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I. Introduction
Access to health care, stemming from the high costs of medicines, health services and diagnostics, has become a major source of concern in developing countries. The enormity of the problem arises from the fact that a majority of the country’s population cannot afford the high cost of health care and hence they find themselves excluded from the modern health care systems that developing countries boast of. As a result, the disease burden in the case of both communicable and non-communicable diseases has remained at unacceptably high levels.

The problems afflicting health care systems stem from the fact that disease prevention forms a relatively small part of the overall efforts; in other words, there is an overwhelming dependence on the curative element. The lack of preventive health care is particularly galling in the case of children, where the system lags behind most other major economies in providing healthy life to their young population. A stark example in this regard is the inability of the immunization programme for improving child mortality to make any dent in the occurrence of vaccine preventable diseases like diphtheria, pertussis, tetanus, poliomyelitis, typhoid, and child tuberculosis.

The overwhelming dependence of the health care system on curative medicines has brought with it two sets of problems. The introduction of the product patent regime under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), has brought with it the spectra of global drug majors imposing their monopoly control over the market for pharmaceuticals. These concerns were somewhat assuaged in the Doha Ministerial Conference in 2001, when the Doha Declaration on TRIPS and Public Health was adopted. While adopting the Declaration, WTO Members agreed that “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. The Ministers affirmed “that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”.

It is in this context that the idea of the Health Impact Fund (HIF) has evolved to achieve the delicate balance between the public policy objective of access to medicine and due recognition of the IP regime. In the HIF, any firm receiving market approval for a new medicine is expected to be offered a choice between (a) exercising its usual patent right through high prices or (b) registering its product with the HIF. Registration would require the firm to sell its product worldwide at an administered price near the average cost of production and distribution. The HIF seeks to reward any new medicine (if priced at the cost of production) on the basis of global health impact. In exchange the firm would
receive from the HIF a stream of payments based on the assessed global health impact of its drug. The HIF is in other words an optional payment for performance of new pharmaceutical products.

In the case of traditional medicines, this idea of payment to ‘new medicine’ would have to be reassessed and if required may be expanded. However, performance indicators like patient usage data, clinical trial data, etc. may remain at par with what was originally conceived as part of the HIF. The China-India Traditional Medicine Health Impact Initiative (CITHII) is an idea in that direction.

II. Traditional Medicines in China and India

China and India have strong stakes in the development and evolution of Traditional Medicine (TM) for ensuring the wellbeing of their people and access to cost effective medicine but there is a need to work out the details. The issue is how to scale-up the already existing systems for wider systemic gains. This may be achieved either by promoting TM in isolation or by integrating them with other systems, like for instance the allopathic system. This would be an interesting development. This may require development of the TM sector to enable this sector to address fundamental health sector challenges. HIF is relevant for TM and we argue that HIF can begin with cooperation on TM in two countries, i.e. China and India. Central to this cooperation is the quest for international resources to enhance access to medicines. The rationale for adoption of TM comes from following facts:

- China and India both have a well developed TM system(s) that caters to a wider population.
- TM in these countries has undergone changes over the years and to a great extent has been modernized in terms of production practices, regulation, organization, and education and training.
- Over the years enormous work has been done in terms of studying these TMs, the respective medicinal herbs and their potential in medicine, and this knowledge can be used in many ways. For example traditional practices can be made more effective, the efficacy of traditional medicinal preparations can be enhanced, and TM can be a new source for drugs.
- In some cases TM can act as a supplement to modern medicinal practices or can be used in post-operative care situations, and this has immense potential in reducing morbidity and mortality. For example recent studies indicate that Traditional Chinese Medicine (TCM) can help in reducing the side-effects for cancer patients who have undergone chemotherapy.
As TM in both countries is regulated by governments, and in China TCM is widely used in the public health system, the issues of data collection, impact studies and studies on efficacy can be addressed.

If TM can help in fulfilling the objectives of HIF it will enhance the credibility and acceptability of HIF as a concept, particularly in the remaining parts of Asia and Africa, where many other variants of TM are being practiced.

II.1 Traditional Indian Medicine (TIM)

India has also established a separate government department for the promotion of Indian traditional medicines. The Department of Indian System of Medicines and Homeopathy (ISM&H) was created in March 1995, and was renamed as Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) in November 2003 with the view to providing focused attention to develop education and research in the realm of traditional medicines. Four different Pharmacopoeia committees are working to evolve uniform standards for AYUSH drugs. Standards for around 40 per cent of the raw material and for around 15 per cent of formulation have been published by AYUSH. There is a proposal to turn the pharmacopoeia committees into modern commissions with adequate representation of stake holders. A pharmacopoeial laboratory for Indian medicines (PLIM), Ghaziabad for standard setting and drug testing for Indian medicines is established as a subordinate office with the Ministry of Health and Family Welfare. The government has also promoted a Scheme of Funds for Regeneration of Traditional Industry (SFURTI), for promoting micro and small enterprises for the production of traditional medicines.

India is home to a rich variety of traditional medicinal systems including Ayurveda, Unani, Siddha and Homeopathy (AYUSH). There are health/medicinal systems of indigenous communities and folk remedies that focus on human and animal diseases/illness. The ownership of this knowledge varies from individuals to families to communities, and at times is not able to be distinguished under any of these categories. While a good portion of the traditional medicinal knowledge is documented there are informal and undocumented practices also. The sheer diversity in terms of medicinal plants and medical knowledge in India is matched by the linguistic and cultural diversity in India.

The AYUSH sector across the country supports the network of 3203 hospitals and 21351 dispensaries. This sector provides massive support to primary healthcare and the newly launched scheme of the National Rural Health Mission (NRHM) during the X Plan period. As a part of NRHM, it is envisaged that all primary health centres would provide
AYUSH facilities under the same roof. AYUSH human resources are to be arranged either by relocation of AYUSH doctors or by hiring AYUSH doctors under NRHM funds. Under the XI Five Year Plan period, government has provided major support to the infrastructure for AYUSH establishments and has also supported educational institutions linked with this sector. There are close to 485 academic institutions providing various courses to students across various schemes of Indian systems of medicines (ISM). Across the ISM the number of institutions for Ayurveda is 242, followed by Homeopathy (185), Unani (40), Naturopathy (10) and Siddha (8). Accordingly, the number of practitioners across the streams also varies. This gets reflected in the industry composition as well (see Table 1) The turnover of the AYUSH industry is estimated to be more than Rs. 8000 crores i.e. Rs 80000 million with exports close to Rs. 1000 crores i.e. Rs 10000 million per annum. A large share of exports (70 per cent) is in raw form.

Table 1: Registered Medical Practitioners under AYUSH and System-wide Details of Manufacturing Units

<table>
<thead>
<tr>
<th>System</th>
<th>Number of Practitioners</th>
<th>Manufacturing Units</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number</td>
<td>Proportion</td>
</tr>
<tr>
<td>Ayurveda</td>
<td>453661</td>
<td>7621</td>
<td>85.68</td>
<td></td>
</tr>
<tr>
<td>Unani</td>
<td>46558</td>
<td>321</td>
<td>3.61</td>
<td></td>
</tr>
<tr>
<td>Siddha</td>
<td>6381</td>
<td>325</td>
<td>3.65</td>
<td></td>
</tr>
<tr>
<td>Naturopathy</td>
<td>888</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homeopathy</td>
<td>217850</td>
<td>628</td>
<td>7.06</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>725338</strong></td>
<td><strong>8895</strong></td>
<td><strong>100</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Source: Department of AYUSH, Status as on 1 January and 1 April 2007.*

II.2 Traditional Chinese Medicine (TCM)
China has launched several efforts at different levels to consolidate gains from TCM and to take it up further by using it as a key component in health R&D. The Chinese policy on intellectual property recognizes innovations related to TCM and grants patents on them. There are several patents obtained on a Tibetan drug for cancer which are obtained in almost 60 countries. China gave around 508 patents on TCM in 2004, which increased to almost 1600 in 2008. This increase in the number of patents is evidence of the rise in R&D expenditure in China. In 2004, US $100 million were allocated for advancing work in TCM, which was enhanced to US $200 million in 2008. With intense focus on quality
and standards, there is an upsurge in TCM exports as well. It is growing at a rate of 10 per cent per annum. EU and the US have signed agreements with China on quality assurance. China has also constituted four technical standardisation committees to work closely with R&D Centres for safety assessment and evaluation of the clinical effects of TCM.

