

## Intellectual Property Rights, Traditional Knowledge and Biodiversity of India

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India is one of the mega-biodiverse countries with different combinations of ecosystems. The biodiversity of India occurs at three levels, namely, species, genetic and ecosystem and most of the times are associated with traditional knowledge and practices. The loss of biodiversity and commercialization of bioresources and associated knowledge have been causing great concern especially when the IPRs are applied to claim monopoly. The negotiations at international and national level for the protection of traditional knowledge and for the conservation of biological resources are now carried out on various issues of implementing the Convention on Biological Diversity (CBD), 1992. India being a party to the Convention is the first to implement it by enacting the Biological Diversity Act, 2002 with a three tiered institutional mechanism established there under. However, the Act still needs more clarifications on the issues of implementation like benefit sharing. This article analyses and clarifies some of these issues and concerns and thus, suggests further actions for the effective implementation of the Act.

**Keywords:** Biodiversity, traditional knowledge, IPR, conservation, NBA

The diversity in the living organisms present on the earth, collectively in land, water and air is called biological diversity or biodiversity. Biodiversity includes millions of races, local variants of species and subspecies, and ecological processes and cycles that link organisms into populations, communities, ecosystems and ultimately the entire biosphere. Biodiversity is mainly recognized at three levels, namely, genetic, species and ecosystem. Genetic diversity refers to variation within individual species; species diversity pertains to the variety of species; and ecosystem diversity refers to diversity of ecosystems and habitats. On the basis of the above classification, the global biodiversity has 1.75 million identified species.<sup>1</sup> These species are distributed in different combinations in different ecosystems. Of these 1.75 million species, only 2.7 lakhs belong to plant kingdom. Humans largely depend on less than 9000 plant species for food, clothing, shelter, medicines, forage and industry. Of these, about 900 species have been domesticated for agriculture and from these about 168 species are specifically cultivated for food and agriculture. With increasing industrialization of agriculture and human dependence on plant species, many plant varieties are decreasing at an alarming rate.

The distribution of plants is not uniform on the earth, 90% of the species are confined to 10% of land area around equator.<sup>2</sup> Moreover, distribution of biodiversity within this narrow equatorial region is also not uniform. Some countries located within this region have abundance of biodiversity while others have only moderate or little biodiversity. Regions which are very rich in biodiversity are called mega-biodiverse countries. There are 17 such mega-biodiverse countries around the equatorial region and India is one among them.<sup>2</sup>

Conservation and sustainable use of biological resources based on local knowledge systems and practices is ingrained in Indian ethos and ways of life. As a result, India has a strong network of institutions mapping biodiversity and undertaking taxonomic studies. The Botanical Survey of India (established in 1890) and the Zoological Survey of India (established in 1916) are primarily responsible for survey of flora and fauna. The National Institute of Oceanography, Goa, and several other specialized institutions and universities further strengthen the taxonomic database. Based on the survey of these institutions, 70% of the total geographical area of the country is inhabited by 46,000 species of plants and 81,000 species of animals.<sup>3</sup> These life forms are

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potentially important for developments in the fields of food, medicine, textiles, energy, recreation and tourism. Some areas which are inaccessible and not yet surveyed are also expected to be rich repositories of endemic and other species. Bioresources in India are mostly associated with traditional knowledge systems used for various activities of people in India for their livelihood. These activities include agriculture, fisheries, medicine, artisans, etc. The introduction of the modern technologies has led to the gradual decline of these knowledge systems.

One of the key results of the industrial revolution of the west is the creation of the intellectual property rights (IPRs) regime - a system based on the western legal theory and economic philosophy.<sup>4,5</sup> IPRs are meant to assure rewards to innovators, and are claimed to have been an important driving force behind the rapid industrial growth in the developed world. They were primarily evolved to protect mechanical and chemical innovations for which identification of novelty, inventive step and innovator is relatively straight forward. Quoting Edwin Hetinger, Chimni<sup>5</sup> opines that grant of property rights is a mere means to ensure that enough intellectual products and countless other goods based on these products are available to users.

