Law Environment and Development Journal
LEAD

PROSPECTS AND CHALLENGES FOR HARNESSING OPPORTUNITIES IN MEDICINAL PLANTS SECTOR IN INDIA

Harbir Singh

VOLUME
2/2

LEAD Journal (Law, Environment and Development Journal)
is a peer-reviewed academic publication based in New Delhi and London and jointly managed by the
School of Law, School of Oriental and African Studies (SOAS) - University of London
and the International Environmental Law Research Centre (IELRC).
LEAD is published at www.lead-journal.org
ISSN 1746-5893

The Managing Editor, LEAD Journal, c/o International Environmental Law Research Centre (IELRC), International Environment House II, 1F, 7 Chemin de Balexert, 1219 Châtelaine-Geneva, Switzerland, Tel/fax: + 41 (0)22 79 72 623, info@lead-journal.org

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This document can be cited as
'Prospects and Challenges for Harnessing Opportunities in Medicinal Plants Sector in India,
2/2 Law, Environment and Development Journal (2006), p. 196,
available at http://www.lead-journal.org/content/06196.pdf

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1 INTRODUCTION

Asia has abundant species of medicinal and aromatic plants (MAPs) and traditional medicine has been practiced in Asia since ancient times. The Chinese and the Indians have made use of medicinal plants to cure ailments for thousands of years. According to the World Health Organisation (WHO), the goal of 'Health for All' cannot be achieved without herbal medicines. While the demand for herbal medicines is growing in developing countries, there are indications that consumers in developed countries are becoming disillusioned with modern healthcare and are seeking alternatives in traditional medicines. There is, therefore, an increasing consumer demand for herbal medicines in developed countries. For example, in Germany the value of prescriptions written for the anti-depressant St. John's Wort is twice that for Prozac, a top selling antidepressant. In 1994, the prescriptions for St. John's Wort were worth DM61 million compared to Prozac which was worth DM30 million.[1] The increasing demands for herbal medicines by consumers in both developing and developed countries, has renewed interest by the multinational pharmaceutical industry in bio-prospecting. But the lack of national legislation or effective international agreements on conservation and sustainable use of bio-diversity has resulted in 'slaughter harvesting' of medicinal plants and massive depletion of biodiversity.

India, with approximately eight per cent of world's biodiversity including plant genetic diversity with medicinal properties, has the potential of becoming a major global player in market for medicinal plants based herbal formulations, medicines and products. Given the extent of biodiversity in India, a major task for all the stakeholders including the policy planners is the identification and guided development of new products with large export potential such as medicinal plants. Recognising and addressing the needs of each of the different stakeholders involved requires a holistic approach for overall development of the medicinal plants sector. Unfortunately, there are no integrated national policies on herbal medicines which could facilitate drug regulators, health administrators, health professionals including traditional and modern practitioners to regulate the market and ensure consumer safety along with conservation, intellectual property protection and sustainable use of medicinal plants.

1.1 Background of the Study

As much as 70 per cent of India's population use traditional medicine.[2] The collection and processing of medicinal plants and plant products are a source of both full and part time employment in the country. Micro-studies suggest that a large number of those employed in this sector are women. Medicinal plants are one of the most important components of the non-wood forest products sector which supplies over 80 per cent of India's net forest export earnings annually.[3]

According to WHO, the international market of herbal products is estimated to be US $ 62 billion which is poised to grow to US $ 5 trillion by the year 2050, but India's share in the global export market of medicinal plants related trade is just 0.5 per cent. This indicates that production, consumption and domestic and international trade in medicinal plants based products is going to grow at a significant rate. For making full use of this potential, India must develop scientific cultivation, post harvest technology, processing, manufacturing, research and extension, patenting and marketing for medicinal plants. The small and poor growers of these plants, mostly located in hills, mountains and inaccessible places must also be made

1 J. Law, 'Making Sense of Herbal Medicines', *SCRIP Magazine* 37-39 (1999).

2 S. Niraj, Meera Iyer and Ram Prasad, The Ayurvedic Medicine Industry: Current Status and Sustainability, Sub Study of the India Country Study of the International Collaborative Research Project on Instruments for Sustainable Private Sector Forestry (New Delhi: Ecotech Services (India) Pvt. Ltd. and International Institute for Environment and Development, London, 2002) and *see* Sushil Saigal, Hema Arora and S.S. Rizvi, The New Foresters: The Role of Private Enterprise in the Indian Forestry Sector (New Delhi: Ecotech Services, (India) Pvt. Ltd. and International Institute for Environment and Development, London, 2002).

3 Food and Agriculture Organisation, Non-wood Forest Products and Nutrition (Rome: Food and Agriculture Organisation, Report of the International Expert Consultation on Non Wood Forest Products, 1995) and *see* Alka Jain, 'Current Trends: Marketing of Minor Forest Produce', 6(1) *MFP News* (1996).

more involved with the processes of commercial production and marketing of these products so that they can increase their earnings and are definitely not exploited.[4] The state governments have to carry forward this task with great zeal.

Though economic importance of medicinal plants is well known, it is considered as a forestry sub-sector (non-timber forest products) in India. Till Medicinal Plants Board[5] was constituted in year 2000, no nodal agency was there to look into medicinal plants as an 'economic sector' and different organisations were dabbling with different aspects of medicinal plants without any focus and co-ordination there by leading to paradox of simultaneous existence of under-utilisation and over-exploitation. Further, the lack of co-ordination has also led to critical research gap, that is, there is a regrettable absence of any research community working on socio-economic and policy aspects of medicinal plants, such as that which exists with regard to agro-technology, biotechnology etc. In fact, scientists working in natural sciences themselves conducted socio-economic research in medicinal plants resulting in generally unprofessional analysis leading to over-simplification of complex issues and providing very general suggestions to tackle socio-economic issues.[6] Keeping in view this limitation, present study is designed to fill in the gaps in the understanding of various issues concerning medicinal plants sector.

