# Chapter 6
# Ethnopharmacology, Traditional Knowledge and Intellectual Property Rights

**P. Pushpangadan, V. George, T.P. Ijinu, and S. Rajasekharan**

**Abstract** Over the last three decades, a great awakening on the link between sustainable livelihood and ecological health has emerged. Access and Benefit Sharing (ABS) was conceived as a tool for equity and as an opportunity for sustainable development. In India, the authors have developed the first model of benefit sharing that implemented in letter and spirit Article 8 (j) and Article 15.7 of the Convention on Biological Diversity (CBD). The authors, while at the Jawaharlal Nehru Tropical Botanic Garden and Research Institute (JNTBGRI), demonstrated that indigenous knowledge systems merit support, recognition and fair and adequate compensation. 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. The major challenge is to develop appropriate national policies and legal framework to provide a conducive and enabling environment to undertake bioprospecting and biotechnological innovations, giving adequate attention to the administrative as well as the legal aspects of IPR protection, benefit-sharing procedures and conservation and sustainable use of biodiversity and the associated traditional knowledge. The chapter details the development of ethnobiology in India, bioprospecting and national legislations for the protection of traditional knowledge and sustainable utilization of bioresources.

**Keywords** Ethnobiology • Sustainable use • IPR • Bioprospecting • *Sui generis system* • Ayurveda

P. Pushpangadan (✉) • V. George • T.P. Ijinu
Amity Institute for Herbal and Biotech Products Development,
Peroorkada P.O., Thiruvananthapuram 695 005, Kerala, India
e-mail: palpuprakulam@yahoo.co.in

S. Rajasekharan
Jawaharlal Nehru Tropical Botanic Garden and Research Institute,
Thiruvananthapuram 695 562, Kerala, India



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## 6.1 Introduction

Traditional knowledge (TK) and ethnobiology are community-based knowledge systems that have been developed, preserved and maintained over many generations by the local and indigenous communities through their continuous interactions with plants and animals. Ethnobiology is the information on plants and animals and their relationship with human society. It is associated with traditional communities, and therefore, it is unique to a given culture or society and is developed as a result of the coevolution and coexistence of both the indigenous culture and their traditional practices of resource use and ecosystem management. TK is a general term, which refers to the collective knowledge, beliefs and practices of indigenous/local people on the sustainable use and management of their ambient resources. Through years of observations and analysis, trial and error or experimentations, the traditional communities have been able to identify useful as well as harmful elements of their ambient flora and fauna. Such knowledge (acquired through ages) has always remained as part of their life, culture, traditions, beliefs, folklores, arts, music, dance, etc. TK covers a broad spectrum of the local and indigenous people's traditional life and culture, art, music, architecture, agriculture, medicine, engineering and a host of other spheres of human activity. TK thus can be of direct or indirect benefit to the society as it is often developed, in part, as an intellectual response, to the necessities of the day-to-day challenges of the indigenous societies. Protection and maintenance of TK of local and indigenous communities are vital for their well-being and sustainable development and for their intellectual and cultural vitality.

## 6.2 Genesis of the Subject Ethnopharmacology

Ethnopharmacology as a scientific term was first introduced at an international symposium held at San Francisco in 1967 (Efron et al. 1967) while discussing the theme 'Traditional Psychoactive Drugs'. But later Rivier and Bruhn (1979) made an attempt to define ethnopharmacology as a 'multidisciplinary area of research concerned' with observation, description and experimental investigation of indigenous drugs and their biological activities. It was later redefined by Bruhn and Helmstead (1981) as 'the interdisciplinary scientific exploration of biologically active agents traditionally employed or observed by man'. In its entirety, pharmacology embraces the knowledge of the history; source; chemical and physical properties; compounding; biochemical and physiological effects; mechanism of action, absorption, distribution, biotransformation and excretion; and therapeutic and other uses of drugs. A drug is broadly defined as any substance (chemical agent) that affects life processes. Therefore, briefly, the main component of ethnopharmacology may be defined as pharmacology of drugs used in ethnomedicine. However, none of the above-said definitions captures the true spirit of this interdisciplinary subject. Ethno- (Gr., culture or people) pharmacology (Gr., drug) is about the intersection of medical

ethnography and the biology of therapeutic action, i.e. a transdisciplinary exploration that spans the biological and social sciences. This suggests that ethnopharmacologists are professionally cross-trained – for example, in pharmacology and anthropology – or that ethnopharmacological research is the product of collaborations among individuals whose formal training includes two or more traditional disciplines. In fact, very little of what is published as ethnopharmacology meets these criteria.

Hansen et al. (1995) suggested that the objectives of ethnopharmacology should focus on:

1. The basic research aiming at giving rational explanation as to how traditional medicine works
2. The applied research aiming at developing traditional medicine into modern medicine (pharmacotherapy) or to develop its original usage by modern methods (phytotherapy)

The scientific evaluation and standardization of traditional remedies using exclusively the parameters of the modern medicine are both conceptually wrong and unethical. The evaluation of traditional remedies particularly those of the classical traditions has to be based on the theoretical and conceptual foundation of these classical systems of medicine but may utilize the advancements made in modern scientific knowledge, tools and technology. In fact, it is important to combine the best of the elements of concept and practice from traditional medicines and modern medicines with the objective to improve the healthcare system of humankind. Such an integrated approach to study and develop the holistic healthcare system is termed as the ethnopharmacological approach. The concept of ethnopharmacology research in India evolved in the 1980s independent of this international initiative.

Ethnopharmacology research in India was initiated at the Regional Research Laboratory (RRL), Jammu, in 1985, and it was observed that subjecting the traditional herbal remedies including the remedies of the classical systems like Ayurveda, Siddha and Unani to the parameters of modern medicine is not only foolish but suicidal. Both these systems are conceptually quite different. The concept of disease, its etiology, manifestation and approach to treatment, etc., are all viewed on a holistic basis contrary to the reductionistic approach of modern medicine. Only an integrated approach that combines the best of theory, concepts and methods of the classical systems of medicine such as Ayurveda, Siddha and Unani with the modern scientific knowledge (phytochemistry and pharmacology) can bring in the desired results.

