5.1 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. 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.

5.2 Background of the Study

As much as 70 per cent of India’s population use traditional medicine. 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.

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 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. 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 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. Keeping in view this limitation, present chapter is designed to fill in the gaps in the understanding of various issues pertaining to registration of medicinal plants sector.

5.3 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 Subcontinent. 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. Medicinal plants procured from cultivated private fields account for ten per cent of the total medicinal plants in active trade. The forests of Himachal Pradesh and the 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 interventions 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. Seasonal variation and age has 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 5.1, 5.2, 5.3)

Table-5.1: Priority Species of Medicinal Plants based on Commercial Value

<table>
<thead>
<tr>
<th>Plant</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhatoda Zeylanica</td>
<td>Vasaka</td>
</tr>
<tr>
<td>Plant</td>
<td>Common Name</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Pluchea lanceolata</td>
<td>Rasna Rasna</td>
</tr>
<tr>
<td>Saraca indica</td>
<td>Ashoka</td>
</tr>
<tr>
<td>Terminalia</td>
<td>Chebula</td>
</tr>
<tr>
<td>Terminalia arjuna</td>
<td>Arjun</td>
</tr>
<tr>
<td>Azadirachta indica</td>
<td>Neem</td>
</tr>
</tbody>
</table>

### Table 5.2: Priority Species of Medicinal Plants based on their Importance

<table>
<thead>
<tr>
<th>Plant</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plantago ovata</td>
<td>Isabgol</td>
</tr>
<tr>
<td>Bacopa monnieri</td>
<td>Brahmi</td>
</tr>
<tr>
<td>Centella asiatica</td>
<td>Mandukparni</td>
</tr>
<tr>
<td>Withania somnifera</td>
<td>Aswagandha</td>
</tr>
<tr>
<td>Andrographis paniculata</td>
<td>Kalmegh</td>
</tr>
<tr>
<td>Swertia chirata</td>
<td>Chirayta</td>
</tr>
<tr>
<td>Tinospora</td>
<td>Guduchi</td>
</tr>
<tr>
<td>Emblica</td>
<td>Amla</td>
</tr>
<tr>
<td>Commiphora wightii</td>
<td>Guggul</td>
</tr>
<tr>
<td>Phyllanthus amarus</td>
<td>Bhumyamalaki</td>
</tr>
<tr>
<td>Podophyllum</td>
<td>Papra</td>
</tr>
<tr>
<td>Asparagus racemosus</td>
<td>Shatavari</td>
</tr>
<tr>
<td>Picrorhiza kurroa</td>
<td>Kutki</td>
</tr>
<tr>
<td>Streblus asper</td>
<td>Shakhotaka</td>
</tr>
</tbody>
</table>

### Table 5.3: Priority Species of Medicinal Plants based on potential for further Research

<table>
<thead>
<tr>
<th>Plant</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holarrhena</td>
<td>Kutaja</td>
</tr>
<tr>
<td>Crataeva nurvala</td>
<td>Varun</td>
</tr>
<tr>
<td>Valeriana jatamansi</td>
<td>Tagar</td>
</tr>
</tbody>
</table>
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 of these plants for intensive attention over next five years. 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 plant.

5.3.1 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 and an average annual income of Rupees 120,000 per hectare through mixed cropping of high altitude medicinal herbs. 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).

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.

5.3.2 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 present chapter 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:

(i) 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;

(ii) 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;

(iii) 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;

(iv) 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. Wild American Ginseng root based on perceived potency is ten times as valuable as the cultivated root. Some of the major problems in field cultivation of medicinal plants identified by the researchers are:

(i) Non-availability of verifiable data on availability and consumption of medicinal plants;

(ii) Absence/ignorance of cultivation technology;

(iii) Ignorance of cultivation economics (medicinal plants as pure crop may be uneconomical);

(iv) Land availability due to land ceiling act and State Forest Act;

(v) Inadequate irrigation facilities;

(vi) Non-availability of planting materials;

(vii) Lack of knowledge and training in post-harvest handling of medicinal plants;

(viii) Lack of quality assurance and standardisation of medicinal plants;

(ix) 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, it clearly shows the need for species specific promotional activities targeting different types of producers in different agro-eco regions for promoting medicinal plant cultivation

5.3.3 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. 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 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 is 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. The following factors make medicinal plants trade difficult:

(i) No inventories of medicinal plants at all-India basis;

(ii) 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;

(iii) 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.

