Protecting Traditional Knowledge in Siddha System of Medicine

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The Siddha system of medicine (SSM) is an ancient system that is practised in Tamil Nadu in South 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 generating interest in research on the scope of personalized medicine, it is important that the various intellectual properties concerning SSM is protected on an urgent basis. The People’s Biodiversity Register (PBR) is an ideal solution to the issue of economic and knowledge losses due to biopiracy and lacuna in protecting the intellectual property in SSM. A well documented PBR is an intellectual property registry of a village/region and would facilitate in appropriate sharing of benefits acquired from exploitation of bio-resources of a region.

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

This paper focuses on protecting the intellectual property (IP) of the knowledge holders of Siddha system of medicine (SSM), an Indian system of medicine practised mainly in Tamil Nadu and other Tamil speaking regions of the world. 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. Siddha medicines are produced using herbs, medicinal plants, animal and marine resources. As SSM depends on natural resources, it can provide a base for cumulative innovations in the biopharmaceutical segment based on recombinant DNA 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 and 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 modern pharmaceuticals are also generating interest in research on the scope of personalized medicine using traditional knowledge (TK).

Considering the fact that SSM focuses on addressing the root cause of the disease rather than treating the disease symptoms, it is highly probable 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. Protecting this stock of knowledge about the resources itself is the first step in protecting the intellectual property (IP) in SSM.

This paper discusses the usefulness of preparing an IP registry of SSM in the lines of People’s Biodiversity Register (PBR). PBRs are 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 vaids and practitioners who use local biological resources. Further PBRs can also be used to validate their medicinal practices, adapt the useful ones and discard the incorrect ones. Most importantly, the codified information that is available in the form of olaichuvadi (palm leaf scripts) and other forms of knowledge systems, can be documented under the Traditional Knowledge Digital Library (TKDL) system. Initiated by the Government

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of India in 2001, TKDL is an effort to provide information on traditional knowledge (TK) to patent examiners to prevent the grant of wrong patents. PBR can aid in compiling information (which is known but not commonly available in public domain) for TKDL.

Here in this paper, IP of the Siddha medicine practitioners is meant 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 patients without formal training at an 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 use them in a sustainable manner.

### Status of Siddha Medicine in Tamil Nadu

#### Regulation and Number of Practitioners

Siddha system of medicine is governed by the Central Council of Indian Medicine (CCIM) through the Indian Medicine Central Council Act, 1970 (IMC, 1970). As per Government of India instructions, the Government of Tamil Nadu enacted the Tamil Nadu Siddha System of Medicine (Development and Registration of Practitioners) Act, 1997. The Tamil Nadu Siddha Medical Council is the statutory registration body for the registration of Siddha practitioners only. For practising in Tamil Nadu, registration with the Council is compulsory. The Tamil Nadu government has attached special importance to the growth and development of SSM as it is part of 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’. With this aim in mind, the Government of Tamil Nadu has started providing SSM in its government health care along with the modern allopathic medicine.

Besides, there are several institutions imparting education in SSM. The Government Siddha Medical College and Hospital in Palayamkottai is the oldest institution teaching SSM. In 2005, the National Institute of Siddha was set up in Chennai to impart post graduate education 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. Table 1 presents the number of Siddha medical practitioners registered with Tamil Nadu Siddha Medical Council.

### 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). During the six year period from 2004 to 2010, the numbers in absolute terms have increased. The newly set up National Institute of Siddha alone treats about 1000 out patients every day and has facilities for 120 indoor patients of Siddha Medicine.

#### Table 1 – Number of Siddha practitioners in Tamil Nadu

<table>
<thead>
<tr>
<th>Class</th>
<th>No of registered practitioners in 2010 (percentage)</th>
<th>No of registered practitioners in 2004 (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIM &amp;BSMS</td>
<td>3845 (45.05)</td>
<td>2487 (34)</td>
</tr>
<tr>
<td>LIM, LAM, etc.</td>
<td>6 (0.07)</td>
<td>6 (0.08)</td>
</tr>
<tr>
<td>GCIM</td>
<td>3 (0.03)</td>
<td>3 (0.04)</td>
</tr>
<tr>
<td>B class</td>
<td>2245 (26.30)</td>
<td>2245 (31)</td>
</tr>
<tr>
<td>C class</td>
<td>24 (0.28)</td>
<td>24 (0.33)</td>
</tr>
<tr>
<td>Enlistment</td>
<td>2411 (28.25)</td>
<td>2409 (33)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>8534 (100)</td>
<td>7174 (100)</td>
</tr>
</tbody>
</table>

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 denotes 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.

