Intellectual Property Rights and Assessment of the Raw Materials (Crude Drugs) Used in Indian Systems of Medicine

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There are two types of Ayurvedic medicines prepared in the country. First is the classical drugs (based on classical literature of the Ayurvedic System of Medicine as given in Schedule-A of the Drug & Cosmetics Act, 1940). Second is the ‘patent and proprietary’ (P.P.) medicine manufactured by the pharmaceutical industry of the Indian Systems of Medicine (ISM) on their own developed formulations (by adding or deleting in the original classical formulations). In all these formulations, 90% drugs of plant origin are used in their own natural forms as roots, stems, leaves, fruits, and their modified structures and their derivatives like gums, exudates, etc. Since these crude drugs raw material may not have been evaluated scientifically on botanical, pharmacognostical, chemical and pharmacological parameters, etc. it is therefore, necessary to screen them out for various ailments. Pharmaceutical industry of ISM in the country is very large and manufacturing its drugs on the basis of licence issued by the Drug Control Authorities of the respective States. Position of drugs of ISM as to how they are procured, obtained from various resources in the country is not known exactly. The activities attributed to a single plant for various ailments are quite scanty. Their trade history, supply and demand, involvement of national level institutions and their trade mark etc is also not authentically established. Government of India is busy in laying down its standards in the form of pharmacopoeial monographs for quality control purposes.

Looking into all these aspects it is necessary that the aspects of intellectual property rights and assessment of raw material (crude drugs) used in ISM is given top priority. The impact of intellectual property-related issues like TRIPS Agreement on the status of crude drugs used in ISM has been discussed. The format proposed by the Forum of Parliamentarians on Intellectual Property Rights is given in the paper and the proposals are given by the author under each item for their adherence to solve the patenting problem of the raw material of ISM industry in the country.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as contained in the Final Act of the Uruguay Round, seeks to strengthen intellectual property protection in order to promote world trade and rapid international economic developments that will arguably produce a virtual technological transformation of human society, and much of the natural world along with it. In contrast, the United Nations Framework Convention on
Biological Diversity (Biodiversity Treaty) seeks to preserve as much as possible of the natural world and human society’s traditional, essentially agrarian, relationship to it, and to promote the concept of sustainable development. The debate over these two treaties has exposed a series of conflicts between technology rich industrialized countries located in the temperate zone of the northern hemisphere, and the biodiversity rich developing countries located primarily in the tropics and the southern hemisphere.

The question of implications of the General Agreement on Trade and Tariff (GATT) at the Uruguay convention and the TRIPS Agreement, as apprehended, would bring India under economic constraints needs a thorough and in-depth study at the scientific (environmental, agricultural, medical), intellectual and also at the political level to evolve ways and means to reduce its impact and to get the best out of it.

**TRIPS and Pharmaceutical Industry of ISM**

As far as the pharmaceutical industry in the conventional sense is concerned, it would be sharing the common lot of the universal impact. But as far as the ISM (Ayurveda, Unani and Sidha) pharmaceutical industry is concerned India has to be more vigilant and rightfully more assertive, though much of the commitments have already been made while accepting the GATT resolution at Uruguay and the matter on the world scene has been decided and closed.

India had some chance to assert itself in so far as the application of the TRIPS Agreement is concerned, specially in case of drugs of ISM and their exploitation by India before any other country starts in putting its claim on a legitimate ground that the science of Ayurveda and invention of its numerous drugs and formulations have been made by its scholars and added to their perfection during the last several years.

In this regard, the objections raised to the TRIPS Agreement in India are of immense importance. After a few months of the Uruguay Round of GATT negotiations the reaction in India was so vehement that it rocked the whole country. In the month of October 1993 at Bangalore protest against the patenting of agricultural products took place. The Karnataka State Farmers’ Association, headed by MD Nanjundaswamy, said that farmers were demonstrating for collective control over seeds and plants specifically targeting the W R Grace, a U.S. based chemical company. Basis of the complaint of the Indian farmers with the U.S. company was the ‘neem’ tree (*Azadirachta indica*) of India which is blessed with many medicinal virtues and is rightly called the ‘village pharmacy’. This fast growing, ever green tree provides leaves, barks, flowers and seeds for curing a number of ailments in ISM. Its twigs are used as antiseptic toothbrushes (*Datoon*) by Indian peasants, and its oil is used in India as a natural insecticide and contraceptive, and for making soaps. Even the tooth pastes like ‘Neem toothpaste’ is made out of neem. Timber of neem is also resistant to termites. A report by the National Research Council, USA, in the Year 1992
showed how the neem could function as a ‘tree for solving the global problems’.