5.3.4 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.

5.3.4.1 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.

5.3.4.2 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.”

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. 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’.

5.4 Bio-Prospecting & Intellectual Property Rights (IPR) Issues

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. 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. 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.

5.5 Provisions of Registration of Geographical Indication under the Act

Protection to a GI against infringement is granted only after registration. Although registration is not compulsory yet the registration provides better legal protection against any infringement. Legislation in India is very detailed as to the particular conditions for registration. If the application for registration fulfils all the requirements under the Act, then after examination it is technically approved. The proposed GI is then published for a period of objection before the final approval. The all process requires about 12 months to complete. Foreign applicants who wish to register their GI in India have to follow a similar registration procedure, applying through an India-based representative, and providing an address for services in India. Foreign and domestic GIs are granted the same rights under the Indian GI Act. But before filing an application for registration of a GI it is a must to check whether the
indication comes within the ambit of the definition of a GI under *Section 2(1) (e)* of the Act.

### 5.5.1 Eligibility for Registration

Two types of stakeholders are directly involved in a GI. The first is the applicant and second is the authorized user of the GI. According to *Section 11* of the Act, any association of persons or producers, or any organization or authority established by or under the law for the time being in force can apply for the registration of a GI but following conditions need to be satisfied:

(i) The applicant must represent the interest of the producers of the concerned goods;

(ii) The application should contain the details of the applicant together with address. If there is a large number of producers a collective reference to all the producers of the goods may be made in the application;

(iii) The application should be addressed to the Registrar of Geographical Indications along with prescribed fee.

The application must show the uniqueness of the product due to its geographical origin, a combination of human and natural factors. A single application may be made for registration of a geographical indication for different classes of goods and fee payable therefore shall be in respect of each such class of goods. The application must be in writing in triplicate in the prescribed format. The application has to be signed by the applicant or his agent and accompanied by a statement of case. The applicant must have an address for service in India. Generally, application can be filed by:

(a) a legal practitioner, or

(b) a registered agent.

### 5.5.2 Authorities for Registration of Geographical Indications

The Act is administered by the Controller General of Patents, Design and Trademarks, who is also the Registrar of Geographical Indications. The Central Government may appoint such officers with such designations as it thinks fit for the purpose of discharging,
under the superintendence and direction of the Registrar, such functions of the Registrar under this Act, as he may from time to time authorise them to discharge. There is also the constitution of a Consultative Group of technical experts, chaired by the Registrar, to ascertain the correctness or otherwise of the particulars furnished in the application.

5.5.3 Documents which must accompany the application for Geographical Indication registration

The documentation process is extremely rigorous and requires elaborate audio-visual documentation. Section 11 (2) of the GI Act specifies the documentation requirements for applying for a GI in India. Rule 32 (1) of the GI Rules also lays down these provisions and in addition stipulates a few more documentation requirements. The actual filing of an application to register a GI in India must contain at least the following:

(i) Statement as to how the geographical indication serves to designate the goods as originating from the concerned territory of the country or region or locality in the country, as the case may be, in respect of specific quality, reputation or other characteristics of which are due exclusively or essentially to the geographical, environment, with its inherent natural and human factors, and the production, processing or preparation of which takes place in such territory, region or locality, as the case may be;

(ii) The class of goods to which the geographical indication shall apply;

(iii) The geographical map of the territory of the country or region or locality in the country in which the goods originate or are being manufactured;

(iv) The particulars regarding the appearance of the geographical indication as to whether it is comprised of the words or figurative elements or both;

(v) A statement containing such particulars of the producers of the concerned goods, if any, proposed to be initially registered with the registration of the geographical indication as may be prescribed;
(vi) An affidavit as to how the applicant claims to represent the interest of the association of persons or producers or any organization or authority established by or under any law;

