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Access and Benefit Sharing and the Biological Diversity Act of India: A Progress Report

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Abstract: Biological Diversity Act, 2002 was enacted in the parliament of India on 5th February 2003 and to implement the above act the National Biodiversity Authority was established in September 2003. Following this the Biological Diversity Rules 2004 were notified as well as various sections of the BD Act simultaneously. For effective functioning of the National Biodiversity Authority the Regulation/Guidelines /notifications were being prepared and notified based on priority. Since the BD Act is in force in India, the application for Access for Bioresources and associated Traditional Knowledge (for research and/or commercial use), Transfer of Research Results (Technology), approval for Patent (IPR) applications and Third Party Transfer of Bioresources were received regularly and approved by the National Biodiversity Authority in accordance with the BD Act. The nitty-gritty of the process of the approval of application for access of bioresources, the criteria for benefit sharing and the recent developments in the National Biodiversity Authority in connection with access and benefit sharing are shared in this paper for transparency in the ABS process.

Keywords: ABS India, Biological Diversity Act, 2002 progress till 2008.

Introduction

India is one of the 12 mega biodiversity countries of the world as well as one of the mega-diversity countries. Demographically, it is the second-largest populated country in the world and a majority of its population still directly depends on biological resources for their livelihood. With only 2.5 per cent of the total land area, India accounts for 8 per cent of the recorded species of the world which includes countless millions of races, subspecies and local variants of species and the ecological

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processes. India is very rich in terms of biological diversity due to its unique bio-geographic location, diversified climatic conditions and enormous eco-diversity and geo-diversity. India embraces three major biological realms, viz. Indo-Malayan, Eurasian and Afro-tropical and is adorned with 10 bio-geographic zones and 26 biotic provinces.[1]

Plant Diversity

About 850+ species of bacteria, 14,500+ species of fungi 6,500+ species of algae and 17,500+ species of flowering plants are reported from India till today[2]. At National level, the information on flowering plants has been documented in 24 Fascicles by the Botanical Survey of India in addition to eight volumes covering general aspects of flora of India, such as physiography; geology; climate; botanical history; phyto-geographical divisions; endemism; centers of diversity and phyto-geographical affinities; exotics; ethno-botanical, medicinal and plants of other economic value; plant based industries; wild relatives of cultivated plants; endangered plants, habitats and their conservation; protected area network; botanic gardens and the statistical analysis of the flora have been published.

Faunal Diversity

So far 89,451 species of fauna have been identified from India and insects alone account for 59,353 species. Amongst invertebrates, parasitic forms, Meiofauna and Soil Fauna (Annelida) exhibit a very high degree of endemism at species level. Overall, 34.90 per cent of insect species are endemic to the Indian region and more than 40 per cent of Indian leech, freshwater sponges and molluscs also show endemism. Among vertebrates, highest degree of endemism at species level is seen in Amphibia followed by Reptilia, Aves, Mammalia and Pisces.[3] Fisheries in India play an important socio-economic role. More than six million fishermen and fish farmers in India depend on fisheries and aquaculture for their livelihood. The harvestable potential of marine fishery resources in the Indian Exclusive Economic Zone has been estimated at about 3.9234 mt. A total fish production of 8.09 million tonnes (3.26 million tonnes from the marine sector and 4.83 million tonnes from the inland sector) had been achieved at the end of the 2007.

Crop Diversity

India's preponderance of native tribal and ethnic groups has contributed significantly in the conservation and diversification of

biodiversity. Its cultural and ethnic diversity includes over 550 tribal communities of 227 ethnic groups spread over 5,000 villages. These people have traditionally protected patches of forests in the form of sacred groves dedicated to deities and more than 50,000 sacred groves have so far been reported from various parts of the country which harbour several species of flora and fauna. India holds a prominent position among the eight vavilovian centres of origin of cultivated plants, which is the geographic region where crops exhibit maximum diversity in terms of number of races and botanical varieties.[4] In India, rice landrace variability exists both in indigenous crops as well as those introduced from other parts of the world. Today, about 166 crop species and well over 324 species of wild relatives of crop plants are recognized and utilized for food production. Wild edible plants account for nearly 1000 species serving various purposes: 145 as roots/tubers, 526 as leafy vegetables/greens, 101 for buds/flower, 647 for fruits and 18 for seeds and nuts.

