

E- Journal of Academic Innovation and Research in Intellectual Property Assets (E-JAIRIPA)

Vol. 1 (01), Dec 2020, pp. 29-46



A CRITICAL ANALYSIS OF IMPLEMENTATION OF ACCESS AND BENEFIT SHARING IN INDIA

Alaknanda*

ABSTRACT

There are millions of species across the world and India has tremendous varieties of species including plants, animals and biological genetic resources that could be potentially useful to humans. Significant potential benefits can be obtained by accessing these genetic resources by making use of them. Since the latter half of 20th century, we have witnessed significant growth in international momentum to establish legal regime for regulating access to genetic resources by the biological rich developing countries. This momentum led to the entry into force of the Convention on Biological Diversity (CBD), an international legal framework which sought to encourage formation of mutually beneficial relationships between the users and providers of genetic resources based on bilateral agreement. India, by virtue of being a ratifying state, was legally obligated to enact the Biological Diversity Act (B.D. Act) in the backdrop of the increasing an enormous number of instances encompassing biopiracy cases. Certain examples of the cases of biopiracy are the Neem Case, the Basmati Cases and the Turmeric Case in which the biological resources and traditional knowledge of the indigenous people in India were misappropriated from them and patents were obtained in relation to them in foreign countries without any prior approval from the Government of India. Access and benefit sharing with the noble idea of extending the monetary and non-monetary benefits to the traditional and indigenous community in India has failed to successfully recognize the benefit claimers and make them a part of the ABS negotiation. Lack of awareness amongst these primitive tribes about their rights under the grand scheme of CBD and subsequent legislation by India has led to the failure of appreciating the rich biological diversity and traditional knowledge in India. The objective of the research paper is to revisit the biological diversity law and framework in

^{*} ALAKNANDA, Assistant Professor, Amity Law School, Amity University Noida.

India and analyze the implementation of access and benefit sharing with respect to some recent cases. The research paper also focuses on the objective of analyzing judicial doctrines and developments for the protection of biodiversity in India and balancing patent with public welfare and rights of the indigenous people in India.

TABLE OF CONTENT

I. INTRODUCTION	32
II. HISTORICAL BACKGROUND	33
III. THE INDIAN FRAMEWORK	34
IV. THE PATENT REGIME AND THE CONTENTIOUS CASES OF NEEM AND	
TURMERIC	35
V. COMPARISON BETWEEN CENTRAL AND WEST BENGAL BIOLOGICAL	
DIVERSITY RULES:	37
A. PROCEDURE FOR ACCESS TO BIOLOGICAL RESOURCES	38
B. REVOCATION OF ACCESS OR APPROVAL	38
C. RESTRICTION/PROHIBITION ON ACTIVITIES RELATED TO ACCESS TO	
BIOLOGICAL RESOURCES	39
D. BIODIVERSITY MANAGEMENT COMMITTEE ('BMC')	39
VI. ACTIVITIES UNDERTAKEN AND PROGRAMS CONDUCTED BY THE WEST	Г
BENGAL BIODIVERSITY BOARD	39
A. BIODIVERSITY MANAGEMENT COMMITTEES IN WEST BENGAL	40
B. PREPARATION OF PEOPLE'S BIODIVERSITY REGISTERS IN DISTRICTS OF	F
WEST BENGAL	40
C. SPREADING AWARENESS	41
VII. THE INDIAN JUDICIARY AND ACCESS BENEFIT SHARING	41
A. APPLICATIONS CHALLENGING THE MADHYA PRADESH SBB THAT LED T	Ю
THE ABS GUIDELINES, 2014	41
B. AYURVEDA INDUSTRY AND THE CIDMA PIL	42
VIII. IMPORTANT COURT ORDERS	43
IX. PROBLEMS WITHIN THE ABS REGIME IN INDIA:	44
X. CONCLUSION	45

I. <u>INTRODUCTION</u>

The objective of this paper is to primarily focus on the conflict that has ensued between the patent regime and the body of traditional knowledge in India. The first section establishes the growth of Indian legislation on biological diversity and provides an outline of the workings of the authorities established under their aegis. The second section looks through the lens of an Indian traditional knowledge conservationist at the patent regime, and makes use of the case studies of neem and turmeric patents to do so. In the third part of this paper, an overview of the stance of the Indian judiciary has been summarized. Finally, the last part puts forth an analysis of a potential bridging between the TK and patent law in the form of the Traditional Knowledge Digital Library. The paper also examines the status of the biodiversity rules implemented in the state of West Bengal.

