Value Addition and Commercialization of Biodiversity and Associated Traditional Knowledge in the context of the Intellectual Property Regime

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Received 1 August 2005

Genetic resources and associated traditional knowledge (TK) have great potentials, and their contributions to global economy and global intellectual property regimes are enormous. They are the key resources for sustainable bioprospecting and value addition processes. The existing intellectual property (IP) laws do not entail IP rights to TK holders either at national or international level. The absence of coherent and legally binding instruments to accord protection to intellectual as well as customary rights of the TK holders is a major impediment to value addition and technology transfers involving the use of genetic resources and associated TK. This paper provides an overview of the issues involved in value addition to bio-resources and protection of IPR of TK holders, takes stock of the international and national legal and policy initiatives, and suggests a few measures to promote value addition, technology transfers, and IPR protection for TK holders.

Keywords: Access and benefit-sharing, biodiversity, bioprospecting, CBD, IPR, technology transfer, traditional knowledge, TRIPS, value addition

Knowledge-based, value-added product development and its commercialization has become one of the fastest economic activities in the world. The liberalization of the global trade policies and other economic reforms evolving currently with the emergence of the United Nations Convention on Biological Diversity (CBD) and the World Trade Organization (WTO) requires a deeper study and understanding, especially in the light of the latest path breaking achievements in science and technology. The history of human civilization and development of economic systems are all inherently and inveterately interwoven with our biological resources. Economic activity of humankind continues to derive its sustenance directly or indirectly from the biological resources. The unknown potentials of genetic diversity found in the biological organisms, particularly the plants represent a never-ending biological frontier of inestimable value. Genetic diversity will enable breeders to tailor crops to meet the increased productivity, adapt changing climatic conditions, disease resistance and to meet the other essential needs and future aspirations of human-kind. Biogenetic resources are the primary source of valuable genes, chemicals, drugs, pharmaceuticals, natural dyes, gums, resins, enzymes or proteins of great health, nutritional and economic importance.

The combined world market for products manufactured using the bioresources are now estimated to be over US $500 billion.

The new thinking centred on the concept of ‘knowledge engineering’ for building up future ‘knowledge assistance’ and ‘knowledge industries’ is now gaining attention and acceptance both nationally and internationally. Biodiversity-rich countries with a long history of cultural diversity have generated immensely valuable knowledge systems on the use of biological and genetic resources. Such knowledge is known as traditional knowledge (TK). Making the best use of the TK and generating new knowledge, products and technologies is the method of generating economic wealth. However, generation of such technologies and their subsequent commercialization requires proper safeguarding by protecting the intellectual property rights (IPR) of the holders of such knowledge, so that they can also achieve economic prosperity and help in sustainable development.

Biodiversity and Traditional Knowledge

Biodiversity is the variety and variability of living organisms on the planet and it forms the bedrock for sustainable economic development. The greatest part of the global biodiversity (species diversity!) is found in animals and microorganisms. Over two-third of the estimated 300,000 species of higher plants in the...
world occurs in the tropical forests of South America, Africa, Madagascar and tropical Asia including New Guinea and tropical Australia. Most of the countries located in these regions are interestingly the Third World Countries (TWCs) blessed with almost all known type of topographic and climatic conditions ranging from tropical to temperate and alpine zones. India is rated as one of 17 megadiverse countries with over 1,26,756 species of plants, animals, fungi and microorganisms identified and classified. The flowering plants identified and documented so far constitute 17,500. The rich biodiversity of India is matched with an equally rich cultural diversity and a unique wealth of traditional knowledge system, developed, preserved and practiced by millions of ethnic and indigenous people living in the rural and forest areas.

Biodiversity performs two most important functions. Firstly, it regulates and maintains the stability of climate, water regime, soil fertility, and quality of air and overall health of the life support systems on earth. Secondly, biodiversity is the source from which human race derives food, fodder, fuel, fibre, shelter, medicine and raw material for meeting his other multifarious needs and industrial goods required for the ever changing and ever increasing needs and aspirations. Biodiversity is thus the biological capital of our planet and it forms the foundation upon which human civilization is built.

TK is a community-based system of knowledge that has been developed, preserved and maintained over many generations by the local and indigenous communities through their continuous interactions, observations and experimentations with their surrounding environment. It is unique to a given culture or society and is developed as a result of the co-evolution and co-existence of both the indigenous cultures 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 sustainable use and management of their ambient resources. Through years of observations and analysis, trial, 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 society as it is often developed, in part as an intellectual response to the necessities of their life. Protection and maintenance of TK of local and indigenous communities is vital for their well-being and sustainable development and for their intellectual and cultural vitality.