The concept and methods of ethnopharmacology research thus developed by the authors involved experts from diverse disciplines, like Ayurveda and Siddha, and scholars of Sanskrit and Tamil languages (who can correctly interpret the classical texts of Ayurveda and also its theoretical basis like ‘Sankhya’ and ‘Vaiseshika’ philosophy), ethnobotany/ethnomedicine, chemistry, pharmacognosy, pharmacology, biochemistry, molecular biology, pharmacy, etc. The main objective of this approach was to develop appropriate techniques to evaluate the traditional remedies in line with the classical concepts of Ayurvedic pharmacy and pharmacology such as the

'rasa', 'guna', 'veerya', 'vipaka' and 'prabhava', in other words 'Samagra Guna' of the 'Draya Guna' concept of Ayurveda.

However, the first fully fledged ethnopharmacology division was started in 1992 at JNTBGRI, and the team could successfully demonstrate the integrated approach and could develop novel scientifically verified standardized herbal drugs. Some herbal drugs developed at JNTBGRI after filing patents were released for commercial production. Ethnopharmacological impulse to modern medicine can lead to many novel useful drugs. Traditional medicine in general is a powerful source of biologically active compounds. Ethnopharmacology has become a scientific backbone in the development of active therapeutics based upon the traditional medicine of various ethnic groups. The ultimate aim of ethnopharmacology is the validation of these traditional preparations, either through pharmacological findings or through the isolation of active substances. Harmful practices can be discouraged such as the use of plants containing tumour-producing pyrrolizidine alkaloids. The selection of plants for serious study depends basically on two approaches. One approach is the random screening of plants for their medicinal value. Another approach is the ethnopharmacological survey of plants of a particular region or cultural group based on their use in the traditional system by choosing a specific therapeutic target. The screening programme based on ethnoparmacological information has more success rate than the random screening (George and John 2008). The first and most important stage in a drug development programme using plants is the collection and analysis of information on the use(s) of the plant(s) by various indigenous cultures. Ethnobotany, ethnomedicine, folk medicine and traditional medicine can provide information that is useful as a prescreen to select plants for experimental pharmacological studies (Bigoniya 2008).

## 6.3 The Tribal Scenario in India

After independence, the national government inherited a tribal scenario evolved out of conflicting policies of the development. There was hardly any useful data to comprehend the 'felt needs' or the real needs of the varied tribal groups numbering well over 250, spreading over a large spectrum, ranging from the preliterate *Andamanese* and the *Abujhmadias* to the acculturated *Bhilalas* and the *Khasis*. They followed varied vocations, depending upon their level of cultural development, from hunting and food gathering to slash-and-burn cultivation, settled agriculture or even iron smelting. Rich in cultural heritages, they spoke various dialects and practised different customs and rituals during marriage, childbirth and death ceremonies. From animism to monotheism, they followed an array of religious beliefs, rituals and practices. Land tenure systems were different and so were the personal laws.

On the basis of historical, ethnic and sociocultural affinities, the tribal communities living in different regions can be divided as follows:

1. Northeast India comprising the states of Assam, Arunachal Pradesh, Nagaland, Manipur, Tripura, Mizoram, Meghalaya and Sikkim
2. Sub-Himalayan region of the North and Northwest India comprising the northern sub-mountainous districts of Uttar Pradesh and Himachal Pradesh
3. Central and Eastern India constituting West Bengal, Bihar, Orissa, Madhya Pradesh, Andhra Pradesh and the Andaman and Nicobar Islands
4. Southern India covering Tamil Nadu, Karnataka, Kerala, Pondicherry and Lakshadweep
5. Western India including Rajasthan, Maharashtra, Gujarat, Daman and Diu and Dadra and Nagar Haveli

## 6.4 All India Coordinated Research Project on Ethnobiology (AICRPE), Ministry of Environment and Forest, Government of India

The All India Coordinated Research Project on Ethnobiology (AICRPE) launched by the Union Ministry of Environment and Forests (MoEF) from 1980 to 1998, under the initiative of eminent scientists of the country like Dr. M.S. Swaminathan, Dr. T. N. Khoshoo and Dr. E. K. Janaki Ammal, was perhaps the first ever comprehensive study about the tribal population of India with a focus on their traditional knowledge. The study was conducted through 27 premier national institutes to gather and document the fast-disappearing traditional knowledge of tribal communities.

The traditional knowledge to be tapped with the appropriate benefit-sharing mechanism could mean wealth for the tribes in particular and the country in general. Forests have been the home of many of these tribes, and they have a deep-rooted association with the forest and nature around. Their relationship with the forests has always been harmonious with their whole life revolving around the forests and forest resources. They have acquired unique knowledge about the use of the wild flora and fauna through generations, most of which is either lesser known or hitherto unknown to the outside world; this treasure of traditional knowledge (TK) system, if subjected to scientific scrutiny, could benefit them, the country and the humankind in many ways. The inroads of modernization are presently posing a threat to the TK system, and this age-old wisdom is in the imminent danger of being lost (AICRPE 1992–1998).

### 6.4.1 Workshop on Ethnobiology and Tribal Welfare

A national workshop on ethnobiology and tribal welfare was organized on behalf of the Ministry of Environment and Forests, Government of India, in association with the International Institute of Ayurveda (IAA), Coimbatore, Tamil Nadu, by the AICRPE Coordination Unit. The aim of this workshop was to bring together the senior administrators, planners, scientists and voluntary agencies associated with tribal welfare programmes as well as the tribal representatives in order to interact and evolve ways and means by which the information generated from AICRPE could immediately be translated into action. The 3-day deliberation emerged in the context of the fact that the destruction of the material resource base due to deforestation has caused great hardship and economic loss to tribals. After the discussions on the various issues and problems of the tribals and also keeping in view the AICRPE project findings, specific recommendations were made for improving the socioeconomic status and quality of life of the tribal people, and the same was submitted to the Ministry of Environment and Forests, Government of India (Pushpangadan 1993).

