicant to disclose (a) the source of genetic resources and associated traditional knowledge; (b) the country providing genetic resources and associated traditional knowledge; (c) available documentary

information regarding compliance with access and benefit sharing requirements and information known to the applicant (following a specified level of effort for enquiry) regarding persons involved in the subject matter of the application and the country of origin of genetic resources and associated traditional knowledge (Sengupta, 2003). The disclosure requirements may be useful in improving substantive examinations and in assuring the integrity of determinations under traditional intellectual property legal requirements, in providing greater certainty as to the validity of granted rights or privileges and in reducing the need for revocation of improperly granted intellectual property (Sarnoff and Correa, 2005).

The amendments made to the Indian Patent Act 1970 now require all the applications that have used any natural resource to mention the source and origin of the resource. Section 10 which deals with the content of the patent application necessitates disclosure of the origin of biological materials and Section 25 states that if there is no complete information about the biological information or their geographical origin is wrongly mentioned then the patent can be revoked.

Further a patent can be opposed either in the pre-grant stage or post-grant stage, for not mentioning the source of natural resource or for providing incorrect information on the same. The amendment made in 2002 to the Indian Patent Act of 1970 also has stated that TK or aggregation or duplication of known properties of traditionally known components can not be patented. The Plant Variety and Farmers Rights Protection Act also necessitate the mention of the geographical origin of the plant resources seeking protection.

- (5) A PBR providing information on various medicinal plants, their availability status and quantity would help in prioritizing production for a company, address the issues in quality and non-availability through appropriate R & D expenditure, to evaluate effect of alternative resources.
- (6) As Siddha is practiced only in Tamil Nadu, creation of PBRs and making it available with the formal training institutes would help in disseminating information about the local knowledge and the local resources widely.

- (7) A PBR would also help in understanding the scientific reasons for adopting certain SSM practices and help in the process of validation.
- (8) Validated process could be continued and widely adopted or even serve as a research tool. Importantly, such process can be scaled up for wider use, through the adoption of modern biotechnology tools and, as mentioned earlier, provide a base for cumulative innovations.

3.2 *Local Indigenous Efforts to Conserve TK*

Traditional knowledge is subject to erosion if less number of people learn, practice and access it or the availability of the natural resources is restricted or become extinct. While the state government's effort to set up the Tamil Nadu Biodiversity Board has come recently, it has a long way to go in setting up the Biodiversity management committees that will be entrusted with the task of preparing the Peoples Biodiversity Register for the entire state. However, localized efforts by various non governmental organizations have already taken place/ going on in several parts of the country. In the following paragraphs a highlight of the efforts of a NGO in preparing the local knowledge register is provided.

Covenant Centre for Development (CCD) is an NGO operating in Madurai in Tamil Nadu. It has made efforts towards conservation of medicinal plants and in preparing a local knowledge register. CCD has formed a Medicinal Plants Conservation (MPC) committee, which focuses on livelihood promotion of women using medicinal plants. MPC is done in 15 sites identified in three states namely Karnataka, Kerala and Tamil Nadu. Both in situ and ex situ preservation measures are taken. Forest department in each of the state takes care of the in situ cultivation. Ex situ cultivation is where similar forest atmosphere is created elsewhere, taking care of legumes and other plants that have to grow along with the main plant which is undertaken by CCD.

Documentation of TK often becomes a challenge since the TK practitioners do not use their knowledge for monetary purposes and the knowledge is transmitted as *mantra* to the other person. Hence, they believe that if it is taught to many who do not respect the sacred values of the *mantra* the efficacy of the treatment is lost. Therefore, CCD reaches the elderly people,

motivates them to part with their knowledge and assures that the knowledge shared by them is not for commercialization, but for conservation and sustained use.

Once the classification of the data was done, the results of CCD showed that knowledge on biological resources was more with the socially backward castes that work more closely with natural environment than others. With this data, CCD has done two types of documentation on home remedies and medical practices. In the first stage, CCD prepared a list of commonly known/occurring diseases in that area in the local language. Information was sought on the common indigenous practices followed to cure the illnesses that were reported. Secondly, origin of medicine, use of the plants, and preparation of the medicine and the method of administering the medicine were listed. It was also learnt whether the community would be ready to part with the knowledge in return for monetary compensation.

At the second stage validation of the practices was done. In order to do validation workshops were conducted to understand the practices and identify those practices that need to be encouraged and researched and those which were wrong and need to be discontinued. In the revalidation workshop certain health conditions were chosen and the name of the disease, symptoms and causes were discussed before the community and practitioners from other ISM as well as modern medicine practitioners. Where there was divided opinion among practitioners, further research was carried out. Totally wrong practices were discouraged. By this methodology CCD claims to have validated 21 diseases in 6 places. This is codified and documented as the IPR of that region. The printed books of this were given to the village head, panchayat president and the district collector, who declares it as the IPR of that region. Though the book is open for consultation, if any of the practice is to be commercialized, benefit sharing has to be worked out. This project was started in 1999 and the book was in place in 2001 even before the BDA 2002 was formally adopted. The NGO disseminates the knowledge back to the community through a publication called *Poorvigam* published in vernacular language and the *Naattu Vaidhya Convention* held in May every year. Based on the evidence the villagers are encouraged to grow a common kitchen herbal garden.