TWCs are not only rich in biodiversity but also have a strong cultural history. For example, a megadiverse country like India has more than 7000 year’s continuous cultural history and thus very rich in TK. The accumulated wisdom, knowledge, beliefs and practices embodied in the TK systems were handed down to generation by an unbroken tradition and culture. This is still a living tradition in many parts of the biodiversity-rich TWCs. A study of such knowledge system of traditional societies about the plant world is the subject matter of the science ‘Ethnobotany’. Modern drug hunters consider ethnobotany as a cost-effective means of locating new and useful compounds of great pharmaceutical value. It is well accepted that the possibility of finding a potential bioactive compound through random screening of plant samples is 1 in 10,000 and that of hitting a marketable drug is 1 in 4. In contrast, the success rate of finding a bioactive molecule through selective screening based on ethnobotanical leads is 1 in 100 and that of discovery of a drug is 1 in 2. Many plant-derived drugs employed in modern medicine were first ‘discovered’ through ethnobotanical investigation. The traditional societies in India as well as in other TWCs have always considered the natural resources and the associated TK system developed by them as commonly owned properties to be cared and shared by all and never to be commodified for the purpose of selling or marketing. It was with the coming of the westerners that the process of commodification and trading of bioresource and associated knowledge started.

Genetic resources and associated TK have great potentials and their contributions to global economy and global intellectual property regimes are enormous. Ranging from subsistence uses by indigenous and local communities for their livelihood security to the high-tech research and development programmes on bioprospecting, genetic resources and associated TK find an ever increasing demand and utility in a diverse array of sectors such as biopharmaceuticals, biotechnology (including agricultural bio-
technology and health care), crop protection, agricultural seed production, horticulture, phytomedicines, cosmetics and personal care, and a myriad of other areas of products and processes development based on wild and domesticated genetic resources and their derivatives extracted from both in situ and ex situ sources.

Bioprospecting and Development of Value added Bio-products

Humankind has been prospecting biodiversity from the very dawn of his civilization. Modified use of bio-resources for food, medicine and other material requirements had been the traditional form of bioprospecting. 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 identification and/or isolation of commercially valuable products (genes, biochemicals) compounds, derivatives and/or any other tangible and in-tangible 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 has thus three facets—chemical prospecting, gene prospecting and biotic prospecting. It 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.

Strategies for Product Development and Technology Transfers

The strategies for biodiversity-based value-addition processes, product development and diversification, by-product utilization, technology transfers, commercialization, etc. may vary from case-to-case depending up on a number of factors, such as availability of the biological and genetic resources and associated knowledge; scientific and technological capabilities of the country; priorities of consumption and trade at domestic and global levels; legal and policy frame-works and political will of a country to support promising value-addition programmes; and other relevant considerations in accordance with its national legislations. Value addition to biodiversity may thus include several activities and programmes starting from grass root level microenterprises to high-tech national or international bioprospecting or bioindustrial ventures. While it is important for any nation to consider promotion of both entrepreneurial microenterprises and economically intensive macroindustrial ventures as a national agenda, it is equally important for members of the biodiversity-rich TWCs to develop bilateral or multilateral biopartnerships in the areas of scientific value addition of biodiversity and associated TK.

The TWCs can adopt a two-prong strategy for developing bioindustrial partnership based on biodiversity and biotechnology:

(i) Less technologically intensive low cost biotechnologies for location-specific product and processes development based on local biodiversity resources, e.g. herbal technologies – Herbal drugs, functional foods, nutraceuticals, cosmeceuticals, natural dyes/gums, biopesticides, biofuels, etc.

(ii) High-tech biotechnology for bioprospecting involving highly sophisticated infrastructure, high cost and highly skilled human resources, e.g. vaccines, enzyme/proteomics, transgenics, diagnostics, gene therapy, etc.

Value-addition to Biodiversity & TK: Key Issues of IPR Concerns

TWC members are still at the receiving end as far as the development of special value-added products and herbal technologies are concerned. The developed countries, on the other hand, are emerging as super powers with their biotechnological strength. This North-South divide has been in existence for years and will continue to remain so, until the biodiversity-rich countries of South strive their best to develop capability in biotechnology, bioinformatics and related technologies. The major concerns of the developing countries with regard to access to and transfer of genetic resources and biotechnology are: (1) prevention of biopiracy and misappropriation, (2) development of international systems of protection of TK and (3) means for fair and equitable benefit sharing and technology transfer.

One of the key issues involved in prospecting and
commercialization of TK-derived technologies and products is the inadequacies in providing protection of TK through appropriate intellectual property laws and policy measures at national and international levels. Increasing incidences of misappropriation or misuse of TK for obtaining IPR rights without even acknowledging the role and contribution of TK holders are mounting with the recent booms in bioprospecting involving the use of genetic resources and associated TK. The turmeric, ayahuasca and neem patent stories are a few examples to cite\textsuperscript{12-15}. Establishing legally binding instruments and mechanisms to ensure the prior informed consent (PIC) of TK holder(s) and arriving at mutually agreed terms (MAT) for benefit-sharing, third party transfers, IPR claims, and commercialization of the products or technologies derived from the use of TK associated with genetic resources are other concerns that are being discussed and debated at international forums, such as CBD, FAO, WIPO, UNEP, etc. Access and Benefit-Sharing (ABS) is a central issue concerned with the implementation of many of the national and international legal and policy instruments and mechanisms on biodiversity, IPR, protection of TK (including Traditional Cultural Expressions (TCE) and Folklore), technology transfers, etc. The international conventions and treaties such as the CBD and ITPGRFA\textsuperscript{16} (International Treaty on Plant Genetic Resources for Food and Agriculture) now allow the Contracting Parties to have regulated access to and transfer of genetic resources and biotechnologies, based on the principles of PIC and MAT. In line with CBD guidelines, several TWC members have enacted their own national laws for effective implementation of the CBD objectives.

