Access and Benefit sharing mechanisms in India: The why, what, how?

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***Abstract*—Humans have been using biological resources for the purposes of food and medicine since time immemorial. Wide range of sectors, such as the pharmaceutical, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage, have undertaken research and have developed commercial products from genetic resources derived from biological resources. Our lush green forests into barren deserts and wastelands due to unsustainable practices. For fuel wood and prawn farming, Mangroves have been cleared leading to decrease in the habitat essential for breeding marine fish. There has been a rampant decline of biological diversity owing to over-exploitation. As such, in the past decade, countries have increasingly used access and benefit sharing (ABS) as a legal mechanism to support the conservation and sustainable use of the world's biological diversity. The existing international framework for ABS of genetic resources and associated Traditional knowledge is the Convention on Biological Diversity (CBD), the CBD was formulated in the United Nations Conference on Environment and Development in Rio de Janeiro, Brazil. (UNCED) To achieve the objectives of the Convention on Biological Diversity (CBD), the Biological Diversity Act in 2002 and notified the Rules, 2004 was enacted by the Government of India. The implementation of the Act and Rules at national, state and local levels are overseen by the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the Biodiversity Management Committees (BMCs) respectively. Two protocols have come into existence after the coming into force of the CBD. First is the Cartagena Protocol on Biosafety, wherein the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnological inventions, has been deliberated. Second is the Nagoya Protocol, which focuses on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. The Nagoya Protocol sets out the rules and mechanisms for access to genetic resources and associated Traditional knowledge, the principles of fair and equitable benefit sharing between the indigenous communities and the companies have been enumerated under the protocol. The purpose of this research paper is to highlight the existing problems in the Access and benefit sharing system and advocate towards rebranding India's benefit sharing regime into a more definite, credible, transparent and fairer regulatory framework.**

***Index Terms*—Benefit-sharing, Nagoya-Protocol, Cartegena-Protocol, Equitable, Access, Convention on Biodiversity**

I. INTRODUCTION

The biological diversity in common parlance is an assorted pool of genetic diversity providing infinite possibilities to create more varieties, and resultantly enriches existing stock of resources. As per the Convention of Biological Diversity 1992 (CBD), "Biological diversity means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems"[1]. A legal framework and approach known as Access and Benefit Sharing (ABS) regulates the use and access of genetic resources and related traditional knowledge, as well as the just and equal distribution of the advantages of their use among the indigenous communities that supply the resources and knowledge. Delivering on the United Nation's Sustainable Development Goals (SDG), ABS is being used as an economic tool for conservation and sustainable use of genetic resources. The ABS approach stems from the UN Convention on

[1] Article 2 of the Convention of Biological Diversity 1992

Biological Diversity recognizing the countries' rights over their biological diversity. The Nagoya Protocol outlines a mechanism through which fair and equitable benefits are shared between the indigenous communities and the companies, agents. There are other international treaties and agreements that regulate or affect the sharing, transfer and access to genetic resources are UN *International Treaty for Plant Genetic Resources for Food and Agriculture* (Plant Treaty), *Trade Related Impacts of Intellectual Property Rights* (TRIPS). In furtherance of implementation of objectives of these International Conventions and Treaties, every nation tailored its own domestic legislation to accommodate the concept of ABS in its respective legal systems. India is no exception to this. India adopted the Biodiversity Act, 2002 to encompass a regime on biodiversity, nevertheless issues like red-tapism, delays and acquiescence plague around the well-defined legal framework regarding ABS. This paper attempts to analyze various legal issues and challenges for implementation of ABS Mechanism in India and endeavors to recommend plausible solutions to address the issue.

II. NEED FOR SUSTAINABLE USE OF GENETIC RESOURCES

Plant-genetic resources (PGR) come under the ambit of 'common-heritage of mankind's rendering PGRs into 'freely accessible commodities.' Amidst great significance, PGRs encountered devices to protect them. In the past decade several nations have deliberated on providing the PGRs a platform where there would be fair and equitable sharing of genetic resources between the providers and the recipients. A need was felt for protection of our natural habitat and ecosystems, and as such the nations thought of encompassing the preservation of biological resources under the UN's Sustainable Development goals and vowed for prudent use of resources to save for future generations.

III. NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS 2010

An agreement was formulated upon the success of CBD, 1992, to address the issue of Access and Benefit-sharing of genetic resources, which constituted one of the main concerns of the Convention.[2] The protocol came into force on October 29, 2010, in Japan, effective from October 2014 after ratification by from member countries. India became a signatory on May 11, 2011. The protocol has been adopted by 128 member countries from the UN and EU, to ensure access to genetic resources and to advocate for judicious use of resources.