Another national conference, as part of the AICRPE, to streamline the traditional knowledge towards a sui generis regime in the post-World Trade Organization (WTO) scenario named 'Dhishana 2008' was organized in association with the Ministry of Environment and Forests, Government of India, during 23–25 May 2008, at Thiruvananthapuram, Kerala. This was also supported by the other ministries and agencies of the Government of India. The major objective of the conference was to evolve appropriate sui generis mechanisms in the context of CBD, WTO and Trade-Related Aspects of Intellectual Property Rights (TRIPS) requirements. Scientists, legal luminaries, policymakers and activists together with the representatives of TK holders from tribal and nontribal backgrounds came together for the purpose. The conference came out with the Thiruvananthapuram Declaration on Traditional Knowledge (TDTK), a landmark document on TK and biodiversity, with focus on tribal communities of Kerala (Pushpangadan and Pradeep 2008).

### 6.4.2 Appropriate Policy Guidelines Derived in the National Seminar: Dhishana

Appropriate national policy guidelines on biodiversity and access and benefit sharing on biogenetic resources and traditional knowledge are in place in many like-minded countries. One of the priority actions for these countries would be to evolve effective mechanisms for developing as well as implementing relevant legal instruments that could facilitate regulated access and benefit-sharing regime with stringent provisions to prevent any illegal and inappropriate access and transfer of genetic resources and associated knowledge by any individual or corporate bodies with vested interests. The second important priority of these countries would be to

concentrate their efforts in developing national and regional science and technology (S&T) capacity building and human resource development programmes for harnessing the wealth of biogenetic resources and traditional knowledge shared by these countries. Building up equitable bioprospecting partnership among the countries based on mutually agreed terms and transparent legal and policy support will be a promising area that will help multilateral exchange or transfer of biological resources, associated information and knowledge and relevant technologies, besides helping to build up human resources in the most advanced areas of biotechnology, herbal technology and information technology. Mutual trust and cooperation built through multilateral stakeholder consultations between the countries and other groups of developing countries or countries with economies in transition can go a long way in bringing a new era of bio-partnership. Since the like-minded countries have shared concerns and interests to protect their biodiversity and traditional knowledge systems, any collective efforts of the group will help them challenge the threats of increasing incidences of biopiracy and misappropriation of intellectual property rights (IPR) of their biodiversity and traditional knowledge systems by the powerful lobbies of biotechnologists. What is more important at the national level for all like-minded countries is to reaffirm their commitment in evolving a transparent and viable mechanism for regulated access and benefit sharing of genetic resources and associated traditional knowledge. 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. This should be integrated with the information on the existing S&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, the sustainable use, bioprospecting and economic valuation of bioresources and traditional knowledge.

Fundamental issues of the Indian policy like the present modalities in signing the international protocols and treaties were addressed as also the basic problems of the tribal areas and conservation of biodiversity. Prof. M.S. Swaminathan in one of his addresses said that the path towards sustainable food security is ‘evergreen revolution’ which will help increase productivity in perpetuity without the associated ecological harm. He stressed the need for blending traditional knowledge with modern science. He added that it is only such a blend that would empower us in the area of meeting the challenges posed by climate change and transboundary pests, as well as the shrinking per capita water availability and the expanding biotic and abiotic stresses.

The majority of the tribal representatives were critical of the trade motive in tribal medicine and did not want to have direct deals with any company. ‘Our knowledge is divine and we honour it, selling it to foreign companies is ruled out’, said K. K. Suresh, a tribal healer and leader from the Kurichia community in Wayanad. Prathapi Guni, from the Guni tribal community in Udaipur, Rajasthan, told about an instance where the Gunis refused to share the knowledge of a formulation when asked by an Indian company for making a drug as they did not trust them. According

to the tribal healers, there has to be a mechanism of the government that will be an intermediary between the tribes and the companies if at all some drugs are produced. They are willing to share the knowledge with a government agency but not with a private company.

The conference was attended by more than 350 delegates and invitees from the different parts of the country including the representatives from tribal communities of Arunachal Pradesh to Kerala. The 3-day national conference came to an end with very meaningful deliberations, and there was an immense cross flow of information. Broadly, the following major conclusions were arrived at:

1. The TK, mainly the tribal knowledge, is undergoing erosion and needs to be protected.
2. There is a hesitation among the tribal people about allowing access to their knowledge to private companies for trade; trade is not their objective.
3. They expect the government to build a mechanism with their representation, and this should deal with all matters of TK.
4. The need for a case-specific legal system, what is called sui generis, but not aimed at catering to international pressure, is needed for safeguarding and promoting the knowledge and getting returns from the same.
5. There has to be revalidation of TK, wherever these are made use of outside the locale, say when healing techniques of one tribal group are used by others.

The Indian TK, including Ayurveda, is self-contained and they have their own scientific explanation; these need not be explained by modern science and its methodology.

## 6.5 Protection of Traditional Knowledge

Over the last three decades, a great awakening on the link between sustainable livelihood and ecological health has emerged. This understanding has led to various international, regional and local dialogues, development of laws and regulations in conservation and sustainable use of trade and commerce of bioresources. Side by side, research and development in science and technology led to enhanced value addition in primary biological products thereby creating wealth from the bioresources. The developmental strategy of the world in general is now focused on achieving a new world order marketed by equity and human welfare. The whole gamut of sustainable development of biodiversity is expressed in terms of conservation and sustainable utilization. The UN regulations like the Convention on Biological Diversity (CBD) have provided a basic framework for countries to evolve appropriate regulatory mechanism for achieving the above goals. Immediately after the adoption of CBD in December 1993, in June 1994 another international agenda of the World Trade Organization (WTO) emerged to control the economic order of the world. Throughout history, biodiversity has been the common asset of the local communities, with both resources and knowledge being freely exchanged, and the

concept of sovereign rights or property rights of genetic resource was alien to the traditional communities of the third world countries. CBD has honoured these traditional practices and offered protection under Article 3, Article 8(j), Article 10(c), Article 15.7, etc. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of WTO brought in 1995, however, had a different agenda. CBD is founded on the principle that the local communities are dependent on biodiversity and should continue to benefit from it. The WTO administers a global trading system, much of which is founded on the private monopoly rights of traditional corporations over biodiversity.

