

## Impact of the Biological Diversity (Amendment) Act 2023 on Biodiversity Protection Regime in India: An Empirical Study

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The Biological Diversity Act of 2002 discusses the core concepts of ‘Benefit Sharing’ and ‘Sustainable Development’. It was very recently in 2021 that the Biological Diversity (Amendment) Bill was introduced which came into effect from April 2024. This Amendment Act has been under great surveillance and criticism as it brings to light several issues which shall impact the indigenous groups, their habitat, and their right of access to benefit-sharing as it eases the process of complying with the access to benefit-sharing requirements of the Biodiversity Act of 2002, especially for domestic companies. It further mentions that AYUSH practitioners and codified traditional knowledge holders shall be exempted from the principle of benefit sharing. The amendment has also decriminalised the offences established under the Act where the power has been given to an adjudicating authority, a government official, to hold inquiries and lay down cases to impose these penalties. The researchers aim to reflect on the ambiguity of the Biological Diversity (Amendment) Act 2023. For this, the researchers have undertaken empirical as well as doctrinal research to look into the opinions and judgments of the stakeholders of the biodiversity protection regime in India like Biodiversity Authorities, AYUSH practitioners, traditional knowledge users, and environmental and IP law researchers. The researchers also aim to suggest further changes in the biodiversity protection regime in India relying on the issues around the current amendments to the Biological Diversity Act of 2002.

**Keywords:** Access to Benefit Sharing, Biological Diversity (Amendment) Act, 2023, Biological Diversity Act, 2002, Convention on Biological Diversity, Nagoya Protocol, Sustainable Development

The planet Earth comprises all different kinds of life forms which are referred to as biodiversity. The Biological Diversity Act of 2002 defines biological diversity or biodiversity under Section 2(b). It includes various living organisms from all over the earth and comprises the ecological variations and complexes of which they are part. The planet’s human activities have brought about biodiversity problems, including bio-piracy, which is the unlawful exploitation of biological resources and the related traditional knowledge that belong to Indigenous groups, thereby resulting in a loss to the earnings of Indigenous people.<sup>1</sup>

India has always understood the importance of protecting its abundant biological resources. It is thus a part of the United Nations Convention on Biological Diversity (CBD) and has done so since 1994.<sup>2</sup>

A key piece of legislation, The Biological Diversity Act of 2002, echoed India’s resolve to protect its various ecosystems and traditional knowledge

systems. India started an amendment process to align itself with international advances and modern necessities. The Biological Diversity (Amendment) Act, of 2023 (the Amended Act) was passed as a result of this process. This legislative change is significant to analyse since it will significantly impact many industries that depend on biodiversity.<sup>3</sup>

The amendments outline a wide range of measures that address issues such as supporting local medical systems, accelerating research, decriminalising offences, attracting international investment, simplifying compliance norms for domestic industries, and excluding AYUSH practitioners and codified traditional knowledge holders from sharing the benefits with the indigenous groups. The Amendment Act has also eradicated criminal punishments and imposed penalties which shall be adjudicated by an officer of administrative position.

The paper explores the background of the Biological Diversity Act in India and analyses the debate and modifications brought forth by the 2023 amendment. It is significant because it clarifies

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important instances like the *Divya Pharmacy v Union of India* ruling of 2018, which influenced the conversation around benefit-sharing and intellectual property rights in the field of biodiversity specifically for domestic companies and, also the powers of the State Biodiversity Boards. The paper seeks to analyse the nuances of the amendment and how and to what extent will it affect the policy framework mentioned in the preamble of the Act of 2002. The researcher will also delve into the aspects of the international regime of protection of biodiversity vis-à-vis the legislative regime in India.<sup>4</sup>

The judgments, writings of the Nagoya Protocol, and the goals and preamble of the Convention on Biodiversity serve as literature for this issue at hand. The gaps have been explained by the researcher in the further parts of the paper by delving into the judgments, international conventions and treaties and the changes brought about by the Amendment Act of 2023. Even after the amendment there still is no clarity on the powers of the State Biodiversity Authority concerning just being a spectator body or having regulatory powers as well. The lack of clarity and gap in the literature concerning the benefit-sharing norms under the modern developing world and the absence of clear intention of the legislature to recognise benefit-sharing norms under the biodiversity protection regime in India are analysed to lay down the following objectives, questions, and methodology of the study.