1.2 Objectives

The specific objectives of this study are:

1. To understand the current situation, trends and potentials of medicinal plants;

2. To explore the nature and extent of problems in realising the potential;

3. To review the implications of sectoral and inter-sectoral policies on medicinal plants; and

4. To suggest suitable technology, institutional and policy changes for accelerated development of medicinal plants sector.

This paper is divided into five sections. First section provides background of the study. An account of present status of medicinal plants sector is given in section two followed by an assessment of opportunities and constraints in medicinal plants sector particularly under the changing global scenario in section three. Section four highlights issues concerning intellectual property rights (IPRs) protection of medicinal plants and herbal products and the policy initiatives at national and international levels. The last section summarises the overall assessment and offers suggestions for suitable measures and mechanisms for accelerated development of the medicinal plants sector.

2 PRESENT STATUS

2.1 Resource Base, Conservation and Utilisation

There are about 45,000 plant species (nearly 20 per cent of the global species) are found in the Indian Sub-continent. Of these, about 3,500 species of both higher and lower plant groups are of medicinal values. Of around 500 medicinal plant species used by the contemporary *Ayurvedic* industry, around 80 per cent are procured from wild areas, mostly notified as forest land.[7] Medicinal plants procured from cultivated private fields account for ten per cent of the total medicinal plants in active trade.[8] The forests of Himachal Pradesh and the

4 This has been the vision of the Scientific Advisory Committee to the Cabinet and also of the Foundation for Revitalisation for Local Health Traditions (FRLHT).

5 The Medicinal Plants Board was set up under a Government Resolution No. Z.18020/19/97-M.P.Cell notified on 24 November 2000 under the Chairpersonship of Union Health & Family Welfare Minister.

6 J. Holley and K. Cherla, The Medicinal Plants Sector in India (New Delhi: International Development Research Centre, 1998).

7 R. Gupta, 'Conservation and Utilisation of Indian Medicinal Plants', 6(2) *Indian Journal of Plant Genetic Resources* 131 (1993) and *see* Foundation for Revitalisation of Local Health Traditions, Medicinal Plants of India: Guidelines for National Policy and Conservation Programmes (Bangalore: Foundation for Revitalisation of Local Health Traditions, 1997).

8 *See* Niraj, Iyer and Prasad, note 2 above.

Western Ghats are known to supply a very large proportion of the medicinal plant requirements of India.

Cultivation of medicinal plants at the farm level is one of the intervention being focused and tried to meet their ever increasing demand. The crucial point is that all medicinal plants cannot be cultivated because of their agro-climatic requirement specificity. Further, the effect of agro-climatic conditions on the chemical composition and therapeutic properties of medicinal plant species are well recognised and documented in Ayurveda.[9] Seasonal variation and age have a bearing on the composition of drugs. These factors limit the number of medicinal plants which are amenable for cultivation and extent to which it can be cultivated. On the other hand, technology and institutional arrangements influences which species are preferred for cultivation and who are going to grow them. Given these facts, there is an urgent need to assess priority species for future planning.

Most important Indian medicinal plants have been identified on the basis of their medicinal importance, commercial value and potential for further research (Tables 1, 2, 3).[10]

Table 1: Priority species of medicinal plants based on commercial value

Plant	Common Name
Adhatoda Zeylanica	Vasaka
Pluchea lanceolata	Rasna
Saraca indica	Ashoka
Terminalia	Chebula
Terminalia arjuna	Arjun
Azadirachta indica	Neem

Source: Exim Bank (1997)

9 S. Sarkar, Medicinal Plants and the Law (New Delhi: World Wildlife Fund, Occasional Paper Series 3, 1996)

10 Export Import Bank of India, Indian Medicinal Plants: A Sector Study (Mumbai: Export Import Bank of India, Occasional Paper No. 54, 1997).

Table 2: Priority species of medicinal plants based on their importance

Plant	Common name
Plantago ovata	Isabgol
Bacopa monnieri	Brahmi
Centella asiatica	Mandukparni
Withania somnifera	Aswagandha
Andrographis paniculata	Kalmegh
Swertia chirata	Chirayta
Tinospora	Guduchi
Emblica	Amla
Commiphora wightii	Guggul
Phyllanthus amarus	Bhumyamalaki
Podophyllum	Papra
Asparagus racemosus	Shatavari
Piccorhiza kurroa	Kutki
Streblus asper	Shakhotaka

Source : Exim Bank (1997)

Table 3: Priority species of medicinal plants based on potential for further research

Plant	Common Name
Holarrhena	Kutaja
Crataeva nurvala	Varun
Valeriana jatamansi	Tagar
Vilo odorata	Banafsha
Aconitum	Ativisha
Aloe barbadensis	Ghrita
Ocimum sanctum	Tulsi

Source: Exim Bank (1997)

Clearly, it appears that single criteria approach is not capable to taking care of socio-economic aspects of different stakeholders benefiting from the medicinal plants sector. The Scientific Advisory Committee on Herbal Products has recommended that the government should focus attention on cultivation and marketing of 45 medicinal plants over the next 20 years. The Committee has short listed seven[11] of these plants for intensive attention over next five years.[12] These herbs have been short-listed taking into account their documented use in traditional system of medicine and the volume of their domestic and export demands besides the endemic nature of the plants. The action plan envisaged includes preparation of cultivation protocols, post harvest protocols, clinical trials and formation of national level associations for each of the plants.