Among different kinds of IPRs, patents are the limited monopoly granted to inventors generally for a period of 20 years for their inventions and innovative creations.<sup>6</sup> Patents are generally viewed as a means towards encouraging invention and innovation in society. An invention to be granted patent needs to satisfy three patentability requirements as laid down in Article 27(1) of TRIPS Agreement:

- (a) invention should be new,
- (b) involve inventive step or should be non-obvious, and
- (c) capable of industrial application.

IPR regime is now extended to the biological resources beyond the conventional domain of mechanical and chemical innovations. It is argued that the evolution of modern IPR regime, as it exists today, has essentially evolved in response to a need in the aftermath of industrial revolution within Europe and does not in principle provide protection for the knowledge of the traditional communities in public domain.<sup>7</sup> Many people have expressed the view that imposition of the current IPR systems will not be suitable for the protection of traditional knowledge

(TK).<sup>8</sup> TRIPS Agreement is incompatible with the international human rights norms and hinges rights of the indigenous and local communities over their natural resources and knowledge associated with those resources. The existing IPR regime also does not provide protection for the inventions that are based on the prior existing knowledge,<sup>9</sup> e.g. knowledge held in the public domain. Many have opined that the current IPR framework is ill equipped to reward the innovations that have originated from a community of people. The TRIPS Agreement also does not provide any specific mention about the traditional knowledge and innovations which are in the public domain. In actual sense, IPRs are utilized as legal means to appropriate the traditional knowledge of the communities.<sup>7</sup> In some countries, patents are granted for processes, products, inventions, naturally-occurring plants, animals, human generic material, microorganisms and parts or components of plants and animals such as, genes, cells, DNA sequences and biological, microbiological processes and non-biological processes.<sup>10</sup>

The grant of patents on non-original innovations (particularly, those linked to traditional medicines), which are based on what is already a part of the traditional knowledge of most of the developing and mega-biodiverse countries without their consent have been causing a great concern. Though, consent is taken in some cases, it is however for an agreed purpose, temporary in nature and mostly given on the basis of trust that recipients respect and uphold the conditions and customary laws of the land. In reality, TK cannot be alienated from the community by transferring ownership to another person or corporation because that knowledge is part of their distinct and collective identity and has meaning in the context of that community and not outside it.

#### **Biodiversity Related Traditional Knowledge and IPRs**

Due to the growing demand for the bio-products in the recent decades, commercialization of the traditional knowledge associated with the bioresources has been on pace all over the world. This has adversely affected the livelihoods of TK holding societies and also caused serious threat to the biodiversity. Hence, a need for the protection of TK and bioresources has been raised and has become a topic of international debate.<sup>11</sup>

#### **The Values and Contributions of Traditional Knowledge**

TK is widely known as a valuable attribute of biological diversity and is one of the important sources of sustainable development in most of the

developing countries. TK is associated with many fields such as, agriculture, medicine, art and architecture, music, folklore, etc. where biological resources are the main components utilized. In India, TK in its various forms fulfills the human needs of the local and indigenous people in different ways. TK has also contributed much to the forest conservation, soil conservation, seed conservation and crop biodiversity. This has led to the sustained food production, crop yields and health care. Pharmaceutical companies have been making use of the TK of tribal people to identify plants and their ingredients for developing new medicines. Researchers screening plants for useful substances can cut down the time taken by getting specific information from tribal healers on the variety of plants used for treating different ailments. International agricultural research centres have been using plant genetic resources drawn from crops of local farming communities in developing countries to enhance agricultural biodiversity and to produce higher-yielding varieties.