### Research Objectives

1. To understand and analyse the development of the Biological Diversity Act, 2002 in the light of proposed amendments.
2. To determine the impact of the Biological Diversity (Amendment) Act 2023 on various stakeholders and regulatory agencies and further judicial pronouncements
3. To evaluate the amendments taking into consideration access benefit sharing and the fair and equitable sharing of benefits laid down by the Nagoya Protocol.

### Research Questions

1. Whether the amendments are justifying the very objective and rationale of the Biological Diversity Act.
2. What is the impact of the revised framework on regulatory procedures and how have stakeholders reacted to it?

3. Whether the amendment act has effectively addressed the access benefit sharing and the fair and equitable sharing of benefits laid down by the Nagoya Protocol.

For this analysis, the researcher will not extend beyond the Indian legal frameworks and also will only focus on the Convention on Biodiversity and the related protocols. Engaging with stakeholders like biodiversity authorities, AYUSH practitioners, researchers studying intellectual property and environmental legislation, subject matter experts, and wildlife conservationists are all part of the empirical study and the scope of the study includes conducting the empirical study on various stakeholders of the Biodiversity Act of 2002.

### Research Methodology

The research methodology is mixed-method and it includes doctrinal and non-doctrinal. The doctrinal study addresses the developmental phase of the Biological Diversity Act. The international community through various conventions like the Convention on Biological Diversity, 1992, the Cartagena Protocol on Biosafety the Convention on Biological Diversity, 2000, and the Nagoya Protocol on Access and Benefit-sharing, 2010 contributed towards the development of the Biological Diversity Act, 2002. Researchers have analysed through doctrinal methods the current international regime related to biodiversity along with Indian Court judgements to understand the legal issues with the proposed amendments.

Primarily the researchers have consulted the various experts in the field, especially officials from National and State Biodiversity Authorities, AYUSH practitioners, academicians and researchers from environmental studies, practising advocates from environmental law, subject matter experts, wildlife conservationists, etc. Researchers have used a purposive sample method for this research as it is most suited to the current study. Researchers have also relied upon the theoretical study to analyse the implications of the Amendment Act and compare it to the old Act of 2002.

### Legislative History of India on Biodiversity Protection

After 1990, India transitioned drastically from a close to an open economy which led ways to issues like exploitation of natural resources, and loss to indigenous groups due to extreme commercialisation and emerging issues like biopiracy. This was the result of

industrialization and commercialisation and a lack of policies on the protection of biodiversity and traditional knowledge. The government nevertheless decided to take the lead in creating a legislative framework known as the Biodiversity Bill of 2000.<sup>5</sup> The Biological Diversity Act of 2002 was based on this bill and was passed by both the Lok Sabha and the Rajya Sabha on 2 December 2002, 11 December 2002, and 5 February 2003, when the President signed it and the Act came into effect from this date onwards. The Act in India was based majorly on the principles of the Convention on Biodiversity 1992 and in 2004 the Biological Diversity Rules were also laid down to ensure the smooth conduct of the law.<sup>6</sup> The Act of 2002 was laid down to offer rules to conserve biological diversity, practise sustainability and fair and equitable sharing of the benefits with the indigenous groups. The Act covers the following uses which should be practised considering the aims and objectives of the legislation: 'usage of bio-resources for commercial or research purposes; conducting of any bio-survey and bio-utilisation of such indigenous resources; and the grant of intellectual property rights for any invention derived from research or information on biological resources obtained from India'. It offers a structure for sharing the advantages that result from using and gaining access to biological resources.

The National Biodiversity Authority (further referred to as NBA), State Biodiversity Boards (further referred to as SBBs), and Biodiversity Management Committees (BMCs), each with specific duties and jurisdictions, are part of the decentralised structure that implements the Biological Diversity Act of 2002. Through the issuing of permissions, the NBA will control actions about the fair and equitable sharing of benefits and access to biological resources and ensure adherence to the objectives of the legislation on bio-diversity protection in India. To encourage biological variety protection, sustainable use, and recording, each local body within its jurisdiction is required to form a Biodiversity Management Committee (BMC). Earlier under Section 41 of the Act of 2002 before the amendment of 2023, it was the duty of the BMC to maintain the Peoples' Biodiversity Registers at the community level to document as well as safeguard bio-resources and associated knowledge.<sup>7</sup>

### **The Biodiversity Amendment Act of 2023 and related Lacunae thereof**

The Biological Diversity Amendment of 2023 was a further path taken in the biodiversity protection

regime in India, taken after the *Divya Pharmacy v Union of India* and others 2018 judgment. The judgment majorly looked into the role of State Biodiversity Authorities in demanding fair and equitable benefit sharing with the local and indigenous groups from the Indian entities. Divya Pharmacy, the petitioner in this case, belongs to the trust which was supplying these materials under issue in the judgment. It was decided that biological resources would serve as the primary component and raw material for the ayurvedic items that the petitioner manufactures. The notices that the Uttarakhand Biodiversity Board (UBB) sent to the petitioners, required them to pay Fair and Equitable Benefit Sharing (FEBS) as stipulated under the Biological Diversity Act, 2002 and the Rules and Regulations adopted thereunder, aggrieved them. The applicable provisions under the case were of the 2002 Act without the recent amendments.