CBD, on the other hand, is based on the principles of equity and ethics and, therefore, has far more flexible provisions concerning protection of the rights of traditional communities over their intellectual property and traditional resources. Article 8(j) and Article 15.7 of CBD explicitly express the need for recognition and rewards for indigenous people's contributions to conservation and sustainable use of biodiversity. It reads as: 'Respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices'. The other important provisions of CBD that call for support and recognition of indigenous and traditional technologies are contained in Articles 10(c), 11, 12, 13 and 16. However, Article 16 is the one that is unequivocal about the protection of IPR of the traditional communities. More detailed discussions and critical analysis on CBD and TRIPS, particularly on those provisions relating to informal innovations of IPR protection for traditional communities, are available in Gadgil and Devasia (1995), Dutfield (2005), Gupta (2001) and Mashelkar (2001).

The Biodiversity Act is an important national legislation that provides provision for the protection of the traditional knowledge of the local and indigenous communities. The current IPR regime does not allow any of such provisions for recognition and reward for IPR based on knowledge of traditional communities. India's Biodiversity Act is in line with the CBD which essentially aims at conservation of biological diversity, sustainable use of its components and a fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated knowledge. TRIPS stipulates that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of the technological knowledge in a manner conducive to social and economic welfare and to a balance of rights and obligations' (Article 7, TRIPS).

Article 27 (3b) of the TRIPS requires the members to provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. These are the two rather contentious provisions in TRIPS which the developing country members like India need to address carefully. The main pitfalls in the TRIPS provisions are the failure to recognize the informal

innovations emanating from traditional societies and imposing developing countries to develop sui generis system for plant variety protection based on the 1991 International union for the Protection of New Varieties of Plants (UPOV) model (Shiva 1994). The UPOV model is designed to provide protection for the rights of plant breeders and other formal types of innovations. It excludes the rights of farmers who produce, select, improve and breed a plethora of diverse plant varieties (Shiva 1994). However, the commitment to TRIPS makes it obligatory for the members, especially the developing countries, to bring their national legislations pertaining to the protection of patents and other intellectual property rights in harmony with the provisions of TRIPS, besides developing appropriate sui generis models for the protection of plant varieties.

### *6.5.1 Intellectual Property Rights, Patenting and Sui Generis System*

The CBD acknowledges the IPR of the collective wisdom and common resources of the communities as a sovereign property, whereas TRIPS recognizes IPR as the monopolistic rights of individual or corporate innovators. This disparity provides the developing countries like India with enormous challenges and opportunities. Several countries are now working towards amending their existing laws or enacting few national legislations including sui generis model to make them compatible with the CBD and TRIPS provisions. The Government of India is quite sensitive to the fast changes that are taking place and has displayed strong commitment for the conservation and sustainable utilization of the bioresources and traditional knowledge systems of our country. The conservation of the country's rich biodiversity to ensure the livelihood security and improvement in the quality of life of the traditional communities is given a predominant position in the policies and programmes now being evolved by the various acts executed by the government. The major challenge is to develop appropriate national policies and a legal framework to provide a conducive and enabling environment to undertake bioprospecting and biotechnological innovations, giving adequate attention to the administrative as well as the legal aspects of IPR protection, benefit-sharing procedures and conservation and the sustainable use of biodiversity and the associated traditional knowledge. The Government of India has already enacted three major national legislations, viz. (i) Patent Second and Third Amendment Acts, (ii) Bio Diversity Act and Biodiversity Rules and (iii) Plant Variety Protection and Farmers' Rights Act (PVPFR Act) and PVPFR rules. These legislations contain adequate provisions that would help safeguard the sovereign rights of the country over its biological resources, protect the indigenous knowledge systems associated with biological diversity and recognize the farmers' rights to save, use, exchange, share or sell the plant varieties which they have developed, improved and maintained over many generations. The PVPFR Act also has a similar clause for opposition for revocation of a plant variety, if there is a

valid claim attributable to the contribution of the people of a village or local community in the evolution of that registered variety.

The Biodiversity Act, 2002, and the Biodiversity Rule, 2004, and the Plant Varieties Protection and Farmers Right Act, 2001, are examples of the same. The Bio Diversity Act has an enabling provision in Section 36.5 empowering the central government for protecting the knowledge of local people relating to biodiversity, inter alia through the registration of such knowledge at the community/panchayat level and developing a sui generis system of IPR protection. The Plant Variety Protection and Farmers Right Act, 2001, and Rules, 2003, deal primarily with the protection of plant breeders rights over the new variety developed by them and allow entitlement of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties which the latter have developed, improved and maintained over many generations. There are important provisions in this Act that stipulate the need of the breeder or any applicant for registration of a new plant variety to disclose any information regarding the use of genetic material conserved by any tribal or rural farmers in the breeding for the development of the new variety. The Act also ensures compensation to the contributions of any village or local communities to the development of a variety registered under this Act. Such compensations will be deposited to the National Gene Fund. The Patent Second Amendment Act 2002 and Third Amendment Act 2005 also make it mandatory to disclose the source and geographical origin of the biological material in the specification when used in an invention (Sec 8D). It also stipulates that nondisclosure or wrongful disclosure of the source of biological material and any associated knowledge will result in opposition to the grant of patent or revocation of patent (Sec 18(j); Sec 25(1), (j) and (k); Sec 25 (2) (j) and (k)).