At this point the turnover of TCM is US $30 billion which is nearly 25 per cent of the total drug sector. Exports were around US $1.5 billion. TCM crucially depends on plant extracts and decoctions which are the two main export items. They constitute 80 per cent of the total exports. At this point the destination of 65 per cent of exports is Asia, while China exports TCM products to 95 countries.

In 2009, the total production of TCM products was valued at US $33.8 billion\(^5\), up by 24% over the previous year, while the medicine industry growth was 20%. TCM’s contribution is about 26% of the total of the entire medicine industry. In 2009, the prices of some TCM raw materials rose. However, the cumulative profits of the TCM industry increased by 27% over the same period, while the cumulative profits of Chinese patent drugs and prepared herbal medicines increased by 25% and 40% respectively over the same period in the last year.\(^6\)

In 2009, TCM foreign trade surplus reached US $900 million. Surplus for TCM materials US $0.46 billion, and US $0.5 billion for plant extracts, while foreign trade deficit reached US $16 million in Chinese patent drugs and US $23 million in health products. Both extractive and Chinese medicinal crop trades achieved surplus. Export of extractives accounted for 44.8% of the total export volume of TCM products while that of the prepared Chinese medicinal prepared drug in pieces accounted for 38%. Since 2003, the Chinese patent drug trade has been in deficit, which exceeded US $23 million in 2009.\(^7\)

III. CITHII (China-India Traditional Medicine Health Impact Initiative)

As discussed earlier, in the recent past, both China and India have launched major initiatives to revitalise the TM sector in their respective economies. It is interesting to note that each country has found different ways to accomplish these objectives.

In the realm of standards China has already published pharmacopoeia. The first volume was out in 1960 and with the last revision was published in 2010. The new policy document on TCM of 2009 was a major boost in this direction. There are some proprietary issues with the ownership of knowledge related to TM in China, as most of
this knowledge is with individuals, families or with various community members. The Chinese government has already established a TCM Development Fund, for promoting the production and development of the TCM sector. The 2009 policy has also announced a list of essential medicines, which included almost 102 TCM products in the list of essential drugs. The latest plan on R&D for Public Health from 2010-2050 indicates the important role TCM can play in health R&D and in meeting health policy objectives. For example it states that

Traditional Chinese medicine has its own characteristics and advantages in the research field of the public health in China, and plays an important role in the respect therapy of complex chronic diseases as well as medical services in the rural areas. We should study sub-health and complex chronic diseases by using modern biological means as well as the traditional Chinese medicine characterised with integrity and systematization, so that the convergence of Eastern and Western medicines may be realized step by step in the near future.8

In order to promote integration across various medical knowledge streams AYUSH came together with the Indian Council for Medical Research (ICMR) and the Council for Scientific and Industrial Research (CSIR) to launch what is called a golden triangle partnership (GTP) to bring safe, effective and standardised Indian medicines. AYUSH has taken several initiatives to promote each of the knowledge streams within the Indian medicine system. There are separate research councils for each one of them. The government has also established a Traditional Knowledge Digital Library (TDKDL). It has a database of 77000 formulations collected from 14 Unani texts and a large number of Ayurvedic formulations. Digitization and development of databases can be linked with bioinformatics and the information from TM systems can be used by researchers in Western medicine and vice-versa. India and China have IT industries that are capable of meeting such needs.

Both China and India may come together to support and evolve a jointly funded China-India Traditional Medicine Health Impact Initiative (CITHII). Initially this may be a bilateral venture, confined to the firms and research institutes from the two countries alone, but later on may be opened to other countries and regions as well. CITHII will combine the objectives of the HIF with relevance to TM in both countries and hence will be a win-win approach for the HIF. CITHII draws on HIF’s core objectives and links that with the public health needs in both countries. In that sense CITHII is a variation on the idea of the HIF.
III.I Idea of HIF

The idea of the HIF is to reward innovators in proportion to the measurable net health impact of their innovations. This would be given every year from the HIF in proportion to their share of the health impact created by all eligible innovations. The idea is to promote innovations for attaining public policy objectives in the realm of the health sector. There are several designs possible for a reward mechanism. The HIF has a completely open approach to the possibility of various permutations and combinations under the framework of a reward structure that promotes innovation and access. The reward would be proportionate to the share of the health impact of registered products or firms, who would get a share of the fixed fund for ten years.

The reward disbursement to the registered firms with HIF at or before the time of marketing approvals for their drugs would go through following steps:

\[ \text{Payment} = S \times F \]

S= Estimated Health Impact of the product divided by the sum of estimated health impact of all the products eligible in that year.
F= Amount available from HIF for a particular year

The HIF would issue royalty free production licenses in all jurisdictions against all patents required to manufacture and distribute the product covered under the HIF. This may boost generic competition. Thus, the larger the health impact, the larger the reward. The firms registering with HIF should agree to sell the product at a low price world wide, equal to the average cost of manufacturing. The government would be the main contributors to the fund.

The key question before the HIF would be to select products which would be funded under the HIF scheme.

The following criteria have been identified for the HIF eligibility of a product:

- New drugs patent protected in major patent offices with marketing approvals.
- New approved indications for existing drugs when the new indication is patented.
- *A drug soon to go off patent is not eligible for HIF support.*
- Agreement to provide sales data after receiving HIF support
- Yearly registration fee to cover costs of health impact assessment.
• Assessment period for new products would be ten years and five years for new uses.
• HIF would set price range for products, which would be adjusted through inflation index.
• Ceiling on payments ($50,000 to $100,000 per QUALY are cost effective).

It is important to clarify that HIF would not fund research costs or the costs of clinical trials and other regulatory costs.

**Intellectual Property Rights Impact**

The HIF does not affect the current IPR regime in any way and does not need any change to work effectively. The HIF minimises the scope for any effort for the evergreening of patents and wasteful litigation on IPR violations. The firms would be able to use new patents for new indications. The HIF offers the strongest incentives for those products for which monopoly exploitation under the current patent system is most inadequate. There is no bar on patenting those medicines under the HIF. After ten years of reward, the beneficiary should offer a royalty free open license for generic versions of the product.

**Health Impact Measurement**

One of the most important institutional pre-requisites is an agency which can compute data related to health impact measurement. With the rising cost of health care there are growing efforts to systematically analyse epidemiological evidence. In the UK (NICE), Canada (CADTH), and Sweden (SBU), agencies have been established for assessing the clinical, economic, social and ethical implications of new and established health technologies. They review and synthesize data and disseminate their assessments to help decision-making, so that they promote efficient delivery of high quality care. In the case of HIF, however, it would depend more on the registrants to provide data regarding the usage of the supported drug, to be supplemented with other approaches such as QUALY, DALY and feedback on Surrogate Endpoints. The health impact assessment is to be performed every year. Contributing members may decide what framework they wish to follow but the board of the Fund may have representatives from the affected community as well. The HIF proposal does discuss some details (including proportion of voting rights etc.) on the format of such a board but as mentioned it is largely up to the members. It is expected that member countries would contribute in proportion to their GNI but suggests measures to avoid protracted struggles over contributions. It is envisaged that a reasonable minimum funding level for HIF is around US $60 billion or roughly 0.01 per cent of global income.
III.2 Applicability of HIF for TM

There are some challenges that TMs face in general and a few specific ones to these economies. Some of the major challenges are related to the intellectual property protection of TM, such as, they are not seen as meeting the criteria of novelty, as they represent a pre-existing knowledge base which is largely practiced in a particular area by a specific group of community members, or is already there in the classic documents. Moreover the production of TM does not fall within structured industrial production as is the case with Western medicine. Since it is highly individualised the formulations are produced at limited levels and in each such formulation the contents may vary, hence uniformity in standards is an issue. But these are not insurmountable problems and in fact can be overcome with specific solutions. The challenge of the modernization of TM is not a new challenge. A study of growth and development of TM in both countries shows that TM systems and practitioners have been sensitive to these issues and have found innovative solutions and have not hesitated to use modern S&T or organizational practices. If anything, TM in both countries today is more vibrant and has played an important role in meeting health needs. So, new challenges can be seen as new opportunities as well.