To shed light on the true intentions of the Legislature when creating the aforementioned laws, the Court referred to the history of both international agreements and the numerous provisions of the Biodiversity Act. To ascertain the actual meaning of 'fair and equitable benefit sharing', the Court declared that any ambiguities in our national statute must be seen in the context of the Convention on Biological Diversity and the Nagoya Protocol. In light of the statutory function granted to the State Biodiversity Authority under Section 7 read with Section 23 of the Act, the Hon'ble High Court ultimately held that the National Biodiversity Authority has the authority to enact any necessary regulations (in this case, the 'Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014') by Section 64 of the Act, which grants the power to State Biodiversity Board to act under it.<sup>8</sup>

After the verdict of the Uttarakhand High Court in *Divya Pharmacy v Union of India*, the ambiguities in the law related to biodiversity protection in India came to light. One of the major issues as highlighted by the case discussed above was the extent to which the Indian entities need to seek permission to use the resources of indigenous groups and also whether is there any distinction between the applicability of the fair and equitable benefit sharing norms under the Act. Another major clarification which was needed after the judgment was about the reach of powers of State Biodiversity Boards and National Biodiversity

Authority. The judgment elucidates the control of the State Biodiversity Boards, but a few other basic issues like of implementation of these norms remain unclear and ambiguous. The State Biodiversity Authority has got more legal recognition and power after the ABS Guidelines were issued by the National Biodiversity Authority in 2014, under the enforcement of the Nagoya Protocol on Access to Benefit Sharing of which India is also a part. The judgment explains that the State Biodiversity Authority has the main role of regulation, which also comprises asking for benefit sharing from companies and defining the conditions to be levied on the user against access to genetic resources biological materials and traditional knowledge as well.<sup>9</sup>

The Biological Diversity (Amendment) Act, of 2023, often known as the ‘Amendment Act,’ was originally introduced in the Lok Sabha in December 2021. Before being submitted to a Joint Parliamentary Committee, the Bill sought public comment. The Bill included the committee’s recommendations, which had to be provided by December 2022. On August 3, 2023, it was reintroduced in Parliament and was further granted presidential approval. It came into effect in April 2024, incorporating all the changes in the old Biological Diversity Act of 2002.

### **Regulatory Mechanisms for Foreign Entities**

Concerning the meaning of non-Indian entities reliance has been made on the Companies Act of 2013 as per the amendment of Section 3 of the Act of 2002- ‘incorporated or registered in India under any law for the time being in force, which is controlled by a foreigner within the meaning of Clause (27) of Section 2 of the Companies Act, 2013’.<sup>10</sup> A whole reading of Section 3 as per the amended provisions seeks to clarify what category of persons cannot undertake activities which include ‘obtaining any biological resource occurring in India or knowledge related to such resources for research or commercial utilisation or bio-survey and bio-utilisation without the approval of National Biodiversity Authority’.<sup>11</sup> Section 3 of the Act covers the following categories of individuals: individuals who are not citizens of India, citizens of India who are non-residents as mentioned under clause (30) of Section 2 of the Income-tax Act, 1961, and also covers ‘corporations, associations, or organisations that are not registered or incorporated in India’ or that are registered or

incorporated in India under any currently enacted law and that are ‘controlled by someone outside the nation as defined by clause (27) of Section 2 of the Companies Act, 2013’.<sup>12</sup>

Thus, the new law brings into the picture the Companies Act of 2013 to define foreign-controlled companies and after the amendment ‘only those Indian entities which are controlled by a foreign entity as per the Companies Act 2013’ will need authorisation from the National Biodiversity Authority ‘to obtain any biological resource occurring in India or related knowledge for any work such as research on bio-resources or commercial utilisation of bio-resources or bio-survey on such resources and bio-utilisation of such resources’. Formerly, this kind of approval had to be requested by every Indian firm that had even a small amount of non-Indian involvement in its management or share capital.<sup>13</sup>