The Biodiversity Act in 2002 and Rules in 2004 are based broadly on the objectives of CBD with special focus on the aspects of equitable sharing of benefits arising out of the sustainable use of biodiversity and traditional knowledge. The salient features of the Act are to:

(i) Regulate access to biological resources of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources and associated knowledge relating to biological resources
(ii) Conserve and sustainably use biological diversity
(iii) Respect and protect the knowledge of local and indigenous communities related to biodiversity
(iv) Secure sharing of benefits with local people as conservers of biological resources
(v) Conserve and develop areas important from the standpoint of biological diversity as biological diversity heritage sites
(vi) Protect and rehabilitate threatened species
(vii) Involve institutions of self-government in the broad scheme of the implementation of the Act through constitution of committees

The Act in general is more of regulatory in nature but contains the following important clauses pertaining to the protection of IPRs of traditional communities and benefit sharing:

(a) People's knowledge shall be protected through registration of local, state and national level by a sui generis system of IPRs (Clause 36(4) and 41).
(b) Any person applying for IPR in India and abroad relating to biological resources occurring in and accessed from India shall obtain prior permission of national authority and abide by the benefit-sharing conditions imposed by the authority (Clause 6).
(c) The national authority shall oppose the grant of IPRs worldwide relating to biological resources or knowledge derived from India (Clause 18(4)).
(d) No foreign agency can access biological resources occurring in India and related knowledge without prior informed consent of the national authority (Clause 3).
(e) The National Biodiversity Authority (NBA) in consultation with local bodies shall impose terms and conditions for securing equitable sharing of benefits. Monetary benefits shall be deposited to the National Biodiversity Fund, except in cases where the biological resources and knowledge are accessed from a specific individual or group of individuals; in which case the monetary benefits shall be directly made to the providers (Clause 21). The national fund would be used to reward people for their conservation efforts and knowledge as claimed by the village-level management council (Clause 41).

The Bio Diversity Act is to be viewed as an important national legislation as it provides provisions for the protection of the traditional knowledge of local and indigenous people and secures the IPRs arising out of the use of such traditional knowledge and traditional biogenetic resources. The current IPR regime does not allow any such provision for the recognition of the role of traditional communities in IPR.

With the changing global scenario on conservation of biodiversity leading to the UN Convention on Biological Diversity (CBD) at Rio de Janeiro in 1992 and its adoption in December, 1993, the trade sector also underwent changes. The General Agreement of Trade and Tariff (GATT) Uruguay Round particularly through the Trade-Related Intellectual Property Rights (TRIPS), World Trade Organizations (WTOs) and TRIPS agreement obliges all members to provide intellectual property protection for plant varieties at the national level, either through patents or 'an effective sui generis system' or both. Many developing countries including India have signed both in the CBD and WTO. India has now initiated legal procedures and evolved other management strategies during the past one decade.

## 6.6 Bioprospecting of Traditional Knowledge

Biodiversity represents (1) a priceless resource with many actual uses and potential values to humanity and (2) a complex self-sustaining ecological system that helps maintain the integrity and resilience of the biosphere. These two complementary perceptions would lead to the surmise that biodiversity is an invaluable natural resource, which needs to be conserved and sustainably utilized for the benefit of the present as well as the future generations of humankind. Humankind has tapped only a fraction of this great nature's genetic library. Bioprospecting is the systematic search for genes, natural compounds, designs and whole organisms of forest/wildlife with potential for product development.

Modern prospecting involves well-organized research and methodologies. Bioprospecting in essence means an activity involving survey, exploration, documentation and evaluation of biological resources and their derivatives and/or associated TK, leading to the identification and/or isolation of commercially valuable products (genes, biochemicals), compounds, derivatives and/or any other tangible and intangible components including IPR-covered processes, technologies and services derived from wild or domesticated biodiversity. With the advent of new tools and techniques, the power of bioprospecting has been incredibly increased. Modern bioprospecting now includes systematic search for genes, natural compounds, designs and whole organisms of either domesticated or wild source with a potential for product development. Bioprospecting is essentially an action-oriented multidisciplinary programme with the end in view of generating both knowledge and avenues for the development of a diverse array of IPR-covered, value-added products and their commercialization with appropriate benefit-sharing arrangements.

The prospects of exploring biodiversity for new medicines, foods, crops, insecticides, pesticides and other commercially valuable genetic and biological products and processes are booming, thanks to the rapid development in biotechnology (particularly genomics, proteomics, enzymatic and transgenic technologies), herbal technology and information technology, and this exploration of biodiversity for commercially valuable genetic and biochemical resources is termed as 'bioprospecting' (Eisner 1989; Reid et al. 1993). In short, bioprospecting involves investigation of genetic resources or biochemicals for new commercial leads (Laird and ten Kate 2002) and includes three major areas such as 'chemical prospecting, gene prospecting and bionic prospecting' (Mateo et al. 2000). The major bioprospecting areas are depicted in Fig. 6.1.

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 biotechnology offers the key tools relevant for these bioprospecting sectors. The ways in which they use genetic resources 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