Source: Government of Tamil Nadu, Performance Budget, 2011-12 and 2004-05

#### Table 2 – Details of patients treated in 2004 and 2010

<table>
<thead>
<tr>
<th>System</th>
<th>2004 Out patients</th>
<th>2004 In patients</th>
<th>2010 Out patients</th>
<th>2010 In patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siddha</td>
<td>15475528</td>
<td>199857</td>
<td>20231946</td>
<td>157936</td>
</tr>
<tr>
<td>Ayurveda</td>
<td>383977</td>
<td>19128</td>
<td>980916</td>
<td>33419</td>
</tr>
<tr>
<td>Unani</td>
<td>187317</td>
<td>20354</td>
<td>224264</td>
<td>15050</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>1099756</td>
<td>18261</td>
<td>1595621</td>
<td>19985</td>
</tr>
<tr>
<td>Naturopathy</td>
<td>25153</td>
<td></td>
<td>149215</td>
<td></td>
</tr>
<tr>
<td>and yoga</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>17171731</td>
<td>257600</td>
<td>23181962</td>
<td>226390</td>
</tr>
</tbody>
</table>

Source: Government of Tamil Nadu, Performance Budget, 2005-06 and 2010-11
patients. There is however, no clear estimate of the number of people who are treated by traditional Siddha practitioners.

Issues Surrounding SSM

Number of Practitioners

Following the Drugs Enquiry Committee (also known as Chopra Committee) Report which focused on regulating the medical education and registration of practitioners to weed out the quacks from the system, the practitioners are 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) nattuvaidiyars or non-graduate practitioners classified as ‘C’.5

Table 1 reveals 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 varmakkalai (acupressure on vital points on the body) are concentrated in a particular region. The traditional bone setters (who set the fractured bones without surgery) are popular and preferred by people from all socio-economic backgrounds for their efficacy and relatively cheaper cost of treatment.5 However, it is not clear whether the list of practitioners provided by the government covers all these traditional practitioners with particular specialization. The advantage of the hereditary practitioners and those who trained under an Asan (a trained teacher) is that they are exposed to practical aspects of Siddha, right 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 have failed.7 Also, it is not uncommon to find that after their BSMS degree, these graduates often train in and even practice allopathic medicine as the law of the land enables them to do so if they are registered practitioners.8 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 medicine.9 Concerning toxicology, yoga and varma therapy, these specialties though are inscribed in the syllabus of governmental colleges, they are hardly taught and practised.5

There have been instances where colleges have invited traditional practitioners to demonstrate knowledge that goes beyond the text books10 and also offer electives such as snake venom and varma therapy, which are well known in this region. 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.

Use of Natural Materials and Their Availability

There are 7483 units producing medicines in the Indian system of medicine (ISM) sector, which comprise of both organized and unorganized sectors. Only approximate figures pertaining to the demand for herbal and other resources by these units is known. According to the report of the Taskforce on Medicinal Plants11, 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., while the rest is 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 from different parts of the country who procure the raw material from undisclosed sources, often collected by unskilled persons for a nominal price. Further, ‘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’.

Siddha medicine uses plant, animal, 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 forest laws are stricter than before, some of the biological resources are no longer available and, therefore cannot 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 for heart, are no longer allowed access to 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. 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.

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 of the budget that is allocated for health annually. As with any other programme, 70 per cent of it would go for administration and salaries. Hence, the actual amount that is going towards R&D, strengthening regulation, training, etc., has to increase significantly, if the system has to survive.

The other alternative is to undertake cultivation of medicinal plants in places other than its original habitat. However, respondents particularly, Tamil Nadu Medicinal Products Company Limited (TAMPCOL), and Indian Medical Co-operative Pharmacy and Stores (IMPCOPS), who supply to the Government healthcare facilities in Tamil Nadu and the officials from forest department reveal that cultivation of medicinal plants in places other than their natural habitat poses several hurdles. 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 farmers would otherwise get.

For example, *Kilzanelli* 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 *Kilzanelli* 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 IP content that would serve as a valuable reference for Siddha drug manufacturers. However, once the catalogue of creative knowledge in the memory of the traditional healers is lost, several of the medicinal plants would become weeds.

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 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 by these agencies presently to (a) sustainable aspects of the raw materials; and (b) the benefit sharing practices with the community/individuals that supply raw materials. 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. 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, manufacture 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 database 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.
Issues in Standardization

There are two types of regulations governing manufacture of Siddha medicine. One set governs the manufacturing practices in the form of set procedures called good manufacturing practices (GMPs). 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 is that each medicine comprises of minimum 20 ingredients. Non-availability of a few ingredients in the composition adds to the problem. Hence, matching and maintaining the uniqueness of each of the ingredient to bring out their combined effect in the final product while at the same time maintaining their standards becomes the herculean task for its manufacturers.