The Act further mentions under Section 4 that the results of ‘any research on any biological resource which is occurring in or obtained or accessed from India, or any other related traditional knowledge’ shall only be transferred to anyone under Section 3 (majorly covering foreign entities) for any kind of monetary consideration or even without it, after obtaining the approval of the National Biodiversity Authority. This is explained in Section 4 of the Act but with some caveats. For example, the section does not apply if research papers are published or knowledge is shared at a seminar or workshop that receives financial support; instead, it must follow Central Government guidelines, which again gives the government enormous authority to decide how research based on bioresources is circulated. However, if the research findings are applied to additional research, registration with the National Biodiversity Authority will be required. Moreover, if the research findings are used for the grant of any intellectual property rights, either inside or outside of India, or for commercial purposes, prior approval from the National Biodiversity Authority will be required.<sup>14</sup>

### **Dilemma of Approval or Intimation: IP Rights Acquisition**

Before granting any intellectual property rights for an ‘invention based on research or information on a biological resource accessed from India, including those stored in repositories outside of India, or any related traditional knowledge’, approval from the

National Biodiversity Authority is required for foreign companies or any person or entity covered by Section 3(2) of the Act, as per Section 6(1) of the Act of 2002 following the 2023 amendment.<sup>15</sup> On the contrary, before granting any intellectual property rights, such as a patent based on bioresources, as per the recently added Section 6(1A) of the Act, an Indian entity covered by Section 7 of the Act has to only register with the National Biodiversity Authority.<sup>16</sup>

As a result, to expedite the grant procedure, Indian nationals and businesses covered by Section 7 merely need to register with the National Biodiversity Authority before any kind of IP right grant, negating the need for previous approval at the time of application which is mandatory for non-Indian entities. This distinction has made granting IP rights on bioproducts easier for domestic companies but still difficult for foreign companies.<sup>17</sup>

Section 6(1B) as changed after the 2023 amendment added that domestic companies covered under section 7 of the Act have obtained any IP right based on any bio-resource, have to seek approval of the NBA only at the time of commercialisation. This stands equal for both domestic and foreign companies.<sup>18</sup> In the process of doing so, the Authority may impose conditions, such as the sharing of financial benefits resulting from the commercial use of the rights, as stipulated by Section 6(2) of the Act of 2002 following the 2023 amendment, or it may impose a benefit sharing fee or royalty, or both.<sup>19</sup>

### **Power of State Biodiversity Board: Exemptions lying therein**

As discussed in the previous chapter, *Divya Pharmacy v Union of India* is one of the landmark judgments related to the discussion of the power of the State Biodiversity Board to incorporate access to benefit-sharing norms. The Court in the judgment made it clear that the State Biodiversity Boards are not just spectator bodies rather they have regulatory powers as well to promote access to benefit sharing.<sup>20</sup>

The amended Section 7<sup>21</sup> provides a different set of regulatory mechanisms for Indian entities or entities not mentioned under Section 3 of the Act<sup>22</sup> which have no foreign control mentions. These entities apart from the prior intimation to the State Biodiversity Boards before accessing any biological resource and its related knowledge for commercial utilisation and monetisation also have to adhere to clause (b) and (ba) of Section 23 and sub-section (2) of Section 24.

Section 23 under its clause (a) has been completely amended by the 2023 Act to include the power of the State Biodiversity Boards 'to advise the State Government on issues concerning biodiversity conservation, the sustainable use of its elements, and the just and equitable distribution of benefits resulting from the use of biological resources or traditional knowledge related to, following the rules or directives issued by the National Biodiversity Authority or the Central Government'.<sup>23</sup>

These provisions as per Section 23(b) of the amended Act regulate that the powers of the State Biodiversity Boards shall include regulating any activity referred to in Section 7 by granting or rejecting approvals for Indian entities or entities not covered under Section 3 of the Act which means bodies with no foreign control and completely domestic.<sup>24</sup> The major addition of this amendment was clause (ba) which empowered the State Biodiversity Boards after the judgment of the *Divya Pharmacy*, to determine the fair and equitable sharing of benefits norms while the National Biodiversity Authority approves on its behalf.<sup>25</sup>

Further to this Section 24(2), gives power to State Biodiversity Boards if the State Biodiversity Board believes that 'any activity is detrimental or contrary to the aim of conservation and sustainable use of biodiversity of fair and equitable sharing of benefits, it may by order, restrict or reject such activity'. It is still ambiguous whether the Act wishes to ask the Indian entities to only inform the State Biodiversity Authority or State Biodiversity Authority can also approve and disapprove their application for usage of bio-resources on the ground of access to benefit sharing.

