



Traditional Knowledge Related IPR and their Bioprospecting for Development of Nutraceuticals and Health Care Products

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Abstract

Bioprospecting and bioindustry in the third world have a good relationship with genetic resources and associated traditional knowledge (TK). Nagoya protocol and IPR are mutually supportive demanding regional and community level interactions. Case studies are profiled for each sector to heighten understanding of current ABS practices. Based on the technology transfer of Jeevani, JNTBGRI (Jawaharlal Nehru Tropical Botanical Garden and Research Institute, India) has decided to share 50% of the license fee and royalty with the Kani tribes who provided original lead for the development of drug, Jeevani. Through this equitable benefit sharing, JNTBGRI model/Kani model/Pushpangadan model is claimed to be unique and is claimed to be the only known case where Article 8 (j) and Article 15 of the Convention on Biological Diversity (CBD) was fully implemented and recognized the Intellectual Property Rights of a tribe. The paper suggests a few policy initiatives and it will lead to addition, technology transfers, and IPR protection for TK holders. The details of these aspects are discussed in the paper.

Keywords: Biodiversity; Bioprospecting; Traditional Knowledge; Nagoya Protocol; Kani Model of Benefit Sharing; Value Addition

Introduction

The incredible ability of humankind in exploring the natural resources around him to his advantage has indeed made human species as the most successful/powerful organism on planet earth. Mankind has started their life in the forest system and worked as an integral part of the forest ecosystem. Close association of mankind acquired certain knowledge about the biodiversity by instinct trial or error or experimental methods. Of the 573 communities of tribal and Scheduled Castes are thus eligible to receive special measures. The Oraon adivasis or Kurukh tribe group inhabiting various states in India could be included in the Australoid group. They know their ambient biodiversity by instinct for food, medicine, fuel and other purposes. In 2018, it was recommended by the government of India that all private satellite channels 'refrain' from using the nomenclature 'Dalit' though rights groups and intellectuals have come out against any shift from 'Dalit' in popular usage.

Ayurveda

Ayurveda of ancient India had a clear understanding of rejuvenation therapy known as 'Rasayan chikitsa'. 'Rasa' in Sanskrit means the essence of nutrients and 'ayana' means to circulate in the body without any obstruction. Rasayana is thus one of the eight clinical specialties of Ayurveda. Rasayana is a specialized procedure practiced cleansing the body from various toxic substances and help to rejuvenate the body system by specialized food that gives powerful antioxidants and revitalize the body. The functional efficiency can be revived and revitalized system by elaborative and specialized system of practice to rejuvenates the whole body and develop vitality and longevity and regain youthfulness of the body. This kind of specialized herbal therapies for the treatment of diseases that are obstinate and incurable [1].

Functional food and nutraceuticals

With the advancement of molecular biology and genetic engineering, and their ability to understand and manage health prob-

lems at molecular level have increased. Right food and nutrition that suits genetic constitution are well understood. It is therefore, possible to design individualized food based on one genetic make-up called 'nutrigenomics'. The nutritional experts in the close of 20th century led to the nutritional recipes can be best for maintaining a healthy life. The development of health foods/pharma foods or nutraceuticals is therefore depending on the value addition in the tradition of natural food of India which has over 5000 years of heritage. People living in the various agroclimatic regions and age groups have prepared various food items that suit them best. These will have tremendous impact on health securities of the nation with Rasayana and phytochemicals and phytonutrients that gives the best health and prevent diseases. Thus, it will be a great challenge for the nutritionist, physician, food technologist and food chemists in the years to come.

Strategies for development of nutraceuticals in India

There are many future strategies for this group of companies must include:

- o Production and marketing of functional 'me too' products in case the original product or functional ingredient is not protected by patents.
- o Exploitation and further R&D for development of functional ingredients discovered by researchers of scientific institutes.
- o Development and marketing of specific functional niche products with the help of innovative suppliers.
- o Development of functional ingredients in specialized biotech companies.
- o Production of functional private label brands.
- o Collaboration with scientific institutes in the area of fortification of the normal food to make it a functional food, thereby providing a value added product.

Need for strong R&D

There is an urgent need to establish a highly competent R&D institution in India to scientifically investigate the traditional diets and health food of Ayurveda and develop novel scientifically validated standardized globally marketable health foods/functional foods/health foods and nutraceuticals. Thus R&D institute may develop appropriate parameters for quality control, assessing safety and efficacy, shelf life etc.

The traditional knowledge in India functions through two social streams particularly the traditional medicine. One is the local folk stream which is prevalent in rural and tribal villages of India.