2.2 Economic Potential

Several studies have clearly brought out the economic potential of medicinal plants in different agro-climatic conditions. The potential return to the farmers from cultivation of medicinal plants is reported to be quite high Researchers have estimated that the cultivation of certain high altitude Himalayan herbs could yield products priced anywhere between Rupees 7150 to 55000 per hectare[13] and an average annual income of Rupees 120,000 per hectare through mixed cropping of high altitude medicinal herbs.[14] Some low-altitude crops from the Amarkantak region of Madhya Pradesh showed substantial net returns for four profitable species – *Curcuma angustifolia* (Rupees 48000), *Rauwolfia serpentina* (Rupees 54000), *Acorus calamus* (Rupees 27000) and *Chlorophytum tuberosum* (Rupees 13000).[15]

11 Bacopa Monnieri, Rauwolfia Serpentine, Aloe Vera, Centella Asiatica, Taus Baccatal/ Taxus Wallichiana, Chatharanturs Roseus and Artemisia Annua.

12 Technology Information Forecasting and Assessment Council (TIFAC), Herbal Products - Current Status, Vision and Action Plan (New Delhi: Technology Information Forecasting and Assessment Council, 2001).

13 M.C. Nautiyal, 'Cultivation of Medicinal Plants and Biosphere Reserve Management in Alpine Zone', *in* K.G. Saxena ed., *Conservation and Management of Biological Resources in Himalaya* (New Delhi: Oxford and IBH Publication Ltd., 1995).

14 K.S. Rao and K.G. Saxena, Sustainable Development and Rehabilitation of Degraded Village Lands in Himalaya (Dehradun: Himvikas, Publication No. 8, 1994).

15 O.G. Goswami and P. Bhatnagar, 'Economic Returns from Cultivation of Medicinal Plants in Amarkantak', 14 (3) *Vaniki Sandesh* (1990).

The foregoing review indicates that there are several studies touching various aspects of medicinal plants but only spherically. More research is needed for proper planning for conservation and utilisation of medicinal plants keeping in view their ecological and aesthetic values. Further, there was not a single study which addressed the issues in feasibility and viability of cultivation, marketing and trade and bio-prospecting issues in a holistic manner.

2.3 Technology Generation and Uptake

Developing appropriate technologies for cultivation of medicinal plants is a critical factor in ensuring continuous and uniform supply of raw material for herbal industry and halting the degradation of natural resource base. The author explored these issues by undertaking field visits and interaction with key informants. According to one estimate, of the 500 plant species used for production of medicines by Indian industry, less than 20 are currently under cultivation in the country. It may be mentioned here that the Indian Council of Agricultural Research (ICAR) has developed a number of techniques to increase the quality and yield of many of the cultivated species. It is reported that public sector research institutions in India have standardised practices for the propagation and cultivation of a total of nearly 40 species. But information on actual level of adoption of these agro-technologies at farm level is not available. Following insights were gained about technology generation and uptake by farmers:

- The present focus of medicinal plants research (particularly in ICAR) is mainly on developing agro-technologies for the mandated crops. The discussions revealed that while suitable plant varieties and agro-technologies for medicinal plants are available, their adoption by farmers needs further encouragement;

- One of the major constraints in encouraging cultivation of medicinal plants is the absence of formal marketing linkages. Thus, the lack of assured marketing is one of the biggest hurdles in medicinal plants sector;

- Urgent action is needed for addressing the problem of marketing. Though contract farming may be one of the viable options for giving a boost to

cultivation of medicinal plants, effective legislative measures are needed to enforce the contracts. In the past, there have been certain cases when the contracting party (buyer) backed out at the last moment putting the supplier (farmer) in trouble;

- It was also noted that forest officials do not allow even collection of germplasm by the scientists from the reserve forest areas. At the same time, local people (mostly tribals) collect medicinal plants from the forests and sell in the market at cheaper rates. Though this is an illegal practice but this goes on unabated.

Most often a question is asked as to why the cultivation of medicinal plants is not picking up? Perceived perceptions prevail upon facts in this regard. Though cultivation often presents a viable and sustainable alternative to wild harvesting, the profit from and the apparent abundance and perceived potency of wild collected plants make this an unlikely alternative.[16] Wild American Ginseng root based on perceived potency is ten times as valuable as the cultivated root.[17] Some of the major problems in field cultivation of medicinal plants identified by the researchers are: [18]

- Non-availability of verifiable data on availability and consumption of medicinal plants;
- Absence/ignorance of cultivation technology;
- Ignorance of cultivation economics (medicinal plants as pure crop may be uneconomical);
- Land availability due to land ceiling act and state Forest Act;
- Inadequate irrigation facilities;
- Non-availability of planting materials;
- Lack of knowledge and training in post-harvest handling of medicinal plants;
- Lack of quality assurance and standardisation of medicinal plants;
- Inadequate marketing set-up for selling cultivated medicinal plants.

Taking into consideration the agro-climatic conditions required and duration of medicinal plants, the Scientific Advisory Committee to the Cabinet categorised 45 identified medicinal plants into: a) twenty three medically important herbs of short life cycle that can be cultivated all over India by farmers in between traditional crops, b) eleven endangered Himalayan plants requiring cool temperatures and height for proper growth, which can be preferentially cultivated by farmers from the Himalayas and Nilgiris and c) eleven tree species having indigenous as well as export demand. The Committee feels that since this tree category requires long years to reach maturity, these can be taken up for cultivation by Forest Departments and even included in Social Forestry Programs.

Thus, the literature clearly shows the need for species specific promotional activities targeting different types of producers in different agro-eco regions for promoting medicinal plant cultivation.

2.4 Marketing Potential

The international market for medicinal plant based products is estimated at US$ 60 billion and is growing at the rate of seven per cent per annum. The global herbal market is expected to grow to Rupees 250 billion by 2010. India's potential in market for medicinal plants is evident with the facts that the medicinal plants required to prepare 50 per cent of the drugs mentioned in British Pharmacopoeia are reported to be present in Western Himalayan region alone. Further, this region caters to about 80 per cent of *Ayurvedic*, 46 per cent of *Unani* and 33 per cent of allopathic system of medicines and contributes a major share to the economy of the rural farmers and tribals.[19] On the basis of number of traders and annual turnover markets for medicinal plants may be divided into three categories major, medium and minor. But major export takes place from Mumbai (the

16 J.W. Sheldon, M.J. Balick and G.M. Laird, 'Medicinal Plants: Can Utilisation and Conservation Coexist?, 12 *Advances in Economic Botany* (1997).