The effort of the international community for sustainable biological diversity can be traced back to the United Nations (UN) Conference on Human Environment commonly known as the Stockholm Conference of 1972.¹ The Stockholm conference was the first UN Conference focused on environmental issues. The manifesto of Stockholm convention stated that the earth's resources are finite and there is an urgent need to safeguard these resources for the survival of the present and future generation.

In the year 1992, 20 years after the Stockholm Convention, UN Conference on Environment Development (UNCED) known as the Earth Summit² was held in Rio de Janeiro, Brazil from June 3- 14, 1992 as a worldwide mandate for economic development with protection to the environment. The Rio Declaration laid down 27 principles for sustainable development and protection of environment.

Since the latter half of 20th century, there was a growing international momentum to establish legal regime for regulating access to genetic resources. This momentum led to the entry into force of the Convention on Biological Diversity (CBD)³, an international legal framework which

¹ United Nations Conference on Human Environment (Stockholm Conference), retrieved from: https://sustainabledevelopment.un.org/milestones/humanenvironment, last accessed on 27th of August, 2020.

² United Nations Conference on Environment and Development, retrieved from: https://www.un.org/geninfo/bp/enviro.html, last accessed on 27th of August, 2020.

³THE CONVENTION ON BIOLOGICAL DIVERSITY, Retrieved from: https://www.cbd.int/ (last accessed on 27th of August 2020)

sought to encourage formation of mutually beneficial relationships between the users and providers of genetic resources based on bilateral agreement. The Convention on Biological Diversity (CBD) which is a multilateral treaty having the goal of conservation of biological resources, sustainable use of its components and fair and equitable sharing of benefits arising from the utilization of genetic resources was signed at the Earth Summit on 5th of June, 1992 and came into force on 29th of December, 1993. The CBD has two supplementary protocols which are the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable sharing of Benefit Arising from their Utilization (ABS),⁴ which was adopted on 29th October 2010 in Nagoya, Japan and came into force on 12th of October, 2014 and the Cartagena Protocol on Biosafety to the CBD which was signed on 15th of May, 2000 at Montreal, Quebec, Canada and came into force on 11th of September, 2002.

A big 'stakeholder' that cuts across all countries is industry, which has made huge inroads in these past nine years. The bio-industry and the governments supporting it are the key players in the rule-setting on access. As of date, 193 countries of the world are part of the CBD (with the exception of USA). Each of these, depending on the extent of biological wealth they possess and the technological prowess they command, is either a user and/or provider country of *genetic resources*⁵.

II. HISTORICAL BACKGROUND

Genetic resources historically formed part of common heritage of mankind (hereinafter referred to as CHM) and were treated as belonging to global commons. The countries that were rich in biological resources were not able to fully utilize and benefit from their biological resources consisting of species, crops and plant varieties like rubber, cocoa, quinine etc. as they were being rampantly smuggled abroad.⁶Due to technological innovation and development, a large number of industries started evolving the use of genetic resources and have become active in bioprospecting i.e. "the collection and exploration of biological resources for commercial

⁴ THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION (ABS) TO THE CONVENTION ON BIOLOGICAL DIVERSITY, retrieved from: https://www.cbd.int/ (last accessed on 27th of August, 2020)

⁵ Vishwas Kumar Chouhan, *Protection of Traditional Knowledge in India by Patent: Legal Aspect* IOSR Journal of Humanities and Social Science, Volume 3, Issue 1 (Sept-Oct 2012) p 35.

⁶W. Lesser, Sustainable Use Of Genetic Resources Under The Convention On Biological Diversity: Exploring Access And Benefit Sharing, WALLINGFORD, CAB INTERNATIONAL, 127-135 (1997).

purposes."⁷Most well-known industries actively indulging in bioprospecting are pharmaceutical and agricultural industries which are involved in the fields of cosmetics, biotechnology, personal care, botanical medicine, horticulture, crop protection etc.