In addition to the above regulatory mechanisms, the most important and controversial change incorporated by the Amendment Act of 2023, was the expansion of the domain of exemptions under Section 7 regarding who shall not be required to give any prior intimation to State Biodiversity Boards or follow any access to benefit-sharing norms under the Act. The 2002 Act stated exemptions to only 'use by local people and communities including growers and cultivators of biodiversity, and vaidas and hakims practising indigenous medicine'.

Now after 2023, it has been changed to exemptions under the biodiversity protection regime being given to the users of the 'codified traditional knowledge, users of any cultivated medicinal plants and their

products, the local people and communities of the local indigenous area, including the cultivators of biodiversity and exemptions given to vaid, hakims and registered AYUSH practitioners but covers only those who have been practising indigenous medicines, including Indian systems of medicine as a profession for sustenance and livelihood'.<sup>26</sup>

This thus broadens the exemptions under the access to benefit sharing norms of the biodiversity protection regime in India.

### **Decriminalisation of the Biodiversity Act of 2002**

Section 55 of the Act, which formerly said that violating Sections 3, 4, or 6 might result in up to five years in prison, a fine of at least INR 10 lakh or both has been revised under the Amendment Act of 2023. The revised clause, however, does away with the imprisonment element mentioned under the old Act of 2002 under Section 58 which has been removed by Section 39 of the Amendment Act of 2023 in favour of a larger fine.<sup>27</sup> Sections 3, 4, 6, and 7 violations as mentioned above, under the revised Act, carry penalties of up to INR 50 lakh.<sup>28</sup> The maximum penalty is a hundred times the minimum penalty, meaning that there is a broad range of fines that can be imposed, from one lakh to one crore rupees. There is no distinction made by the Act according to the nature of the offence. The only distinction found in the Act is related to the penalties to be imposed in case of violation of the orders by the National Biodiversity Authority or State Biodiversity Boards.

Furthermore, an adjudicating official appointed by the Central Government under Section 55A, who shall not be below the 'rank of Joint Secretary to the Government of India or Secretary to the State Government' may impose an 'extra penalty of up to INR 1 crore'.<sup>29</sup> The adjudicating officer along with other officials as empowered under Section 55B, has the authority to conduct 'searches, seizures, and collect evidence'.<sup>30</sup> Such an authority to conduct search and seizure has been added after the amendment but will be empowered by the Central Government to conduct any such activity with no clear explanation in the act determining the conditions under which such activities can be conducted.

The removal of the criminal punishment provisions will lessen the impact of punishment given in case of violation of the rights of indigenous groups and usage and exploitation of bio-resources. Also, giving power to an adjudicating official to determine the penalty

and raise it further makes the process arbitrary and ambiguous. The official will be someone designated by the Central Government thereby exercise of complete power by the legislature in judicial matters can be observed.<sup>31</sup>

### **Determination of Benefit Sharing Agreements**

Other changes in the Amendment Act of 2023 include the changes in Section 21 of the Act of 2002 which discussed the parameters for determination of benefit sharing by the National Biodiversity Authority.<sup>32</sup> Earlier the marginal heading of the Act of 2002 read the word 'equitable' only which determines the ambit of benefit sharing by the National Biodiversity Authority but after 2023 it is read as 'fair and equitable' benefit sharing norms.

Further to this, the major loophole here is to give immense power to the hands of the biodiversity management committees which are controlled by the National Biodiversity Authority, thereby giving power to the National Biodiversity Authority to decide the benefit-sharing norms amongst the users and local management committee with no say of indigenous groups directly ignoring the needs of the actual stakeholders which are the indigenous groups.<sup>33</sup>

Some positive changes by the Amendment Act of 2023 include changes under Section 18 of the Act which has empowered the National Biodiversity Authority 'to create regulations with the permission of the Central Government for the determination of fair and equitable sharing of benefits. It can also advise the State Biodiversity Boards on any issue about the implementation of the Act, control any activity mentioned in sections 3, 4, and 6, and take appropriate and necessary actions 'to oppose the grant of intellectual property rights in any nation outside of India dependant on any biological resource that is obtained from India'.<sup>8</sup>

### **Empirical Study on the Biological Diversity (Amendment) Act, 2023**

A 13-item questionnaire was prepared specifically for the opinion survey and distributed by email and/or WhatsApp (google link). The objective of obtaining informed consent was limited to using the data for this research study. The identities of the respondents have not been disclosed. Purposive sampling was used since the respondents are hard to identify without personal or professional familiarity and no databases, like a standard register, are available. The purposive

sample technique is regarded as one of the key components of this research because of the paucity of practice and understanding of biodiversity.