17 S. Foster, 'Medicinal Plant Development in the United States', *in* N.C. Vance and J. Thomas eds., *Special Forest Products: Biodiversity Meets the Marketplace* (Washington DC: USDA Forest Service, 1999).

18 A. Puranik, 'Opportunities and Constraints for the Production and Development of Medicinal Plants in India', *in* Madhav Karki and Radhika Johari eds., *The Role of Medicinal Plants Industry in Fostering Biodiversity Conservation and Rural Development* (New Delhi: The International Development Research Centre, 1999).

19 *See* Export Import Bank of India, note 10 above.

largest export market), Delhi, Chennai and Tuticorin. Unfortunately, there is no regulated market to control the various marketing practices involved in the entire supply chain.

Understanding of trade in medicinal plants in India is far from satisfactory. The trade in medicinal plants in India as being extremely complex, secretive, traditional, confusing, badly organised, highly under-estimated and unregulated. Also, there is no systematic local, regional or national level data regarding number of species traded, volumes, prices etc. with any one agency. Most of the data is disjointed, scattered, grossly inadequate and incomparable.[20] The following factors make medicinal plants trade difficult:

- No inventories of medicinal plants at all-India basis;
- No reliable system of matching trade names to botanical names. In the trade, a species is known by its local name, which can change from one market to another or from one region to another. For instance, for the trade name *ashok* there are two botanically different species, *Saraca indica and Polyalthia longifolia*. Similarly, for the trade name *chirayata* the two botanical species are *Andrographis paniculata* and *Swertia chirata;*
- Medicinal plants are harvested and traded in their raw form, whether as leaves, fruit, flower, seeds, gum/resin, roots, rhizomes, stems, bark or the whole plant. Since most raw drugs are traded in dried forms, long after their harvest, only the most experienced people in the trade are able to recognise the species by their parts used.

2.5 Policy and Institutional Environment

Lack of co-ordination among various stakeholders in India such as Ministry of Agriculture, Ministry of Environment and Forests, Ministry of Commerce, Department of Indian System of Medicine and Homoeopathy (ISM&H), Department of Science and Technology, State Governments, private traditional medicine sector, research institutes, NGO and international network is identified as one of the major constraint faced by the medicinal plant sector. All these stakeholders have different objective. This mode of working in isolation without considering objectives of other stakeholders has resulted in underdevelopment of medicinal plants sector.

2.5.1 Ministry of Forestry and Environment

Most medicinal plants are covered under sub-section 2(4) (b) of Indian Forest Act and are not subject to regulations unless extracted from the forests. Some items such as bark and wood-oil from certain trees were covered under sub-section 2 (4) (a) and subsequent state amendments to the Act have added several medicinal species to this sub-section which are subject to significant regulation regardless of origin. But at broader level medicinal plants are a component of non-timber forest products as per 1988 Forest policy resolution. The Task Force has recommended that considering the importance of medicinal plants they should be taken out from NTFPs and given due importance for their development.

2.5.2 Ministry of Commerce and Industry

The value added herbal formulations made out of imported species of plants and plant portions as specified above will be allowed freely without any restriction subject to furnishing of an affidavit to the custom authorities at the time of export that only the imported plant species as above have been used for the manufacture of value added herbal formulations being exported. In the event of affidavit proving to be false, on the basis of random sample tests, action would be initiated against the firm under the Foreign Trade (Development and Regulation) Act 1992. Exports are allowed only through the ports of Mumbai, Calcutta, Cochin, Delhi, Chennai, Tuticorin and Amritsar. The Ministry has prohibited export of 29 medicinal plants.[21]

20 *See* Niraj, note 2 above.

21 Beddomes Cycad (Cycas Beddomei), Blue Vanda (Vanda Coerulea), Saussurea costus, Ladies Slipper, Orchid (Paphiopedilium species), Pitcher Plant (Nepentheses Khasiana), Red Vanda (Renanthera imschootiana), Rauvolifia Serpentina (Sarpagandha), Ceropegia Species, Frerea Indica (Shindal Mankundi), Podophyllum Hexandurum, Cyatheaceae Species, Cycadacea Species, Dioscorea Deltoidea, Euphorbia Species, Orchidaceae Species, Pterocarpus Santalinus, Taxus Wallichiana, Aquilaria Malaccensis, Aconitum Species, Coptis Teeta, Coscinium Fenestrum (Calumba Wood), Dactylorhiza Hatagirea, Gentiana Kurroo, Gnetum Species, Kampheria Galenga, Nardostachys Grandiflora, Panax Pseudoginseng, Picrorhiza Kurrooa, Swertia Chirata.

Export of these 29 plants, plant portions and their derivatives and extracts as such obtained from the wild except the 'formulations' made there from is prohibited. The term 'formulation' shall include products which may contain portions/extracts of plants on the prohibited list but only in unrecognisable and physically inseparable form. Hence, at present export of prohibited plants is possible if these are present in some formulation (as against raw form) or if the label of the formulation does not mention the name of the species. It may be noted that the move of U.K. government to include Ayurveda among the list of 'herbal remedies' will seriously cripple the ayurvedic medicine manufacturing industry in the country by affecting their exports.[22] According to this move, each medicine will require special sanction for sale in the U.K. Thus, local, national and international policy environment is the determinant of export from the medicinal plants sector.

The restricted policy intervention by these two Ministries (Environment and Forestry) is of regulatory nature. It does not offer any incentives for different stakeholders. Further, no policy intervention is made in field of market support and other necessary supports. It is worth noting that the Task Force in its report has stated that medicinal plants sector was operating in the 'policy vacuum'.