Moreover, India has rich tradition of conserving nature and natural resources. Worship of trees, forests, rivers, ponds, mountains and association of animals and birds with gods and goddesses have contributed immensely to their conservation. Various traditional systems of *in-situ* conservation of natural resources have been organised and institutionalised. Therefore, a great challenge exists for India to conserve its rich biodiversity while ensuring economical and ecological security.

Multilateral Environmental Agreements on Biological Diversity and India's Responses

India has been playing a major role in the implementation of global, international, regional and national policies and programs related to environment, biodiversity, trade and intellectual property rights. Biological diversity and associated traditional knowledge are two important areas of focus for India, with links to sustainable development. With such a focus, India is Party to the World Heritage Convention (1972), Convention on International Trade in Endangered Species of Flora and Fauna (CITES) (1975), Ramsar Convention on Wetlands (1975), Convention on Biological Diversity (1992), Agenda 21 (1992), UN Framework Convention on Climate Changes (1992), UN Convention to Combat Desertification (1994), the Trade Related Intellectual Property Rights (WTO-TRIPs) 1994, Cartagena Protocol for Biosafety to CBD (2000), FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO, 2001) and others.[5] CBD is the

most comprehensive legal instrument that addresses the issues of access to genetic resources and benefit sharing with explicit links to issues related to traditional knowledge associated with genetic resources. Consequent to the ratification of CBD by India on 18th February 1994 and in pursuance of the Conference of Parties (CoP) decisions of CBD that followed, the Ministry of Environment and Forests - the national focal point of CBD, has taken steps to implement the CBD provisions by promulgating the Biological Diversity Act, 2002 (NBA) in Parliament of India. Recognizing urgent need to develop human resources, capabilities and legal and public policy to enable countries rich in Biodiversity to take an active part in the new economy associated with the use of Biological Diversity, a set of rules to implement the NBA were developed in 2004. India continued to play a crucial rule in furthering global debates on ABS in several international fora including the World Intellectual Property Organisation (WIPO), the Trade Related Intellectual Property Rights (TRIPS) council and others. India also is the founding member of the Like-Minded Mega biodiverse Countries (LMMC) group that worked actively towards a decision to develop an international regime on ABS. In doing so, India continues to insist that the regime must be "legally-binding" for the effective implementation of the ABS requirements enunciated by the CBD.

Biological Diversity Act, Access and Benefit sharing

The Biological Diversity Act, 2002 India, primarily addresses the issues concerning access to genetic resources and associated knowledge by foreign individuals, institutions or companies, and equitable sharing of benefits arising out of the use of these resources and associated knowledge by the country and its people.[6] The Act governs Access and Benefit Sharing (ABS) through a three tier system, National Biodiversity Authority (NBA), State Biodiversity Board (SBB) and Biodiversity Management Committees (BMC). The NBA deals with matters relating to requests for access to bioresources and associated traditional knowledge by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner; imposition of terms and conditions to secure equitable sharing of benefits, establish sovereign rights over the bioresources of India and approval for seeking any form of Intellectual Property Rights (IPRs) in or outside India for an invention based on research or information pertaining to a biological resource and associated traditional knowledge

obtained from India. SBBs deal with matters relating to access to bioresources by Indians for commercial purposes and restrict any activity which violates the objectives of conservation, sustainable use and equitable sharing of benefits. The mandate of the BMCs is conservation, sustainable use, documentation of biodiversity and chronicling of knowledge relating to biodiversity. BMCs shall be consulted by the National Biodiversity Authority and State Biodiversity Boards on matters relating to use of biological resources and associated knowledge within their jurisdiction. In order to safeguard the interests of the local people and to allow research by Indian citizens within the country, free access to biological resources for use within India for any purpose other than commercial use for Indian people has been given to *vaid* and *hakims* (= traditional physicians) and other citizens.

Provisions for setting up of Biodiversity Funds at Central, State and Local levels are provided (Sections 27, 32 and 42) in the Biological Diversity Act, 2002. The monetary benefits, received as fees and royalties for approvals by National Biodiversity Authority is deposited in National Biodiversity Fund and used for conservation and development of areas from where resources have been accessed.

