



Analysis of Status of Access and Benefit Sharing of Biological Resources and Associated Knowledge in India: The Path from Common Heritage of Mankind to Sovereign Right of a Nation

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Introduction

Biological Resources according to Convention on Biological Diversity (CBD, 1992), includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Convention on Biological Diversity has evolved, from adoption of the text of CBD on 29th May 1992, its entering into force on 29th December 1993, during its long journey from COP1 to COP12 from Nassau, Bahamas to Pyeongchang, Republic of Korea. For Enhanced implementation of Strategic Plan for Biodiversity 2011-2020 to achieve Aichi Biodiversity Targets, the Pyeongchang Roadmap has been developed under Gangwon Declaration on Biodiversity for Sustainable development during October 2014. CBD has become a cohesive force taking issues related to people, benefit sharing, environment, sustainable development, conservation of resources all together as mandated by the core principles of CBD. In compliance with Convention on Biodiversity, the National Biodiversity Authority (NBA) was established in 2003 to implement India's Biological Diversity Act (BDA) 2002 and Rules 2004. CBD according to Article 3 and 15 states sovereign right of a Nation to exploit its own resources.

A major achievement of COP 6 was adoption of Bonn Guidelines (Bonn Guidelines, 2002) on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization.

Bonn guidelines was the starting point of taking ABS to a level where countries are putting their own mechanisms for developing guidelines, compatible with national framework

The Bonn Guidelines were developed by CBD to assist in developing access and benefit-sharing strategies, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. Bonn Guidelines serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing. The Bonn guidelines developed by CBD for overall access and benefit sharing strategies gave way to Nagoya Protocol for implementing provisions of Article 8(j) and 15. Presently 195 countries are Parties to CBD of which 168 are signatories (CBD, 1992a) The Nagoya Protocol on Access and Benefit Sharing (NPABS) came into force on 12 October 2014, ninety days after the date of deposit of the fiftieth instrument of ratification, has 58 Parties (59 Ratifications and 91 Signatures). NBA through Ministry Of Environment, Forests And Climate Change (MOEF), notified Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 on the 21st November, 2014, in exercise of the powers conferred by section 64 read with sub-



section (1) of section 18 and sub-section (4) of section 21 of the BDA, 2002 (18 of 2003) and in pursuance of the NPABS arising from their utilization to the CBD dated the 29th October, 2010.

International Provisions

India is a signatory to FAO, TRIPS, and CBD, the major treaties influencing the protection and conservation of Genetic Resources (GR). Article 27.3 of TRIPS compels members to provide protection to plant varieties, it does not mention about any protection to be conferred to animals. Article 53(b) of EPC excludes for protection of inventions concerning animals. Article 3(j) of Indian Patent Act 1097 excludes plants and animals from patent protection. Article 3 and 15 of CBD States the sovereign right of a Nation to exploit their own resources. The Bonn guidelines developed for overall access and benefit-sharing (ABS) strategies gave way to the Nagoya protocol for implementing provisions of CBD. The Developing countries have been pushing for Disclosure of Origin Requirement (DOR) through TRIPS, recognizing the market value of Genetic Resources, there is resentment from developed countries as it would incur additional cost of ABS. The germplasm exchanges between North-North, North-South, South-North and South-South will have implications of Nagoya Protocol. GR misappropriation can be addressed by stringent checks at National boundary and punitive actions should be taken against persons who are illegally involved in smuggling Indian germplasm without approval. A designated lab for verification of germplasm at molecular level for GR needs to be established to curtail misappropriation. These additional measures will be TRIPS and CBD plus and would deter misappropriation of genetic resources and help in sustainably exploiting, conserving Genetic resources.

National Scenario

India has a total of 34,135 Biodiversity Management Committees (BMCs) with Madhya Pradesh leading with 69.6% BMCs (NBA, 2003). NBA has been in the forefront to process

applications since the time of its inception to access to bioresources for research and commercial purposes, transfer of research results, approval for obtaining IPR, and third party transfer of results. NBA has processed a total of 149 applications (NBA, 2003).