Millions of house wives and thousand traditional birth attendants, bone setters and practitioners and experts in snake bite at village level practiced by tribal physicians called 'Vaidyas'. The traditional health system at second level is the scientific or classical systems or the codified system organized medical wisdom with sophisticated foundation and theoretical philosophical explanations that led to other surgical systems in Aurveda, Siddha, Unani, Amchi, Tibetan etc.

All the above systems are deeply rooted in the tradition, culture, and custom of the people. Siddha system by sage Agasthya was believed to be originated in South India and whereas in North India the Ayurvedic system of medicine. The Buddhist monks in the Himalayas and the Unani system which was brought by the Mugalans gained much popularity in the whole of India. The self-reliant medicine system, ethnomedicine is deep rooted in the community's social tradition and knowledge system.

Traditional medicine

The basic similarities prevalent in the Indian and Chinese system of medicine are now being widely appreciated in the world over. Many degenerative gerontological disabilities and metabolic disorders have found to be no cures in modern medicine are now being corrected by the traditional remedies of India and China. 'Rasayana' and 'Panchakarma' method of treatment of Ayurveda are the two important treatment regime attaining greater appreciation and acceptance in this context.

The mechanization and undue objectification of human life and health care systems of the present era have culminated to an extreme nexus between physician and patient by the interpolation of a third entirely mechanical thing, the machine, replacing the creative synthesizing role of the traditional physicians. In contrast to this scenario of the modern medicine, the traditional medicine attempts to embody a holistic approach. It emphasizes the view point that ill health or disease is brought about by an imbalance or disequilibrium of man's physiological, psychological, behavioural, ecological and spiritual environment. Modern health care system stressed more on the curative and to a lesser extent to the preventive aspects of diseases and very little has been done on the health promotive aspects. Problems of health have been replaced by problems of drugs and diseases. Modern medicine is more concerned with the cure of disease but remains indifferent to health preservation. There have been an ever increasing production and consumption of phytomedicines based on various traditional

systems of medicine both in the developing and developed countries. A global market for many traditional medicines in India and China is fast emerging.

All India coordinated research project on ethnobiology and Genesis of Ethnopharmacology research in India

The term 'Ethnopharmacology' was used while discussing the theme 'Traditional Psychoactive Drugs' in this Symposium held at San Francisco in 1967 [2]. Prof. M. S. Swaminathan then (1976) Director General of Indian Council of Agricultural Research, suggested the idea of starting a multi-disciplinary and multi-institutional research program in ethnobiology. Dr. T. N. Khoshoo along with Dr. E. K. Janaki Ammal conceived the project on ethnobiology and it was started first by Department of Science and Technology, Govt. of India in 1982 then transferred to Ministry of Environment and Forest, under the Man and Biosphere Programme (MAB) of UNESCO. Pushpangadan was appointed as the Chief Coordinator of AICRPE.

Indiscriminate and unplanned programme of Govt. of India has resulted in the use of biodiversity use by tribals was affected badly. There were 27 centers in the country and over scientific personnel drawn from Botany, Zoology, Anthropology and Sociology worked in this project. 84.3 million of tribal people belonging to 227 ethnic groups speaking 116 different dialects of 227 subsidiary dialects spoken by tribal of India. The traditional knowledge of these communities using the ambient biodiversity was the major focus of the investigators. Traditional knowledge on about 10,000 plants has been collected during the course of the project. Out of this 8000 were used as medicinal purpose, 950 are found to be new claims and worthy of scientific scrutiny. About 3900 wild plants were used as edible purposes and 250 of them are worthy of investigation. Out of 400 plant species used as fodder 100 are recommended for wider use. 300 wild plants are used by tribals as piscides or pesticides. Of these, 175 are new information worthy of detailed investigation [3].

A workshop on ethnobiology was organized by Ministry of Environment and Forest in 1985 in association with the International Institute of Ayurveda (IAA), Coimbatore, Tamil Nadu by the AICRPE Co-ordination Unit. In this workshop there were 185 participants coming from 30 administrators at the level of Secretary, Directors and Forest Conservators, 35 Scientists, 60 representatives from leading voluntary organizations and 60 tribal representatives. It was resulted from the deliberations of this workshop and

recommended the resource base due to deforestation caused great hardship and economic misery to tribals. There emerged from the discussions and debates of AICRPE project recommendations including the economic status and quality of life of the tribal people [3,4].

A second conference namely 'Dhishana 2008' was organized by Ministry of Environment and Forest at Thiruvananthapuram, Kerala. This conference was supported by the agencies like NMPB, CAPART and DST. The major objective of the conference was to evolve appropriate sui generis mechanisms in the context of CBD, WTO and TRIPS requirements. Scientists, legal luminaries, policy makers and activists together with representatives of TK holders from tribal and non tribal back grounds came together for the purpose. The conference came out with the Thiruvananthapuram Declaration on Traditional Knowledge (TDTK), a land mark document on TK and biodiversity, with focus on tribal communities of Kerala [5].