In the above context, "biopiracy" emerged as a defining context for the corporations and the industrialized countries who were claiming ownership, taking advantage of the genetic resources and Traditional Knowledge (hereinafter referred to as TK) that existed in the developing countries. However, the term biopiracy is rather controversial and imprecise and is generally referred to as "illegal use "or "illegal access" by experts and has been adopted under the Bonn Guidelines.⁸

The idea behind placing genetic resources as global commons is that biogenetic resources are free to be used by anyone in the production of medicines, agriculture etc. However, the fact that bioprospecting industry failed to adequately compensate and involve the stakeholders, led to alternative and destructive uses of biodiversity. Further, the use of biological resources in this form of bioprospecting was unsustainable and threatened species to extinction.⁹

III. <u>THE INDIAN FRAMEWORK</u>

In pursuance of its status as a ratified member to the CBD, India enacted the Biological Diversity Act (BDA)¹⁰, whose objective is to conserve India's biological diversity, ensure sustainable use of its biological resources and ensure equitable sharing of benefits arising out of use of its biological resources. These objectives follow an extremely close pattern with the objectives of the CBD.¹¹ Although the BDA came into existence in 2002, the subsequent Rules notified in 2004 gave it teeth.¹²

⁷Walter. V. Reid et al. A New Lease On Life, in Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, (WASHINTON, DC WRI) (1993).

⁸Graham Dutfield, *Protecting Traditional Knowledge: Pathways To The Future*, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (ICTSD, 7-8(2004).

⁹GOODMAN & V. WALSH, THE STORY OF TAXOL: NATURE AND POLITICS IN THE PURSUIT OF AN ANTI-CANCER DRUG (1st Ed.2001)

¹⁰ Biological Diversity Act, 2002.

¹¹ Convention on Biodiversity, Article 1.

¹² Biological Diversity Rules, 2004.

The BDA sets up a three-tier system¹³ for biodiversity management in furtherance of its objectives: The National Biodiversity Authority (NBA) which is the apex body, state biodiversity boards (SBBs) in each of the 29 Indian states, and the local-level biodiversity management committees (BMCs) that with their respective local self-governments i.e. municipalities and panchayats. As of today, all 29 states have established SBBs and of them, 25 have notified their State Rules.¹⁴

Amongst its responsibilities, the apex NBA is the approving authority under the Act for Intellectual Property Rights (IPR). To achieve this, the Act directs to the NBA persons who wish to apply for any IPR, or base research or information on the biological resources of India. To carry out any of these actions, the approval of the NBA is mandatory, failing which punitive measures in the form of fine up to Rs. 10 lakh, or damages with fine, or imprisonment up to 5 years, may follow.

IV. THE PATENT REGIME AND THE CONTENTIOUS CASES OF NEEM AND TURMERIC

The domains of patent law and traditional knowledge (TK) have always been at loggerheads.¹⁵ The patent regime looks to preserve exclusivity to innovation, which in turn bolsters the innovation paradigm. Its contribution to the paradigm is significant as earlier, with new ideas; the innovators would create a veil of secrecy around them and put them away from use by general society. Now, with exclusive recognition of their ideas, innovators stand to be compensated for their work, and the market stands to benefit from a more multifaceted pool of ideas.

The World Intellectual Property Organisation defines as TK as "knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity". It is a dynamic body of knowledge, and is part and parcel of having a non-commercially guided relationship with the ecosystem.

¹³ Shan Kohli, *Spicy IP Fellowship 2016-17: Biopiracy in the context of the plunder of wheat in India* (March 21, 2016).

¹⁴National Biodiversity Authority, NBA Annual Report 2016-17.

¹⁵ Sharad Vadehra, Conflict between Indian Patents Act and Biological Diversity Act (June 7, 2020)

The two starkest examples from the Indian experience that highlight this void involve the cases of neem and turmeric:

a) Neem

The Neem tree is legendary in India. It consists of potential chemical compounds which is capable of curing various diseases including diabetes, leprosy, skin diseases and ulcers. People in India have been using the seeds, leaves, flowers of Neem tree since a long time due to its medicinal and antiseptic properties. The use of Neem for its medicinal properties is even mentioned in the ancient Indian Ayurvedic texts and well known among the indigenous people of India.