It was India who has shown to the world that it is possible to revoke patents secured by developed countries (particularly USA), based on the indigenous biodiversity and TK of the developing countries\textsuperscript{17}. The case of Ayahuasca in Brazil, neem and turmeric in India are classic examples. But challenging and revoking patents are expensive and time consuming which many of the poor developing nations cannot afford. The Indian Biological Diversity Act (2002), Costa Rican Biodiversity Law (1998), Philippines EO247 (1996), Brazilian Bill of Access to Genetic Resources (2001), Andean Community’s Common System on Access to Genetic Resources (1996), AU Draft legislation on Community Rights & Access to Biological Resources (2000), TBGRI/Pushpangadan

Model of benefit sharing\textsuperscript{18} are some of the laws, policy framework and experimental models developed by the TWCs to protect genetic resources and associated TK.

**International Legal Instruments Regulating Biodiversity and TK**

Rich biodiversity and equally rich cultural heritages are thus two invaluable assets of most of the TWCs. The developmental scenario of the world is now changing fast at breathtaking speed. The TWCs therefore have to be alert and sensitive to the changing global developmental scenario and must adopt and adapt appropriate measures to safeguard their interests and to take the best advantage of the legally binding international laws and multilateral agreements such as CBD, TRIPS\textsuperscript{19} (Trade-Related Intellectual Property Rights of WTO), ITPGRFA, which are now in force. CBD is the first international legal instrument that brought out a radical change from the prevailing common perception on genetic resources as ‘common heritage of humankind’ to a legally binding regime that confers ‘sovereign rights’ to the states over their biological resources and associated TK.

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)\textsuperscript{20} was established in 2001 and it began to study the issues related to providing an international dimension to protection of TK associated with the use of genetic resources. IGC made a series of discussions and debates on TK-related issues with other international instruments such as CBD and WTO-TRIPs. The ongoing discussions and negotiations helped to develop two main forms of IPR related protection to TK: 1. Positive protection-i.e. Establishing legal entitlements for TK holders, 2. Defensive protection-i.e. Safeguarding against illegitimate acquisition of IPR over TK or associated genetic resources. Ensuring the practice of PIC and benefit-sharing agreements with TK holders are other issues involved in TK – derived bioprospecting and technology transfer programmes. Several national governments, WIPO –IGC and CBD secretariat are actively discussing these issues with the participation of local and indigenous communities and institutions. WIPO-IGC is in the process of finalizing the policy objectives and core principles for protection of TK\textsuperscript{21}. National governments have also been addressing the issue of providing IP protection to TK under the existing IP laws or \textit{sui generis} mechanisms, so that the
intellectual as well as customary rights of the TK-holders are respected, recognized and rewarded.

**Access and Benefit Sharing (ABS)**

Access and Benefit Sharing (ABS) has emerged as the most complex issues where the UN-CBD and WTO came on a direct confrontation. Both TRIPs Council of WTO and the Conference of Parties (COP) to CBD have been considering ironing out these contradictions. CBD began to address the ABS issues and their implementations since the Fourth Meeting of the COP held in Bratislava in 1988, which finally led to the development of ‘Bonn Guidelines’22 in October 2001. The Bonn guidelines provide the parties and stakeholders with a framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits through standard practices and procedures of Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and Material Transfer Agreements (MAT) and other relevant agreements. The Guidelines provide details of an overall strategy and essential steps, elements and principles to be adopted in developing ABS regime by parties and stakeholders.

Benefit-sharing is an important component in any ABS or technology transfer contracts involving genetic resources and associated TK. MAT in accordance with Article 15.7 of UN-CBD should pay adequate attention to reaching an agreement on fair and equitable sharing from the commercial or other utilization of the resources and the TK accessed. The benefit-sharing mechanisms and formula may significantly vary depending upon for the purpose for which the genetic resources and/or TK are accessed25. The monetary benefits (e.g. license fees, royalties) need to be fixed depending upon the actual capital inputs including S&T inputs, human resource inputs and intellectual inputs provided by the participating countries in any joint prospecting/biopartnership programmes. Although the Bonn guidelines provide a conceptual as well as practical framework for ABS, a coherent framework for benefits arising from sustainable use of genetic resources and/or traditional knowledge is almost impractical. Therefore, the TWCs have to address the benefit-sharing issues with a balanced and flexible approach. Also there is a need for the Like-Minded Megadiverse Countries (LMMC) and other regional groups of biodiversity –rich countries to strengthen collaborative partnership among their members to build up capacity building in all relevant areas of biodiversity, biotechnology, intellectual property, information management, etc. Such regional cooperation would be helpful to develop national legal and policy frameworks on ABS and to harmonize the various statutory mechanisms through conscientious discussions, besides developing a joint strategic action plan to deal with all ABS and related issues at international forums.