In the *Karantha Malai* region, 9 colleges and the CCD together have prepared

a register identifying the medicinal plants, birds and TK and submitted to the panchayat. Similarly in *Kolli Hills*¹⁵ the Sustainable Life Trust has created a tribal health knowledge register. Maintained by the community this written resource would provide a way of tapping local learning for the benefit of future generations and for the protection of the current populace. With a population of around 40,000, which consists of mostly Scheduled Tribes, the region is known for its traditional herbal medicines and local healers, and the *nattu vaidyas*. Eighteen local healers participated in the survey documented by female village resource persons. Personnel from local non-government organizations trained the village resource persons (VRP) to record information. The purpose of the exercise was fully explained to the *vaidyas* beforehand and they signed an informed consent document prior to the investigation. The VRPs assembled a list of the 15 primary health problems of the region: each healer was then interviewed individually about each of the conditions and their local remedies. Meanwhile, local ayurvedic and siddha doctors verified the reports and conducted their own correlating research and a botanist collected and recorded the various herbs used by the healers. Only one *vaidya* refused to participate saying that revealing the secrets of his medicines would reduce their potency. The resulting trial register provided the local name for the disease condition, its description, causes and diagnostic features as understood by the *vaidyas*. The treatment provided was also recorded including the local names of the ingredients and the details of its preparation and application. The list of plants was indexed and attached to the register. Comments from modern doctors on whether the remedy was proven to be beneficial were added, which proved that of the 55 remedies analysed, all but one were effective.

Indian Institute of Science and Foundation for Revitalisation of Local Health Traditions (FRLHT) in Bangalore have made efforts independently to create PBRs. Using the rapid assessment of local health traditions approach in a participatory manner, FRLHT has documented and validated ethno veterinary practices in Karnataka. This study examined 120 plant resources for 20 health conditions and found 70 per cent of the remedies had positive evidence from various systems of medicine. 12 remedies have gone through the pilot clinical studies to be produced by local enterprises (Santhanakrishnan et al., 2008). Once the products reach the commercial stage, it would be of

¹⁵ This paragraph draws from Dhanapal's 'Written Word Protects', *Down to Earth*, April 15, 2005.

interest to understand the benefit sharing strategies designed in this particular case. The last evidence reiterates the fact that SSM could be the base for cumulative innovations and a valid research tool.

4. Conclusion

This paper discussed the status and issues surrounding Siddha medicine and the usefulness of preparing a people's biodiversity register in regions where the concentration of siddha practitioners is found. This data base which once prepared would be an IP registry of the region and would serve very useful purposes and have significant positive implication for the protection of traditional medicinal knowledge. This is a very complex multi-disciplinary task extending from information collection stage to validation stage. The local governments will have to be appropriately sensitized at the very beginning about the issue. Substantial financial and training resources are required for collecting such information. Sensitization of the knowledge holders is another important task and requires prior informed consent of the knowledge holders in preparing the documentation. While we do not claim that this is the most ideal solution to address the issue of protecting the traditional Siddha medicine, PBR could be an ideal tool to complement the tasks of state biodiversity board of protecting the resources and traditional knowledge. Documentary evidence of the availability of resources is required to situations where such IPs could be already present. Such evidence can also be put to use to realize the full potential of the IP. It would play an important role in deciding patentability of applications. We are not sure whether creating the data base will promote knowledge systems within Siddha medicine, but it could promote more research and be used as the basis on which further work would evolve. Validation could help in discarding incorrect practices and popularizing the validated practices. There is a need to mainstream the mechanisms for dealing with public domain and private domain knowledge disclosures. Also safeguarding of already disclosed information in terms of misuse beyond the Siddha catchment needs a thoughtful approach.¹⁶

The efficacy of the Siddha medicine depends on genuine raw materials and appropriate method of production. One of the ways to ensure that the system will continue to be followed is by protecting the traditional knowledge

¹⁶ Thanks to Y. Gokhale for drawing attention to this.

about the appropriate use of raw materials. The popularity of SSM over the years has declined because consumers are not sure of the raw materials and the effectiveness of the drugs. In its place the modern medicine, where people are equally unaware of the raw materials has gained momentum. The reason is that the modern medicine reaches after the clinical validation is done. Hence, PBR can play an important role in weeding out incorrect practices and popularize the validated practices to ensure that people are getting appropriate treatment.

Appendix 1

Memorandum of Understanding between (a) Council of Scientific and Industrial Research, Rafi Marg, New Delhi 110 001, (b) Department of Indian Medicine And Homeopathy, Govt. of Tamilnadu, Chennai 600 106 and (c) Tamilnadu Medicinal Plants Farms And Herbal Medicine Corporation Limited (Tampcol) Govt. of Tamilnadu, Arumbakkam, Chennai 600 106.

Executed at Chennai on 26th September, 2001

The objects of the Memorandum of Understanding as follows

1. To provide technical advice and appropriate training to Indian Medicine and Homeopathy Department persons.
2. To provide appropriate methods of storage of plant and raw materials.
3. To provide assistance in Agro technologies for growing of plants selected by this department.
4. To provide assistance on process control and other engineering aspects of the manufacturing process presently adopted.
5. To screen Siddha medicines for Bio-activity and to identify the Potential molecule for the Bio-activity.
6. To isolate individual molecule, which enhances the activity and absorption or reduce the toxicity of the bio-activity molecules.
7. To provide assistance for plant screening and identification of lead molecules, to develop those molecules further to obtain enhanced activity and reduced toxicity.

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Phone : +91-02717-242366, 242367, 242368
Fax : +91-02717-242365
Email : gidr@gidr.ac.in
Website : www.gidr.ac.in

Gota, Ahmedabad 380 060, Gujarat, India.

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Email : gidr@gidr.ac.in

Website : www.gidr.ac.in

Gota, Ahmedabad 380 060, Gujarat, India.