3 OPPORTUNITIES AND CONSTRAINTS

3.1 Strength and Weaknesses

A SWOT analysis of Indian medicinal plants has established that this sector has several strengths such as enormous biodiversity, all types of soil and climate, a rich heritage of Indian System of Medicine (ISM), a strong base of Research and Development laboratories, skilled manpower, lower production and manpower costs and a well-developed pharmaceutical industry.[23]

With its vast wealth of knowledge on medicinal plants and herbs, India is the most suitable country for conducting fundamental and application oriented research in this field. In fact, next to information technology and biotechnology, research in medicinal plants, which combined the fruits of both these technologies, should emerge as the most sustainable growth sector in the years to come.

However, despite these inherent strengths, huge resource base and enormous economic potential of medicinal plants, many constraints hinder the growth of this sector. Price fluctuation, competition from synthetics, exporters' non-compliance with rules and regulations of importing countries and consequent refusal, quality constraints, asymmetric information with suppliers about the total world-trade in medicinal plants, limited number of botanical suppliers and traders who have a very strong bargaining power vis-à-vis the growers, irregular supply, inappropriate methods of collection and storage leading to sub-optimal levels of active constituents and consequent increase in price of their derivatives are some of the major constraints faced by this sector.[24]

3.2 Research and Development Issues

Research in medicinal plants at various stages in the value addition chain is being done by research and development organisations in Government of India, under Ministry of Agriculture (through ICAR), Department of Science and technology (CSIR), Ministry of Health and Family Welfare (CCRAS), Ministry of Environment and Forests (through ICFR) with State Forest Departments and corporate sector, Defense Research and Development Organization (DRDO) and SAUs (Table 4). But according to Scientific Advisory Committee to the Cabinet, research and development (R&D) in medicinal plants is beset with the following problems:

- There is no focus on a few numbers of plants at one time, which should be determined at the national level. Too many plants are taken up for research and focus is lost;
- Poor intra-institutional linkages lead to non-availability of data on past and current research and therefore there is duplication of work;
- Nature of priorities assigned in mandate of these organisations is different and hence the focus is diffuse;

22 T.Ramavarman, 'U.K's Move Threatens Ayurveda Industry', *The Hindu*, 31 July 2002.

23 *See* TIFAC, note 12 above.

24 *See* Export Import Bank of India, note 10 above.

- No interaction between these research institutions and growers on one hand and industry on the other hand. Therefore, research conducted by institutions does not reach farmers and research institutions do not come to know about needs of industry.

Therefore, the need of the hour is an integrated approach which addresses various issues in the supply chain right from farm to firm and consumer.

Table 4: Institutions involved in the R & D and promotional policy of medicinal plants

Agency	Sector	Description of activities
AICRP MAPNRC MAP, Anand	ICAR (Government)	Domestication and breeding of medicinal plants
RRL Jammu and Jorhat CIMAP Lucknow	CSIR (Government)	Agro-technology of medicinal plants
CDRI Lucknow	CSIR (Government)	Screening of medicinal plants and drug development
NBRI Lucknow	CSIR (Government)	Development of Pharmacopoeial standards of drugs
State government ISM Directorates	Government	Herbal gardens established by State Directorates of ISM in Gujarat and Karnataka
Ministry of Environment and Forestry.	Government	Scheme for grant in aid for establishment of ethno-botanical gardens Scheme for medicinal plants under Wasteland Board
State Forest Departments (SFD)	Government	Herbal gardens established by SFD in Gujarat, Karnataka, Kerala, Madhya Pradesh and Orissa
State Government Department of S&T	Government	Herbal gardens established in TBGRI, Thiruvananthapuram and KFRI, Peechi, Kerala
NABARD	Bank	Announced policy of financial support for cultivation
World Bank	Bank	Support for research on medicinal plants
Exim Bank of India	Bank	Support for research on medicinal plants and Ayurvedic industry
M.S. Swaminathan Research Foundation	NGO	Encouraging tribal and communities to conserve ethno-botanical plants
Winrock International India	NGO	Support for research on Ayurveda industry.

Source: Compiled from different publications.

4 BIO-PROSPECTING & INTELLECTUAL PROPERTY RIGHTS (IPR) ISSUES

4.1 World Scenario

The increasing importance of medicinal plants in fulfilling the health care needs particularly of developing countries has also been emphasised in various fora which stressed on sustainable utilisation of medicinal plants.[25] Under TRIPS Agreement, members have to make patent protection available for at least 20 years for any invention of pharmaceutical product or process. Debate is going on regarding: a) what will be implications of this on availability of pharmaceuticals in poor countries like India and b) what amendments are needed in national patent Acts in order to take advantage of the provisions available in TRIPS Agreement for establishing a balance between incentives for investment in research and wide accessibility of pharmaceuticals. Some opine that the optimal global framework for pharmaceutical patents might require differentiating the protection given to products in accordance with their extremely different global market. To make differential protection a feasible mechanism, it is proposed that patent owners have to choose either protection in the rich countries or protection in poor countries (but not both), whenever they have a pharmaceutical innovation related to a listed global disease.[26] Owners of patents related to non-global disease, on the other hand, would be allowed protection worldwide. In this background, increasing awareness of the value of traditional knowledge and bio-diversity resources as economic and tradable commodities, renewed interest in global bio-prospecting, the application of traditional knowledge about medicinal plants to aid the search for novel chemical compounds and new pharmaceuticals together with the impact of agreement on TRIPS on pharmaceuticals including traditional medicine has necessitated worldwide focus on IPR in the context of traditional medicine.