**Indian Initiatives on Bioprospecting and Protection of IPR related to TK**

Department of Biotechnology

The Department of Biotechnology, Government of India, initiated the network programme on “Bioprospecting of biological wealth using biotechnological tools” during the 9th plan involving 13 institutions. The objectives of the first phase of this programme were: (i) Characterization of biodiversity in different agro ecological regions through remote sensing and GIS based studies, (ii) Bioresources mapping, inventorisation and monitoring of biological diversity, (iii) Characterization and conservation of Himalayan endangered species including medicinal and aromatic plants, (iv) Bioprospecting of molecules and genes for product development.

Some of the significant achievements under the bioprospecting programme on biomolecules and genes included:

1. Prospecting of bioresources for pesticidal, therapeutic and agriculturally important compounds.
2. Construction of cDNA library for a mangrove species, *Avicennia marina*
3. Isolation of 24 genes with implication on stress tolerance for mangrove and cold desert plants
4. Identification of novel salt tolerant nitrogen fixing and phosphate solubilizing bacteria from a wild rice.

The leads obtained from the first phase of the bioprospecting have been taken up for detailed investigation with a focus on product and process development and their commercialization. The focus of the second phase of the bioprospecting programme is on (1) production of biomolecules for industrial and medicinal use (2a) novel genes/promoters to address biotic and abiotic stress (2b) genes for transcription factors (2c) metabolic engineering pathways (3) nutritional enhancement 3(a) bio-availability of elements 3(b) crop improvement including proteins, fats and carbohydrates (4) microbial diversity.

**CSIR Coordinated Programme on Drug Discovery**
CSIR has initiated a coordinated programme on drug discovery with a network of 19 CSIR laboratories and other R&D institutions working in the area of traditional systems of medicines and universities. The programme which was initiated in 1996 aims at discovering new bioactive molecules from plants, fungi, microbes, insects, etc. using new techniques of both synthesis (combinatorial chemistry) and bioevaluation (medium and high through put screening). The programme also includes discovery of molecules based on mechanism of the disease, functional genomics, antisense agents, etc. Currently bioevaluation of the following eleven major diseases is in progress: 1 Bacterial infections 2. Malaria 3. Tuberculosis 4. Filariasis 5. Hepatitis 6. Hypertension 7. Memory 8. Leishmaniasis 9. Inflammation and Arthritis 10. Diabetes 11 Cancer. Out of targeted 700 plant species, screening of 300 has been completed which has yielded 10 vital lead molecules/extracts and twenty inter-laboratory discovery groups have been constituted for the various further evaluation/standardization and synthesis.

New Millennium Indian Technology Leadership Initiative (NMITLI) on Drug Prospecting

The Planning Commission, Government of India and the Council of Scientific and Industrial Research (CSIR) in India has embarked on a few bio prospecting programmes with some specific targets/goals – such as the inter laboratory collaborative programmes on biomolecule/drugs, drug prospecting. The Planning Commission sponsored the NMITLI, one of the most innovative bioprospecting programmes. NMITLI has major herbal drug development programme for developing effective herbal remedies for hepatic disorders, arthritis and diabetes, which has shown highly encouraging results within a short period of less than one year. Four CSIR laboratories namely; National Botanical Research Institute (NBRI), Lucknow; Regional Research Laboratory (RRL), Jammu; Indian Institute of Chemical Biology, Kolkata; and Indian Institute of Chemical Technology, Hyderabad; and a large number of medical colleges/hospitals like Kings Edward Memorial Hospital, Mumbai; Nizam Institute of Medical Science, Hyderabad; All India Institute of Medical Sciences, New Delhi; Bhartiya Vidyapeeth Deemed University, Pune; Bhartiya Vidyamandala’s Swami Prakashanand Ayurvedic Centre, Mumbai; are the research partners in this programme. Kottakkal Arya Vaidya Pharmacy, Arya Vaidya Pharmacy, Coimbatore, Dabur Pharmaceuticals.

Traditional Knowledge Digital Library (TKDL)

India has already two important task force programmes relating to creation of a Traditional Knowledge Digital Library (TKDL) and designing a Traditional Knowledge Resource Classification (TKRC). The Department of Indian Systems of Medicine and Homeopathy (ISMH) spearheaded the initiative. The ISMH set up the TKDL task force, by drawing experts from the Central Council of Research of Ayurveda and Siddha, Banaras Hindu University, National Informatics Centre, Council of Scientific & Industrial Research, and Controller General of Patents and Trade Marks. The Indian TKRC has information on 5,000 subgroups and the structure of TKRC is compatible with the International Patent Classification (IPC). TKRC would help enhance the quality of patent examinations by facilitating the patent examiners to access pertinent information on traditional knowledge in an appropriately classified form.

NBRI, Lucknow, has recently launched a programme to establish a multimedia web-based database (plantsofindia.org) on plant genetic resources and the associated traditional knowledge systems including that of the tribal communities of India.