(vii) The standards benchmark for the use of the GI or the industry standard as regards the production, exploitation, making or manufacture of the goods having specific quality, reputation, or other characteristic of such goods that is essentially attributable to its geographical origin with the detailed description of the human creativity involved, if any, or other characteristic from the definite territory of the country, region or locality in the country, as the case may be;

(viii) The particulars of the mechanism to ensure that the standards, quality, integrity and consistency or other special characteristic in respect of the goods to which the geographical indication relates which are maintained by the producers, maker or manufacturers of the goods, as the case may be;

(ix) The particulars of special human skill involved or the uniqueness of the geographical environment or other inherent characteristics associated with the geographical indication to which the application relates;

(x) Where the geographical indication is a homonymous indication to an already registered geographical indication, the material factors differentiating the application from the registered geographical indications and particulars of protective measures adopted by the applicant to ensure consumers of such goods are not confused or mislead or confused in consequence of such registration;

The application thus, includes a description of the method of production, historical proof, and a map.

5.5.4 Prohibition of Registration of certain Geographical Indications

The following are the geographical indications that cannot be registered in India:

(i) The use of which would be likely to deceive or cause confusion; or

(ii) The use of which would be contrary to any law for the time being in force; or

(iii) Which comprise or contain scandalous or obscene matter; or
(iv) Which comprise or contain any matter likely to hurt the religious susceptibilities of any class or section of the citizens of India; or

(v) Which would otherwise be disentitled to protection in a court; or

(vi) Which are determined to be generic names or indications of goods and are, therefore, not or ceased to be protected in their country of origin, or which have fallen into disuse in that country; or

(vii) Which, although literally true as to the territory, region or locality in which the goods originate, but falsely represent to the persons that the goods originate in another territory, region or locality, as the case may be.

In *Payyannur Pavithra Ring Artisans and Development Society v. K. Balakrishnan* an application for registration as GI was filed by Payyannur Pavithra Ring Artisans and Development Society for a uniquely crafted ring ‘Payyannur Pavithra Mothiram’ shaped like a knot and considered being a sacred ornament. After recommendation of the consultative committee, the said application was accepted for registration and accordingly an examination report was issued by the registry, asking the Applicant to comply with few more requirements to proceed for further Registration. The Applicant complied with the requirements of the examination report. Accordingly, the application was published in GI Journal No. 7 dated 7th September, 2005. However, the notice of opposition was filed by Shri. K. Balakrishnan on the grounds:

(a) That the Applicant is not representing the interest of the producers of a particular region.

(b) That it is a sentimental and religious matter of the society and cannot be considered as goods of GI.

The court held that the Applicant fulfilled all the requirements of the *Section 11* of the *Geographical Indications of Goods (Registration and Protection) Act, 1999* and hence the objection of the Opponent is not sustainable. Further, it was held that the ring was the product available in the particular region and famous in the name of Payyannur Pavithra Ring having specific quality and as applicant already submitted
the certified Map in support of the Application, the product Ring is the goods of GI and use of sentimental of religion does not bar for registration.

5.5.5 Examination by the Competent Authorities

After the preparation of application is completed, it can be filed and submitted by a legal practitioner or a registered agent and submitted to the Registrar of Geographical Indications, Chennai along with the prescribed fee. Upon receipt of an application, the Registrar shall examine the application and the accompanying Statement of Case as required under Rule 32 (1) as to whether it meets the requirements of the Act and the Rules and for this purpose i.e., he is to scrutinize the application for any deficiencies. The applicant should within one month of the communication in this regard, remedy the same. Registrar shall ordinarily constitute a Consultative Group of not more than seven representatives chaired by him from organization or authority or persons well versed in the varied intricacies of this law or field to ascertain the correctness of the particulars furnished in the Statement of Case referred to in Rule 32 (1) which shall ordinarily be finalised within three months from the date of constitution of the Consultative Group. Thereupon, the Registrar shall issue an Examination Report on the application to the applicant. Subsequent to examination, the Registrar may refuse the application altogether or may accept it either absolutely or subject to certain conditions, modifications, etc. Compliance, if any, is to be done within two months from the date of communication of the Examination Report to the applicant. If within two months from the date of communication mentioned above, the applicant does not amend his application according to the proposal aforesaid, or submit his observations to the Registrar or apply for a hearing or fails to attend the hearing, as the case may be, the application shall be dismissed. Once the objections raised in the Examination Report are satisfactorily responded to by the applicant, and the application is accordingly accepted by the GI Registry, it is advertised in the GI Journal, which is a bi-monthly, bi-lingual (English and Hindi) statutory publication, within three months of acceptance. After advertised in a GI journal, if the application did not receive any objection from any public organization or individual, then it is deemed as accepted and to be awarded GI certification. The Registrar is also empowered to withdraw an application, if it is accepted in error, after giving the applicant an opportunity of being heard.
5.5.6 Opposition to Registration