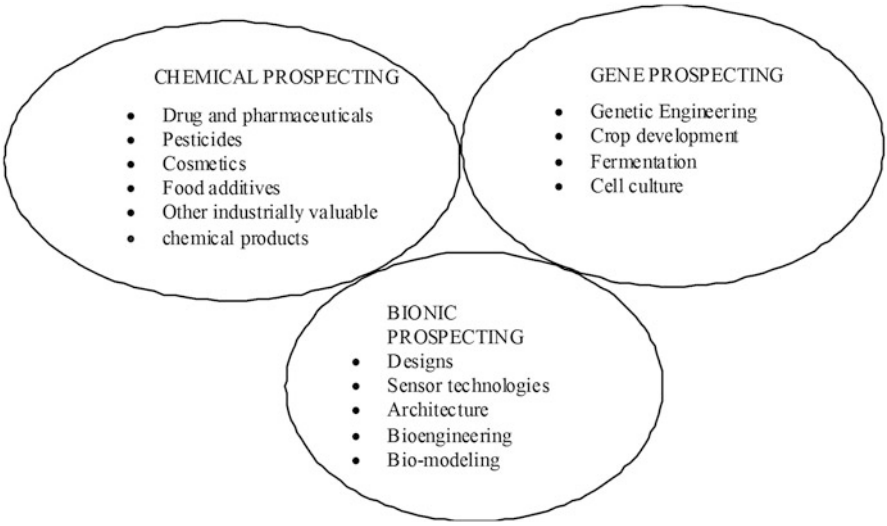


**Fig. 6.1** Major bioprospecting areas

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 policies 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 bioindustrial regimes. They use genetic resources in significantly different ways. There is diversity of genetic resources used and biotechnological interventions within and between the bioprospecting sectors which are influenced greatly by the following factors: (1) the size of industries and markets for the products, (2) the role of natural products in these markets and percentage of sales contributed by genetic resources and (3) the relationship between commercial products and the genetic resources from which they are developed (Laird and ten Kate 2002). The annual global sale values of various bioprospecting sectors are presented in Table 6.1.

## 6.7 International Regime on Access and Benefit Sharing

Developing the international law and policies to put ABS into practice is, however, far from simple. In addition, the role of traditional knowledge in bioprospecting further complicates matters. On many occasions, it is the traditional knowledge held

**Table 6.1** Annual global sale values of various bioprospecting sectors

| Sectors | Annual sale values |
|---|---|
| Pharmaceuticals | US $ 300 billion (1998 figures) |
| Crop protection | US $ 30 billion (1997 figures) |
| Agricultural seed | US $ 30 billion (1997 figures) |
| Horticulture | US $ 16–19 billion (1998 figures) |
| Botanical medicines | US $ 20 billion (1999 January–November figures) |
| Cosmetic and personal care | US $ 75 billion (1998 figures) |
| **Total** | **US $ 471–474 billion** |

Laird and ten Kate 2002

by indigenous peoples and local communities that provides clues as to the potentially useful properties of a genetic resource. The ABS was conceived as a tool to promote fairness and equity at the interstate level; however, traditional knowledge demands regulatory action at the intrastate level. Indigenous peoples and local communities reside within state boundaries, and their rights, subject to international human rights norms, are regulated by national law. Furthermore, the use of the intellectual property rights system has resulted in a series of famous biopiracy cases involving the misappropriation of traditional knowledge, including those related to turmeric, neem, ayahuasca and hoodia. The international law on ABS thus needs both to address the practical aspects of ABS transactions and to serve broader aims related to fairness, equity and justice (Tsioumani 2015). In addition, the international law needs to guide the development of domestic legislation on ABS and ensure fairness in transnational ABS transactions in order to reduce asymmetries both among parties in each individual transaction and among developed and developing states (Morgera et al. 2014).

The growing concern over monopolization of benefits led genetic resource-providing countries to restrict access to genetic resources and associated traditional knowledge. The CBD, ITPGR (2001) and the Bonn Guidelines (2002) provide a broad framework for ABS procedures. In light of the asymmetries between states providing and using genetic resources, as well as the growing expectations concerning the commercial value of biodiversity, ABS was conceived as a tool for equity and as an opportunity for sustainable development. The idea behind it was developing countries host most of the world's biodiversity, and thus commercial products developed on the basis of these genetic resources benefit mostly the companies and consumers in developed countries, and part of these benefits should flow back to the countries of origin of genetic resources.

Many countries from the South felt that while the Bonn Guidelines elaborated on access, they have left the benefit-sharing aspect relatively unspecific. The voluntary nature of the guidelines has been judged as insufficient for implementing the ABS provisions of the CBD. In order to further implement the third objective of the Convention and its ABS-related provisions, the World Summit on Sustainable Development, held in Johannesburg, called for an action (IISD 2009) to negotiate within the framework of the Convention on Biological Diversity an international

regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. In 2004, in response to this call for action, the Conference of the Parties (COP) mandated the Ad Hoc Open-Ended Working Group on ABS (COP 5 decision V/26) to elaborate and negotiate an international regime on access to genetic resources and benefit sharing with the aim of adopting instrument(s) to effectively implement the provisions in Article 15 and 8(j) of the Convention and the three objectives of the Convention, and at its ninth meeting, in 2008, in Bonn, Germany, the COP agreed on a schedule of meetings to complete the negotiations before its tenth meeting in 2010 at Nagoya, Japan. The objective of the Nagoya Protocol is the fair and equitable sharing of benefits arising from the utilization of genetic resources, with a view to contributing to the conservation of biodiversity and the sustainable use of its components. Benefit sharing is envisaged through appropriate access to genetic resources, the transfer of relevant technologies and funding. Benefit-sharing obligations also arise from the use of traditional knowledge associated with such genetic resources and genetic resources held by indigenous and local communities. In this regard, the Nagoya Protocol is particularly innovative; it is the first time that such obligations are triggered by the use of traditional knowledge for research and development purposes in an international legally binding instrument. The Protocol is also innovative in detailing measures to ensure compliance with ABS-related obligations – an aspect that was neglected under the CBD (Tsioumani 2015).

The Nagoya Protocol entered into force on 12 October 2014 having been ratified by 54 countries at that time. The first meeting of its parties (COP/MOP 1) was held from 13 to 17 October 2014, during the second week of the 12th meeting of the Conference of the Parties (COP 12) to the CBD. The major achievement of the first meeting of the Parties to the Protocol was the establishment of a compliance committee and agreement on procedures and mechanisms to promote compliance and address cases of noncompliance. The second meeting of the Conference of the Parties, serving as the meeting of the Parties to the Nagoya Protocol, will be held in Los Cabos, Mexico, in November 2016 (COP 12 Decision).