National Legal and Policy Frameworks

Access to and transfer of genetic resources and technologies (including biotechnologies and ‘traditional technologies’ of local and indigenous communities), recognition and reward for IPRs of traditional communities, and equitable sharing of benefits arising out of sustainable use of the accessed resources and technologies are the key issues that are being debated and discussed at national and international forums. The Indian legislations {the Biological Diversity Act 2002, Plant Variety Protection and Farmers Rights Act- PVPFR 2001, Patent (Amendment) Act 2005} address these issues and suggest provisions to implement them under the framework of relevant international laws subject to national priorities.

Biological Diversity Act 2002

As per the provisions contained in the Biological Diversity Act, the national, state and local biodiversity boards/committees are entrusted to oversee and implement benefit sharing mechanisms, documentation of bioresources and traditional knowledge, material transfers, access agreements on genetic resources and technologies, etc. The Act stipulates norms for access to biological resources and traditional knowledge based on three ways:
(i) Access to biological resources and traditional knowledge to foreign citizens, companies and NRIs based on ‘prior approval of NBA’ (Section 3 of the Act).

(ii) Access to Indian citizens, companies, associations and other organizations registered in India on the basis of ‘prior intimation to the State Biodiversity Board’ concerned (Section 7 of the Act).

(iii) Exemption of prior approval or intimation for local people and communities, including growers and cultivators of biodiversity, and vaidas and hakims, who have been practicing indigenous medicines (Section 7 Of the Act).

Transfer of Research Results

The Act does not permit any person to transfer the results of any research relating to biological resources obtained from India for monetary consideration to foreign nationals, companies or NRIs without the prior approval of the Authority.

Procedure for Prior Approval before Applying for IPR (Rule 18, Sub rules 1-6)

All the conditions for granting approval for transfer of research results shall be applicable to any person desirous of applying for a patent or any other intellectual property rights, based on biological resources and knowledge obtained from India.

Procedures for Third-Party Transfer of Accessed Biological Resources Or Knowledge (Rule 19, Sub rules 1-6)

The Act permits transfer of accessed biological resources or traditional knowledge to a third party on the basis of the prior approval of the Authority.

Criteria for Benefit Sharing

The Act, subject to Section 21 and Rule 20 of the Biodiversity Rules, insists up on including appropriate benefit sharing provisions in the access agreement and mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The Authority shall develop guidelines and shall notify the specific details of benefit sharing formula in an official gazette on a case-to-case basis. The suggested benefit sharing measures may include ‘monetary benefits’ such as royalty, joint ventures, technology transfer, product development, and ‘non – monetary benefits’ such as education and awareness raising activities, institutional capacity building, venture capital fund, etc. The time frame and quantum of benefits to be shared shall be decided on case-to-case based on mutually agreed terms between the applicant, authority, local bodies, and other relevant stakeholders, including local and indigenous communities. One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge was accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits shall be paid to the National Biodiversity Fund. Five percent of the benefits shall be earmarked for the Authority or State Biodiversity Board towards the administrative service charges.

The Protection of Plant Varieties and Farmers’ Rights (PPVFR) Act, 2001 (Act 53 or 2001)

The PPVFR Act 2001 and the Rules framed under this Act, called the PPVFR Rules 2003, deal primarily with the protection of plant breeder’s rights over the new varieties developed by them and the 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. The Act is a deviation from the 1991 UPOV Model and can be regarded as an alternate ‘sui generis’ system that accord protection of the rights of the formal innovations of a plant breeder and the informal knowledge system and traditional plant varieties of the farmers as well. The important provisions contained in this Act relevant to ABS are those on the protection of farmers rights and the mechanisms suggested for compensation or benefit-sharing for the contributions of local communities or farmers in the development of a new plant variety.

The Patent (Amendment) Act 2005

This Act, which is an amendment to the Patent Act of 1970, is significant in the sense that it stipulates disclosure of the ‘source and geographical origin of the biological materials in the specification, when used in an invention’. This issue of disclosure of source and geographical origin is a contentious one that the LMMC and other developing and least developing countries are still pushing ahead with the WTO-TRIPS. The new Patent Act of India includes two important clauses for revocation of a patent on the grounds that: (i) complete specification does not disclose or wrongly mentions the source of geographical
TBGRI Benefit Sharing Model: A Case Study