CITHII can give priority to those innovations based on TM that have not been commercialized because industry is not keen to invest in production for many different reasons. It is often argued that TM has not come up with relevant innovations that can meet health needs. This is not true however, because TM is used in many ways in health R&D. In India itself there are successful examples of TM used as a resource for developing new drugs and treatments. Under the New Millennium Indian Technology Leadership Initiative (NMITLI) project⁹ using the reverse pharmacology approach, a plant-based botanical drug was developed for psoriasis. It is now under Phase 3 clinical trials. Development of a herbal vaccine adjuvant based on Ayurveda is another project that has made promising headway. It has been pointed out that reverse pharmacology can play an important role in using TM knowledge, and ICMR has established an advanced center of reverse pharmacology with a focus on malaria, sarcopenia and cognitive decline.¹⁰

Another promising area where CITHII can help in enhancing access to innovations is that of herbal drugs. India has made some remarkable progress in this. For example under the NMTLI scheme a herbal drug for osteoarthritis has been developed. From the formulations that underwent clinical trials the best one was chosen and two patent applications including one under the Patent Cooperation Treaty have been filed. CSIR is engaged in the task of finding an industrial partner for further commercialization and marketing.¹¹
The TM approach to some diseases is more complex than the biomedical approach; citing the work of Chaudhury\textsuperscript{12}, Madhulika Banerjee provides the example of bronchial asthma to illustrate how using Ayurveda can be a better approach. She points out that ICMR-sponsored research for validating traditional knowledge did make headway, but could not progress beyond a certain point as industry was not keen to take the innovations further and commercialize them. CITHII can play an important role in such cases. It can certainly encourage commercialization of herbal drugs that have been validated and tested, irrespective of patent rights, and can work with agencies like ICMR and CSIR or similar agencies in China in helping the wider use of research and innovation. We propose that to begin with agencies in both countries can undertake a study of relevant developments in both countries in TM and find out innovations that can benefit from CITHII. This can include innovations that could not be commercialized because industry was not keen while the research councils lacked the capacity to commercialize. Examples like herbal vaccine adjuvant may find a wider application if they are properly commercialized. But the agencies may not be able to do that or to reward the industry for improving access. CITHII can come up with guidelines in such cases and, as suggested earlier, the health priorities in both countries can be identified. Once this is done the role of TM in meeting those priorities can be investigated and the appropriate innovations based on TM can be identified. After this the issues in further development and commercialization can be addressed. Some innovations like a herbal drug for osteoarthritis, and a botanical drug for psoriasis may find wider application in both countries. In such cases CITHII can indirectly encourage joint production and commercialization. So what CITHII needs is a road map with clear cut objectives. We believe that this is possible and that this is the right time for a project like CITHII.

There are issues like standardization that need a fresh look, and the old dichotomies like science vs. tradition or ‘modern medicine is scientific while traditional medicine is useful but unscientific’ should not deter taking this approach. According to Madhulika Banerjee:

Ayurveda need not anymore be integrated solely in the terms of biomedicine but in terms negotiated with biomedicine in which it truly exchanges knowledge with a sense of self-respect for its own. It is possible to achieve this without there being a confrontationist stance by viewing the process as a different set of terms of integration. No longer it is necessary to see this exercise as a ‘modern medicine’ versus ‘complementary medicine’, ‘modern science’ versus ‘traditional science’, but collaboration with a view to enhancing the benefits of medical knowledge for humankind.\textsuperscript{13}

CITHII can use this concept and break new ground in fulfilling the health needs of two countries that are home to ancient traditions of medicine as well as to about a third of
humankind. CITHII can pioneer new approaches and in the initial stages it can take up one or two projects in each country on a small scale and based on the lessons learnt it can expand this further. We have indicated some preliminary thoughts on this elsewhere in this chapter. These can be debated and developed further. Once the objectives are made clear and the priorities are identified by both countries, then CITHII can frame guidelines on registration, evaluation/impact assessment and guidelines for calculating and paying the reward.

To conclude, we think that CITHII is a workable idea and we can make the way as we go. There are challenges ahead and some of them will be unique but this should not deter us from walking the talk. The challenges can be overcome and credible solutions can be found as CITHII will draw upon both ancient wisdom and modern thinking and practice in order to spur innovation and enhance access to drugs.

III.3 Objectives of CITHII
We highlight some of the objectives of CITHII below. There can be other objectives like the development of mechanisms for the prevention of misappropriation to TM. These objectives can be decided upon after discussions and a consensus can be arrived at:

1. CITHII should be developed to encourage the innovation of TM in both countries so as to address the health requirements of poor populations, and should also explore how best TM may also serve global objectives by evolving criteria for the selection of drugs at cost effective terms. Planners in both countries are aware of the importance of TM and both countries have plans to use TM in a big way. So CITHII will be compatible with the thinking of policy makers, and the policy frameworks in both countries can be conducive to CITHII
2. CITHII may also support developing uniform standards for drug trials and impact assessment. This may further be extended to evolve a common methodology for clinical trials. The work at the ISO established (TC429) Technical Commission for Standardisation of TCM at Shanghai, may be utilised for joint gains. There is no agency so far in either of the economies for impact assessment. As Indian systems of medicine and TCM are widely used in other countries in Asia such a plan on clinical trials’ standardisation would be relevant for them also. Both India and China can take the lead in this and use this to facilitate South-South and regional co-operation in TM.
3. Scientific validation of single/simple formulation for developing herbal drugs, facilitating product development, technology transfer, commercialization and
benefit sharing can be some of the objectives of CITHII. To begin with CITHII can identify priority areas/issues and focus on them. According to the report cited above\textsuperscript{14} one of the goals is: “By around 2030, we must establish a biomedical system that integrates modern life science with traditional Chinese medicine” (P 34). The thinking in India is not very different from this.

4. Conservation and cultivation of selected medicinal plants for developing balanced ecological approaches. This may need the introduction of R&D activities to deal with the implications of climate change on medicinal/food plants. Both India and China are parties to the CBD and have strong research programs and action plans on climate change research. There is enormous scope for bilateral co-operation and joint research in this. It is possible to develop integrated approaches to medicinal plant conservation, their utilization in TM, research on medicinal plants and sustainable use of medicinal plants. CITHII will fit well within such approaches and will be compatible with plans on medicinal plants and TM.

IV. Interventions through CITHII
The following are ways CITHII may ensure the delivery of effective, standardised, efficacious TM drugs. At the outset, it requires the development of procedures-related standards, clinical trials and ways to protect traditional medicines under the modern intellectual property regime. Some of these are enumerated below:

IV.1 Strengthening the Regulatory Structure and Guidelines for TM
Traditional medicines (TMs) are primarily herbal, animal and mineral based medicines applied singularly or in combination to treat, diagnose and prevent illnesses or maintain wellbeing.\textsuperscript{15} There has been a global resurgence of interest in TMs primarily because of their use by almost 75 per cent of people in rural areas in India, and elsewhere. TMs therefore are important for the national health care system in India. However, there is some continued concern about the quality, safety and proven efficacy of some TMs used in the country. This issue has been discussed at various national and international fora for some time and there have been several sustained attempts in India to address these concerns and several policy initiatives have been put into place to comprehensively address these anxieties.