**Position of Drugs of ISM under Indian Law**

Under Indian law, agricultural products can not be patented. The TRIPS Agreement obliges the signatories to provide protection for plant varieties either by a patent or by an effective *sui generis* system of protection. The TRIPS Agreement sets forth specific standard concerning the availability, scope and use of intellectual property rights. In the Agreement the following articles are included detailing what constitutes adequate patent and trade secret protection.

Article 27 (1) of the TRIPS Agreement states that, subject to various qualifying provisions, patents are to be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Article 27 (2) states that members may exclude from patentability invention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.

Article 27 (3) states that members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members are to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

This latter provision in Article 27(3) was the principal target of the protests by the Karnataka State Farmers’ Association in India.

Article 28 includes among the exclusive rights that a patent shall confer upon its owner the right of assign (i.e. transfer) the patent and to conclude licensing contracts. Article 30 states that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate rights of the patent owner, taking into account the legitimate interests of third parties.

Article 31 states that, where the law of a member country allows for any other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, twelve detailed standards must be met. These standards are at least as demanding as the standards set forth in the US Clean Air Act for the compulsory licensing of air pollution technology.
Amendments Required

In view of the above, it is desirable that the Department of Industrial Policy & Promotion to consider the implementation of TRIPS Agreement under WTO obligation. Provisions under Article 27 (3) of TRIPS, amendments be made in Patents Act, 1970 under 3(J) as given below:

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<th>Article 27(3)(B)*</th>
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<td>3(J) Plants, minerals, metals and animals other than microorganisms, and essentially biological process for the protection of drugs or medicine. Taken for minerals/animals.</td>
<td>As regards protections to plant varieties, it may be taken for minerals/metals and also for animals and the option will be sui generis system and not through patent.</td>
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If a new patent is to be registered for any invention (whether product of process) the inventor should submit the proof for his/her invention other than the definition given under 3(J) above.

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Screening of Raw Materials

For patent rights with respect to properties/actions, efficacy, etc. screening of the raw materials (plant, mineral and animal) has to be done as one single medicinal plant is attributed with a number of medicinal properties/-action/therapeutic uses, etc. as given in the Indian classical texts as well as modern scientific literature. Screening for their pharmacological activities for their single chemical constituent or active constituent. (therapeutically effective compound) has to be done throughout the country for the drugs used in ISM as a whole. The Forum of Parliamentarians on Intellectual Property Rights has suggested that the patenting authorities may be provided with the information in a format described in Annexure 1.

Trade History of Raw Materials

The history of trade of raw materials (crude drugs of plant, mineral and animal origin) goes back to antiquity. Many drugs of plant, mineral and mineral origin available in this country have been exported to middle eastern, European and western countries through crude drug dealers and the drugs of foreign origin have been imported into India for manufacturing the drugs of ISM since remote past. A number of drugs of Indian origin are being exported to China, Malaysia, Korea and many middle-east countries. Similarly, a number of drugs of Chinese, Indonesian, Malaysian and middle-eastern countries are imported into India through various channels especially through the crude drug dealers.

*It has been changed as given above in place of the original definition, which is probably coined for the aspect of biodiversity and not for drugs. For the drugs the newly-coined definition may be adopted and recommended to the Department of Industrial Policy and Promotion, Ministry of Commerce & Industry, though the original definition has been taken from the TRIPS Agreement given under Article 27(3).
in our country for centuries. The trade in the raw material is a billion dollar business but without any exact information on their supply and demand for our country to abroad and vice versa. So far there is no agency in the country to provide the authentic data in respect of supply and demand of the raw material used in ISM. The Medicinal Plants Cell has already been established in the Department of ISM & H, a few years back, to look into such type of matters on the basis of recommendations of the Regional Seminars on Medicinal Plants held at Jamnagar, Coimbatore, Guwahati, Nainital and Manali, sponsored by WHO. The proceedings of these seminars, already published, provide immense information on different aspects of medicinal plants.

There are 1,500 to 2,000 medicinal plants species reported to be used in ISM. The Ayurvedic Formulary of India, Pt.-I, gives a list of 351 drugs, Unani Formulary of India gives a list of 342 and the Siddha Formulary of India gives a list of 311 drugs of plant origin. On this aspect a paper entitled “Medical Plants used in ISM, their Procurement, Cultivation, Regeneration and Import/Export aspects—A Report” has been published by the author, gives a total background on different aspects concerning with the medicinal plants used in ISM.