The data was compiled and analysed. The survey was given to 152 possible respondents, and 34 legitimate questionnaires were returned to the researchers, resulting in a 22.3 per cent return rate. This could be because of the sensitivity and confidentiality of the discussed subject matter. The researchers further identified that government officials are hardly willing to answer the survey because of the reasons best known to them.

The following nine elements provoked opinions :

- (i) The 2023 amendment to The Biological Diversity (Amendment) Act 2023 and its relationship with of Nagoya Protocol.
- (ii) The Biological Diversity (Amendment) Act 2023 and the compliance norms for domestic companies.
- (iii) The Biological Diversity (Amendment) Act 2023 and its ambit for AYUSH practitioners and holders of codified traditional knowledge from sharing benefits with local and indigenous groups.
- (iv) The Amendment Act and benefit sharing requirements under it.
- (v) Extent of authority given to Government Officials of the National Biodiversity Authority as adjudicating officers and control over local biodiversity communities.
- (vi) Prior approval or intimation to the regulatory authority based on the origin of the entity for obtaining biological resources occurring in India or associated knowledge under the Amendment Act.
- (vii) Suggestions on the Amendment Act which proceeds towards profit-making rather than the benefit-sharing of stakeholders.

Research shows that a maximum of respondents (73%) have asserted the fact that The Biological Diversity (Amendment) Act, 2023 incorporates the concept of the Nagoya Protocol which emphasises access to genetic resources and fair sharing of benefits. Whereas the critical approaches i.e. 21% of the respondents have pointed out that the amendment act of 2023 violates Nagoya protocol and its basic principles. The remaining respondents believe in partial acknowledgement and not entirely following the Nagoya Protocol which is very interesting to note.

One of the critical parts of compliance, 53% of respondents has identified the moderate effectivity of the compliance norms for domestic companies. This is because the amendment act has not been implemented strongly or we may say that we need to see the enforcement of the amendment act entirely to check the compliance norms which are still ambiguous owing to the confusion between only intimation under Section 7 of the Act or regulatory power of SBB under Section 23 and 24 of the Act. There are 38% & 3% of respondents have pointed have 'Effective' and 'Highly effective' compliance norms respectively and these respondents are from direct beneficiaries, stakeholders or first respondents. We have 6% of responses dealing with 'not effectiveness' of the amendment Act.

Considering the stakeholder's benefit, while answering this question researchers have identified that the respondents are having 3 different answers. 32% of respondents state that they are 'Not Sure' & 'No' for the provision which excludes AYUSH practitioners and holders of codified knowledge from sharing benefits with local and indigenous groups. They further said that the provision is not beneficial for stakeholders. Whereas another set of respondents i.e. 33% said that the provision provides benefits to the stakeholders. Interestingly, 3% of respondents have identified that it depends on the usage of the provision by the stakeholders. That provides the broader ambit for the interpretation of the said provision. In such a situation, it might lead to disputes in the future while implementing the mentioned provision. The respondents further provided their comments on the changing provision as follows:

- It may risk diminishing the direct role of local communities in determining benefit-sharing provisions, potentially marginalizing their involvement and traditional rights.
- The local groups can get the benefits as determined by the National Biodiversity Authority, but it also exempts the Ayush practitioners which leads to a 50-50 win-lose stake.
- Nagoya protocol includes research as part of the utilisation of genetic resources/Traditional Knowledge. Excluding this will impact the local communities' role in determining the benefits under the legislation.

One more important aspect of the amendment act is, the benefits for AYUSH practitioners and traditional knowledge holders the research shows that

the amendment act provides significant benefits. Around 56% of the respondents have asserted that the amendment act provides benefits to AYUSH practitioners and holders of codified traditional knowledge holders. However, 12% of the respondents have denied that the amended provision will benefit the AYUSH practitioners and codified Traditional Knowledge holders. Other than that, 32% of the responses show an inability to understand the interpretation of the provision whether it is giving benefits or not. Other than that, the researchers specifically requested comments addressing the said provisions and the mixed approach from the respondents which are as follows:

- Removal of research and bio-survey activities from the purview of benefit-sharing requirements violates the basic principle mentioned under the preamble of the Act regarding fair and equitable sharing of benefits. The local communities should be given the power to decide on such issues and benefits arising out of even research activities should be shared with them as it is their land and Indigenous knowledge on which the research is being conducted
- The amendment appears to weaken the 'principle of fair and equitable sharing of benefits' by excluding 'research and bio-survey activities from benefit-sharing requirements', potentially diminishing the role of local communities and indigenous groups in having a say in access to benefit-sharing norms related agreements.