In fact, the first major policy initiative by the Government of India as National Policy (2001)\textsuperscript{16} focused on the Indian Systems of Medicine, as TMs derived from herbal sources sometimes pose a serious challenge for regulators regarding their development, testing
and use. The policy document focused on a range of issues like drug standards, regulatory structure for TMs, how these regulations are to be enforced, drug development approval processes including pre-clinical toxicity studies, toxicology, clinical trials, standardization and quality control etc. This initiative comes in common with similar attempts being undertaken globally to bring in systems of quality control and standardization of herbal products, following reports of detection of heavy metals and other contaminants toxic to people.

**IV.1.1 Quality control and standardization of TMs**

Over the last three decades many measures have been taken by the Government of India, Ministry of Health & Family Welfare, and the Drug Controller General of India (which is the national regulatory agency for drugs in India), on quality control and standardization of TMs. Subsequently, the Department of Indian Systems of Medicine and Homeopathy (ISM&H) took over this responsibility for all regulatory, commercial and other issues concerning TMs in India since 2005.

To alleviate the fear and anxiety of the people who take TMs, it is imperative that they should be safe and efficacious for the disease conditions prescribed; often TMs fail to meet these standards. There should therefore be systems of ensuring consistency in composition and proven biologic activity as essential requirements. A host of problems are encountered in these plant-based products, such as identifying the correct plant species, collecting from the same plant part, in the same season, variability from different locations due to variable agro-climatic conditions, the kind of harvesting procedures in each of these zones, use of fertilizers, pesticides and growth promoters, methods of extracting the intended compound from the plant parts etc., all of which have been known to affect the quality, shelf-life, and efficacy of TMs.

It is therefore necessary to have robust quality control standardization methods including correct identification of the plant, and its parts, through chemical and biochemical methods to ensure correct use of the intended plant material as a TM. Methods such as chromatography can help identify markers for fingerprinting the plant, as well as active compounds to ensure optimal pharmacologic activity that would help towards standardization. Such lack of standardization of herbal drugs also puts the researchers at a disadvantage as they would not be able to use the same sample for research, with potentially distorted results in the analyses.

In addition, sometimes the plant products used in TMs are either expensive or not readily available during all seasons, or the systems of manufacturing are not rigorous, and
adulteration becomes a serious problem. The adulterants include other plant material, toxic metals, microorganisms, microbial toxins, pesticides etc. Similar labeling of plants in different regions compounds the problem. Even chemicals such as ephedrine, chlorpheniramine, methyltestosterone, and phenacetin; lead, cadmium, arsenic, mercury etc. have been detected in TMs, exposing patients to serious risk. It is therefore imperative that appropriate quality control measures have to be put in place during preparation and processing of the plant herbal raw materials, processing and final formulation.

**IV.1.2 Clinical Trials for TMs**

Just a fraction of the thousands of medicinal plants used worldwide has been tested rigorously through the conventional systems of gathering of evidence viz., randomized controlled trials (RCTs). For some TMs there are not even data from animal studies and prescription practices are simply based on anecdotal experiences from the traditional practitioners, even for widely used herbal products. Such observations cannot replace data from well designed randomized controlled trials. For many of the TMs, there are no proven scientific safety and efficacy data, which may need to be generated from properly designed randomized control clinical trials.

Similarly, there are few evidence-based studies on the efficacy and safety of traditional Indian medicines as there are few such RCTs. Even where data are available, they are limited or gathered from experimental animals.

Even trials conducted do not report hard efficacy endpoints, and duration of observation periods is generally short in order to quickly introduce the TM into the market. The clinical relevance of the observed effects therefore is not always clear, as can be seen from many trials of hepatoprotective agents done with an open and uncontrolled design. As most acute liver conditions have a process of natural recovery, it is difficult to link the improvement to the herbal product. Also, most products do not carry the ingredients or their relative quantities with the needed detail. All these are pointers to the urgent need to have robust RCTs to evaluate and gather evidence to establish the safety and efficacy of TMs.

**IV.1.3 Global Regulatory Systems**

The US FDA regulations distinguish between TM used as dietary supplement and as a drug. Herbal medicines are currently marketed as botanical products as their extensive though uncontrolled use in humans may require less preclinical information to support initial clinical trials than the synthetic or highly purified drugs. Requirements for a
botanical product that has not been previously marketed anywhere in the world are more extensive. Certain additional information (CMC, toxicology, human use) is required to assist FDA in determining the safety of the product for use in initial clinical studies. If the product is prepared, processed, and used according to methodologies for which there is prior human experience, sufficient information may be available to support such studies without standard preclinical testing.

While generally TMs are considered relatively safer than Allopathic drugs, there are reports of severe side effects and also relevant interactions with other drugs can occur. Besides, drug interactions of herbal drugs are also of serious concern. For example, hypericum extracts can decrease the concentration of a variety of other drugs by enzyme induction. Lack of regulatory standards regarding the efficacy and safety of herbal products did not arouse much concern in the past, as these products were often perceived as so safe that even if they were ineffective, little harm resulted. However, the situation is changing now and there is an increasing body of literature on the side effects and interactions of herbal medicines. Besides the direct risks of adverse effects and drug interactions there is an indirect risk that an herbal remedy without demonstrated efficacy may compromise, delay, or replace an effective form of conventional treatment. The WHO therefore has urged governments to establish regulatory mechanisms to control the safety and quality of products used as TMs.

**IV.1.4 Indian Scenario**

The Indian National Policy on Indian Systems of Medicine (2001) has identified a need for efficacy trials for the therapeutic claims of patent and/or proprietary (P & P) medicines. A Task Force on Pharmaceuticals and Knowledge Based Industries (1999) has identified the reasons for low Indian exports of herbal products due to inadequate or lack of standards of quality and other factors as: i) the quality of the products; ii) lack of or limited non-availability of scientific data on the TMs; iii) government or reliable third party certification of conformity with the compliance of good manufacturing practices; iv) certificate of analysis; v) price competitiveness; vi) lack of proper documentation of the availability of free sale; viii) proper packaging; viii) timely delivery schedule etc.

Recognizing the need to focus on the areas of quality, documentation, standardization and clinical evidence, the Central Drugs Standard Control Organisation (earlier DCGI), Directorate General of Health Services, Ministry of Health & Family Welfare, New Delhi has issued Good Clinical Practice (GCP) guidelines (2001) for the conduct of clinical trials of herbal remedies and medicinal plants used in TMs.
These guidelines divide the TMs into various categories primarily based on: i) whether the product and its intended/recommended use are as per the traditional medicine literature; and ii) whether the product deviates from the description in the traditional texts.

The following are recommended steps for clinical evaluation:

- For those TMs and medicinal plants that are to be clinically evaluated for use in the Allopathic system and which may later be used in Allopathic hospitals, the procedures laid down by the office of the DCGI’s for other allopathic drugs should be followed.
- When an extract of a plant or a compound isolated from the plant has to be clinically evaluated for a therapeutic effect not originally described in the texts of traditional systems or, the method of preparation is different, it has to be treated as a new substance or new chemical entity (NCE) and the same type of acute, sub-acute and chronic toxicity data will have to be generated as required by the regulatory authority before it is cleared for clinical evaluation.
- An extract or a compound isolated from a plant, which has never been in use before and has not ever been mentioned in ancient literature, should be treated as a new drug, and therefore, should undergo all regulatory requirements before being evaluated clinically.