There are three key remaining areas to address to help make the ABS regime more functional: contractual mechanisms for access and for benefit sharing; domestic legislative, policy and administrative measures in both user countries and provider countries; and clarifying questions at the international level including the possibility of unregulated genetic resources in certain areas (Tvedt and Schei 2014). It is therefore increasingly urgent for the CBD to make ABS work as was intended. The entry into force of the Nagoya Protocol represents a step in this direction. The new instrument, however, cannot reach these goals alone and so much will rely on functional implementation for moving forward.

India has been a regular victim of misappropriation of genetic resources and associated traditional knowledge, which have been patented in other countries (well-known examples include *haldi* and neem). It is expected that the Access Sharing and Benefit (ABS) Protocol, which is a key missing pillar of the CBD, would rectify this problem (Mehta 2014).

As the genetic resources and traditional knowledge are transferred from the provider country to the user (industry), property rights including intellectual property rights (IPR) are the most relevant critical factors in the access and benefit sharing of genetic resources concept. There are two possibilities that exist for strengthening the property rights of resource managers. On the one hand, national governments can ensure that the local level participates in the property rights over biodiversity and the benefits that arise from their use. On the other hand, international and national patent law requires the disclosure of the origin of genetic resources when IPRs are granted (Mehta 2014). It is hoped that the Nagoya Protocol would address the imbalance arising from property rights distribution. The Protocol has strengthened the local level by asking the parties to take legislative, administrative or policy measures to ensure that benefits arising from the utilization of genetic resources that are held by indigenous and local communities are shared in a fair and equitable way with the communities concerned.

### *6.7.1 The First Indian Model of Benefit Sharing*

Based on a lead obtained from a Kani tribe of Kerala, the authors have developed an antifatigue, immuno-enhancing herbal formulation named 'Jeevani'. With the technology of production of this drug being transferred to a pharmaceutical company on payment of a license fee and a royalty of 2 % on the ex-factory sale of product, TBGRI resolved to share 1:1 of the license fee and royalty with the Kani tribe. Currently this model is acclaimed as the model to be emulated in similar situations elsewhere in the world. Although this model was worked out in early 1994 in full consultation with the Kani tribe, it took almost 3–4 years to effect this model mainly because of the inherent inability of the 'Kani' people to receive the benefit. Finally the majority of the members of the Kani tribe resolved to form a trust which was then registered, and in February 1999, the license fee and royalty due to them was transferred to the trust. The trust continued to receive the royalty accrued from the drug developed from their knowledge of a lesser-known wild plant during the entire period the patent was in effect.

This model is perhaps a unique experiment ever done, wherein the benefits accrued from the development of a product based on an ethnobotanical lead were shared with the holders of that traditional knowledge. Considering the significant outcome of this model in community empowerment, income generation and poverty eradication of a tribal community, Pushpangadan was awarded with the UN-Equator Initiative Prize (under individual category) at the World Summit on Sustainable Development held in Johannesburg in August 2002. Now with the CBD, Bonn and World Intellectual Property Organisation (WIPO) guidelines and our national legislation on biodiversity in position, the JNTBGRI or Kani case study could be taken as an ideal model of equitable benefit sharing involving genetic resources and associated traditional knowledge.

Recently, the Ministry of Environment, Forest and Climate Change (MoEF 2014) brought out a regulation called Guidelines on Access to Biological Resources

**Table 6.2** Benefit sharing as per ABS regulations, India

| Annual gross ex-factory sale of product | Benefit-sharing component |
|---|---|
| Up to 1,00,00,000 rupees | 0.1 % |
| 1,00,00,001–3,00,00,000 rupees | 0.2 % |
| Above 3,00,00,000 rupees | 0.5 % |

and Associated Knowledge and Benefits Sharing Regulations, 2014. They have written about the procedure for access to biological resources, for commercial utilization or for biosurvey and bio-utilization for commercial utilization. When the biological resources are accessed for commercial utilization or the biosurvey and bio-utilization leads to commercial utilization, the applicant shall have the option to pay the benefit sharing ranging from 0.1 to 0.5 % at the following graded percentages of the annual gross ex-factory sale of the product which shall be worked out based on the annual gross ex-factory sale minus government taxes as given in Table 6.2.

The collection of fees, procedure for the transfer of results of research relating to biological resources, mode of benefit sharing for the transfer of results of research, procedure for obtaining intellectual property rights (IPR), mode of benefit sharing in IPR, obligations of applicant in the event of the commercialization of IPR, procedure for the transfer of accessed biological resource and/or associated knowledge to third party for research/commercial utilization, mode of benefit sharing for the transfer of accessed biological resource and/or associated knowledge to the third party for research/commercial utilization, conducting of noncommercial research or research for emergency purposes outside India by Indian researchers/government institutions, determination of benefit sharing, sharing of benefits, processing of applications received by NBA, etc., have been described in detail.

## 6.8 The Key Issues Between Genetic Resources, Traditional Knowledge and IPR

The key issues are the relationship between the genetic resource and traditional knowledge on the one hand and the claimed invention on the other. This includes clarification of the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions, and how far these obligations ‘reach through’ subsequent inventive activities and ensuing patent applications. The degree of clarity and predictability of impact of any disclosure requirement, and thus its practical impact, is likely to depend on whether the requirement can be analysed or expressed in terms of patent law.

Another key issue is the legal basis of the disclosure requirement in question and its relationship with the processing of patent applications, the grant of patent and the exercise of patent rights. This raises also the legal and practical interaction of the

disclosure requirement with other areas of law beyond the patent system, including the law of other jurisdictions. Some of the legal and policy questions that arise are as follows:

– The potential role of the patent system in one country in monitoring and giving effect to contracts, licenses and regulations in other areas of law and in other jurisdictions and the resolution of private international law or 'choice of law' issues that arise in interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of GR/TK
– The nature of the disclosure obligation, in particular, whether it is essentially a mechanism to assist with the monitoring of compliance with non-patent laws and regulations or whether it incorporates compliance

## 6.9 Sharing of Benefits According to the Biodiversity Act

1. Where approval has been granted by the NBA for research or for commercial utilization or for transfer of results of research or for intellectual property rights or for third party transfer, the mode of benefit sharing shall be as follows:

   (a) 5.0 % of the accrued benefits shall go to the NBA, out of which half of the amount shall be retained by the NBA and the other half may be passed on to the concerned State Biodiversity Board (SBB) for administrative charges.
   (b) 95 % of the accrued benefits shall go to the concerned BMC(s) and/or benefit claimers:

Provided that where the biological resource or knowledge is sourced from an individual or group of individuals or organizations, the amount received under this clause shall directly go to such individual or group of individuals or organizations, in accordance with the terms of any agreement and in such manner as may be deemed fit.