4.2 Indian Scenario

The Indian government has designated the Ministry of Environment and Forest (MoEF) as the nodal agency for biodiversity related issues. As part of its efforts for biodiversity conservation, the MoEF has set up eight biosphere reserves, 87 national parks and 448 sanctuaries under Wildlife (Protection) Act, 1972, altogether covering more than four and half percent geographical area of the country. But, weak physical infrastructure and inadequate documentation coupled with poor public awareness and delays in framing policies and implementing approach is hurting India.

In terms of policy, medicinal plants in India have generally been lumped into the broad category of Minor Forest Produce (MFP). Even the relatively progressive 1988 Forest Policy Resolution continues to use this terminology. Relatively more accurate designation for these products may be termed as Non Timber Forest Products (NTFPs). But increasing importance of medicinal plants necessitates that they should be taken out from NTFPs and given due importance for their development. A policy dialogue has already been initiated regarding medicinal plant conservation and statements of support for such a policy are forthcoming from many of the stakeholders in the sector, including the private companies which depend upon a continuous source of raw material supply. More recently governmental, non-governmental and private sectors have started the process of developing and enacting a national policy on medicinal plant. These initiatives mainly focus on documentation relating to properties, natural distribution, ecological tolerances and uses of valuable medicinal plants, identification of forest areas rich in medicinal plants and formulation of their management plan.

4.3 Recent Policy Initiatives

There have been several cases when, in the environment of a 'policy vacuum', the medicinal plants wealth of developing countries was used in an inappropriate way. Such cases were the pre-cursor to some national legislative efforts culminating into detailed legal provisions for conservation and sustainable use of medicinal plants resources.

25 Alma Ata Declaration, 1978; The Chiang Mai Declaration, 1988; Convention on International Trade of Endangered Species (CITES), 1973; The Arusha Declaration, 1990; First World Congress on Medicinal and Aromatic Plants for Human Welfare, 1992; Convention on Biological Diversity (CBD), 1992, and The Doha Declaration, 2001.

26 Jean O. Lanjouw, Intellectual Property and the Availability of Pharmaceuticals in Poor Countries, (Washington DC: Centre for Global Development, Working Paper No. 5, 2002).

4.3.1 Task Force on Conservation and Sustainable Use of Medicinal Plants

The Planning Commission constituted a Task Force (Chairman: Dr. D.N. Tewari, Member, Planning Commission) in 1999 to provide policy directives, measures for sustaining the resource base, achieving an equitable marketing system and thriving pharmaceutical industry (ISM&H), regulation of domestic and international trade, besides facilitating protection of patent rights and IPR of medicinal plants. The Task Force emphasised that medicinal plants represent not only a valuable part of India's biodiversity but also a source of great traditional knowledge. The report emphasised that medicinal plants can be viewed as a possible bridge between sustainable economic development, affordable health care and conservation of vital biodiversity. For ensuring sustainable and equitable development of medicinal plants sector, the report recommended, among others, establishment of 200 Medicinal Plants Conservation Areas (MPCA), 200 'Vanaspati Vans' in degraded forest areas and establishment of Medicinal Plants Board for an integrated development of this sector. The Task Force recommended several actions that were needed on the part of the government, institutions, etc to strengthen India's capacity in the protection of its intellectual property rights. In particular, it recommended creation of digital databases of India's traditional knowledge as a priority activity to provide evidence of this knowledge in public domain as well as India's ownership of the knowledge. It also called upon Research and Development institutions to maximise their patenting efforts.

The recommendation for establishing Medicinal Plants Board did materialise in the year 2000, but till date, the Board lacks adequate staff and other physical infrastructure. For efficient and effective working of the Board, sufficient manpower and other resources should be provided on the lines of other commodity boards (for example, Tea Board, Coffee Board, Spices Board). Since various aspects of medicinal plants are covered under different ministries, coordination among these departments becomes critical.

4.3.2 Traditional Knowledge Digital Library (TKDL)

Protection and preservation of traditional knowledge have been a matter of concern to India particularly after reported cases of bio-piracy. It was felt to adopt a critical and scientific approach to the problem of grant of wrong patents in our traditional knowledge. Therefore, the Department of Indian System of Medicine and Homoeopathy (ISM&H) constituted an inter-disciplinary Task Force which came up with a methodology for creating a Traditional Knowledge Digital Library (TKDL) - an electronic database of traditional knowledge in the field of medicinal plants. The primary objective of TKDL is that of avoidance of grant of patent on the traditional knowledge of the country. The Cabinet Committee on Economic Affairs approved early establishment of TKDL in Ayurveda in the first instance followed by similar digital libraries in other systems of Indian medicines, such as Unani, Siddha, Yoga, Naturopathy etc. (CSIR 2001). Such a database would enable the Patent Officers all over the world to search and examine any prevalent use/prior art, and thereby prevent improper grant of patent based on knowledge in public domain, including knowledge associated with medicinal plants.[27] This issue has also been taken up at the international level in the Inter-Governmental Committee of the World Intellectual Property Organisation to ensure that TKDL is prescribed as a non-patent literature and to ensure that patent examiners are duty bound to search the said database for any prior art.

The Task Force on TKDL found that out of 4896 references on 90 medicinal plants in the United States Patents & Trademarks Office (USPTO) patent database, 80 per cent of the references were on seven medicinal plants of Indian origin. The international acceptance of the TKDL project is promising. India's traditional knowledge database has been selected for pilot study by 170 member states.

In addition, the National Medicinal Plants Board under the Union Health Ministry, has decided to set up export promotion Zones exclusively for medicinal plants and Herbal products in Tamil Nadu, Andhra Pradesh, Gujarat, Haryana and Rajasthan, which have a well developed base for cultivation and processing of medicinal herbs. The Tamil Nadu Government in its

27 The Indian government has since authorised the National Institute of Science Communication and Information Research (NISCAIR) to ink non-disclosure agreement with patent offices in other countries to access its TKDL digital database only for patent research.

Government Order No.189 dated 2 July 2002 regarding waste land development proposes leasing of land for corporate houses, small companies and co-operatives. Among several proposed crops for cultivation on these lands, it included medicinal plants also.