The GCP Guidelines also provide general procedures to be followed on clinical trials of herbals, toxicity studies, need for standardization, and compliance with GCP in all clinical trials. Some of the recommendations are:

- Plants and herbal remedies should be prepared strictly in the same way as described in the literature while incorporating GMP norms for standardization.
- For herbal remedies, it may not be necessary to undertake Phase 1 studies.
- If there are reports suggesting toxicity or when the herbal preparation is to be used for more than 3 months, toxicity studies (4-6 weeks toxicity study in 2 species of animals) are needed for phase 2 trials.
- For Phase 3 trial toxicity studies (4-6 weeks toxicity study in 2 species of animals) are needed.
- Clinical trials should be carried out with herbal preparations only after standardization and identification of markers to ensure that the substances being evaluated are always the same.
- Ethical guidelines (patient information, informed consent, protection of vulnerable populations etc) for biomedical research should be followed.
- Clinical trials should be approved by the appropriate scientific and ethical committees of the concerned Institutes.
- Clinical trials should be carried out only when a competent Ayurvedic, Siddha or Unani physician is a co-investigator

The global resurgence on the use of TMs in health is because many poor people in developing countries use them as the primary means of treatment for diseases, coupled with the absence of satisfactory therapeutic regimen in Allopathic systems for several chronic conditions that is somewhat fulfilled with TMs. In addition, the global trend towards evidence–based medicine makes it imperative to systematically study and evaluate these TMs for claimed efficacy, besides their safety. In India currently, there are concerns about the use of untested, sub-standard or even spurious TMs in the market as the systems of non-Allopathic medicine is relatively less regulated for various reasons. There is also increasing realization in the developed countries that some TMs are safe and efficacious for various conditions that Allopathy has no ready answer for. This increasing potential for exports reiterates the need to ensure that TMs conform to the highest global standards. There is rich experience from the modern Allopathic system that could be used productively to put into place robust methods to generate credible evidence for their claimed efficacy for a given disease condition. Even the industry that manufactures TMs is also keen to ensure such global standards.

There have been various efforts in India by the Indian Council of Medical Research, New Delhi to test and evaluate TMs for some selected disease conditions. The approach has been to assemble a group of experts from both systems of medicine to identify potential TMs. With the help of experts in pharmacology, chemistry and other areas standard samples of the TMs are prepared for conducting RCTs in Allopathic medical colleges. Recently there have been other initiatives such as the Golden Triangle Project involving several S&T agencies in India to take forward this initiative. Yet, the success of China in successfully implementing GAPs, GLP, GCP and GMP as also integrating traditional systems of medicine with the so-called modern systems is worth studying. India has successes in this area, as does China, and such experience sharing would go a long way in ensuring that the TMs which could provide sustained and affordable health care to the poor in both countries could be achieved.

**IV.1.5 Scenario in China**

International Organization of Standardization (ISO) has set up the Secretariat of TCMS and TCM Technology Committee (Code: ISO/TC249) in Shanghai. The committee has 18 member countries and ten observer countries. The establishment of TC249
demonstrates ISO’s recognition and expectation of standardization of traditional medical science and traditional medicines, especially that of Traditional Chinese Medicine Science (TCMS) and TCM. China has included TCMS and TCM international standardization into its national strategies. Now, China has 27 national standards and 209 trade standards on TCMS and TCM. The Secretariat will choose from them the mature ones for preparing international standards through rational procedures.  

At present, each procedure of TCMS and TCM has its separate standard, such as GAP standard for TCM planting, GEP standard for extraction, GMP standard for production, and GSP standard for terminal operation. It is now necessary to establish a complete set of standards covering the entire industry chain and all the steps so as to guarantee the stability of TCM products. Standardization is the prerequisite for the making of TCMS and TCM globally acceptable in terms of standards and well-established protocols so that TCM meets the exacting needs of modern world. In 2002, British TCMS and TCM Supplier Association and China Chamber of Commerce for Medical Health-care Product Import and Export officially signed a cooperation memorandum, adopting symbols and approval procedures to realize stricter quality control over the TCMS and TCM products entering British market. The two sides will establish a quality approval mechanism. At the first stage, TCM raw materials will go through approval procedures. At the second stage, the patented TCMS and TCM products will go through approval procedures. 

Under the Chinese administrative set-up, the department responsible for the work of TCM is the State Administration of Traditional Chinese Medicine of PRC (SATCM). The process of regulatory approval of TMs in China involves the draft development of regulation by SATCM or SFDA (State Food and Drug Administration), and it seeks others’ opinions and comments from the Ministry of Health, China Medicine of Minorities, related companies and the public, then regulation is placed for approval by the Legislative Affairs Office of State Council (LAOSC). LAOSC will publish the final regulation formally, eg. TCM regulation of PRC.

The process of clinical trials and generating evidence of their efficacy has been regulated in “Good Clinical Practice” (GCP), issued by SFDA in 2003. Chapters 2 and 4 of GCP lay down the rules on preparation in clinical trials and trial schemes.

In 2008, SFDA issued Additional Regulations for Registration Administration, compound prescription of TCM. Under this, studies done for 6 terms can be considered as pre-clinical toxicity study materials, but evidence from long term use through pre-clinical toxicity and clinical trials is a must.
IV.2 Cooperation and Joint Approach to IPRs in Traditional Medicine

The protection of intellectual property inherent in TM in both countries has been a matter of serious concern for both China and India. This concern stems from two factors. First, the misappropriation of traditional knowledge in the TM systems by persons and firms who have otherwise nothing to do with the systems. Many of these misappropriations are by pharmaceutical companies, both small and large, and without any benefit accruing to the holders of the knowledge.

A second concern is about protection of innovations and developments in the TM systems. The two countries have been voicing these concerns in international fora such as the Council for Trade Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO) and the Inter Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO). It may be more fruitful if the two countries can work together in this area more closely in the future.

It needs to be recognized that both countries have been using the conventional intellectual property right regimes to prevent misappropriation of TM knowledge as well as to extend as much protection to TM as possible.

Cooperation between China and India in intellectual property rights matters could broadly be classified in the following five categories:

- Cooperation in protecting TM from misappropriation
- Cooperation in adapting conventional IP system to the special requirements of TM
- Cooperation in developing a sui generis model for protection of TM
- Cooperation in development of innovations based on TM and protection of the intellectual property thus generated
- Cooperation in integration of TM in public health programmes

The overall objectives of cooperation between the two countries will be:

- Providing low cost medicines for lower-income people in both countries
- Ensuring that TM formulations and knowledge are not misappropriated
- Setting up protection system and innovation-driving mechanism on TM
- Enhancing the R&D capability of developing countries
IV.2.1 Cooperation in Protecting Traditional Medicine from Misappropriation

As stated at the outset, the major concern is about the misappropriation of TM knowledge. This, however, is a much complex issue since the sources and exploiters are diverse.

Development of TM databases like the Traditional Knowledge Digital Library of India, and the Traditional Chinese Medicine Patent Database of China could be one of the means for protecting TM from being misappropriated. Making disclosure of source of origin of genetic resources mandatory in patent applications is another strategy. As of now both China and India have such provisions in their patent laws. A common approach to have a provision of source of origin not only of genetic resources but also the source of the prior art in an invention mandatory in the patent application internationally will go a long way in safeguarding TM from misappropriation. The norms of the Convention on Bio Diversity (CBD) that there should be prior informed consent and an equitable benefit sharing agreement for accessing any genetic resource could also be extended to such a broad framework. This will ensure that traditional practitioners get proper returns for their efforts in preserving and nurturing the TM systems. The establishment of an international protocol for Access and Benefit Sharing will be useful in achieving the objectives of CBD on equitable access and benefit sharing. The outcomes of the recently concluded meeting at Nagoya pave the way for this.