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 GMPs, which assures users that the medicines are manufactured adhering to standard manufacturing practices. However, a sufficiently large manufacture of Siddha medicine takes place in the unorganized sector, which is difficult to be brought under any regulation. The GMPs not only cover manufacturing practices but also set standards for procurement of raw materials. These requirements in short are called as Schedule T requirements.

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 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, siddhars and hakeems (practitioners of ISM), who prepare medicines on their own to dispense to their patients and do not sell such drugs in the market are exempted from the purview of GMP.

In issues relating to standardization and adopting GMPs, particularly, for accessing standard raw materials in the preparation of the medicines, creation and maintenance of the PBR would offer some solution.

Protection of Traditional Knowledge through PBR

Convention on Biological Diversity (1992) was the first binding international legal instrument for protecting the traditional knowledge (TK). But Article 8 j actually dilutes the protection offered by the CBD by stating that the ‘parties have to take measures as far as possible and as appropriate’. India is party to the Convention and enacted the Biological Diversity Act in 2002 (BDA, 2002). The main objectives of the BDA are: (1) 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 bodies.

The National Biodiversity Authority 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 3 shows, applications claiming IPR through the use of biological resources are higher than the other categories indicating the interest in this area.

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

Note: *inclusive of 13 applications that were not applied in prescribed form and fee
Source: www.nbaindia.org (as on 23 December 2011)
State Biodiversity Boards (SBBs) look after the applications for the access to the bio-resources by Indians, Indian companies and institutions. SBBs also have the power to restrain any activity that violates the objectives of conservation.\textsuperscript{17}

At the next lower level, state governments with the help of local government bodies 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 Peoples’ Biodiversity Register (PBR). PBRs are 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 vaidas and practitioners using local biological resources.

BMCs play a very crucial role in the protection of biodiversity. Both NBA 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.\textsuperscript{18,19} 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 its website. For instance, on medicinal plants and wild plants of medicinal importance, the information sought includes 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 use for market or own use, community/knowledge holders.

Thus, people’s Biodiversity Register is expected to serve as a tool to (a) document, monitor\textsuperscript{20} 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) create awareness about the environment and biodiversity; and (e) to perpetuate and promote the development of practical ecological knowledge of local communities and of traditional sciences such as Ayurveda and Unani medicine.\textsuperscript{21}

Biodiversity register, in other words, is an atlas which maps the local resources as well as knowledge and is highly location and time specific. In the context of IP it is an extremely valuable database. Since these are time specific information, it has also been proposed to update this database at timely intervals. 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 knowledge holders, but also 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 IP of that region giving all information and an important step in preventing both ‘knowledge and biopiracy’. It also serves two purposes: (1) providing information to databases like the Traditional Knowledge Digital Library (TKDL) and (2) improving the ‘bargaining power of the communities’.

The bargaining power of the communities will increase if they know the resources that are under their control which would be useful in deciding the benefit sharing strategy as well. If the communities, who possess the categories of traditional knowledge (including ethno-botanical information), are vested with the right to control them physically their territories, it would help them to impose limitations on users of biological resources within their territories which is the crux of achieving such community based conservation.\textsuperscript{22} This has been happening in a few places in India where people have been effectively using the provisions of the Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 to exercise control over resources in the form of community rights (e.g. Mendha-Lekha village, Gadchirol, Maharashtra). India has enough of policy and legal instruments to actually evolve effective community based conservation and safeguarding of resources that can empower such community based knowledge resources.

Preparation of PBR, however, is a multidisciplinary task and involves huge financial and human resources. First and foremost, people need to be
sensitized to the need and the purpose of such a register. On the PBR exercise of documenting knowledge, Gadgil et al., note ‘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’.21

Use of PBRs

Citing evidences from different geographical locations of India, Gadgil et al. note that PBRs have a significant role in (1) providing authority to the communities to regulate access to harvest bio-resources in 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 bio-resources of a region.21 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.

Use of PBR Database in Estimating the Number of Siddha Practitioners

Table 1 discussed earlier, gives an estimate of number of traditional Siddha practitioners, of which a large percentage belonged to those practitioners, who had received training in the SSM in the traditional way. During field work by the author, a few of the practitioners opined that these figures had been grossly under-estimated and there were many more hereditary practitioners, who were not 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 along with their area 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. Although these are part of the syllabus, they are hardly taught in colleges. During the field work, from the interaction with a traditional Siddha practitioner who has set up a college in Municirai (in Tamil Nadu, India), the author learnt that this particular college brings in hereditary practitioners with specific expertise to teach the students. ‘The olaichuvadi constitute an important part of the knowledge of traditional practitioners, but nowadays, they are scarcely used because rare are the practitioners capable of reading and understanding them; they prepare medicines from formulas which were rewritten from manuscripts in notebooks by their parents.’ As PBR is not only an inventory of biodiversity but also of the knowledge system associated with biological diversity, information transcribed from palm leaf scripts, will make the TKDL’s source of information list on Siddha longer and help in opposing patents based on SSM.