In the recent decades, there has been an increased demand for the traditional medicines (TM) all over the world. Over 80% of people from developing countries depend on TM for health needs. A study shows that even in developed countries a significant percentage of people have used traditional medicine at least once, for example, 50% in the USA, 75% in France and 90% in the United Kingdom. The level of expenditure on traditional medicine is also rising. In US, the total out-of-pocket expenditure for complementary and alternative medicine was estimated at US\$ 27 billion, in Australia, A\$ 800 million is spent annually and in UK it has reached £500 million. The world market for herbal medicines, including herbal products and raw materials, has been estimated to reach US\$ 43 billion with an annual growth rate between 5 and 15%.<sup>12</sup>

According to All India Coordinated Research Project on Ethnobotany, the indigenous communities are acquainted with the use of over 9000 species of plants and specifically for the purpose of healing they know the use of over 7500 species of plants. The global market for herbal products, with its appeal ranging from pharmaceuticals and health foods to cosmetics, toiletries and ethnic products, is estimated to touch US\$ 5 trillion by 2020.<sup>13</sup>

#### Threats to TK

##### *Loss of Biodiversity and Traditional Lifestyles*

In India, a significant part of the land, forests and habitat of tribal people and local communities is being

affected by human activities like deforestation, logging, road construction and dam projects, mining, urbanization and conversion of forests to land for agricultural plantations.<sup>14</sup> The loss of resources and habitat has disrupted the social and ecological context within which the communities have made use of their traditional knowledge.

TK accounts as a valuable attribute of the indigenous and local communities that depend on it for their health, livelihoods and general well-being. TK is also considered as manifestation of culture. Traditional low-input agricultural systems, based on extensive and applied knowledge about natural processes and local ecosystems have successfully enabled millions of people to subsist for thousands of years in some of the most hostile environments.<sup>15</sup> However, many TK based agricultural systems have also declined. The traditional lifestyles of the indigenous communities have been urbanized with the migration of large chunk of indigenous and tribal people from rural areas to the urban areas. The impact of modernization/westernization on these communities, commercialization of agriculture with the introduction of export crops and spread of market economies, etc. have made international communities take the initiatives to protect and conserve biodiversity and knowledge related to the use of biological resources.

Protecting such an important element of heritage of a nation is imperative in situation where it is under a threat of erosion. Dutfield<sup>16</sup> expresses a view:

‘[t]he knowledge, innovations and practices of indigenous people and local communities are manifestations of their cultures. Protecting a people’s culture means maintaining those conditions that allow a culture to thrive and develop further... Therefore, protecting a people’s cultural heritage involves *inter alia* maintaining the link between people and natural features of the landscape and naturally occurring species of plants and animals’.

The current international negotiations on the issue of protection of TK, the term protection is mostly seen as providing a framework to encourage the maintenance of practices and knowledge embodying traditional lifestyles. But in its actual sense, protection as provided by Article 8(j) of CBD also requires promotion of ‘wider application’ of TK. Some describe protection in this context as ‘a tool for facilitating access to TK’ and some say that

preservation of TK is not only a key component of the right to self-identification and a condition for the continuous existence of indigenous and traditional people; it forms a central element of the cultural heritage of humanity.<sup>1</sup>

### **Biopiracy**

The most complex set of problems facing the future of traditional knowledge comes from the misappropriation of this knowledge from the local communities and tribal people who should be its rightful owners. In the traditional system of India, there has not been a system of private ownership of knowledge in relation to the use of biodiversity such as farming, fishing, animal rearing, healing and use of medicinal plants.<sup>17</sup> Even though there is private ownership of land or the demarcation of rights by different communities to forest areas, tribal people and local communities have generally shared their knowledge of the use of seeds, medicinal plants and techniques of production, harvesting and storage, and also shared the seeds and genetic materials. This system of cooperative innovation and community sharing is threatened by the new system of knowledge rights represented by IPRs and the TRIPS regime. Many pharmaceutical corporations and bioprospectors are misappropriating TK and making huge profits in the form of what is popularly known as biopiracy. Many critics condemn, the northern '[c]orporations are surveying remote areas of the world for medicinal plants, indigenous relatives of common food crops, exotic sweeteners, sources of naturally occurring pesticides...genetic material and knowledge of the indigenous people'. The epithet 'biological colonialism', 'genetic imperialism', and even plain 'plunder' dominate many instances of the biopiracy narratives.<sup>18</sup> The rampant commodification of TK through its exploitation and appropriation has accelerated the debate of protecting TK and its subset TM. In most of the cases, developing countries were the victims of these misappropriations by the researchers, scholars and institutions from outside the community with neither the consent of the community nor agreements to share benefits arising from the use of the knowledge, made them to counter the western 'protectionist' measures in the form of IPR for the knowledge that was already known to this part of the world. In this aspect, India holds the view<sup>19</sup>