IV.2.2 Cooperation in adapting conventional IP system to the special requirements of traditional medicine

Both China and India have been using the conventional intellectual property systems to get as much protection for their TM as possible. Both countries can engage in exploring avenues to increase the level of this protection. The ways to adapt the conventional intellectual property regime, particularly the patent system, to the special needs of TM could be explored by the two countries jointly. Making the declaration of the source of origin of the genetic material used in an invention mandatory is one such step. Since the methods of the pharmaceutical industry manufacturing modern medicine and TM systems differ, this needs research. Such protection need not necessarily be limited to patents but could extend to other intellectual property rights such as trade marks, trade secrets, confidential information and so on. The two countries may also examine whether with some changes the conventional systems can cover more TMs.
IV.2.3 Cooperation in Developing a Sui generis Model for Protection of Traditional Medicine

It is well recognized that it is difficult to fully solve the problem concerning protection of TM knowledge under the present patent regime which is based on the Western pharmaceutical industry approach. The methodological and ideological dichotomy between Western and traditional medicine results in the direct exclusion of TM from the patent process. One will have to explore other avenues including perhaps a sui generis system suited to the Eastern traditional medicines. This is because the basic foundations and principles as well as the research and development methods of Western medicine and TM vary. Not only in their manufacturing process but in their basic medical orientation, physiological theories, etiology, diagnosis, therapeutics and pharmacology the TM systems differ from Western medicine [Fang].

Table 2 indicates that the R&D pattern of TM is quite different from that of the modern pharma industry and consequently the conventional patent system is not fully tuned to protect the same.

Table 2: Comparison between Traditional Medicinal Knowledge R&D and Modern Synthetic Pharmaceutical Knowledge R&D

<table>
<thead>
<tr>
<th></th>
<th>TCM</th>
<th>MPK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theoretical Approach</strong></td>
<td>Holistic</td>
<td>Reductionism</td>
</tr>
<tr>
<td><strong>Practice</strong></td>
<td>Medication and non-medication</td>
<td>Medication</td>
</tr>
<tr>
<td><strong>Configuration</strong></td>
<td>Crude product</td>
<td>Synthetic product</td>
</tr>
<tr>
<td><strong>Core Knowledge</strong></td>
<td>Prescription</td>
<td>Formula</td>
</tr>
<tr>
<td><strong>Determination of active substance</strong></td>
<td>Difficult</td>
<td>Easy</td>
</tr>
<tr>
<td><strong>Quality control</strong></td>
<td>Unstable</td>
<td>Stable</td>
</tr>
</tbody>
</table>

Keeping this in mind, the two countries can cooperate in the matter very much.

In order to achieve the objectives of cooperation set out above, the two countries may also coordinate their intellectual property related work in international fora such as the World Trade Organization, World Intellectual Property Organization and World Health Organization, particularly on the changes needed in the intellectual property regimes to
accommodate the needs and requirements of TM systems. Since the general approaches of both countries to the issues by and large are the same as seen from their interventions and observations in the TRIPS Council of WTO, the Inter Governmental Committee on Intellectual Property and Genetic Resources and Traditional Knowledge and Folklore of WIPO, this cooperation may be easy.

**IV.2.4 Cooperation in development of innovations based on traditional medicine and protection of the intellectual property thus generated**

This is the most crucial area in providing solutions to public health problems not only China and India but also in other developing and least developed countries. The need for a joint approach to this task does not need any reiteration. Traditional medicines are rich sources of leads for new drugs to fight major health problems. These leads need to be further worked on keeping in view the differences in environmental and climatic conditions prevailing in different parts of the world and even the genetic variations between different groups of people. Development of new innovations may necessitate considerable investment in R & D. In the area of TM, there is also the need to develop objective assessment criteria and standardization leading to elaborate pharmacopoeia. The Health Impact Fund could be a source of financial resources for such efforts.

The two countries may consider, besides the patent based and private industry driven approach, other alternatives to drive innovation in TM. Unorthodox approaches to drug discovery and how they can be fitted into the HIF scheme may have to be explored.

It may also be necessary to further explore the possibilities of how public-private partnership models in developing innovative drugs in TM systems can be fitted into the HIF.

**IV.2.5 Cooperation in integration of traditional medicine in public health programmes**

Current policies on Intellectual Property Rights at international level are not all that conducive to making health care widely available and affordable in developing countries. China and India can cooperate and work to ensure that TM gets its due share in international intellectual property and health care regimes. This is essential since affordability is an issue in public health. TM systems by and large are not as costly as modern Western medicine. India has taken certain steps in this direction already. For example, Seven Ayurvedic drugs are included in the National Reproductive & Child Health (RCH) Programme for use by mothers & children. These medicines are- *Ayush Ghutti, Bal Rasayana, Soubhagya Shunthi, Ark Ajwain, Ark Pudina, Punarnavadi Mandoor and Ksheerbala Tel.* The Chinese government too embarked on aggressive
integration of the TCM system with the modern medicine system in public health programmes.  

The efforts should see that TM is fully integrated in the public health programmes of countries and also given due share in international programmes. In programmes like the Health Impact Fund this may require a different approach to TM than the one towards modern medicine.

**IV.2.6 Indian Scenario**

India has used the patent law both as a preventive mechanism against misappropriation and also as a positive mechanism for protection of new inventions in TM systems. But traditional knowledge per se cannot be patented in India. The law ensures that existing TM knowledge is not patented, as it provides that an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components is not patentable. The patent law along with the Biodiversity legislation of India also provides that where any genetic material is obtained for the invention, it should be with the prior informed consent of the holders and with proper access and benefit sharing agreement with them or with the national authority concerned. The Disclosure of Origin and Prior Informed Consent requirements have been incorporated in the Indian Patents Act.

More than the misuse of TM knowledge in India, misappropriation of the same abroad has been a matter of serious concern for India as patents were granted by the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) on Indian Traditional Medicine knowledge. One of the most celebrated cases is the patent on wound healing properties of turmeric by USPTO. The Indian Council of Scientific and Industrial Research (CSIR) had to spend a large amount to get the wrongly granted patent revoked on the basis of prior art recorded in ancient Indian Ayurvedic texts, including application of turmeric post surgery. Another such case was the European patent for anti-fungal qualities of Neem (Azadirachta indica). An Indian Non-Governmental Organization successfully fought against the grant of this patent on pre-existing Indian medicinal knowledge. These and other similar cases led to a strategic rethinking by India which resulted in a new mechanism.

The new measure developed as a major defensive mechanism by India to protect TM knowledge from being misappropriated is the Traditional Knowledge Digital Library (TKDL). TKDL provides information on TM knowledge existing in the country, in languages and formats understandable by patent examiners at International Patent Offices (IPOs), so as to prevent the grant of wrong patents. The project TKDL involves
documentation of the traditional knowledge available in the public domain in the form of existing literature related to Ayurveda, Unani, Siddha and Yoga, the four major Indian TM systems, in digitized format in five international languages, namely, English, German, French, Japanese and Spanish. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval has been evolved for about 25,000 subgroups against the fewer subgroups that were available in earlier version of the International Patent Classification (IPC), related to medicinal plants, minerals, animal resources, effects and diseases, methods of preparations, mode of administration, etc. Presentation on Traditional Knowledge Resource Classification (TKRC) at IPC Union led to the creation of WIPO-TK Task Force consisting of USPTO, EPO, JPO, China and India by (IPC) Union for enhancing the sub-groups in IPC for classifying the TK related subject matter and considering the linking of TKRC with IPC. In February 2002, a Committee of Experts recommended the inclusion of approx. 200 subgroups on TK against the few existing sub-groups on medicinal plants, and linking of TKRC to IPC and thus, a new main group was included in IPC i.e. A61K 36/00 with 207 subgroups covering different categories of plants, as shown in Table 3 below.