W.R. Grace and the Department of Agriculture, USA filed for a patent over a fungicide extracted from Neem seeds before the European Patent Office (EPO).¹⁶ The EPO initially granted the patent, but faced opposition at the hands of the coalition formed by the Council for Scientific and Industrial Research (CSIR), international NGOs, and Indian farmers.¹⁷ The coalition submitted evidence that the fungicidal effect of neem seed extract had been known and in use by Indian farmers for centuries and were not an invention, as had been claimed. This challenge was successful, the EPO revoked the patent in 2000.

b) Turmeric

Turmeric is a common household item used as flavoring in Indian cooking, in addition to having medicinal properties. The use of turmeric is well known in India and it has been an age-old practice of using turmeric as an antiseptic, skin care product, cooking ingredient and for other household activities.

In 1995, the University of Mississippi applied for a patent over the "use of turmeric in wound healing" which was contested by the CSIR.¹⁸ The CSIR claimed that turmeric had been used for thousands of years in India for healing wounds and rashes, and the claim of "discovering" its medicinal potential was not legitimate. To support this claim, documentary evidence was

¹⁶Patent victory (October 24, 2000) https://www.thehindubusinessline.com/2000/10/24/stories/042421e2.htm (Last visited on August 25, 2020).

¹⁷ Report of the Commission on Intellectual Property Rights (2002) p. 76

¹⁸ Raj Chengappa, Patents: India wins a victory over turmeric but the war is on (September 8, 1997).

produced citing ancient Sanskrit texts.¹⁹ Here, too, the CSIR was successful, and the patent was revoked.

In the above cases, the patent seekers were looking to patent features that had existed in the natural state of things, and been utilized by local communities in techniques for centuries, thereby forgoing the possibility of novelty. It would only be possible to patent modifications of TK or bio-resources. However, it has not been a simple matter to demarcate the two, considering the deep mistrust and dislike that the developing nations hold of the West and of multinational corporations (MNC).²⁰

V. <u>COMPARISON BETWEEN CENTRAL AND WEST BENGAL</u> <u>BIOLOGICAL DIVERSITY RULES</u>

The Biological Diversity Act, 2002 ('Biodiversity Act') was enacted with the exalted objectives of providing for conservation of India's rich biodiversity, sustainable usage of resources, and working out a fair and equitable mechanism of sharing the benefits derived from biological resources and associated knowledge. It is in furtherance of India's obligations arising out of being a party to the United Nations Convention on Biological Diversity which came into force on June 5, 1992. Each party State is said to have sovereign rights over its biological resources and the Biodiversity Act provides for conservation, usage and sharing of resources situated in India. The objectives of the Act are, in fact, borrowed from those of the UN Convention.

The Act envisages and provides for regulation of access to biodiversity, setting up of National Biodiversity Authority ('NBA') and State Biodiversity Boards and respective functions thereof, duties of Central and State governments, Biodiversity Management Committees and authorizes Local Biodiversity Funds. A close reading of the scheme laid down by the Act depicts an active duty and role sharing between Central and State governments. In this regard, the Central government has notified the Biological Diversity Rules, 2004 ('Central Rules'). The State governments have done the same and following the suit, the Government of West Bengal Biological Diversity Rules, 2005 ('State Rules') to perform its

¹⁹ Presentation by the Indian Patents Office, Proposal to include the Indian Traditional Knowledge Digital Library in the PCT Minimum Documentation.

²⁰Cynthia Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. JOURNAL OF LAW REFORM 433(2006).

obligations under the central legislation. The West Bengal Biodiversity Board ('WBBB') has been set up under the aforesaid Rules.

Although, the State Rules are aligned with the Central Rules with respect to the aforesaid procedures for the most part, there are a few areas where the State Rules diverge from the latter. This aspect of conformity of State Rules with the Central Rules is discussed in greater detail below.

A. PROCEDURE FOR ACCESS TO BIOLOGICAL RESOURCES

Rule 14 of the Central Rules deals with the procedure for granting access to biological resources (and traditional knowledge). Rule 15 of the State Rules is the corresponding provision and it deals with the procedure to be followed by WBBB while granting approvals for access. An application has to be made before the designated authority seeking permission for accessing biological resources. The time given to the NBA by Rule 14(3) of the Central Rules to decide upon an application is six months; Rule 15(2) of the State Rule gives the WBBB 45 days to decide upon the application. Both authorities are however, mandated to consult the concerned local bodies and collect additional information from the applicant and other sources while deciding upon the fate of the application. While the application under Rule 14to NBA has to be made along with a fee of ten thousand rupees, the Rule 1(a) of the State Rules prescribe a fee of five thousand rupees.