IV. AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

TRIPS is an important international agreement that provides the guidance and minimum standards of protection for Intellectual Property's (IP's), TRIPs provide for wide range of IPs such as Patent, Trademarks, Geographical Indication, etc., It does not directly address access and benefit sharing mechanisms, but some of its provisions indirectly deal with ABS, Part II of the Agreement (dealing with „Patents") provides for the standards of IP protection in plants, animals and „essentially Biological Processes." It is stated under Article 27(3)(b) that: "…plants and animals other than micro-organisms, and essentially biological processes to produce plants or animals other than non-biological. and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."[3] India became a signatory of TRIPS in 1995 when it came into effect on January 1st, 1995. The TRIPS framework allows for patents to be granted for inventions, even if the underlying genetic resources were obtained without the proper consent of the country or community providing them. This creates a

[2] Elizabeth Verkey, INTELLECTUAL PROPERTY: LAW AND PRACTICE, 1st ed. 2015, p. 588

[3] Art 27(3)(b) of Trade Related Aspects of Intellectual Property Rights

potential conflict of interest between intellectual property rights and the principles of ABS.

V. INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE 2001

CBD and TRIPS paved the way for severe disruption in free sharing of resources among countries, acting as an embargo on possibilities of development in plant varieties through genetic engineering. A need was felt to make resources accessible, and as such negotiations took place and a treaty was promulgated, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) 2001", on June 29, 2004.[4] A common multi-lateral system (CMS) was devised for countries to pool in their Plant-Genetic Resources (PGRs). The resources could be shared among nations through a framework for equitable sharing of benefits. To procure PGRs nations had to enter a standard contract known as the 'Standard Material Transfer Agreement (SMTA),[5] the contract limited the scope of PGRs for 'breeding' and 'research'. It nevertheless prohibited IP claim over varieties, but if a new variety is created, the user obtained the IP over the new variety. Moreover, the user must deposit a percentage of profit towards fund created for the purpose of invention of new varieties.[6]

VI. LEGISLATIVE INSTRUMENTS FOR ACCESS AND BENEFIT-SHARING: NATIONAL SCENARIO

In pursuance of CBD, India adopted the Biodiversity Act, 2002 as it was a hot bed for floras and faunas. Numerous stakeholders from all around India participated in several rounds of negotiations about the structure that would be put in place to oversee the ABS regime in the nation. It took almost eight years to complete this process, following discussions at several levels. To create the final draft of the Act 2002, the Parliamentary Standing Committee compiled the opinions and replies of all of these parties. The country developed a special framework to control this field after realizing the necessity of regulating the usage of Indian resources by foreign entities and introducing openness and accountability throughout the entire process. Benefit-sharing provisions were addressed in the Act of 2002 and were further enhanced by a specific and intentional mention in another law known as the Protection of Plant Varieties and Farmers' Rights Act of 2001. These laws reflect the situation that exists in India because of its accession to the Cartagena and Nagoya Protocols and CBD. To put it briefly, these laws reflect the methods India uses to carry out its responsibilities under these Treaties. The National Biodiversity Authority must grant permission for the study and commercial use of biological resources to foreign nationals, non-resident Indians, body corporations, and others in India. This need was created by the Act of 2002. When using or gaining access to biological resources and traditional knowledge, Indian users must also notify the State Biodiversity Authority. Anyone who wants to share research findings with a foreign organization or is looking for intellectual property rights must notify the National Biodiversity Authority.

VII. GUIDELINES ON ACCESS TO BIOLOGICAL RESOURCES AND ASSOCIATED KNOWLEDGE AND BENEFIT-SHARING REGULATIONS 2014

On November 21, 2014, the "Guidelines on Access to Biological Resources and Associated Knowledge and Benefit-sharing Regulations 2014 (ABS Regulations)" were released by the National Biodiversity Authority (NBA) in accordance with Protocol 2010. Together with the clauses addressing how they will share the benefit, regulations were made to establish how PGR users were to fulfill their financial commitments.

VIII. PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001

Opportunities were grasped by the breeders, farmers, and researchers to acclaim themselves as owners of

[4] "International Treaty on Plant Genetic Resources for Food and Agriculture", FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, https://www.fao.org/plant-treaty/overview/en/

[5] Article 12(4) of the International Treaty on Plant Genetic Resources for Food and Agriculture 2001.

[6] Article 13(2)(d) and 18(4)(e) of the International Treaty on Plant Genetic Resources for Food and Agriculture 2001.

unique varieties of plants. Prior to the issue's global prominence and discussion during the most recent round of GATT negotiations, most industrialized countries expressed a desire to protect breeders, although some of the Developing countries felt that farmers' interests should be acknowledged as well. One of the first countries to prioritize meeting the needs of its farmers was India. India desired a Plant-Variety Protection system in which farmers and breeders had equal protection, or at least fair protection.[7] In the area of intellectual property protection, the Act was implemented in India to establish the framework for a sui generis protection regime for plant varieties. It resulted from India's commitment to abide by the TRIPS Agreement. As was previously mentioned, Article 27(3)(b) of the Agreement gave the Member nations three choices for creating national laws that would safeguard animals, plants, and "basically biological processes."[8]

IX. IMPLEMENTATION ISSUES UNDER THE ABS MECHANISM IN INDIA

India has numerous apt enactments, but implementation of them remains a challenge, and there is a need for rebranding India's ABS mechanism because of inherent flaws. The potential benefits under the current mechanism are Institutional capacity building (including training); transfer of technology or sharing Research and Development results; setting up of Venture Capital Fund; providing scholarships and financial aids; sharing scientific information etc., According to the ITPGRFA, the Standard Material Transfer Agreement (SMTA) stipulates that the party requesting access to a certain material may only use it for that reason and no other. The agreement is unsure of the scope and type of the ITPGRFA remedy that is available in the event that a party violates the SMTA.