India has the distinction of being the first in the world in experimenting a benefit-sharing model that implemented Article 8(j) of CBD, in letter & spirit. It was the Tropical Botanic Garden and Research Institute (TBGRI), Kerala that demonstrated indigenous knowledge system merits support, recognition and fair and adequate compensation. Based on a lead obtained from Kani tribe of Kerala, Pushpangadan and his co-workers developed an antifatigue, immunoenhancing herbal formulation, named, ‘Jeevani’, developed on the basis of their knowledge of a lesser-known wild plant, Trichopus zeylanicus subsp. tranvancoricus Burkill ex Narayanan, locally known as Arogyapacha i.e. the giver of green health. Much of the scientific investigation on the tribal lead was done at RRL, Jammu, where Pushpangadan (the senior author) and his team initiated the first ever ethnopharmacology research in India. The team at RRL carried out phytochemical and pharmacological evaluation of this plant. The study revealed that the plant contained various biodynamic compounds notably certain glycolipids and non-steroids compounds with profound adaptogenic and immuno-enhancing properties. RRL has filed two patents on the same. In the meantime in 1990, Dr Pushpangadan moved to Trivandrum to assume the position of Director of TBGRI. The technology of production was later perfected at TBGRI and the drug ‘Jeevani’ after necessary clinical study was transferred to a pharmaceutical company on payment of license fee and a royalty of 2% on the ex-factory sale of product. TBGRI at this time resolved to share 1:1 of the license fee and royalty with the Kani tribe. Although this model was worked out in early 1994 in full consultation with the Kani tribe, it took almost 3-4 years to implement this model mainly because of the inherent inability of the ‘Kani’ people to receive the benefit. Their prime concern in the beginning was to evolve a viable mechanism for receiving such funds and utilizing the same for the welfare of the community. Several ways of sharing the benefits were discussed at many levels and it was finally decided to set up a trust fund of the tribe. The very idea of the trust fund had originated from very useful and protracted discussion the senior author had with Prof. Anil K Gupta, the founder and co-ordinator of SRISTI and Honey Bee Network. It took almost two years to transfer the benefits to the tribe. With the help of some local NGOs, TBGRI scientists and some motivated government officials, the tribals were encouraged to form a registered trust with Kani adults as its members. The trust was fully owned and managed by the Kani tribe. About 60% of the Kani families of Kerala are now members of this Trust. In February 1999, the amount due to them (Rs 6.5 lakhs) and which was till then kept by TBGRI in a separate account, was transferred to the Trust. As per the rules of the Trust, the license fee and royalty received on account of the sale of `Jeevani’ drug will be in a fixed deposit and only the interest accrued from this amount will be utilized for the benefits/welfare of the members of the Kani tribe.

In fact, the whole process of this benefit sharing started much before the CBD was evolving. It took almost 3 years for the Kani tribe to receive this benefit.

In addition to the licence fee and royalty that Kani Trust is receiving, a large number of Kani families are now getting benefit from the cultivation of Arogyapacha and supply of the raw-material (i.e. the leaves of the plant) to the pharmaceutical company for the production of the drug. TBGRI has trained many tribal families for the cultivation of `Arogyapacha’ in and around their dwellings in the forest.

The TBGRI model got wide acclaim, acceptance and popularity the world over, because it was the first of its kind that recognized the resource rights and IPR of a traditional community by way of sharing equitably the benefits derived out of the use of a knowledge that has been developed, preserved and maintained by the community for many generations. Such models need to be emulated in similar situation in India and elsewhere in the world.

Comparison of TBGRI Model with Shaman Pharmaceuticals’ Model of Benefit Sharing

Shaman Pharmaceuticals, USA, was an agency that developed a benefit sharing model of a different sort
in 1990s. Shaman Pharmaceuticals pioneered a concept of short term and long-term benefit to the local communities while working with indigenous and local people of tropical forest on the development of new therapeutic agents. The company established a collegial research relationship and collaboration with a number of stakeholders, including scientific institutions, scientists, village communities, and traditional healers. Shaman’s compensation included upfront payment to the local people or host country capacity building. Shaman maintained a fundamental philosophy and procedure to equitably compensate indigenous societies for their intellectual contribution to the identification of useful products in the drug discovery process. Till now, however, the company has made a huge net loss. But it has two compounds in clinical trials, ‘Virend’, a topical antiviral product for the treatment of herpes and ‘Provir’ for a childhood illness caused by a respiratory syncytial virus. Both drugs were retrieved from South American cotton tree. But these drugs have to go a long way till they become marketable products. Shaman’s scientists are also working in Ecuador, Peru, Papua New Guinea and West Africa looking for biodynamic compounds for treating diabetes, non addictive pain killers, antiviral and antifungal compounds with the help of the local mediciners. So far Shaman has not come out with any marketable products nor they have shared the benefit with the indigenous or local people or any other stakeholders. Thus, TBGRI benefit sharing is the only one of its kind in the world that has developed a marketable product, a validated herbal drug, which has been commercialized, and the benefits of which have now been shared equally by the scientific organization (TBGRI) and the stake holders, i.e. Kani tribe.

The sharing of benefits with the Kanis and formation of the Kani trust fund have started showing positive impacts in the sense that the tribal community is now becoming conscious about the values of and rights over their knowledge system and associated biological resources. These developments also have helped in bringing the Kani families to a single organizational framework, so that the benefits accrued from the trust fund could be utilized for the economic well being and social development in the Kani tribal hamlets. The benefit sharing experiments like the TBGRI Model will help empower the traditional communities not only to preserve their traditional knowledge system but also to encourage them to bring in more innovations and value additions to their knowledge and resources.

In the absence of uniform standards and statutory mechanisms, the type of benefit sharing and their ‘modus operandi’ would differ from case to case, depending upon the stakeholder’s contributions, the type of products developed and their processes of development, and several other factors, including the self-reliance and capability of the stakeholder communities, and the political and bureaucratic set up prevailing in a particular country.