**National Level Institutions and Trade Market**

There are many organizations and institutions in the country like CSIR, ICMR and NBPG, etc. working on the cultivation aspects of the medicinal plants used in ISM but still not exact data are available on the supply and demand of the raw materials (crude drugs) to solve this gigantic problem faced by the government. The trade of crude drugs is still in the hands of the private crude drug dealers of different cities such as Amritsar, Mumbai, Chennai, Delhi and Calcutta. Delhi (khari Baoli) is supposed to be the biggest crude drug market in Asia and then comes the crude drug dealers with the name Burra Bazaar Chamber of Commerce, Howrah, in the country. Small markets such as Hyderabad, Kanpur, Nagpur, Dehradun and Guwahati also deal with the crude drugs procuring their raw materials either from the wild sources or through these drug dealers and also through their own contacts involved in this business for centuries together as their ancestral business.

In south India, Tinnervely and Cochin are important places to deal with the trade of crude drugs. There are many importers and exporters in the cities such as Delhi, Mumbai, Chennai, Trivandrum and Calcutta who deal in the import/export of the raw material used in ISM through seaports under the customs control. Many of the drugs available in China, Japan, Malaysia, Indonesia, come through Mayanmar to Guwahati market in the eastern part of the country. Many drugs enter into the country through Tibet and J & K and reach Amritsar market. Many of the raw materials of African and Arab origin specially the gums (like Gum Somali, Mastich, Myrrh, Balsam and
Heeng, etc.) are imported through Mumbai, Kandla, Cochin, Chennai and Howrah ports. A number of drugs of Mediterranean, Iranian and Middle-East origin find entry into the country through the drug dealers and also through contacts with Afghanistan, Pakistan and vice versa. Under the OGL Policy of Import/Export (1988-91) only 52 drugs of plant origin along with 11 of mineral origin find entry into the country. However, drugs like almonds, resins, pistachio are imported into the country as dry fruits. Similarly, a number of drugs of our country are exported to many countries where they have the demand. Condiments and spices like cardamom, peppers, cloves fall under this category. Many of the drugs of Indonesian, Malaysian and Chinese origin are also imported into our country either through seaport of Cochin, Chennai, Howrah or through Bangladesh and Mayanmar by land routes.

Pharmacopoeial Drugs: Supply and Demand

In British Herbal Pharmacopoeia, 246 plant drugs are described in which a number of drugs are Indian origin. In books on medicinal plants of Vietnam and China, 200 and 150 drugs of plant origin respectively are described. Similarly, the WHO publication entitled ‘The Use of Traditional Medicine in Primary Health Care’ describes 48 plant origin drugs. The business and the trade in traditional system of medicines as practised in China and other eastern countries involve millions of dollars business per annum. In our country itself it goes to crores of rupees.

Conclusion

In view of the above, and since no exact information is available on the supply and demand of the raw material used in ISM in the country till date it is, therefore, suggested that the project on “Assessment of Supply and Demand of Crude Drugs (Raw Materials) used in ISM” may be taken up on war-footings to solve the problem of patenting in the country.

References


11 Use of Traditional Medicinal in Primary Health Care, A Manual for Health Problems in South-East Asia (World Health Organization, Regional Office for South-East Asia, New Delhi) 1990.

12 Wealth of India-Raw Materials (Council of Scientific & Industrial Research, New Delhi) Vols I-IX.
Annexure 1—Format on Indian medicinal plants

(As proposed by the Forum of Parliamentarians on Intellectual Property Rights)

Name of the reference book
Name of the plants may be taken from the classical books of Ayurveda, Unani and Siddha, specially those listed in Schedule I of the Drugs and Cosmetics Act, 1940. This may be assigned to the various organizations and institutions engaged in this field specially the Department of ISM & H.

Sanskrit name
For this, the classical books available in the respective systems may be screened by these organizations.

Colloquial names
For this, the books like Glossary of Indian Medicinal Plants, The Wealth of India, Kirtikar and Basu, and Materia Medica by Nadkarni, etc. may be referred. The Ayurvedic Formularies of India have also given vernacular names for the drugs used in Ayurveda. The Department of ISM & H having the records for the name of the medicinal plants appearing in AFI (Ayurvedic Formulary of India) and NFUM (National Formulary of Unani Medicine) collected from the experts throughout the country.

Botanical names and equivalents
The Ayurvedic Formulary of India, National Formulary of Unani Medicine, The Siddha Formulary of India have given the botanical names with their synonyms for the drugs appearing in these formularies. However, the Wealth of India, Glossary of Indian Medicinal Plants, and Nadkarni’s Materia Medica may also be referred.

Usages as mentioned in ancient text books
This may be done by the experts on the subject of the respective systems in the country.

Modern medical equivalents of the diseases where they are mentioned to be effective
This may be got done by the experts/physicians of the respective systems and members of the respective Pharmacopoeia Committees constituted by the Ministry of Health & Family Welfare in the Department of ISM & H. Further, the equivalents for Ayurveda and Unani terminologies have also given in the respective formularies with their modern equivalents.