Rampant biopiracy deprives holders of traditional knowledge of any benefits. Loss of bio-diversity and associated traditional knowledge will not only deprive the world of a unique knowledge-base but

also threaten the very survival of local communities. IPRs laws must benefit all holders of such IPRs equally – whether they are huge multinationals spending billions of dollars on research or traditional local communities where knowledge has simply been passed on from one generation to other.

The above observation has emphasized on two reasons to protect TK- benefits (economic) and threat to the survival of the local communities (social). Though, economic reasons are the important reasons of protection, social factors such as livelihood, conservation of knowledge, tradition and cultures of indigenous and local communities are equally important for a person to make justification for his advocacy of protecting TK.

### **Patenting of Genetically Modified Organisms (GMOs)**

Despite huge oppositions from various sectors and stakeholders for various reasons, India has established patenting of GMOs including genes of animals and plants. Similarly, there are many cases of patenting of GMOs especially, in agricultural crops in other countries throughout the world, for example:

- The biotechnology company, Agracetus was granted a broad patent in 1994 that covered all transgenic soybeans. Species patents of such kind can be used to stake claims and as a means to block research and competition.<sup>20</sup>
- A GRAIN study covering the period 1982-1997 found 160 biotechnology patents on rice, most of them held by US and Japanese companies. The top 13 rice patent holders had just over half the biotechnology rice patents. In 1998, farmers in India and Thailand protested on the streets against patenting of basmati rice (India) and jasmine rice (Thailand) by a US company.<sup>21</sup>
- Research sponsored by the Guardian showed that as of November 2000, there were many applications filed for patents on 2,181 maize gene sequences, 1,100 potato gene sequences and 288 wheat gene sequences.<sup>22</sup>
- Research laboratories have genetically engineered the Bt gene into crops (including maize, soybean, cotton, potato, rice) so that the plants produce their own insecticide. Due to mergers, the technology is heavily concentrated in few hands, and some companies have obtained very broad patents.<sup>23</sup>

For example, Belgium's Plant Genetic Systems (Aventis) was granted a US patent for 'all transgenic plants containing Bt' whilst the US company Mycogen (Dow Agrosciences) obtained an European patent that covers the insertion of 'any insecticidal gene in any plant'. These types of broad patents create huge market monopolies and thus the prospect of monopoly profits. Since Bt has already been used by farmers for over half a century as an ecological insect control system, the element of biopiracy also lies with these patents.

#### *Protection of Plant Varieties*

Many varieties of staple food crops have been developed by farmers over generations through cross-breeding. Until recently, plants and plant varieties were not patentable in many countries including India. The situation has changed now, in European Union, patent law has been extended to microorganisms and genes of plants, animals and humans. But in US alone, 11,000 patents on plants have been registered since 1985. In India, the Government has also enacted, the Protection of Plant Varieties and Farmers' Rights Act, 2001, for the protection of plant varieties developed by researchers and plant breeders. This has resulted in a mad rush among multinational companies for developing and patenting techniques to decode and identify the best plant genes of food crops. But the farmers who actually developed the food crops would have no effective rights over the varieties that are patented by the transnational companies.<sup>24</sup>