Both Rules mandate that the respective authorities shall enter into a written agreement with the applicant if an approval is granted which shall contain specified terms and conditions. The form of agreement prescribed by the Central and State rules (Rule 14(6) of the Central and Rule 15(5) of the State Rules respectively) are similar on most counts, although all of the conditions given in Central Rules do not find expression in the State Rules.

Both Rules required the relevant authority to take active steps to widely publicize the approvals granted, through print or electronic media. They also require them to periodically monitor compliance of conditions upon which the approval to access was granted.

B. <u>REVOCATION OF ACCESS OR APPROVAL</u>

Revocation can be carried out *suo moto* or on complaint and Rule 15 of the Central Rules and Rule 16 of the State Rules are relevant hereunder. The grounds for revocation listed under the former are violation of any provision of the Act or conditions of approval, failure in compliance

with the terms of agreement, failure in compliance with conditions of access and overriding public interest or for protection of environment and conservation of biological diversity. While the first three grounds find exact reciprocation in Rule 16 of State Rule, the last ground has been modified by the State to the extent that overriding public opinion for protection of environment or conservation has been included.

C. <u>RESTRICTION/PROHIBITION ON ACTIVITIES RELATED TO ACCESS TO</u> <u>BIOLOGICAL RESOURCES</u>

Rule 16 of the Central Rules and Rule 17 of the State Rules deal with this matter. The following grounds for restriction/prohibition are common among the rules: endangered or threatened taxa, endemic and rare species, adverse effect on the livelihoods of the local people, adverse environmental impact which may be difficult to control and mitigate, genetic erosion or affecting the ecosystem function or use contrary to national interest and other related international agreements entered into by India²¹. The State Rules includes destruction of biological resources as an additional ground. Moreover, the State Rules provide that restriction/ prohibition can be ordered only after enquiry, hearing and with consultation of concerned Biodiversity Management Committee while there is nothing explicit under the Central Rules with regard to the same.

D. BIODIVERSITY MANAGEMENT COMMITTEE ('BMC')

Rule 22 of the Central Rules and Rule 21 of the State Rules are considered here. While Rule 22(1) of the former envisages a BMC at the level of local bodies, Rule 21(1) of the latter provides that the said general rule is exempt in panchayat areas where a BMC at block and district level shall suffice. The stipulations pertaining to the composition of BMC, women members and SC/ST members are same under both Rules. The primary function of BMC is the same as well, that is to prepare, update and maintain a People's Biodiversity Register.

VI. <u>ACTIVITIES UNDERTAKEN AND PROGRAMS CONDUCTED</u> BY THE WEST BENGAL BIODIVERSITY BOARD

The WBBB is a statutory body established under Section 22 of the Act. Its mandate includes properly implementing the provisions of the Act and State Rules. In exercise of it functions it

²¹Kothari, Ashish (1994): Conserving Life: Implications of the Biodiversity Convention for India, New Delhi: Kalpavriksh

has undertaken activities pertaining to conservation of biodiversity, sustainable use of its components and equitable sharing of its benefits.

A. BIODIVERSITY MANAGEMENT COMMITTEES IN WEST BENGAL

The primary task has been the constitution of BMC at the panchayati block (samiti) and municipality block levels as per Section 41 of the Act. The WBBB has ensured the setting up of BMCs in this manner.

So far, 200 BMCs have been established across 18 districts of West Bengal. The primary function entrusted to each BMC is preparation of People's Biodiversity Register ('PBR') in consultation with local people. BMC in consultation with NGOs and community institutions can also initiate proposals for declaring Biodiversity Heritage Sites and maintenance of such sites is also the duty of BMC. The BMCs share the responsibility to prepare and implement a management plan for a period of 5-10 years in consultation with the WBBB with the help of a Technical Support Group constituted by the WBBB. BMCs are also required to take initiatives for spreading awareness among the local communities about the uses, sharing and conservation of resources. BMC also is required to advise the WBBB or NBA²², as the case may be, on any reference made it to pursuant to granting/restricting access.