Research shows that decriminalising the offences under the Amendment Act, 2023 can be considered as one of the welcoming provisions, with maximum responses recorded in favour of it i.e. 85.2%. The negative responses specifically pointed out the futuristic approach wherein authorities need to have a very cautious approach. Some of the respondents have also pointed out that even though decriminalisation seems to be a better way to deal with violations of the Act, the Act remains ambiguous on the amount of fine to be levied which has also been addressed under Chapter 3 of the paper.

Responses show that a maximum of respondents agreed that benefit sharing should be handled by national authorities i.e. 58.8%. Furthermore, 23.5% of respondents said that it is not beneficial and should be handled carefully so that it cannot be manipulated by governmental authorities. One of the reasons for this can be Government Authorities may be biased

towards the user and corporations hence there is a chance of collusion. 17.6% of respondents are 'Not Sure' whether it will benefit the stakeholders or not. Sometimes it depends on the incentives of the government officials and other factors that impact their decisions. The other comments answering the questions are as follows:

(i) This may lead to abuse of discretion and ultimately lead to defeat of the legislative purpose

(ii) Granting extensive negotiation power to government officials may ensure consistency and oversight in benefit-sharing agreements, potentially safeguarding the interests of local communities and promoting sustainable resource use. However, this centralized approach could also raise concerns about transparency, accountability, and equitable distribution of benefits, highlighting the need for careful oversight and meaningful stakeholder involvement.

Research holistically portrays that the Amendment Act, 2023 empowers foreign investment in the domain identifying 82% of responses which are in favour. However, there are equal percentages which shows where respondents (9%) who do not agree with empowering foreign investment and who are 'Not Sure' about the possibilities.

The Amendment Act, of 2023 made it clearer to take prior approval or intimation from the regulatory authorities, these questions have provided a mixed approach identifying 44% of the respondents accepting the broad ambit of the legislation. However, 41% of the respondents asserted the fact that it is beneficial but it may cause loss to the companies. 15% of the respondents are 'Not Sure' about either 'broadening the ambit' or 'loss to the companies. Environmental experts claim that the previous rule provided foreign corporations with an unclear approach that was open to misunderstanding and abuse. The amending statute clarifies and removes any confusion regarding the requirement that they still obtain the necessary approvals from the regulatory authorities for foreign companies but remains ambiguous for domestic companies.

As per the responses received regarding achieving the very goal of the Biological Diversity (Amendment) Act, 2023, research shows that 44% of respondents have asserted that it inclines towards more profit-making rather than benefit-sharing of stakeholders. Whereas 41% of respondents have

provided that possibility for the same. Other than that, 6% of respondents specifically denied that the Amendment Act, 2023 proceeds towards profit-making. Without looking into the effective implementation of the Biological Diversity (Amendment) Act, of 2023 it will be difficult to look into the futuristic approach. Interestingly, some of the respondents have specifically commented on the developmental course of the Amendment Act, 2023: Both have to be balanced; the new rules would benefit the companies however the incentive mechanisms would provide impetus to the ongoing lethargic mechanism. Hence, a step in the right direction is needed.

### Conclusion

The analysis of the Biological Diversity (Amendment) Act of 2023 becomes essential as it has a direct impact on the indigenous groups, and their rights of benefit sharing as provided under the Nagoya Protocol. The study also highlights the impact of the activities of the foreign and Indian entities which are using the resources and localities of these indigenous groups.

Various law researchers, environmental law activities, and biodiversity conservationists believe that the amendment focuses more on profit making, making it easier for foreign and especially Indian entities to do business over the bio-resources and this has been explained in the last question of the empirical study conducted by the researchers. 44% of the respondents believed that the amendment puts profit over the benefit of the indigenous groups. It also gives immense power to the government and its officials by making the adjudicating officer someone who is appointed and controlled by the government.