4.3.3 The Patents Act, 2002 and 2005

The Indian Patent Act, 1970 provided specific exceptions to patentability in the field of health and food. These provisions were seen as contradicting the TRIPS Agreement which requires that all WTO member introduce product and process patents in all fields of technology. The Indian Parliament approved the Patents (Second Amendment) Act, 2002 in May 2002 and the Patents (Third Amendment) Act, 2005 in April 2005.

There are a number of new elements in the Patents Act, 2002. Section 3 of the Act is of special interest wherein it is suggested that traditional knowledge be excluded from patentability. This means the knowledge in public domain cannot be patented. Therefore, this clause is significant considering the various systems of indigenous medicines prevailing in India. However, the real issue is whether inventions based on traditional knowledge can be denied intellectual property rights through patents? This demands unambiguous definition of patentable inventions. Another important feature of the Act relates to compulsory licensing (Section 83) with an attempt to incorporate some of the TRIPS' in-built flexibility into the Patents Act. Section 83 requires that patents granted should not "impede protection of public health", should not prohibit the central government from taking measures to protect public health and that patents should be granted to make the benefits of the patented invention available to the public at reasonably affordable prices. But, it is felt, that adoption of a strong compulsory licensing regime cannot be a substitute for strong health-related provisions in the main part of the act.[28] With the third amendment, the Indian Patent Act has been made fully compatible with TRIPS. But in this process, some more possibilities for proper use of traditional knowledge and strengthening the local health systems, within the framework of the TRIPS Agreement, have been ignored. Unfortunately, the latest amendment was the least discussed and debated piece of legislation on Indian patent regime.

Central government's Scientific Advisory Committee to the Cabinet has identified 45 medicinal plants for focus between 2001 and 2020, and seven medicinal plants for focused action during 2001 to 2005. The Committee has also identified key issues, nodal agency to address these Issues and Recommended actions on the part of nodal agencies to address these issues focusing on short listed plants. The major issues are human resource development, research, extension, input supply and market development, infrastructure development, linkage and coordination among various stakeholders in the sector, finance, taxation and incentives. With respect to finance, the National Bank for Agriculture and Rural Development (NABARD) has been identified as the nodal agency and the Medicinal Plant Board as the nodal agency for establishing linkages. Also, the Board would address all issues connected with conservation and sustainable use of medicinal plants leading to remunerative farming, affordable health care and conservation of bio-diversity. The action plan of the Board has envisaged the following activities:

- Encouragement for cultivation of selected medicinal plants backed by buyback arrangements;
- Registering raw drugs traders;
- Simplification of transit permit/ legal procurement certificate for transportation of raw drugs;
- Thirty one selected priority medicinal plants (reduced to 28 subsequently in draft policy on ISM 2001 based on recommendation of three expert committees) which are in great demand both in domestic and international market to be brought into cultivation status for the overall development of the medicinal plants sector;
- General and specialised surveys of the international market for medicinal plants and products to be undertaken for identifying niche areas;
- Registration of farmers/cultivators and traders of medicinal plants to be entrusted to the respective State Medicinal Plants Board/ Vanaspathi Van Societies. (If warranted a law to cover this would be introduced as mentioned in the Draft Policy on ISM);
- Research and Development studies in the areas of post harvest management shelf life, storage and

28 P. Cullet, 'Amended Patents Act and Access to Medicines after Doha', 37(24) *Economic and Political Weekly* 2278 (2002).

simple agro-techniques to be taken up through CSIR, NBRI, CIMAP, ICFRE, RRLs, DBT, Horticulture and Forest Department;

- Constitution of State Medicinal Plants Board in every state/Union Territories of the country for overall development of medicinal plants sector;

- Efforts to create mass awareness about the importance of medicinal plants among the people and publish distribution material for the purpose.

In October 2002, the Government of India approved the National Policy on Indian System of Medicine and Homeopathy (ISM&H) for improving delivery system of such medicines. According to this policy, statutory status would be given to Medicinal Plants Board by 2005 (still awaited!). This measure intended to enable the board effectively broker the demand and supply of medicinal plants within and outside the country in raw as well as finished form. Although the Draft Policy treats ISM industry as a priority industry and as a Green industry (100 per cent tax holiday for five years and 30 per cent for another five years) and emphasis on strategies aiming at 25 per cent incremental increase in export earnings from this sector each year, the critical point which will decide the impact of the policy is going to be its timely and effective implementation.

4.4 Emerging Issues

In India, the National Biodiversity Authority (NBA) has envisaged a three-tier structure of bodies to oversee the conservation and utilisation of biological resources in sustainable manner taking care of ethics and equity issues. NBA seeks to establish biodiversity councils to mobilise local resources, with considerable powers, at the level of local bodies such as panchayats and municipal corporations. Meanwhile, the Task Force opined that, till date, debate on IPRs and bio-diversity has focused on patents and plant breeders' right. The potential value of geographical indications and utility model patents, undisclosed information needs to be examined too as they protect and reward traditions while allowing evolution.

In the first instance of tribals sharing commercial benefits in India, nearly 200 families of 30 Kani tribal settlements in Thiruvanthapuram, Kerala have been given rupees 5.19 lakhs for a drug developed out of the tribal traditional wisdom.[29] A plant named 'arogyapacha' (Trichopus Zaylanicus Gaertn) had proved to be a stamina inducing herb. The Kani Tribals used to eat it raw for instant energy. The Tropical Botanical Garden and Research Institute (TBGRI) developed a drug from the herb. The drug was sent for commercial production after due trials to a Coimbatore based 'Arya Vaidya Pharmacy' for rupees ten lakh as license fee for and royalty of which about 50 per cent has been given to the Kani Community Welfare Trust. The Trust plans to utilise this money for the community development in health and education. The Trust has also decided to give fifty thousand rupees as rewards to three tribesmen who had imparted the secrets of the plant to TBGRI scientists. Further, the State Forest Department has agreed in principle to include 'arogyapacha' in the list of minor forest produces. This will enable the tribals to take up its commercial cultivation under a buy-back arrangement with the manufacturers.