Table 3: New subgroups in IPC

<table>
<thead>
<tr>
<th>S. No</th>
<th>IPC Codes</th>
<th>IPC Categories</th>
<th>No. of Sub groups in IPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Algae</td>
<td>A61K 36/02 to 36/05</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>Fungi &amp; Lichens</td>
<td>A61K 36/06 to 36/09</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>Bryophyta</td>
<td>A61K 36/10</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Pteridophytes</td>
<td>A61K 36/11 to 36/126</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>Gymnosperms</td>
<td>A61K 36/13 to 36/17</td>
<td>5</td>
</tr>
<tr>
<td>6.</td>
<td>Angiosperms</td>
<td>A61K 36/18</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>Dicotyledons</td>
<td>A61K 36/185 to 36/87</td>
<td>148</td>
</tr>
<tr>
<td>8.</td>
<td>Monocotyledons</td>
<td>A61K 36/88 to 36/9068</td>
<td>35</td>
</tr>
<tr>
<td>Total number of Sub-groups</td>
<td></td>
<td></td>
<td>207</td>
</tr>
</tbody>
</table>
The TKDL is an ongoing project and the database is regularly being expanded. The present status of the transcription of TM formulation in the TKDL is presented in Table 4 below:

**Table 4: Number of texts and formulations in TKDL**

<table>
<thead>
<tr>
<th>Discipline</th>
<th>No. of texts (including volumes) used for transcription</th>
<th>Formulations Transcribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayurveda</td>
<td>75 books</td>
<td>86,200</td>
</tr>
<tr>
<td>Unani</td>
<td>10 books</td>
<td>1,23,550</td>
</tr>
<tr>
<td>Siddha</td>
<td>50 books</td>
<td>13,690</td>
</tr>
<tr>
<td>Yoga</td>
<td>15 books</td>
<td>1,145</td>
</tr>
<tr>
<td>Total</td>
<td>150 books</td>
<td>2,24,585</td>
</tr>
</tbody>
</table>

The database is provided free of charge to international patent offices under a non-disclosure agreement. The European Patent Office was the first patent office to access the TKDL in February 2009. During the short period since then, 3 patents had been cancelled by the EPO based on the database, besides withdrawal of 25 patent applications as the applicants realized the futility of their effort in view of TKDL.

Access to the TKDL has since been provided to German Patent and Trade Mark Office and also the USPTO, besides the Indian Patent Office. TKDL has had a salutary effect on preventing wrong patenting of Indian TM. Pharma companies are now being cautious in applying for patents on Indian TM.

**Rewarding the practitioners**

Another important concern in matters relating to protection of TM is the question of ensuring benefits to the practitioners of TM from the commercial exploitation of their knowledge, including developing new Western medicine drugs. Models in this regard are rare. However, India has been a pioneer in this matter by conceiving and implementing a model successfully. The case dates back to 1987 when the scientists of the Tropical Botanical Garden and Research Institute (TBGRI), Thiruvananthapuram, India, got knowledge about the revitalising quality of a local plant Arogyapacha (Trichopus zeylanicus subsp. Travancoricus) from a tribal community, the Kanis. Based on that knowledge, the scientists developed a new Ayurvedic drug, Jeevani, a refreshing, anti-stress and immune stimulating drug. When the drug was licensed to a pharmaceutical
firm, the TBGIR decided to share the licence fee and royalty with the Kanis on a 1:1 ratio. The tribe cultivates and harvests the arogyapacha plants used by the pharma firm.

India is also exploring the possibility of a sui generis legislation for protecting TM and other traditional knowledge based on a right for the traditional practitioners approach.

**Development of New Drugs**

The number, however, is miniscule. One major reason for this is the strict patentability criteria in the Indian Patents Act. It is very difficult to get a patent for minor innovations under the Indian patent law as it provides that “the mere discovery of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant” is not patentable. This applies equally to inventions in all fields of technology and there is no difference between modern pharmaceutical products and products of TM systems. Many innovations in the TM field fail to satisfy this criterion.

Even the total number of patent applications for the sector ‘drugs and medicines’ as a whole is not very high in India as can be seen from Table 5.

**Table 5: Number of drug patent applications and grants in India**

<table>
<thead>
<tr>
<th>Year</th>
<th>Applications filed</th>
<th>Patents granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004-05</td>
<td>2316</td>
<td>192</td>
</tr>
<tr>
<td>2005-06</td>
<td>2211</td>
<td>457</td>
</tr>
<tr>
<td>2006-07</td>
<td>3239</td>
<td>798</td>
</tr>
<tr>
<td>2007-08</td>
<td>4267</td>
<td>905</td>
</tr>
<tr>
<td>2008-09</td>
<td>3672</td>
<td>1207</td>
</tr>
</tbody>
</table>

*Source: Annual Reports of the Office of the Controller General of Patents, Designs and Trade Marks.*

The Indian Patent Office does not treat patents in the field of TM as a separate category. They are examined and granted as part of the pharmaceutical patents. Further, India had been following a process patent regime in pharmaceuticals up to 2005. TMs appear to be more at home in such a regime since most innovations in TM are in process than in new products. Table 6 gives an idea of citations on Indian TM and patents applied and granted at USPTO until September 2005.
After introduction of the product patent regime in pharmaceuticals there have been patents for TM, but their numbers are not very high.

Another intellectual property being used to protect TM in a small way is trade mark. Some companies in the TM systems use brand names and marks to protect their products.

**IV. 2.7 Scenario in China**

Like India, China has also been a victim of bio piracy committed by firms and individuals from the developed world. It, therefore, shares the same concerns of many other developing countries. Patwardhan et al present the following figures for citations and patent data for traditional Chinese medicine for the period covered in Table 7.

Table 7: Citations and patent data for Chinese traditional medicine up to September 2005

<table>
<thead>
<tr>
<th>Database</th>
<th>Chinese Medicine</th>
<th>Traditional Chinese medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>10278</td>
<td>6847</td>
</tr>
<tr>
<td>Science Direct</td>
<td>990</td>
<td>612</td>
</tr>
<tr>
<td>Google scholar</td>
<td>476000</td>
<td>68300</td>
</tr>
<tr>
<td>USPTO (applied)</td>
<td>195</td>
<td></td>
</tr>
<tr>
<td>USPTO (granted)</td>
<td>259</td>
<td></td>
</tr>
</tbody>
</table>
China also has recently introduced a disclosure requirement regarding genetic resources used in an invention in the patent application. This is a major step in preventing misappropriation of traditional Chinese medical knowledge. It has also been employing various means available under the existing IP regime to protect its TM. Patenting has been one such measure. The number of traditional Chinese medicine patent applications in China has reached 1751 which occupies 44 per cent of the whole pharmaceutical patent applications. The annual rate of increase is 26.3 per cent. The number of TM patents of invention owned by the pharmaceutical industry has reached 1388 in 2009, which is 43% of the whole pharmaceutical industry and reflects an annual increase rate of 37.8% compared to 2008.

Chinese TM manufacturers also take to other intellectual property rights such as trademarks and copyright for protecting TM. Besides, China had in October 1992 enacted the ‘Regulations on Protection of Traditional Chinese Medicine Varieties.’ These Regulations provide seven to thirty years protection for TCM divided into two categories. China has also been developing its own TM database to facilitate patent examination. This database contains information about the TM patents granted since 1985. The number of TCM patent publications has been increasing steadily and by 2001, it has reached 50000 in the world.

China too perceives it as fundamentally difficult to solve the problem concerning protection of TM knowledge under the Western medicine-based modern medicine intellectual property protection system.

China has also taken several high-level policies to promote Pharma innovation and IP. Some of these are explained below:

**Amendments to Patent Law:** Chinese Patent Law was revised for the third time on October 1, 2009. As per the revised Clause 50, for the purpose of public health, the administrative department of the State Council can grant compulsory licenses to produce the patented drugs and export them to countries or regions specified in the specifications of relevant international treaties joined by the Peoples Republic of China. The amendment in 2008 in the Patent law changed Clause 63.1 into Clause 69, and added one item as Item (5) which provided to produce, use and import the patented drugs or patented medical apparatus to provide information necessary for administrative approval, and specially produce and import them.

**Healthcare reform package:** Taking healthcare and medicine innovation as an important part of national S&T development, try to capture S&T difficulties, so as to provide
technology protection to public health. Increasing input on medicine science, deepen reform of healthcare S&T system, conform R&D resource on superior medicine sector. Developing medical treatment instruments suitable to the situation of China.