B. <u>PREPARATION OF PEOPLE'S BIODIVERSITY REGISTERS IN DISTRICTS</u> <u>OF WEST BENGAL</u>

Another critical task carried out by WBBB, under the aegis of BMCs is the preparation of PBR which requires significant individual and social involvement. The purpose behind it is to document varied biological resources and create Register of the people, by the people and for the people. The knowledge being documented includes both, information useful for commercial application (thus requiring IP protection) and knowledge having the potential of shared benefits.

Hence, the WBBB has ensured that PBRs not only list the species available in the particular area but create comprehensive documentation of habitats, produce, market price, harvest and transport, processing technology, indigenous knowledge of usage, landscape data, perception changes over time, water resources and conservation efforts. This comprehensive register is divided into components of Lifescape, Landscape, Peoplescape and Timescape.

²² Dr. Suresh Pal, Head, Division of Agricultural Economics, IARI, New Delhi

The means of data collection adopted for PBRs include individual/ specialist interviews, group interviews, field observations made through volunteers and members of technical support groups, and official documents.

C. <u>SPREADING AWARENESS</u>

Understanding and appreciation of biodiversity is lost among members of society either due to competing social issues in the media or a feeling of hopelessness attached with the cause. Therefore, WBBB has been instrumental in conceptualizing biodiversity awareness in a manner that connects it with the everyday life and lifestyle of individual to generate care for the cause.

PBR exercise has enabled active people participation, and planning and conducting programmes to enhance a sense of belongingness among people. It has held meetings with administrators and policy makers in this regard as well.

VII. THE INDIAN JUDICIARY AND ACCESS BENEFIT SHARING

As put forth by NoiwaziGcaba, a South African patent attorney, "Legislation is required and it is required yesterday".²³ This aptly sums up the status of legal system while addressing the gap between grant of patent and the preservation of traditional knowledge.

India, too, has grappled with the ambiguities that exist under its felony framework. Topics beneath the BDA were situation to litigation to make clear ambiguities within the legislation and create a strong framework to be followed. The history of biopiracy of Indian bioresources, and the general loss of goodwill that traditional groups preserve of globalisation and capitalism are imperative to be taken into consideration. The BDA, taking cognisance of this, provides for get right of entry to and benefit sharing. Following is a timeline of the stance of the judiciary on get right of entry to benefit cases:

A. <u>APPLICATIONS CHALLENGING THE MADHYA PRADESH SBB THAT LED</u> <u>TO THE ABS GUIDELINES, 2014</u>

In 2013, the MP SBB moved against numerous agencies that used uncooked cloth which may be categorized as "bioresources" and served notices upon them. The authority had already

²³Vishwas Kumar Chouhan, *Protection of Traditional Knowledge in India by Patent: Legal Aspect* IOSR Journal of Humanities and Social Science, Volume 3, Issue 1 (Sept-Oct 2012) p 35.

requested the apex body, the NBA, for tips on ABS matters that would be perused by means of all SBBs uniformly, but no such response was received from the NBA.²⁴The notices directed the organizations to deposit 2% in their gross sales on economic 12 months basis toward gainsharing in the Biodiversity Fund of the state. The companies spoke back by way of filing before the crucial zone (CZ) bench of the NGT²⁵ which put a stay on SBB's notice against Lilason Breweries. Subsequently, the SBB registered a complaint at Bhopal against the Som Group of Companies under the BDA. The NGT (CZ) directed the Ministry of surroundings and Forests and the NBA to create ABS recommendations, which saw the light of day within the form of the 2014 suggestions. Following the 2014 recommendations, the NGT directed the SBB to difficulty fresh notices to the companies that might be in consonance with the pointers.²⁶With the Guidelines finally being adopted, the cases were disposed of, and the SBB created a committee.²⁷