#### *Patenting of Traditional Medicines*

Patenting of TM described as biopiracy is the most important threat to the biodiversity and TK. Most of the knowledge relating to the use of plants for medicinal purposes resides with the local and indigenous communities. The US Pat No 5,401,504 on turmeric is the classic example of biopiracy, which India had successfully challenged and got it revoked. Turmeric is a native plant of the Indian sub-continent and has been used for many centuries to treat sprains, inflammatory conditions and wounds. The patent was granted by US in 1995 to scientists from the University of Mississippi on the use of turmeric for healing wounds, claiming this to be novel. It was challenged by the Government of India, which provided research papers predating the patent proving that turmeric has long been used in India to heal

wounds. The USPTO then rejected the six patent claims. In case, if India had not challenged this patent, the Indian companies would have been prevented from marketing turmeric for wound healing in the US. Not only turmeric, there were many patents granted and are in the process of granting over the traditional usage of plants and traditional methods by Indians which have been in public domain. The very recent event is the patents on Yoga.<sup>25</sup>

### **Protection of Biodiversity and TK: Issues and Concerns**

#### **Disclosure of Origin and the Prior Informed Consent**

There have been extensive discussions on the introduction of a mandatory requirement for the disclosure of origin of biological resources and/or associated TK used in inventions for which IPRs are applied. India along with other developing countries proposed

'where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, the Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin'. And that, 'the Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge'.<sup>26</sup>

In July 2000, India submitted a paper on 'Protection of Biodiversity and TK' to the TRIPS Council and the Committee on Trade and Environment, stating that there is a need for legal and institutional means for recognizing the rights of tribal communities on their traditional knowledge based on biological resources at the international level, and to institute mechanisms for sharing of benefits arising from commercial exploitation of biological resources using such TK. If this is done, it would enable domestic institutional mechanisms to ensure sharing of benefits of such commercial utilization by the patent holders with the indigenous communities who's TK has been used. India also recommended that the acceptance of this practice of disclosure and prior informed consent (PIC) by all patent offices in

the world is essential to prevent biopiracy. At the domestic front, India has introduced the provisions for disclosure of the source of biological material in Patents (Amendment) Act, 2005.

#### **Access and Benefit Sharing**

The issue of access and benefit sharing is mostly discussed at the CBD negotiations. Article 15 of the Convention addresses the terms and conditions for access to genetic resources and benefit-sharing. It asserts the sovereign rights of nations over their natural resources, and their right to determine access, promoting access and their common use. It notes that access to genetic resources should be on the basis of PIC, and on mutually agreed terms that provide fair and equitable sharing of the results of research and development and the benefits of commercialization and utilization. It also calls for the fair and equitable sharing of benefits derived from the use of TK. In respect of intellectual property, the Convention states, that access and transfer of genetic resources should be consistent with the 'adequate and effective protection of IPRs'. Governments should put in place policies to ensure that, particularly for developing countries, access to genetic resources takes place on mutually agreed terms. It notes that patents and other IPRs may have an influence on implementation the Convention, and governments should cooperate (subject to national and international law) in order to ensure that such rights are supportive of and do not run counter to the CBD's objectives [Article 16].

Although, the Convention was adopted in 1992 and entered into force at the end of 1993, it was not until 1999 that work began in earnest to operationalize these provisions. Though, the provisions of the Convention are binding, they are mostly not mandatory but recommendatory in nature. However, many state parties to the Convention have implemented the objectives and directives of the Convention. According to its prime objectives related to benefit sharing and PIC which is accepted to be important for the developing countries, the Governing Body of CBD agreed on the 'Bonn guidelines on access and benefit sharing' to assist parties, governments and other stakeholders in developing overall access and benefit-sharing strategies, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. More specifically, the guidelines are intended to help them in establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual

arrangements for access and benefit-sharing. A programme for capacity building is already under way to ensure that developing countries are in a position to effectively implement the guidelines and the corresponding provisions of the Convention.