**Protection and Valorization of TK: NGO’s Role**

Efforts of the government sponsored National Innovations Foundation (NIF) and NGOs like SRISTI (Society for Research and Initiatives for Sustainable Technologies and Institutions), MSSRF (M S Swaminathan Research Foundation), FRLHT (Federation for Revitalization of Local Health Traditions), etc., provide the platform to build up the registration and benefit sharing systems at the grass roots. An urgent priority for India is to evolve benefit-sharing models relating to the use of biodiversity and traditional knowledge.

**Community Registers and Peoples’ Biodiversity Registers**

**MS Swaminathan Research Foundation (MSSRF)**

The community gene bank and community agro biodiversity register programmes and Peoples Biodiversity Register (PBR) spearheaded by the MS Swaminathan Research Foundation (MSSRF), Chennai, the Foundation for Revitalization of Local Health Traditions (FRLHT), Bangalore, and the Centre for Ecological Sciences at Indian Institute of Science, Bangalore, are examples of other useful mechanisms and methods to chronicle the biogenetic resources and associated knowledge systems of the traditional communities and local or rural people of the country. PBR is now accepted as a viable mechanism for documenting people’s knowledge and biological resources under the Biodiversity Management Committees (BMC) established under the Indian Biological Diversity Act 2002. Development of comprehensive PBRs at local level is a highly rewarding exercise which would not only help to inventory and document the local biological and genetic resources along with the various actual uses and potential values of such resources, but also
to conserve and sustainably use the biocultural diversity for gainful income generation and IPR generation through value addition and benefit-sharing processes. PBR also ensures active involvement of the local and traditional communities in all decision-making processes related to biological diversity and traditional knowledge, including issues of access and benefit sharing. BMCs are entrusted with the preparation of PBRs and to assist the SBBs and NBA in matters on ABS related to local biogenetic resources and traditional knowledge.

The success story on compilation of community biodiversity registers and community gene bank programmes involving tribal communities of the Jeypore tracts of Orissa with the guidance and support from MSSRF is a good case study that demonstrates how the potential benefits of such community biodiversity programmes help enhance the livelihood options and security of the local and traditional people. This model of community agro-biodiversity programme has won the UN-Equator initiative Prize for poverty eradication and community empowerment at World Summit for Sustainable Development (WSSD) at Johannesburg in August 2002.

Foundation for Revitalization of Local Health Traditions (FRLHT) and Medicinal Plants Conservation Centre (MPCC)

Another community-based participatory conservation programme that has won international acclaim through the Equator Award of 2002 is the medicinal plant conservation and cultivation work achieved by Medicinal Plants Conservation Centre, (MPCC), Pune, with the support of FRLHT. The MPCC with an effective involvement of local communities has developed a decentralized system of nurseries, raising 50,000 plants of 50 different species and linking them with a network of herbal production centres. The propagation and cultivation of medicinal plants in nurseries have helped to reduce the pressures of collection from the wild and hence promoting the conservation of such valuable resources. The linkage with herbal production centres has helped provide economic incentives to the communities involved in the MPCC programme. Such community network programmes on bio-resources conservation and management contribute significantly to the implementation of national policies and programmes on biodiversity, and intellectual property rights and access and benefit sharing involving genetic resources and traditional knowledge.

Prior Informed Consent (PIC) System and Benefit-Sharing Procedures: The NIF Model

NIF, an autonomous society established under the Department of Science and Technology, Government of India in 2000, works for recognizing, respecting and rewarding innovations and outstanding traditional knowledge at the grass roots. NIF and the HONEY BEE Network under SRISTI, Ahmedabad, have been scouting for documenting local innovations and linking their innovations for further valorization with Science and Technology experts, investors and entrepreneurs. NIF maintains a separate National Register for green grassroots technological innovations and traditional knowledge. Until 2003, NIF has scouted about 37000 innovations and traditional knowledge examples from over 350 districts of India. Scouting and documentation; value addition and R&D through a network of S&T experts, institutions, people’s organizations, and rural and urban innovators for developing business and micro-ventures at local levels based on valorization of grass root level innovations; intellectual property rights management; information and technology dissemination; and benefit sharing are the various steps involved in the NIF programme on building of value chain of grass root innovations.

NIF has developed a model for facilitating PIC system for local innovators and traditional knowledge holders. The PIC models seek the innovators’ or traditional knowledge holders’ consent for partial or full disclosure of their innovation and disseminate them through print and web media, and provide NIF mediation for value addition, patenting or other kinds of IPR generation based on the local innovation or traditional knowledge, and for fixing criteria and the terms and conditions for sharing monetary or non-monetary benefits, if any, arising from the value addition, micro-venture development, patenting on a local innovation or traditional knowledge. The PIC process with regard to traditional knowledge holder and other grass root innovations is a quite complex one. This cannot be compared with the formal PIC process recommended for other ABS model involving Government agencies, R&D institutions and other organizations. The awareness, capacities and exposure level of the local innovators to the modern regimes of IPR scientific validation, management, trade policies, etc. is either minimum or low. Empowering these communities with knowledge and awareness on the values and potentials of the rich treasure-trove of knowledge they hold is an important exercise, which NIF has been successfully accomplishing through their scout-
ing programmes, awareness campaigns, competitions and awards distribution conducted for successful innovators. NIF suggests the innovator or the knowledge holder to share their information on the following conditions:

a) With restrictions imposed
b) On commercial basis on terms for technology transfer, upfront payments, royalties, license fees, etc.
c) On non-cost basis for personal application or household use only.
d) With further research and value addition in it
e) Any other conditions