B. AYURVEDA INDUSTRY AND THE CIDMA PIL

The Maharashtra SBB took cognisance of the 2014 Guidelines and issued 1500 notices under Section 8 to AYUSH manufacturers. These notices, citing the Maharashtra Biodiversity Rules, 2008²⁸, Stated that all get right of entry to bioresources need to be filed, and the procedure laid out as well. The producers, but, had been sad with this situation, and contested the applicability of the ABS tips to Indian entities. This has been among the strongest and maximum persistent critiques of the BDA i.e. That the scope of the time period "character", under section 6, is indistinct. Along similar lines, the Kerala SBB and the Uttarakhand SBB had also served notices on establishments within their country jurisdictions. It was in 2015 that pan-India, Ayurveda manufacturers came Collectively as a pressure organization against the Centre and the Ministry of AYUSH to benefit readability at the applicability and scope of the ABS guidelines. Sooner or later, the use of the umbrella of the important India AYUSH Drug manufacturers association (CIDMA), they filed earlier than the Nagpur bench of the Bombay excessive courtroom (HC), seeking rationalization on the notices that had been served on them.²⁹

²⁴ ABS Capacity Development Initiative, National Study on ABS Implementation in India (2014)

²⁵ List of cases before the National Green Tribunal, Central Zone Bench

²⁶ Biodiversity Management Committee v Western Coalfields and Union of India (2015).

²⁷Biodiversity Management Committee.

 ²⁸Maharashtra Biodiversity Board, www.maharashtrabiodiversityboard.gov.in (Last visited on August 25, 2020).
²⁹Supra, note 29.

VIII. <u>IMPORTANT COURT ORDERS</u>

1) Divya Pharmacy V. Union Of India & Ors- High Court Of Uttarakhand³⁰

Court's decision

Having heard each the edges, the court docket realized that the primary difficulty in the be counted is concerning interpretation of the time period "fair and equitable gain sharing" and whether any legal responsibility can be imposed on the Indian entity. The court analyzed the essential provisions of the CBD, Nagoya Protocol, BD Act, 2002 and the 2014 tips of CBD said that the Nagoya Protocol makes no difference between foreign entity and Indian entity in terms of responsibility closer to the area people for ABS association. Therefore, the paradox within the BD Act should be interpreted in light of the global agreements and a purposive interpretation needs to be made. The whole motive of the CBD and subsequent agreements has been to give up the exploitation of genetic sources in developing nations and such exploitation can emanate from both internal or outside the U.S. The Nagoya protocol focused at the indigenous community and to offer them fair and equitable percentage for their know-how transfer. Uttarakhand is a biodiversity wealthy kingdom in India and the nearby groups which live within the excessive Himalayas are specially tribal and subculture pickers of biological sources. Therefore, renovation of the understanding of the area people and offering them FEBS becomes vital. The courtroom whilst analyzing segment 7 of the BD Act held that regulating an interest within the form of call for of charge has been practiced in regulation. Therefore, when SBBs needs rate as a regulator for commercial use of biological resources, it can't be said that the SBBs do now not have strength to achieve this:

- Consequently, NBA has strength to frame regulation for charge and economic compensation and different non-economic advantages underneath section 2(f) and section 21(4) of the BD Act, 2002 and the SBBSs have duties and strength to acquire FEBS below its energy under phase 23(b) and section 7 of the Act.
- This move by the Uttarakhand High Court in clarifying the position of FEBS under the BD Act was welcomed by legal experts and SBBs working in the field of biodiversity.

2) Biodiversity Management Committee V. Western coalfields ltd &Ors.- O.A. 28/2013 (CZ)

³⁰ Writ Petition (M/S) No. 3437 of 2016, decided on 21.12.2018.

<u>Analysis</u>

This example highlighted the fact that the governments under the BD Act aren't running in coordination with every other and every business enterprise is skeptic approximately the action of another. For the successful implementation of the Act and ABS, coordination and accept as true with among these agencies is likewise essential for which intern organisation assembly, talks ought to be organized wherein the SBBs BMC and NBA can talk the problems with one another and work in the direction of conservation and sustainable use of the additives of biological sources. Additionally, the BMCs ought to have professional individuals of their governing frame so has provide an insight about the biological or genetic resources or technical element of the ABS agreement.

IX. <u>PROBLEMS WITHIN THE ABS REGIME IN INDIA:</u>

1. Problem of clear objective of ABS

The concept of benefit sharing in India arose because of rampant biopiracy instances related to conventional knowledge in India like – neem, haldi, basmati rice, turmeric and so on. The existing regime over the safety of TK underneath the international law became no longer sufficient to deal with the issue of ABS. The CBD and Nagoya added a worldwide regime to govern ABS and TK.