National Biodiversity Authority

The Biological Diversity Act of India, 2002 and the Biological Diversity Rules, 2004, is implemented by the NBA established by the Government of India under Section 8. The National Biodiversity Authority also performs functions such as laying down the procedures and guidelines to govern the activities such as access and benefit sharing and Intellectual Property Rights, in accordance with the Article 8 (j) of the CBD. The authority also coordinates the ABS activities of the SBB and BMC by providing them with technical assistance and guidance. NBA advises the government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources, select and notify the areas of biodiversity importance as biodiversity heritage sites under this act and perform other functions as may be necessary to carry out the provisions of the act. The NBA on behalf of the Government of India takes measures to protect the biological diversity of the country as well as oppose the grant of intellectual property rights to any foreign country on any biological resource obtained from India or knowledge associated with such biological resource.

The establishment of the ABS provisions and their effective implementation in the territorial jurisdiction of India is dealt with in the Biological Diversity Act 2002 (Sections 3, 4, 6) and in the Biological Diversity Rules 2004 (Rule 14-20). This act provides for regulated access to biological and genetic resources by bonafide end-users for different purposes, including scientific research, commercial uses, biosurvey, bio-utilization, conservation and other sustainable uses, etc. The overall implementation of the Act is governed by three functional bodies viz. NBA, SBB, and BMC. NBA is the national competent authority to discharge all decisions pertaining to ABS, including prior informed consent process, approval for access and transfer of biological resources and scientific research results and technologies to foreign citizens, companies and non-resident Indians (NRIs), prior approval for applying for IPRs based on biological resources or traditional knowledge obtained from India, fixing criteria for benefit sharing, approval of third – party transfer of accessed biological resources and traditional knowledge, and several other matters related to ABS.

Access to Biological Resources and Associated Traditional Knowledge under the National Biodiversity Act

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, 4, 6 of the Act and Rule 14-20).

(ii) Access permits 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 *vaids* and *hakims,* practicing indigenous medicines (Section 7 of the Act).

The key procedures to be followed for access to biological resources and traditional knowledge are dealt with under Rule 14 of the Biodiversity Rules 2004. These provisions are laid down to ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. Applicants seeking access to biological resources and traditional knowledge are required to

submit an application in FORM I[7] along with an application fee of INR 10,000/-.[8] Once the application is approved for access, an agreement has to be signed by the applicant for access of bioresources.

The NBA through appropriate consultation mechanisms, approve the applications and communicates 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 of the Authority and the applicant. The rule 14 also stipulates the Authority to provide reasons in writing in cases of rejection of an application and give reasonable opportunity to the applicant to appeal. The Authority shall publicise the approval granted through print or electronic media and also shall monitor the compliance of the conditions agreed to at the time of accordance of approval of grant for access, by the applicant.[9] The access procedures are only regulatory in nature, not prohibitive in any manner to any applicant irrespective of their nationality, affiliations, origin, etc. Since inception, NBA has received more than 260+ applications for access, transfer of bioresources and patent protection. Fee has been paid to National Biodiversity Fund as per the BD Rule 2004 depending upon the type of applications.[10]

Revocation of access or approval

Revocation of access or approval granted to an applicant will be done 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, (ii) non-compliance of the terms of the agreement, (iii) failure to comply with any of the condition of access granted and (iv) on account of overriding public interest or for protection of environment and conservation of biodiversity (Rule 15, Sub rule 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 for prohibiting the access and to assess the damage, if any, caused and steps to recover the damages (Rule 15, Sub rule 2).[11]

Restrictions for access to biological resources

The Act imposes certain restrictions on request related to access to biological resources and traditional knowledge if the request is on: (i)

endangered taxa, (ii) endemic and rare taxa, (iii) likely adverse effects on the livelihood of the local people, (iv) adverse and irrecoverable environmental impact, (v) cause genetic erosion or affect ecosystem function and (vi) purpose contrary to national interests and other related international agreements to which India is party (Rule 16, Sub rule 1).[12]

Procedure for prior approval of transfer of research results

The Act does not permit any person to transfer the results of any research relating to biological resources obtained form India for monetary consideration to foreign nationals, companies or non resident Indians (NRIs) without the prior approval of the Authority (Section 4). Approval for such transfers shall be done on the basis of an application to authority in FORM II[13] along with the payment of an application fee of INR 5000/-. The Authority within a period of three months from the receipt of an application shall take a decision on it. As in the case of access permits the Authority shall communicate the approval for transfer of research results to the applicant in the form of a written agreement duly signed by an authorized official and the applicant. The authority shall communicate the reasons in case a request for transfer of research results is not granted and shall give reasonable opportunity and time to the applicant for an appeal, if any (Rule 17, Sub rules 1-6).