The Journals are published on the Registrar of Geographical Indications website and any person can file a notice of opposition within three months (extendable by another month on request which has to be filed before three months) opposing the GI application published in the Journal. The registrar shall serve a copy of the notice on the applicant and, within two months from the receipt by the applicant of such copy of the notice of opposition, the applicant shall send to the Registrar in the prescribed manner a counter-statement of the grounds on which he relies for his application, and if he does not do so, he shall be deemed to have abandoned his application. Where the counter-statement has been filed, the registrar shall serve a copy on the person giving the notice of opposition. Thereafter, both sides will lead their respective evidences by way of affidavit and supporting documents. A date for hearing of the case will be fixed thereafter. If the application passes through the specified time period unopposed, or in the event of an opposition, if it is decided in favour of the applicant, the Registrar is required to register the concerned GI as well as the authorized users and include the particulars in the GI Register. Any person aggrieved by an order or decision can file an appeal to the Intellectual Property Appellate Board (IPAB) within three months. On application made in the prescribed manner to the Appellate Board or to the Registrar by any person aggrieved, the tribunal may make such order as it may think fit for cancelling or varying the registration of a geographical indication or authorised user on the ground of any contravention, or failure to observe the condition entered on the register in relation thereto. Under the Act the Appellate Board or the Registrar of GI has the power to remove the GI or an authorized user from the register.

5.5.7 Validity for Geographical Indications in India

When an application of GI has been accepted, the Registrar registers the geographical indication and the applicant is issued a certificate with the seal of the Geographical Indications Registry. The registration of a geographical indication is for a period of ten years. Renewal is possible for further periods of 10 years each provided the application for renewal with the prescribed renewal fee is made before
the expiration of term. If a registered geographical indication is not renewed within prescribed period of time, it is liable to be removed from the register.

5.5.8 Effect of Registration

Registration is *prima facie* the evidence of validity. A registered GI is protected against infringement as it confers right to institute the legal proceedings against infringement. Any right to a registered GI is not a subject matter of assignment, transmission, licensing, pledge, mortgage or any such other agreement. Upon registration of a GI, the Registrar is required to issue each to the applicant and the authorized users a certificate sealed with the seal of the GI Registry. The date of filing of the application is deemed to be the date of registration. Registration is essential towards ensuring better legal protection of GIs in India.

5.6 Medicinal Plants & Intellectual Property Laws

Agriculture has come under the subject of IPR, only after the creation of World Trade Organization (WTO) as a consequence of the General Agreement on Tariffs and Trade (GATT) Uruguay Round agreement. It was thought that Agreement on Agriculture (AoA) is the central focus of WTO negotiations, since agriculture is lifeline of development of most countries in the world. It plays a pivotal role in ensuring food security, providing livelihoods, generating foreign exchange and determining the allocation of natural resources (Murphy, 2003). However, dominant interest within the AoA circles around greater market access and increase in volume of commodity flows. Agreement on Trade-Related Intellectual Property Rights (TRIPs) is the outcome of WTO which has direct impact on farmers’ livelihood, food security and economic development of the country. TRIPs provides mechanism for common protection and enforcement of IPR such as copyrights, trademarks and patents and also to make rules intended to limit international trade in counterfeit goods. The agreement also recognized that there are no uniform standards in the protection and enforcement of IPR and also no multilateral framework of principles. There is various legal protection mechanisms available under the TRIPs for Herbal Medicine Plants that can be harnessed the benefit in India’s interest are as follows:

5.6.1 Protection of Plant Varieties and Farmers’ Right Act (2001)
It allows the registration of three types of plant varieties. These are farmers’ variety, extant varieties and new varieties. Although, most of the Herbal Medicine Plants that are in cultivation, are farmers’ varieties and an instrument is available now to safeguard these varieties from piracy by registration. However, much benefit cannot be achieved in Herbal Medicine Plants by the farmers because rule states that all the extinct varieties are to be registered within the three years from the date of enforcement of this Act. According to the Act, extant varieties include farmers’ varieties also. Only possibility left now is to register the farmers’ variety as new variety since provision is available for the farmers also to register new varieties.