The Guidelines identify steps in the access and benefit-sharing process, with an emphasis on the obligation to seek the PIC of providers. They also identify the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers and stress the importance of involvement of all stakeholders. They also cover other elements such as incentives, accountability, means for verification and dispute settlement. Finally, they enumerate suggested elements for inclusion in material transfer agreements and provide an indicative list of both monetary and non-monetary benefits. Although, they are not legal binding, the fact that the guidelines were adopted unanimously by some 180 countries gives them a clear and indisputable authority and provides welcome evidence of an international will to tackle difficult issues that require a balance and compromise on all sides for the common good. This was reinforced by the call of the World Summit on Sustainable Development, held in Johannesburg in August/September 2002, for countries to negotiate, within the framework of the CBD, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. It is expected that the Bonn Guidelines will form a part of that broader framework and will serve as a vital tool for the full implementation of the Convention and safeguarding of the natural wealth on which all human societies depend.

#### **Indian Initiatives for Protection**

To conserve the biodiversity and counter the problem of biopiracy, India made a maiden effort in the world by enacting the following three legislations in the Parliament:

- (a) The Protection of Plant Varieties and Farmers' Right Act, 2001;
- (b) The Biological Diversity Act 2002; and
- (c) The Patents Amendment Act, 2005.

#### **Protection of Plant Varieties and Farmers' Right Act, 2001**

India is the original home for many crops such as, rice, little and kodo millets, red gram, moth bean, jute, pepper cardamom, many vegetables and fruit species. These plants were identified from the wild, selected and cultivated by Indian farmers over hundreds of

years. The present wealth of varieties in India includes both crops that have originated in the country and those that were introduced from other countries in the past. The introduced crops include wheat, sorghum, maize, pearl millet, ragi, groundnut, gram, sugarcane, cotton, tea, rubber, etc. Recently, few crops like soybean, sunflower, oilpalm and kiwi fruit were also introduced in India. Indian farmers have evolved a rich diversity out of these introduced crops. During the long process of selection, conservation and cultivation, farmers have gained extensive knowledge of each variety. This knowledge includes suitability of variety for specific growing seasons and conditions, its maturity duration in different seasons, resistance to different diseases, pests, and other natural vagaries, suitability to different soils, and quality of the produce. Its availability with farmers is as highly valuable to modern scientific improvement as the genetic diversity of crop plants. This makes the contribution of farmers to plant genetic diversity as important as the contribution scientists make in developing modern plant varieties. Therefore, when scientists are given the right to own new varieties created by them, this right concurrently recognizes the right of the farmers on their varieties. The Protection of Plant Varieties and Farmer's Rights Act, 2001 (PPVFR Act)<sup>27</sup> therefore, seeks to protect the rights of farmers and breeders on plant varieties. The Act recognizes the individual and community roles played by farmers in the improvement and conservation of varieties. Under the PPVFR Act, Plant Breeder's Right (PBR) on a plant variety is established by registration of the variety. By registering a plant variety, the person becomes its PBR holder. The PBR holder can be one person, a group or community or an institution. The PBR holder alone has the exclusive right to produce, sell, market or distribute the seeds or planting material of that variety. Other important features of the PPVFR Act are provisions with regard to researcher's rights, benefit sharing between breeders and farming or tribal communities who have contributed to genetic diversity used by the breeder and establishment of a national gene fund to promote conservation.