By giving extreme freedom and exemptions to AYUSH practitioners, users of codified traditional knowledge the amendment gives them the allowance to infringe upon the territory of the local groups and commercially use their resources and they shall not be bound by the access to benefit-sharing norms created under Conventions and Protocols. This has been the opinion of more than 50 per cent of stakeholders that the amendment shall give more power to the AYUSH practitioners and the users of codified traditional knowledge, the vaidas and hakims to exploit the resources of the Indigenous groups. They shall also not be bound to take prior permission from the State Biodiversity Boards in such cases. Thus, the majority of the stakeholders of the research think that the

amendment act shall impact the beneficiaries of the biodiversity protection regime in India, mostly in a negative manner since it is more industry-centric not favouring the indigenous communities. One of the respondents in the question analysed mentions that 'Nagoya protocol includes research as part of the utilisation of genetic resources/Traditional Knowledge. Excluding this will impact the local communities' role in determining the benefits under the legislation. Thus, addressing the third objective of the research and according to the theoretical and empirical research conducted by the authors, the amendment act does not satisfy the requirements of the Nagoya Protocol specifically the provisions covering the aspect of benefit-sharing. The Biological Diversity Act of 2002 was created on the lines of the Nagoya Protocol as discussed in the first objective of the research and the preamble of the 2002 Act aims to follow the same which has not been followed thoroughly by the amendment act as analysed by the authors in previous chapter. The research concludes that the provisions of exclusion given to AYUSH practitioners and codified traditional knowledge holders give them immense liberty which shall lead to the exploitation of the local groups.

The Act amends the Biological Diversity Act, of 2002 to simplify compliance requirements for domestic companies thus paving an easier path for them. The changes are tremendously significant because they affect research and innovation in a wide range of businesses that rely on biodiversity, including traditional medicine, pharmaceuticals, agriculture, and cosmetics. These amendments affect a wide range of sectors, including traditional medicine domains that include AYUSH disciplines, research and bio-surveying organisations, indigenous communities with traditional knowledge, and intellectual property rights sectors that are heavily reliant on biological resources. They also affect biotech and pharmaceutical companies that operate both domestically and globally.

According to the empirical research conducted by the researchers in this paper, it is highlighted that around 80% of the stakeholders believe that such an amendment will promote the business of domestic and foreign companies and also that the regulatory norms for domestic companies remain ambiguous.

### Recommendations

The researchers after a detailed analysis of the empirical study and as per the opinions of different

stakeholders suggest that amendments according to societal needs and industry requirements are necessary but it has to be done keeping in mind the impact on indigenous groups and their bio-resources. A few provisions of the Amendment Act of 2023 which need further changes are:

- (i) Exemptions given to AYUSH practitioners, vaid, hakims, and users of codified traditional knowledge should be curtailed keeping in mind the access to benefit-sharing norms of the Convention on Biodiversity and Nagoya Protocol. It should be taken into consideration that the interests of the local and indigenous groups should not be hampered while enforcing such amendments.
- (ii) The need for the criminalisation of offences is important as it is required to create a harsher punishment if someone violates the interests of the indigenous groups and their biodiversity. However, according to chapter 4.5 of the empirical study analysis, the respondents around 82 per cent welcomed the idea of decriminalisation of the offences under the Act. Some of the stakeholders thought that the range of fines to be imposed under the Act and the ambiguity to impose them should be rectified further. Further to this, the adjudicating officers should not only be government officials but rather a person of judicial domain is also important to look into the jurisprudential aspects and aims and objectives of creating such a law.
- (iii) The powers of the Central Government on Biodiversity Management Committees should not be unlimited and while drafting the agreements on access to benefit sharing between users and indigenous groups the opinion of the groups should also be taken into consideration. In the current amendment, the agreements are entered into between users and the Committees represented by the National Biodiversity Authority thus limiting the role of the actual stakeholders which has been expressed by various stakeholders of the empirical study conducted. The suggestion here is to curtail the powers of the NBA on the local management committees to let the indigenous groups have a say in the matter of access to benefit sharing.
- (iv) It is still ambiguous whether the Act wishes to ask the Indian entities to only inform the State

Biodiversity Authority or State Biodiversity Authority can also approve and disapprove their application for usage of bio-resources on the ground of access to benefit sharing. Thus, there has to be a clarification provision on the powers of the State Biodiversity Authority as mentioned under the Act. The judiciary and the legislature both give different opinions on this subject matter which is essential to regulate the activities of domestic companies. As per the responses analysed, 53% of respondents have identified the moderate effectivity of the compliance norms for domestic and small companies and that it does not make the regulatory mechanism easier for domestic and small companies rather there remains a line of ambiguity.

- (v) The line of demarcation related to regulatory protocols between domestic and foreign companies or domestic companies controlled by someone in another nation, creates ambiguity in the framework of biodiversity protection. Also, it awards extra protection and ease of doing business to domestic companies which might later lead to exploitation of indigenous groups. Thus, this also needs to be modified in India's biodiversity protection legislative regime.

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