5.6.2 Protection through the Biological Diversity Act (2002)

The key features of this Act are: 1) To regulate access to biological resources of the country with the purpose of securing equitable share of benefits arising out of the use of biological resources and its associated knowledge 2) To conserve and sustainable use of biological resources, 3) To respect and protect knowledge of local communities related to biological resources. 4) To share the benefits with local people as conservers of biological resources and owner of knowledge and information relating to use of biological resources and 5) Conservation and development of areas of importance for biodiversity. Herbal Medicine Plants constitutes a great deal of biological resources and its usages have been recognized by the Act.

Even after developing IP by using the country’s Herbal Medicine Plants bio-resources through proper legal permission, one has also to take approval from the National Biodiversity Authority (NBA) for filling an application for any form of IPR. This provision will take care of benefit sharing that will emerge due to utilization of our biological resources.

5.6.3 Geographical Indication of Goods (Registration and Protection) Act (1999)

Geographical Indications is an important protection measure for safeguarding the agricultural goods or for that matter any other goods manufactured at a given location which has the quality related to that geographical location. With the Geographical Indication of Goods (Registration and Protection) Act 1999, the varieties from which
the medicines prepared from certain genotypes and at a particular location having a
good quality can be protected after registering it under this act with the Controller
General of Patents, Designs and Trade Marks. There are few examples existing in
medicinal plants that a product is known by its location such as Trinvelly Senna, Java
citronella, Neemach Ashwagandha, etc. Many more can be registered in future.

5.6.4 Traditional Knowledge Digital Library (TKDL)

Since the time immemorial, folk medicines are using herbs in their preparations. This
knowledge is disseminated through person to person through practice without having
any written form. Therefore, there is no proper record of these practices. Collection,
documentation and validation of various folk medicines, in addition to other various
traditional knowledge have been initiated by National Institute of Science
Communication and Information Resources of Council of Scientific and Industrial
Research and also by few other NGOs. This documentation will help in opposing any
piracy of patent as experience in case of neem and turmeric.

5.6.5 Patent Protection

Varieties of Herbal Medicine Plants developed using modern plant breeding
techniques cannot be patented as such as per the Indian patent law. But the process of
developing such varieties can be protected through patents. Similarly, process of
extraction of active ingredients, product developments by using Herbal Medicine
Plants and usages of Herbal Medicine Plants for new purposes is patentable subject
matter in the national law if they meet the standards of novelty, inventive steps and
industrial applicability.

5.7 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, nongovernmental 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.

5.7.1 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.

5.7.1.1 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.

5.7.1.2 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 interdisciplinary 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. 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 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.

5.7.1.3 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 members 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. 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:
(i) Encouragement for cultivation of selected medicinal plants backed by buyback arrangements;

(ii) Registering raw drugs traders;

(iii) Simplification of transit permit/legal procurement certificate for transportation of raw drugs;

(iv) 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;

(v) General and specialised surveys of the international market for medicinal plants and products to be undertaken for identifying niche areas;

(vi) 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);

(vii) Research and Development studies in the areas of post harvest management shelf life, storage and simple agro-techniques to be taken up through CSIR, NBRI, CIMAP, ICFRE, RRLs, DBT, Horticulture and Forest Department;

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

(ix) 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.

5.7.2 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. A plant named ‘aorgyapacha’ (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 ‘aorgyapacha’ 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. 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. 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.

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:

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

(ii) 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?

(iii) 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:

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

(ii) 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;

(iii) 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.

5.8 Concluding Summations

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-Law, Environment and Development Journal 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, there 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.