Internationally Recognized Certificate of Compliance (IRCC)

India still has to comply to International Norms of adhering to Common format for Internationally Recognised Certificate of Compliance as evidence to grant Prior Informed Consent (PIC) and for adhering to establishing Mutually Agreed Terms (MAT). Permits or their equivalent constituting an internationally recognized certificate of compliance (CBD, 1992) are minimum provisions needed by clearing house as a proof of PIC and MAT. According to Article 6, paragraph 3 (e) of NPABS (Nagoya Protocol, 2010), for access to genetic resources, the Country should issue a permit or its equivalent and notify the Access and Benefit-sharing Clearing-House. A common format is to be used for registering permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent (PIC) and of the establishment of mutually agreed terms (MAT) in accordance with paragraph 3 (e) of Article 6 of the NPABS (Nagoya Protocol, 2010). The information related to PIC and MAT, according to paragraph 2 (c) of Article 14 is to be provided to ABS Clearing-House. In accordance with paragraph 2(c) of Article 14 of NPABS (Nagoya Protocol, 2010), permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms should be made available to the Access and Benefit-sharing Clearing-House Paragraph 2 of Article 17 reads "A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an **Internationally Recognized Certificate Of Compliance**" dealing with Monitoring the utilisation of genetic resources. Paragraph 3 of





Article 17 establishes an Internationally Recognized Certificate of Compliance to serve as evidence that the genetic resource which it covers has been accessed in accordance with Prior Informed Consent (PIC) and that Mutually Agreed Terms (MAT) have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent. Paragraph 4 of Article 17 of NPABS (Nagoya Protocol, 2010), sets minimum information required by the Internationally Recognized Certificate of Compliance (IRCC), including issuing authority, date of issuance; provider; unique identifier of the certificate; the person or entity to whom prior informed consent was granted; Subject-matter or genetic resources covered by the certificate; confirmation that mutually agreed terms were established; confirmation that prior informed consent was obtained; and commercial and/or non-commercial use. These are minimum standards set out through IRCC to be reported to ABS Clearing-House that can be enhanced by National countries.

Access to Biological Resources

Is access to bioresources the same thing as Prior Informed Consent? The Bonn Guidelines were drafted as a result of outcry emanating from Developing countries to have a provision where in compliance to Biological resources, sovereign rights of a nation, compliance is made to access and benefit sharing. However in response to the Bonn guidelines, hurriedly responding, the Government of India, created National Biodiversity Authority, and as a part of Rules 2004 of BDA, four forms were incorporated to comply with. These provisions are on paper, because from 2006 to 2014 only 19 approvals have been given by NBA. Adding the latest figures at the time of writing this paper, the figure stood at 22. A vast country of India giving 22 approvals for its biological resources seems inadequate. There are several issues that should also be taken care of to stop unauthorised access to biological resources. According to section 40 BDA, 2002(18 of 2003), many biological resources are

listed as commodities. Marine Products Export Development Authority (MPEDA), under the Department of Commerce allows ornamental fish trade under commodities. There should be coordination and liaison of MPEDA with NBA for enforcing the access that any commodity is not accessed as biological resource in the name of commodity. Any indigenous or cultured, that has potential to replicate, should be routed through NBA. this is not the case. a lot of genetic resource exchange takes place in the name of commodity . The EXIM policy lists, fishes as commodity, live, food or ornamental value.

Arbitration Clause of Nagoya Protocol

Article 18, paragraph 1 of Nagoya protocol, for implementation of Article 6, paragraph 3 (g) (i) and Article 7, encourages providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including the jurisdiction, applicable law; options for alternative dispute resolution, such as mediation or arbitration. Unlike WTO, CBD has not used its arbitration clauses. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of NPABS (Nagoya Protocol, 2010). In compliance of Article 18 of Nagoya Protocol, Article 18, paragraph 1(c) as an option for alternative dispute resolution, such as mediation or arbitration, WIPO Alternative Dispute Resolution (ADR) for Biodiversity (WIPO-ADR, 1994) can be utilised for disputes relating to patents, genetic resources, traditional knowledge, plant varieties, environment, and food. The usefulness of ADR in this area has also been recognized in diverse international fora. Like, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity encourages mutually agreed terms including options for alternative dispute resolution. Selected Areas of Dispute where WIPO can arbitrate include access



and benefit sharing, bio-prospecting agreements, compliance, intellectual property agreements, licensing, misappropriation, misuse, mutually agreed terms (MAT), patent disclosure, prior informed consent (PIC), research and development agreements, Standard Material Transfer Agreements (SMTA), technology transfer. The potential stakeholders can be custodians of genetic resources, government agencies, indigenous communities, industry, insurance companies, research institutions, states, traditional knowledge holders and users, universities intergovernmental organizations, nongovernmental organizations,.

Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulation, 2014; Monetary Benefit sharing provisions

The Ministry of Environment, Forests And Climate Change, through National Biodiversity Authority has notified in exercise of powers conferred by section 64 of Biological Diversity Act 2002, regulations called as "Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014 notified on 21st November 2014 on ABS. The guidelines contain 17 Sections covered monetary benefits through regulation 3, 4, 7, 9 and 12.

1. Regulation 3 of the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (GABRAKBSR, 2014) expresses mode of benefit sharing for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization. Article 3 seems to have been written off in haste and seems misleading as it lowers percentage of monetary benefit sharing obligations on the trader without approval, in the range of 1.0 to 3.0% and on the manufacturer in the range of 3.0 to 5.0% of the purchase price of the biological resources. On Prior benefit sharing negotiation, the benefit sharing obligations increase and shall be not less than 3.0% in case the buyer is a

trader and not less than 5.0% in case the buyer is a manufacturer. This article may promote traders and manufacturers not to indulge in prior benefit sharing negotiations for monetary gain and low benefit sharing. For high economic value biological resource, the benefit sharing may include an upfront payment of not less than 5.0%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB

2. Regulation 4 of the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (GABRAKBSR, 2014) provides option of benefit sharing and categorises graded percentages of monetary benefit sharing at the rate of annual gross ex-factory sale of the product that was accessed for commercial utilisation. Till Rs One crore, the benefit sharing component is 0.1%, i.e. Rs 10,000. Annual gross ex-factory sale above Rs One crore up to three crore, fetches 0.2% or Rs 60,000, Above 3 crores, 0.5% i.e. Rs 1,50,000 would be paid as benefit sharing component. The guidelines have introduced a Nagoya plus provision by determining financial structure. How far the financial mechanism will reward the benefactors and stake holders is yet to be seen.
3. Regulation 7 provides for monetary and non monetary mode of benefit sharing for transfer of results of research. In monetary benefit case the applicant has to pay to the NBA 3.0 to 5.0% of the monetary benefit received by the applicant
4. Regulation 9 provides for the mode of benefit sharing in IPR. If the applicant himself commercialises the process/ product/ innovation, the monetary sharing shall be in the range of 0.2 to 1.0% .If the applicant assigns / licenses the process / product / innovation to a third party for commercialisation, the applicant shall pay to NBA 3.0 to 5.0% of the fee received (in any form including the license / assignee fee) and 2.0 to 5.0% of the royalty amount received annually from the assignee/ licensee



5. Regulation 12 provides for mode of benefit sharing for transfer of accessed biological resource and/ or associated knowledge to third party for research/ commercial utilization. The applicant transfer or shall pay to the NBA NBA 2.0% to 5.0 % of any amount and/ or royalty received from the transferee, as benefit sharing, throughout the term of the agreement. In case the biological resource has high economic value, the applicant shall also pay to the NBA an upfront payment, as mutually agreed between the applicant and the NBA. Regulation 15 provides for sharing of benefits for approval granted for biological resource or associated knowledge by NBA for research or for commercial utilization or for transfer of results of research or for Intellectual Property Rights or for third party transfer. 5.0% of the accrued benefits shall go to the NBA, out of which half of the amount shall be retained by the NBA and the other half may be passed on to the concerned SBB for administrative charges. 95% of the accrued benefits shall go to concerned BMC(s) and/ or benefit claimers.

Patent Search on Biological Resources having Commercial value

WIPO Patent Database was used to search patent documents in the area of Biological Resource. The potential of resources of Biodiversity to commercialise is tremendous. The patent documents show the importance of natural

products that can be used for commercialisation through licensing and benefit sharing, thereby improving the status of communities and countries where these natural resources occur. The table is shown as below;

Patent Search	Number of Patents
Oleoresins	81
Biodiversity	152
Fragrance	1871
Emulsifiers	7202
Colours	7530
Cosmetics	24102
Genetic	44385
Extracts	97063
Enzymes	103989
DNA	130564
Drugs	139899
Biological	173749
Genes	183126
Food	290977

Epilogue: In an endeavour to cater to International standards and norms, India is fine listing its Nagoya plus provisions through Guidelines of 2014. International norms would guide in creating a National atmosphere that would help the local communities for their associated knowledge of Biological resource

References

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