2. Genetic resources as "material"

Underneath the CBD, the genetic assets have been described as "genetic fabric which has actual or ability value". Whilst the preliminary debates about ABS began at some stage in the Eighties and Nineties, ABS became proposed to be now not confined to just get right of entry to genetic assets but additionally to the utility of modern biotechnology at the genetic assets and assessing their genes and biochemical on the premise of it.

3. <u>Commercial utilization in a collaborative research</u>

While some collaborative research is really aimed at having no commercial motive, some of collaborative studies that does clean business pursuits. On account that collaborative research is exempted underneath segment five of the BD Act, 2002 from the scrutiny of NBA, there need to

be strict type between collaborative projects which has industrial goals and ones which do now not. The NBA proposed to place a public note on 'dos and don'ts' underneath phase 5 of the BD Act, 2002; however, the be aware has yet no longer been positioned in public domain.

4. Monetary benefits

Development of technology is a first-rate hassle in the genetic sources company international locations. Consequently, further to the economic blessings which arise from the production of stop product, there ought to additionally be a version of governing non-monetary advantages at the negotiation desk like switch of era at time of bioprospecting and R&D phase. This may enhance the technological soundness of the provider nations.³¹

5. Insufficiency of funds

The SBBs do not have sufficient funds to organize awareness programme for the implementation of the ABS in their state.

6. Pendency of cases

The utility for industrial usage of sources by way of corporations frequently end up in the court docket technique in which the corporations claim that the authorities constituted do now not have powers to alter activities referring to biological assets or are aggrieved by using the ABS amount to be paid via them. One such instance changed into the Divya Pharmacy case which has already been mentioned before. The pendency of instances within the courts, tribunals like NGT also account to slow rate of implementation of ABS in India.

X. <u>CONCLUSION</u>

The international agreements, framework on biodiversity has set a high aim for the conservation and sustainable improvement of the environment. The responsibility to have a sturdy mechanism dealing with ABS and conservation is on the country. The case research on ABS implementation in India genuinely suggests that in spite of having a comprehensive framework to implement ABS, there are still major issues and loopholes in terms of monitoring and regulating the access and benefit sharing of biological resources. Lack of know-how some of the indigenous network, the incapacity of the NBA, SBB and BMC has resulted into denial of right to get entry to and

³¹Key challenges and Practical Ways forward for the Implementation of Nagoya Protocol on Access and Benefit-Sharing

benefit sharing to the local community. The times of biopiracy are still making headlines whilst the authorities and the genetic resources are beneath consistent risk in India.

Getting admission to and benefit sharing is a complex process and involves a number of steps. ABS agreements require thorough knowledge and education of the officers, awareness of all the stakeholders and at the same time agreed negotiation among them.

What ABS desires is a strong tracking mechanism at three levels, the Center, the State and at the local level. The primary undertaking of monitoring bodies have to be to scale back the practice of biopiracy by way of mutual cooperation with other government just like the patents workplace, airport and port government and so forth. India must take sturdy steps against such actors of biopiracy and for which a pan India degree criminal focus need to be unfold approximately get entry to genetic assets.

The mere idea of programs in the shape of seminars and conference will not solve the issues and grass-root focus and training programme at panchayat level is essential. Consequently the BMC must together with professional member, neighborhood member attain out to these indigenous communities and educate them about the importance of the ABS. Unless the indigenous network have faith and trust in the authorities the hassle of biopiracy cannot be resolved, therefore common visits by way of officers, organizing village degree gatherings will help the government connect with the indigenous network. This approach is imperative for the success implementation of ABS.

The task of entirety of People's Biodiversity Register (PBR) need to be completed at the earliest with the assistance of the stakeholder so that the real benefit claimers may be recognized and price range can be allocated and used by them. The SBBs have to widely publicize such information so that there is no scope of dispute concerning the gain claimers beneath the Act. India ought to take the exceptional practices from nations like South Africa, Australia and Bhutan in order to have a more economic and stronger ABS settlement. Similarly, the authorities under need to involve and motivate people participation in their working.

Finally, the Indian legal guidelines governing ABS ought to be revised and provisions from Bonn pointers and Nagoya Protocol need to be enacted to make the comprehensive framework governing ABS even stronger. There ought to be updation of the price of financial advantages inside the 2014 ABS guidelines, after reading the marketplace charge and annual income after utilization of genetic resources.