Procedure for Prior Approval before Applying for IPR: (Section 6 of the Act and 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 form India. The format for making such applications (FORM III)[14] is annexed to the Biodiversity Rules 2003.

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 associated knowledge to a third party on the basis of the prior approval of the Authority through a process of submitting an application in FORM IV[15] along with the payment of an application fee of INR 10,000/-. The other procedures remain the same as those stipulated for access to biological resources and traditional knowledge under Rule 14.

Criteria for Benefit Sharing

The Act, according to Section 21 and Rule 20 of the Biodiversity Rules,[16] insists upon 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 National Biodiversity Authority is in the process of developing a guideline based on the provision of the Biological Diversity Act, 2002 and the same will be notified with the specific details of benefit sharing formula in an official gazette on a case-to-case basis. While granting approvals for access, NBA will impose terms and conditions so as to secure equitable sharing of benefits. These benefits *inter alia* include:

a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
b) transfer of technology;
c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bioutilization;
e) setting up of venture capital fund for aiding the cause of benefit claimers;
f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

The Biological Diversity Act provides for setting up of biodiversity funds at national, state and local levels. Benefits will be given directly to individuals or group of individuals only in cases where biological resources or associated knowledge are accessed directly through them. In all other cases, monetary benefits will be deposited in the Biodiversity Fund which in turn is used for the conservation and development of biological resources and socio-economic development of areas from where resources have been accessed. 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 is 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 ABS procedures stipulated under the Biodiversity Act, 2002 are in line with the provisions of international laws and policies, particularly CBD and the Bonn Guidelines. The entire procedures as described in the Act can contribute substantially to facilitate an international regime of ABS on genetic resources and traditional knowledge.

Some Recent Developments under the NBA

The implementation of different sections of the Biological Diversity Act is the major task of NBA. Guidelines on Collaborative Research Projects (under Section 5 of the BD Act) involving transfer or exchange of biological resources or information relating thereto between institutions, including government sponsored institutions of India and such institutions in other countries has been prepared and notified.[17] Establishment of Designated National Repository (DNR) (Section 39) is an essential part of the infrastructure for biodiversity conservation. DNR consists of service providers and repositories of preserved specimen consisting of all fauna, herbarium (dried plant material for research), the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. DNRs also contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics." National Biodiversity Authority India has prepared guidelines on Designated National Repository and it is in the process of notification. The other guidelines such as access to bioresources or associated knowledge for research or for commercial purpose by foreigners (Section 3 of the BD Act) and determination of equitable benefit sharing arising out of the use of accessed biological resources, their by-products,

innovations and practices associated with their use and applications and knowledge (Section 21 of the BD Act), transfer of results of any research relating to any biological resources occurring in or obtained from India for further research or for commercialization (Section 4 of BD Act), intellectual property rights of invention based on any research or information on a biological resources obtained from India (Section 6 of the BD Act), biological resources normally traded as commodities (Section 40 of the BD Act), and areas of importance as Biodiversity Heritage sites (Section 37) are in the process of notification under the Act.

Conclusions

India's National Biodiversity Act and Rules form the core of India's commitment to implementing the CBD. Focus of the Act is broader than presented in this article. However, implementation of the Act requires human resource, institutional, financial capacities that still need to be strengthened along with much needed increase in awareness of public at local level in order to make the Act relevant and useful for conservation and development.

Efforts are underway to ensure the experience of India's implementation can be adequately reflected in the global negotiations on development of the international regime. In this regard, we welcome opportunities to share our experiences on development and implementation of the Act and Rules to all those interested. While national actions are based on national priorities, global influences they can make are enormous.

Endnotes

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