Major bioprospecting areas in traditional knowledge

Bioprospecting of traditional knowledge covers a wide range of commercial activities, including pharmaceuticals, biotechnology, seed, crop protection, horticulture, botanical medicine, cosmetics and personal care, food and beverage sectors etc [6,7]. The major players of bioprospecting include multinational companies (in private and public sectors), R & D institutions, universities, botanic gardens, etc. Genetic resources and associated traditional knowledge provide the key resources and biotechnologies offer the key tools relevant for these bioprospecting sectors. The ways in which they use genetic resources and biotechnologies would vary among and between these sectors depending upon the ultimate aim and targets of each bioprospecting activity. The quantum of genetic resources or their derivatives used, the leads from associated traditional knowledge accessed or utilized, and the methodological framework of various techniques and tools employed would differ significantly in each bioprospecting activity. These are guided by a number of requisite factors such as the capability of the bioprospecting companies or institutions in terms of infrastructure, human resources and technological capabilities, as well as the existing national and international policy and legal frameworks that facilitate free and regulated access to genetic resources, or their derivatives and/or the associated traditional knowledge, and more importantly the ultimate objectives of the bioprospecting mission envisaged. For example, among the above-mentioned major players in bioprospecting programmes, the pharmaceutical and agrobiotechnology industries are the prominent ones and have a

major stake in the global bio industrial regimes. They use genetic resources in significantly different ways. There is diversity of genetic resources use and biotechnological interventions within and between the bioprospecting sectors, which is influenced greatly by the following factors such as 1. size of industries and markets for the products, 2. role of natural products in these markets and percentage of sales contributed by genetic resources, and 3. relationship between commercial products and the genetic resources from which they are developed [7].

Significance of bioprospecting of traditional knowledge

Bioprospecting of Traditional knowledge can contribute significantly towards sustainable development, if managed within the strictures of national and international laws and policies. Despite the criticism on bioprospecting as one way of commercial exploitation of bioresource with the only motive of economic returns and protection of industrial properties, the scope and utility of bioprospecting are many, particularly for the biodiversity – rich countries of the tropics. The new international legal instruments such as Convention on Biological Diversity (CBD) could facilitate bioprospecting an equitable partnership that would be socially, economically a biologically sustainable. Tropical rain forests and marine biomes supporting coral reefs are potential natural resources bases that constitute the biological capital for successful bioprospecting endeavors. The diversity of indigenous cultures and the treasure of indigenous knowledge systems also provide vital leads to undertake sustainable bioprospecting programmes in the tropical developing countries like India, Brazil, Mexico, Malaysia, etc.

The genetic diversity and chemical polymorphisms displayed by tropical biota represent an untapped resource wealth. Harnessing this genetic wealth through modern chemical and gene prospecting methods form the focus of the drug and pharmaceutical programmes initiated by several multinational biotech or biomedical firms like Glaxo International, Merck and Co. Inc., National Cancer Institute, U.S.A., Pfizer, etc. Gene prospecting aimed at production of improved varieties of plants, livestock, transgenic organisms are also yet another aspect of bioprospecting.

Chemical and gene prospecting of wild biological resources of actual or potential values will have significant application in agriculture, medicine and industry. Bioprospecting can bring forth substantial economic returns from the products and processes to be derived from biodiversity and biotechnology. For an example, in an analysis Mendelsohn and Balick [8] estimated that a complete collection and screening of all tropical higher plant species

(i.e., 125,000 spp.) should be worth about \$ 3-4 billion to a private pharmaceutical company and about \$ 147 billion to a society as a whole. Their analysis also predicted that the higher plants in the world's tropical forests would contain 375 potential pharmaceuticals of which 48 have already been discovered. Similar estimates on the value of several others unexplored or untapped resources of NWFPs (Non-Wood Forest Products) of tropical forests would indicate the scope and magnitude of possible economic benefits this biome could render to humanity [9].

WTO/TRIPS agreement (1995) do not recognize any informal knowledge/innovations of traditional community for granting intellectual property rights. Moreover, WTO and TRIPS do not insulate TK from IPR piracy by interested groups. Intellectual Property Rights is recognized by national and international laws and patents can be sold like any other commodity. Starting with industrial applications, later on arts and literature were also covered under the regime of the General Agreements in Tariff and Trade (GATT). The attempt to include TK under the IPR regime is the latest development.