In the new regime of WTO, there is acute danger of bio-piracy involving intellectual theft, resource theft and economic theft.[30] However, some researchers view that article 27.2 of TRIPS provides protection from exploitation through bio-piracy because Articles 7 and 8 of TRIPS can be effectively used to stop or reject patent applications which attempt to patent indigenous knowledge either directly or indirectly or with minor modification.[31] The spate of biotechnological activities which have made possible the use of specific DNA sequences obtained surreptitiously from another country has developed a sense of plant genetic resources insecurity among the gene rich countries.[32]

The Task Force highlights the issue of wrong patenting because of the feature that the knowledge which may be in a public domain in one country may be a new knowledge in other country. It also states that the question whether all such patents be opposed or not should be addressed on the following three basis:

29 H.J. Chowdhery and S.K. Murthi, *Plant Diversity and Conservation in India: An Overview* (New Delhi: Vedam Books, 2000).

30 J.R. Sharma, 'PGR Issues: National Concern and Global Conflicts with Special Reference to Medicinal and Aromatic Plants', 21 *Journal of Medicinal and Aromatic Plant Sciences* 1111 (1999).

31 *See* Chowdhery, note 29 above.

32 *See* Sharma, note 30 above.

- Would the Indian trade both domestic and foreign, be affected by not opposing the patent?

- What would be the time and cost involved in opposing a patent? The time and cost would depend on how quickly all the necessary information could be allocated, collated and presented?

- Have necessary ground and factual information been established to oppose the patent successfully?

The Task Force views that sovereign rights enshrined in the Convention on Biological Diversity, 1992 are passing into private hands through patents. It has suggested some points for considered in future negotiations as:

- A patent application dealing with bio-resources should necessarily disclose the source (geographical origin of the bio-resources);

- It should list the Known uses of the bio-resources in the prior art so that patent examiners could apply appropriate tests at the time of scrutiny;

- There should be global initiative to document traditional and indigenous knowledge;

- Patent applications should be subject to pre-grant opposition to avoid costly litigation at a later stage.

5 CONCLUSIONS AND LESSONS LEARNT

The importance of the medicinal plants sector can be gauged from the fact that herbal medicines serve the healthcare needs of about 80 per cent of the world's population. According to the World Health Organisation (WHO), the goal of 'Health for All' cannot be achieved without herbal medicines. While the demand for herbal medicines is growing in developing countries, there are indications that consumers in developed countries are becoming disillusioned with modern healthcare and are seeking alternatives. This has renewed interest by the multinational pharmaceutical industry in bio-prospecting. But the lack of national legislation or effective international agreements on conservation of biodiversity has resulted in 'slaughter harvesting' of medicinal plants and massive depletion of biodiversity. This trend does not augur well for sustainable use of medicinal plants resources.

India, with approximately eight percent of world's biodiversity including plant genetic diversity with medicinal properties, has the potential of becoming a major global player in market for medicinal plants based herbal formulations, medicines and products. According to WHO, the international market of herbal products is estimated to be US $ 62 billion which is poised to grow to US $ 5 trillion by the year 2050, but India's share in the global export market of medicinal plants related trade is just 0.5 per cent. Given the extent of biodiversity in India, a major task of all the concerned including the policy planners has to be the identification and guided development of new products with large export potential. India has set a vision regarding its medicinal plants sector and some major policy initiatives have been taken in this direction. Still, strategic actions based on research on issues identified above will be needed to realize the vision. However, the fact that all medicinal plants are not amenable for cultivation should not be ignored. Hence, conservation and cultivation must go together with prioritisation for development of the medicinal plants sector as a whole. To harness the potential of this sector, we should have an economic outlook, realistic policy and effective planning strategy. Since available evidences are inadequate to fully capture the complex issues of this sector, three is a dire need to undertake in-depth socio-economic and policy research analysis to fill the gaps in understanding the dynamics of medicinal plants sector.

The Indian government has no doubt taken certain policy measures for protecting country's invaluable biodiversity as well as meeting international obligations under post-WTO regime. Though these initiatives are appreciable, there exists enough scope for making these measures more focused and effective. We may begin with conservation and on-farm cultivation of priority species as reported by various high-level expert committees. At the same time, the industry estimates for raw material demand should be available well in advance so as to regulate demand-supply scenario optimally. This is important if we have to ensure development of this sector in a sustainable manner.

Effective policy making for this sector calls for awareness raising, coordination and engagement of all the stakeholders. One of the immediate tasks for conserving medicinal plants diversity is to effectively implement the provisions on conservation and sustainable use of biodiversity (Biological Diversity Act, 2002) and the Patents (Amendment) Act, 2005. The available flexibility under TRIPS provisions should be utilised fully for protecting the pool of our plant genetic resources and traditional knowledge in an effective way. Capacity building is another important area which would be a major source for harnessing the potential of medicinal plants sector. Perhaps the greatest challenge in making trade a positive force for development is ensuring that the benefits accelerate development in the poorest countries and for the poorest people. The root cause of many health problems in developing countries is poverty. Therefore, a national policy on utilising medicinal plants for herbal medicines need to be developed soon which should ensure that all herbal medicines in the market are safe, effective, of good quality, reasonably priced and are prescribed and utilised rationally. It is equally important that the interests of the growers are well protected by supply of modern technologies, services and credit supplies and above all a good marketing system. The national policy should have effective provisions for ensuring equitable benefit sharing for all stakeholders. This would go a long way in fulfilling traditional healthcare needs and ensuring conservation and sustained utilisation of medicinal plant resources of the country.

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