The PIC model of NIF has both advantages and disadvantages. The whole process of disclosure and dissemination of the local innovations, either partially or fully, needs to be examined, whether they affect adversely in eventual exclusion of potential innovations from possible valorization and IPR claims and also any possible misappropriation of such potentially useful innovations by others, and thereby depriving the local innovator of his/her intellectual property and customary rights.

The benefit sharing mechanism suggested by NIF’s PIC models include four kinds of benefits viz. 1. Monetary-Individual (MI)-includes: monetary awards, license fees or royalty from commercial exploitation of technology or traditional knowledge, or any other monetary gain by entrepreneurial process. This will be firstly paid to the individuals, who may in turn share part of this with the community, innovation promotion fund and institutions helping the value chain 2. Monetary Collective (MC)- covers: trust funds, micro-venture funds, common property infrastructure, etc to be shared with the communities 3. Non-Monetary Individual (NMI) such as recognition, a citation in a public function, dissemination of one’s creativity through media or in workshops or other public function, or using appellation on the product developed, business venture, etc 4. Non-Monetary Collective (NMC)- includes: recognition to communities at appropriate levels for their collective wisdom, knowledge and social or cultural organizations, etc.

The NIF benefit-sharing procedures also suggest separate formula and modules for each kind of innovation on a case-to-case basis. Benefit sharing formula involving valorization with public or private R&D and the community or individual innovators needs to be evolved based on stakeholder consultations and on the degree of contributions by each stakeholder through an effective cost-benefit analysis. The existing complexities in the structure of the traditional knowledge domain itself, and also the very nature of the existing IPR system that accord protection only for the formal innovation based on the criteria of novelty, non-obviousness and utility, are some of the major impediments in evolving any uniform guidelines or model for access protection and benefit sharing involving traditional knowledge systems held in traditional communities or the grass root level innovators. However, NIF’s efforts to networking with the grass root innovators so as to promote the local innovation and valorization of such knowledge, protection of the intellectual property rights, and equitable benefit sharing are gaining wider acceptance and credibility both nationally and internationally.

**Conclusions**

Genetic resources and associated TK are important leads for bioprospecting and bio-industry. Judicious and harmonious use of these resources in bioprospecting can lead to sustainable human development in biodiversity – rich countries of the Third World. The disproportionate distribution of biodiversity wealth and associated TK and biotechnological capability in South and North countries continues to be a barrier in building up mutually beneficial bio-partnerships among and between these countries. The inadequacies of existing IPR system to accord legal protection to TK related to genetic resources are yet other issues of deep concern at national and international levels. The recent spurt of activities spearheaded by international agencies such as UNEP, FAO, WTO, and ILO etc. to study the complementarities and possible harmonization of the various international legal instruments and policy frameworks on biodiversity, IP, TK are expected to bring in some positive changes in near future. The negotiations on harmonizing CBD and WTO-TRIPS with reference to the disclosure requirements of source and country of origin, PIC and benefit – sharing in patent applications related to genetic resources and TK are still underway at The TRIPS Council. The national governments in biodiversity-rich TWCs are also actively pursuing their agenda to ensure the incorporation of the above dis-
closures requirements in to the TRIPs provisions. Development of a legally binding international regime on ABS within the framework of CBD is a significant initiative by the CBD Secretariat and it will help the CBD-TRIPs harmonization process effective. The incorporation of disclosure requirements on source and country of origin of genetic resources and/or TK used in patentable innovations will improve the quality of patents while helping to prevent misappropriation or wrong patenting and promote fair and equitable benefit-sharing among the stake holders.

Value-addition to bioresources and TK and technology transfers involving TK holders and their community organizations/institutions are key processes that will not only help ensure the social, cultural, spiritual, economic and technological empowerment of the communities, but also to promote further enrichment of their TK and traditional resource wealth. The issue of providing legal IPR on TK in line with the existing IPR regime is a complex one because of the very nature and clustered pattern of distribution of TK held within and between various communities across the world. Positive and defensive protection measures along with development of sui generis laws may perhaps be the best and immediate options for countries like India to provide IP rights to TK holders. The disclosure requirements, even if adopted under TRIPs, can only help in preventing misappropriation or wrong patenting, besides ensuring the benefit sharing with the country(s) of origin of genetic resources and/or associated TK used in an invention. What is required urgently is to develop a national legislation (sui generis) to accord IPR protection to TK-drawn innovations. This can help more synergetic public-private-community partnerships in bioprospecting and value-addition programmes in our country.

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