Provided further that where benefit claimers are not identified, such funds shall be used to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.

2. Where approval has been granted by the State Biodiversity Board under these regulations:

The sharing of accrued benefits shall be as follows – the SBB may retain a share, not exceeding 5 % of the benefits accrued towards their administrative charges, and the remaining share shall be passed on to the BMC concerned or to benefit claimers, where identified.

Provided that where any individual or group of individuals or organizations cannot be identified, such funds shall be used to support conservation and the sustain-

able use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.

## 6.10 Certain Activities or Persons Exempted from the Approval of NBA or SBB According to the Biodiversity Act

The following activities or persons shall not require approval of the NBA or SBB, namely:

(a) Indian citizens or entities accessing biological resources and/or associated knowledge, occurring in or obtained from India, for the purposes of research or biosurvey and bio-utilization for research in India
(b) Collaborative research projects, involving the transfer or exchange of biological resources or related information, if such collaborative research projects have been approved by the concerned ministry or department of the state or central government and conform to the policy guidelines issued by the central government for such collaborative research projects
(c) Local people and communities of the area, including growers and cultivators of biological resources, and Vaids and Hakims, practising indigenous medicine, except for obtaining intellectual property rights
(d) Accessing biological resources for conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or beekeeping in India
(e) Publication of research papers or dissemination of knowledge, in any seminar or workshop, if such publication is in conformity with the guidelines issued by the central government from time to time
(f) Accessing value-added products which are products containing portions or extracts of plants and animals in unrecognizable and physically inseparable form
(g) Biological resources, normally traded as commodities notified by the central government under Section 40 of the Act

## 6.11 National Innovation Foundation

The National Innovation Foundation (NIF) conceived by Prof. Anil Gupta of IIM, Ahmedabad, was established as an autonomous society by the Government of India in 2000. NIF works for recognizing, respecting and rewarding grassroots-level innovations and outstanding TK. NIF and the Honey Bee Network under the Society for Research and Initiative for Sustainable Technologies and Institutions (SRISTI), an NGO based at Ahmedabad, have been scouting for documenting local

innovations and linking their innovations for further valorization with science and technology experts. NIF maintains a separate national register for Green Grassroots Technological Innovations and Traditional Knowledge and so far has screened over 70,000 innovations and TK. The NIF scouting and documentations involve several steps such as:

(a) To coordinate with various governmental and nongovernmental agencies to mount a national campaign to scout innovations with the help of grassroots-level functionaries of education, agriculture, rural development, small-scale industry, Panchayat Raj institutions, etc., or through students during summer vacation, Shodh Yatras (walks through the villages every 6 months for a week or more), advertisements in regional language newspapers, innovators looking for others of their kind, etc.
(b) To screen, document and verify the claims about these innovations and traditional knowledge through various networks of scientific and other institutional initiatives as well as through Honey Bee collaborators, study of existing databases and field visits
(c) To generate and experiment with material and nonmaterial incentive mechanisms for innovators and traditional knowledge holders
(d) To provide assistance in forging decentralized networks of inventors/knowledge experts to strengthen the Honey Bee Network
(e) To obtain prior informed consent (PIC) of the providers of knowledge
(f) To share the innovations permitted by the knowledge providers to be put in public domain through Honey Bee newsletter and other media to enrich the repertoire of the local communities and informal knowledge experts and to support Shodh Yatras in different parts of the country

NIF has so far scouted over 200,000 innovations and TK. NIF maintains confidentiality of the TK recorded until a proper system of safeguarding the knowledge is put in place. But to answer such questions, formalization and legal protection of the national register should be the priority. We, of course, are bound by PIC, which is covered under the contract law.

## 6.12 Conclusion

Ethnobiological research can provide a wealth of information regarding relationships between plants and the traditional societies. Investigations into the traditional use and management of local flora have demonstrated the existence of extensive local knowledge of not only about the physical and chemical properties of many plant species but also the phenological and ecological features in the case of domesticated species. In addition to its traditional roles in economic botany and exploration of human cognition, ethnobotanical research has been applied to current areas of study such as bioprospecting and vegetation management.

The issues of community rights/TK, ABS transfers and intellectual property rights protection related to genetic resources and traditional knowledge are the most contentious ones that keep the developed and developing countries divided in their attitude and approaches. The intricate imbalance in the core objectives and directives of CBD and TRIPS is a major concern for the parties or members of these international laws. Among all the issues being debated between CBD Secretariat and TRIPS Council, the question of providing legal protection to genetic resources and associated traditional knowledge continues to crop up at the intersessional meetings of CBD, TRIPS and WIPO. It is a matter of grave concern that certain countries with advanced technologies are still reluctant to become a party to CBD, but continue to oppose the plea of the developing or the least-developed countries for evolving an enabling and equitable legal mechanism for implementing the international trade and intellectual property laws in relation to biodiversity, genetic resources and traditional knowledge systems.

What is more important at the national level is to reaffirm their commitment in evolving a transparent and viable mechanism for regulated access and benefit sharing of genetic resources and associated traditional knowledge. 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 the information on the existing S&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. The entry into force of the Nagoya Protocol represents a step in this direction. The new instrument, however, cannot reach these goals alone and so much will rely on functional implementation for moving forward.

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