The Various challenges in the ABS system in India are: -

- It is unclear how damages will be computed if a recipient proceeds to patent the plant genetic material in the form in which it was acquired from the supplier. To address this issue, national IP legislation must provide for the revocation of the infringing IP right.
- The B.D. Act 2002 mandates the establishment of Biodiversity Management (BMCs), but due to inadequate funding the BMCs have been unable to fulfill their pivotal functions.
- The terms such as 'fair and equitable sharing' have added a layer of ambiguity within the realm of ABS mechanism in India.
- The institutional framework for implementing ABS is still evolving. There is often a lack of coordination between various government agencies, including the NBA, SBBs, and local authorities, which leads to fragmented governance. Moreover, there is insufficient capacity in terms of human resources, training, and expertise to handle complex ABS negotiations.
- One of the key principles of ABS is ensuring that local and indigenous communities' benefit from the use of biological resources. However, in practice, there is limited involvement of local communities in decision-making processes, leading to their marginalization.
- Indigenous knowledge is central to ABS, but protecting it within the framework of intellectual property law poses a significant challenge. Many traditional knowledge systems in India are orally transmitted and not documented in formal records, making it difficult to prove ownership or establish rights over such knowledge. This lack of documentation also increases the risk of biopiracy, where commercial entities exploit these resources without equitable compensation.
- ABS negotiations can be complex, particularly when multiple stakeholders, such as private companies, government bodies, and local communities, are involved. In some cases, the negotiation process is slow and cumbersome, causing delays in benefit-sharing. Moreover, there is often an imbalance in the negotiating power of stakeholders, with corporations and government bodies holding more leverage over local

[7] R.R. Hanchinal and Raj Ganesh, PROTECTION OF PLANT VARIETIES AND FARMERS‟ RIGHTS: LAW, PRACTICE AND PROCEDURE, 1st ed. 2018

[8] V.K. Ahuja, LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS, 3 rd ed. 2017, p. 61

communities, who may lack technical knowledge or legal support.

- The PVPFRA operates within the broader context of India's intellectual property laws, such as the Patents Act, and the Biological Diversity Act. This overlapping legal landscape can create confusion for farmers and breeders, particularly in cases where plant varieties are protected under both plant variety protection and patent regimes. The lack of clear demarcation between the jurisdictions of various Acts can lead to legal disputes, reducing the effectiveness of the PVPFRA
- One of the most significant challenges to the PVPFRA is the increasing corporate control over seed markets. Many large multinational corporations dominate seed production and distribution, and their market dominance undermines the local seed systems. As commercial seed companies patent and license new varieties, they often require farmers to purchase seeds annually, thereby limiting farmers' traditional practices of saving and exchanging seeds. This commercialization of seeds can also result in the marginalization of smallholder farmers, who may struggle to afford or access commercially protected varieties.
- The emphasis on high-yielding commercial varieties under the PVPFRA can reduce biodiversity in farming systems. These varieties, often developed for uniformity and large- agro-ecological conditions. This shift towards monocropping and the use of genetically modified seeds threatens the resilience and sustainability of farming systems. The Act, while promoting innovation in plant breeding, does not adequately address the environmental concerns related to the commercial use of plant varieties.

X. CONCLUSION

The various recommendations to address the gaps in successful implementation of the ABS system are: -

- Presence of Krishi Vikas Kendra to spread awareness regarding ABS to remotest villages in India.
- Radio information, Advertisements, workshops can disseminate information regarding Benefit-sharing mechanisms available under various enactments in India.
- Amendments to include definitions to terms like ‘fair’, ‘equitable’ in the Biodiversity Act, 2002 to do away with vivid interpretations.
- The ABS framework should be harmonized with other laws such as the Intellectual Property Rights (IPR) system, the Protection of Plant Varieties and Farmers' Rights Act, and the Patents Act. The overlap between these different legal systems can create confusion and contradictions. By clarifying the roles and interaction between these frameworks, the process of obtaining access and sharing benefits can be streamlined.
- The implementation of clear and transparent benefit-sharing agreements between commercial entities and local communities is essential. These agreements should include not only monetary compensation but also non-monetary benefits such as capacity-building, technology transfer, and access to healthcare and education. Local communities should be given a significant role in determining what benefits they receive.
- Our country must actively engage in international dialogues and partnerships related to ABS. Cross-border collaborations will ensure that India’s biodiversity is protected from biopiracy and exploitation by foreign entities. Efforts should also be made to align national ABS policies with global standards, particularly under the framework of the Nagoya Protocol.
- Bridging the gap between traditional knowledge systems and modern scientific research is essential for the development of new, equitable ABS agreements. Collaboration between traditional knowledge holders, researchers, and scientists can create valuable synergies that lead to innovative solutions for sustainable development.