(2) In the case of benefit sharing that arises from the use of TK, PBR will reveal, for instance, information 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 bio-resources 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 creating inventories of available different types of natural resources such as herbs, medicinal plants and animal resources that are used in the SSM.

(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. 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.” However, since the declaration of source biological material used in an invention is prescribed only under the Indian patent law and many countries have not accepted disclosure of origin requirements, there could be hurdles and legal quagmire where territories other than India are involved.

The amendments made to the Indian Patents 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 opposed before or after the grant of the patent. The amendment made in 2002 to the Indian Patents Act of 1970 also stated that TK or aggregation or duplication of known properties of traditionally known components cannot be patented. The Protection of Plant Varieties and Farmers’ Rights Act also necessitates the mention of the geographical origin of the plant resources while 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 practised only in Tamil Nadu, creation of PBRs and making it available with the formal training institutes would help in wide dissemination of information about local knowledge and local resources.

(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.

Local Indigenous Efforts to Conserve TK

Traditional knowledge is subject to erosion when less number of people learn, practice and access it or the availability of the natural resources is restricted or is extinct. While Tamil Nadu set up the Tamil Nadu Biodiversity Board in August 2012 (ref. 25), 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 (NGOs) is already going on in several parts of the country.

Covenant Centre for Development (CCD) is one such NGO operating in Madurai in Tamil Nadu which 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. Both in situ and ex situ preservation measures are underway 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 often orally, as a mantra (sacred hymn) to the other person. It is believed that if knowledge is imparted 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.

CCD has developed two sets 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 this, workshops were conducted to understand the practices and identify those practices that needed to be encouraged and researched and those which were wrong and needed 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 versions in the form of books were given to the village head, Panchayat (local governing body) president and the district collector who declared 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 NaattuVaidhya 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, 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, the region is known for its traditional herbal medicines and local healers, and the nattu vaidhyas (natural healers). 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 vaidhyas beforehand and they signed an informed consent document prior to the investigation. The VRPs assembled a list of 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 vaidhya 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 vaidhyas. 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. Twelve remedies have gone through the pilot clinical studies to be produced by local enterprises. Once the remedies reach the commercial stage, it would be of 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.

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 database when prepared would be an IP registry of the region and have significant positive
implications 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 this may not be the most perfect 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 in protecting the resources and traditional knowledge. Documentary evidence of the availability of resources is required in situations where such IP could already be 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. It is not clear whether creating the database 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 community needs a thoughtful approach.

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 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 popularity. The reason for the rising interest is that the modern medicine reaches the consumer after a clinical validation. Hence, PBR can play an important role in weeding out incorrect practices and popularizing the validated practices to ensure that people are getting appropriate treatment.

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References
4. Post-graduate courses are offered in Gunappadam (pharmacology), Maruthuvam (general medicine), sirappumaruthuvam (special medicine), kachanthaimaruthuam (paediatrics), noinadal (pathology) and nanjuwoolum maruthava neethinoolum (Siddha toxicology and forensic medicine).
7. Personal interaction with faculty at Chennai, Municirai (Kanyakumari district) and practitioners.
8. In a sensational case in Tamil Nadu, the state police arrested a few Siddha practitioners who were practicing allopathic medicine, declaring them as quacks. However the Madras High Court citing a government order issued by the Department of Health and Family Welfare said that the registered practitioners of Indian system of medicine could practice allopathic 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 (20 December 2010).
9. Personal interaction with faculty at Chennai, and practitioners at Madurai and Nagarkovil.
10. Interaction with the management of the college at Municirai.
13. TAMPCOL has signed a memorandum with the Council of Scientific and Industrial Research for various activities including screening of Siddha medicines for bio-activity.

15 In order to standardize the preparations in ayurveda and also conduct shelf life studies, the government, has chosen 10-15 laboratories all over and have given them a few products. These laboratories will have to produce 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 (sources from IMPCOPS and TAMPCOL).

16 Article 8j of the Biological Diversity Act states: ‘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’.

17 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.


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

20 Even though the PBR is visualized as a mechanism for monitoring, the iteration of the process has hardly been thought about.

21 Gadgil M et al., People’s Biodiversity Register - A record of India’s wealth, Amruth (October, Special Supplement) (1996) 1-16.


23 Sengupta Nirmal, Economics of indigenous/traditional knowledge about biodiversity in Biodiversity and Quality of Life, edited by Nirmal Sengupta and J Bandopadhyay (Macmillan Indian Ltd, Delhi), 2005.


26 This paragraph draws from Dhanapal’s ‘Written Word Protects’ in Down to Earth, 15 April 2005.