*Outline of the National Intellectual Property Strategy*: Perfect the protection, exploitation and usage system of genetic resources, avoid loss and usage unreasonably. Harmonize the profit relationship among three parts and setup profit sharing mechanism. Keep traditional resource providers’ rights. Set up protection system for traditional knowledge.

*Guideline for Chinese traditional medicine innovation (2006-2020)*: Attracting social investment and international investment actively, set up diversified input system for TCM.

V. Concluding Remarks

V.1 Joint Approach on Standards and Clinical Trials
As indicated in the previous section, developing a joint approach to standards and clinical trials will benefit both countries. Both countries can work with ISO in them and this will be very relevant for developing global standards for various TM systems. Besides this, such a joint approach will pave the way for more co-operation and capacity building in the TM sector in both countries.

V.2 Joint Approach on IP
While in the case of modern medicine perhaps intellectual protection plays a very crucial role in promoting innovation, it may not be the case in the field of TM. The needs and requirements of TM systems are more of standardization and development of objective tests. Keeping the basic premise of distributing rewards on the basis of the impact of a drug on human health, “…the system may have to amplify its scope to include development of objective technical standards (pharmacopoeia) in the TM system as safe
and effective for use under the conditions prescribed, recommended, or suggested in the labelling.”12 The two countries need to work jointly in the regulatory and IP related areas that are essential to augment the use of TM in these two countries.

Endnotes
1 RIS Policy Brief No. 42, June 2009.
2 Though the figures for AYUSH include homeopathy, our focus in this study is only on Ayurveda, Siddha, and Unani, and not on Homeopathy.
4 ibid.
5 Ratio:1 dollar = 6.8RMB.
9 http://www.csisr.res.in/external/heads/collaborations/nmitli.htm
11 ibid.
13 ibid.
14 Science & Technology on Public Health in China: A Roadmap to 2050 - Chinese Academy of Sciences, 2010
18 ibid.
21 A Memorandum of Understanding with the State Administration of Traditional Chinese Medicine, China was signed on 14th January 2008 for bilateral cooperation for promotion of Traditional Medicine. The MoU envisages bilateral cooperation in the areas of standardization of herbal
medicines, collaborative research in drug development, and development of common strategies for creating greater awareness about the safety and efficacy of TM products. The MoU also envisages cooperation in policies relating to regulation and administration of traditional medicine in India and China. See http://indianmedicine.nic.in/writereddata/mainlinkFile/File67.pdf

“Bio piracy and patenting of indigenous knowledge is a double theft because first it allows theft of creativity and innovation, and secondly, the exclusive rights established by patents on stolen knowledge and steal economic options of every day survival on the basis of indigenous biodiversity and indigenous knowledge. The patents may be used to create monopolies and make everyday products highly priced.” Suri, Gunmala, Puja Chhabra Sharma (2008). “Intellectual Property Rights For Traditional Healers: Indian Perception”, in ANALELE ŞTIINŢIFICE ALE UNIVERSITĂŢII ALEXANDRU IOAN CUZA DIN IAŞI Tomul LV Ştiinţe Economice.

It is worth recalling the following recommendations of the ASEAN workshop on the TRIPS Agreement and traditional medicine held in Jakarta on 15 February, 2001, in order to achieve the principal objective of safeguarding people’s access to traditional medicines to cover their health needs, as well as the additional objectives of:

• Ensuring equitable benefit sharing in case of commercial use of Traditional Medicine,

• Protecting against the use of Traditional Medicinal Knowledge (TMK) and Traditional Medicine (TM) without authorization from the holders of such TMK/TM.

• Creating incentives for continued development of Traditional Medicinal Knowledge and Traditional Medicine,

• Supporting the development of the (traditional medicine) industry,

• Supporting measures to protect the environment and avoid over-exploitation.

The workshop iterated the need for incentives and protection for traditional medicine in the following words:

“In order to ensure that these knowledge systems remain dynamic, incentives will have to be provided. For societies to be innovative, innovation must be rewarded; incentives must be provided to those who are creative and produce new knowledge. Incentives can take several forms: they can be material or non-material, and can be individual or collective. TRIPS and modern IPR laws deal mainly with material, individual incentives. Thus, apart from modifying those, so that they become accessible to holders of traditional knowledge, there may be a need to devise various other types of incentives. These should include non-material incentives, notably due recognition, but also collective, material incentives, comprising for instance the creation of dedicated trust funds, group venture funds etc, in order to enable people to convert their inventions into products and enterprises. Appropriate incentives may also include grants and awards to a community, or assistance with the marketing of their products.

“Another argument in favor of providing incentives and stronger IPR protection for traditional medicines and traditional medicinal knowledge is that without it, neither communities nor individual healers have an incentive to disclose their knowledge, to share their know-how with others. So perhaps the development of appropriate alternatives for protection and of ways to accommodate the needs and desires of the holders of traditional knowledge is ultimately in the interest of its wider dissemination.”

“Mainstream IPRs generally fall short of providing effective protection for traditional medicinal knowledge and biological resources; yet, in case such protection is desired, the - limited - opportunities for making use of conventional IPR should not be discarded. Moreover, protection need not be confined to the options existing under IPR law; other legal concepts could be used, e.g. unfair competition or breach of confidence. Unauthorized publication of a community’s knowledge may be subject to legal challenge on the grounds of breach of confidence, even when
the person disclosing the knowledge has not signed a formal agreement to keep it secret.” Karin Timmermans, “Intellectual property rights and traditional medicine: policy dilemmas at the interface”, in Social Science & Medicine 57 (2003) 745–756.

“TRIPS standards are based on models existing in developed countries for their Pharmaceutical Industry, making it inadequate for developing countries where industry is still growing or is in nascent stage. Besides TRIPS does not provide a clear guidance for Traditional Medicine which is strength of developing countries.” Gummala Suri, Puja Chhabra Sharma, ibid. See also Dutfield, G. 1999. “The Public and Private Domains: Intellectual Property Rights in Traditional Ecological Knowledge,” WP 03/99, OIPRC Electronic Journal of Intellectual Property Rights. Available online at http://www.oiprc.ox.ac.uk/EJWP0399.html


China and India, along with other developing countries have been co sponsors of the following delegation at the WTO TRIPS Council in the Doha Round: “Members agree to the inclusion in the TRIPS Agreement of a mandatory requirement for the disclosure of origin of biological resources and/or associated traditional knowledge in patent applications. Text based negotiations shall be undertaken in Special Sessions of the TRIPS Council, and as an integral part of the single undertaking, on an amendment to the TRIPS Agreement establishing an obligation for Members to require patent applicants to disclose the origin of biological resources and/or associated traditional knowledge, including Prior Informed Consent and Access and Benefit Sharing.”

Dr. S.K. Sharma and Dr. D.C. Katoch, Current Status & Infrastructure of Ayurveda.

Oguamanam, supra.

Section 3(p) of the Patents Act, 1970.

Section 10 (contents of specification) of the Patents Act 1970 provides that the applicant must disclose the source and geographical origin of any biological material deposited in lieu of a description. Also Section 25 (opposition to grant of patent) allows for opposition to be filed on the ground that “the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention”, http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng

ibid.


Patwardhan Supra.
Article 5 (2), states that “no patent right shall be granted for any invention/creation that relies on genetic resources accessed or used in violation of the provisions of relevant laws or administrative regulations”; and Article 26 (5), states that “for inventions/creations that rely on genetic resources, the patent applicant shall disclose, in the application, the direct source and the original source of the genetic resources, and shall, in the case where the applicant fails to disclose the original source, provide a reason for such a failure”. Specific provisions on these two paragraphs have been further set out in the revised Implementing Regulations under the Patent Law, and the Guide on Patent Examination, respectively, to make the amendments operational.

Yanhui Liu and Yanling Sun, China Traditional Chinese Medicine (TCM) Patent Database.


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