### **Biological Diversity Act, 2002**

The CBD states that a member country should facilitate access to its genetic resources by other parties on mutually agreed terms, but that access requires a PIC of the country providing the resources. It also provides for an equitable sharing of any

benefits arising from the commercial use of these resources, or any TK associated with the biological resources subject to domestic legislations. In response to its obligation under the CBD, after 10 years of negotiations and discussions with all the stake holders, India has enacted the Biological Diversity Act in 2002. The Act mainly deals with access to genetic resources by foreign companies, individuals or organizations. The National Biodiversity Authority (NBA) was set up under Section 8 of the Act to deal with requests for access to genetic resources by foreigners, and to manage requests to transfer the results of any related research out of India and to determine benefit sharing arising from the commercialization. The salient features of the Act are to :

- (a) 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 knowledge relating to biological resources;
- (b) conserve and sustainable use of the biological diversity;
- (c) respect and protect knowledge of local communities related to biodiversity;
- (d) secure sharing of benefits with local people as conservers of biological resources and holders of knowledge and information relating to the use of biological resources;
- (e) conserve and develop areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
- (f) protect and rehabile threatened species;
- (g) involve institutions of state governments in the broad scheme of the implementation of the Act through constitution of committees.

The Act prescribes some special provisions for the protection of TK. Among them Chapter II of the Act, regulates access to biological diversity. The Act prohibits 'certain persons' from obtaining any biological resources occurring in India or knowledge associated there to for research or for commercial utilization or for bio-safety and bio-utilization. The Act prevents any person from transferring the results of any research for monitory consideration or other wise to such certain persons without previous approval of the NBA (Article 3,4). Section 6 of the Act, is the key provision dealing with IPRs on biological resources and associated knowledge.

According to this provision, no person shall apply for any IPR, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the NBA.

The procedures for the access and other purposes mentioned in the Act are provided to ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. The NBA, through appropriate consultation mechanisms shall dispose of the application and communicate its decision to grant access or otherwise to the applicant within a period of six months from the date of receipt of the application. The Authority is required to communicate the grant of access to the applicant in the form of a written agreement duly signed by an authorized official. The Rule 14 of the Biodiversity Rules, 2004 also stipulates the Authority to provide reasons in writing in case of rejection of an application and give reasonable opportunity to the applicant for appeal. The Authority shall publicize the approval granted through print or electronic media and also shall monitor the compliance of the conditions agreed by the party and the applicant when approval for grant for access was accorded. The access procedures are only regulatory in nature, but are not prohibitive in any manner to any applicant irrespective of their nationalities, affiliations, origin, etc.

The Act also provides for revocation of the approvals granted to an applicant only on the basis of any complaint or *suo moto* under the following conditions:

- (i) violation of the provisions of the Act or conditions on which the approval was granted, or
- (ii) non-compliance of the terms of the agreement, or
- (iii) failure to comply with any of the condition of access granted, or
- (iv) on account of overriding public interest or for protection of environment and conservation of biodiversity [Rule 15(1)].

After having withdrawn the access permit, the Authority is required to send an order of revocation to the concerned Biodiversity Management Committee and the State Biodiversity Board to prohibit the access and to assess the damage, if any, caused, and steps to recover the damages [Rule 15(2)].

#### *Criteria for Benefit Sharing*

While the NBA gives Indian nationals/researchers permission to access biological resources, it will also lay down some conditions as to how any benefits that arise should be shared with local communities. The Act provides that benefit sharing may include monetary payment, technology transfer or joint ownership of IP rights, but this is not an exhaustive list. The Act, subject to Section 21 and Rule 20 of the Biodiversity Rules, insists upon including appropriate benefit sharing provisions in the access agreement on 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 may be paid to the National Biodiversity Fund. 5% of the benefits may be earmarked for the Authority or State Biodiversity Board towards administrative service charges.

With the assistance of NBA, eighteen State Biodiversity Boards (SBBs) have been formed by their respective state governments. Several biodiversity management committees have also been constituted by SBBs. The main function of the Biodiversity Management Committee (BMC) constituted under each local body as per Section 41(1) of the Act and Rule 22(1-11) of Biodiversity Rules (2004), is to prepare People's Biodiversity Registers, which shall contain comprehensive information on the availability and knowledge of local biological resources and



medicinal or any other traditional knowledge associated with them. Other important functions of the BMC are to advise the SBB and the NBA on matters for granting approval, maintain data about the local *vaid*s and practitioners using the biological resources, besides maintaining a register containing information on access to biological resources and knowledge granted, details of collection fee received and details of benefit sharing derived along with the mode of sharing. NBA has set up eight expert committees to prepare guidelines on different issues. The guidelines for the collaborative research projects have been approved and published in the government's official gazette, however, guidelines on issues like normally traded commodities, intellectual property rights, traditional and tribal knowledge, microbial diversity, etc. are in the line for approval.