Govt. of India has enacted necessary statutes and established several national bodies as in the case of Biodiversity Act (2002), Biodiversity Rules (2004), National Biodiversity Authority and Biodiversity Boards, Protection of Plant Varieties and Farmers Rights Act (2001) and Protection of Plant Varieties and Farmers Rights Rules (2003) etc. Since traditional knowledge is the core strength of India, unlike technology lead innovations in developed countries, a sui generis regime for traditional knowledge is felt essential for the country, on a case to case basis and with due care taken on benefit sharing with indigenous communities. The complex and vast area of traditional knowledge in India, with millions of uses for biodiversity requires a mammoth effort to streamline. The present effort is an attempt in this direction. The AIHBPD team lead by Dr. Pushpangadan of this project has played important roles in the national and global debates in promoting traditional knowledge, IPR and benefit sharing with back up of technology. The recommendation of the conference in the form of Thiruvananthapuram Declaration was issued by a group of eminent scientists, traditional knowledge stakeholders, academicians and activists which is incorporated in the end of this article.

Mutually agreed terms (MATs)

Article 15.7 of CBD stipulates that the results of scientific research and development and any other benefit arising from the sustainable use of a genetic resource accessed by a Party shall be shared with the Contracting Party providing the resource in a fair

and equitable manner based on “mutually agreed terms”. The basic principles for developing MATs are almost the same as discussed above under PIC but may focus more specifically on terms and conditions that both the Parties will agree up on for an effective and transparent, legally binding ABS process. The Bonn Guidelines suggest the following basic requirements for arriving “mutually agreed terms” between the provider and user countries for access and granting of genetic resource.

Permitting only use of resources in order to take into account ethnical concerns of the particular indigenous and local communities concerned and provisions for joint IPR rights according to degree of contributions.

Material Transfer Agreements (MTAs)

All access permits or license or any other means of granting access to genetic resources and associated knowledge should be appended with a standard “Material Transfer Agreement” by the provider country to the user as per prior informed consent and mutually agreed terms. MTAs may vary in their formats and contents depending up on the type of resources and knowledge being accessed and the terms mutually agreed up on by the participant countries.

Conclusion

The value added traditional knowledge of the bioresources and transfer of TK to institutions to carry our further research to ensure the economic use of biodiversity and promote enrichment of the TK are the main agenda. The prerequisite for developing an effective ABS regime is building up a comprehensive information system on all pertinent aspects of availability, diversity, distribution, economic uses and potentials, conservation status of biogenetic resources and associated traditional knowledge along with information on the existing S and T infrastructure and capabilities, including human resource wealth, national and international legal and policy frameworks, current achievements and future plans and priorities for capacity-building for conservation, sustainable use, bioprospecting and economic valuation of their great wealth of bioresources and traditional knowledge.

Recommendations

1. That the Government of India establish a statutory authority for traditional knowledge, with central, state and district level systems, to regulate it and efforts be made to stop its further erosion and support promotion through appropriate funding and other measures.
2. There has to be collective efforts to promote fair and equitable sharing of benefits arising from the use of biodiversity, traditional knowledge and its components and any attempt to pilfer it without consent and benefit sharing be punished by international laws formed with mutual consent.
3. That the Government of India accord a special status to Tribal Healing, after due processes of screening the healers, and accord legal status, and allow them legitimate access to forest and other resources.
4. We demand that equal importance be given to the native streams of healing and other vocations, as now given to predominant systems like modern medicine, and these be made part of the health care apparatus of each country, that is in India Ayurveda and native healing techniques be made primary systems with due honor to the practitioners.
5. That a separate ministry for traditional forest communities be constituted and a new participative and eco-sensitive development paradigm evolved for the sector, taking in to account the felt needs of the people and resources available.
6. That the tribal areas be given sufficient budgetary support and a series of eco-friendly and locale specific microenterprises, say for collection and processing of wild edibles, be started to augment the quality of life in these areas.
7. That a National Tribal Development Corporation be set up with the mandate of revalidating traditional knowledge and promoting these for augmenting the incomes and well being of the tribal communities.
8. That a Consortium be set up for establishing an International Network between the biodiversity rich Nations of the world for protecting TK associated with biodiversity with a view to build a common platform of TK holders, providers, related scientists, social workers and lawyers specialized in IPR related issues to exchange their views and concerns for safe guarding the TK of their respective Nations by adopting common/specific remedial measures.
9. That a multi-pronged capacity building programme be evolved at grass root level exclusively for TK holders/providers of biodiversity rich Nations, for implementing various awareness programmes. This will enable them to take appropriate measures to check bio-piracy of bio-resources and associated traditional knowledge.
10. Ecosystem sensitive local cultures have a strategic value, and this has to be honoured and promoted. The importance of the relationship between cultural diversity and biological diversity in human survival has to be acknowledged.

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