#### **The Patent (Amendment) Act, 2005**

With the adoption of TRIPS Agreement in 1995, India has to amend its patent laws to fulfill its obligations under TRIPS Agreement. Accordingly, in 2005 India has enacted the Patents (Amendment) Act and introduced product patents alongwith some provisions relating to TK. Firstly, the changes made to the definition of the term 'patent' which means a patent granted for an invention under the Act [Section 2(1)(m)] and specifications of 'invention' which are not patentable in Section 3 of the Act which states that 'a mere new use for a known substance' [Section 3(d)] and 'an invention which, in effect, is traditional knowledge or which is and aggregation or duplication or known properties of traditionally known component or components' [Section 3(p)] will not be an invention. Secondly, the inclusion of the new provisions of patent opposition proceedings which can be done on limited grounds under Section 25(1) of the Act as:

- (a) patentability including novelty, inventive step and industrial applicability, or
- (b) non-disclosure or wrongful disclosure mentioning in complete specification, source and geographical origin of biological material used in the invention and anticipation of invention by the knowledge, oral or otherwise

available within any local or indigenous community in India or elsewhere.

Thirdly, inclusion of the provision for the opposition of a complete patent specification of an invention which was publicly known or publicly used in India before priority date of that claim [Section 25(3)(d)].

The reason for the inclusion of all the above provisions is to defy the challenges of misappropriation of the TK which is already in the public domain in India or its use is known to the Indian communities or individuals from the time immemorial. One inference can be drawn from these provisions that all of them are defensive in nature, which can help to oppose the patents granted for the inventions whose source and geographical origin of biological material used or the knowledge, oral or otherwise is available within any local or indigenous community in India or elsewhere. Benefit sharing is not the concern of the Act. But the doubt arises that, which type of TK knowledge is protected under these provisions? To clarify this confusion, the definition of the TK has to be specified in the Act. This leads to a necessity of a *sui generis* system for the protection of TK and its subsets which could be a combination of various systems of protection, i.e. patents, trade secrets, geographical indications and a cultural heritage of the nation.

#### **Conclusion**

There is a strong need for protecting and promoting the traditional knowledge related to biodiversity. If this is accorded its rightful high priority on the national agenda, the government shall allocate a significant budget to facilitate the effective implementation of the Act. To conclude, one can say that India did prove itself as a role model for other countries in protecting the biodiversity and traditional knowledge. However, the pace of implementing activities of NBA needs to accelerate for better results. NBA, needs more support, reviews and feed back from all the stake holders on its activities. The funding and organization of research programmes in universities, government agencies, NGO's or community organizations, to identify, record and register traditional experts in agriculture, health care, fishing, animal husbandry through the People Biodiversity Register programmes by the State Biodiversity Boards and Biodiversity Management Committees may be implemented. In addition,

Government may take the following initiatives for effective protection and conservation of biodiversity and TK:

- Establishing agricultural research programmes and centres for *ex situ* and *in situ* conservation of plant varieties and plant genetic resources, and for developing new plant varieties by making use of the knowledge and innovations of local farming communities, and transferring good practices and varieties throughout the country.
- Setting up or promoting herbal gardens of traditional medicinal plants.
- Ensuring adequate income to the community healers experts on traditional knowledge.
- Incorporating traditional knowledge as part of the curriculum for schools, colleges, universities and research centres.
- Enhancing traditional medicine and healing arts in state-run hospitals.
- Recognizing leaders, experts and innovations in TK in various fields by providing incentives.

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