



Guardians of Nature: Understanding India's Biological Diversity Act, 2002

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India is one of the world's richest countries in terms of biological diversity. To ensure that this biodiversity is conserved, used sustainably, and benefits are shared equitably, the Indian Parliament enacted the **Biological Diversity Act (BDA), 2002**. India is a signatory to the **United Nations Convention on Biological Diversity (1992)** and the **Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (2010)**, both of which inform the spirit of the Act.

With recent amendments effective from April 1, 2024, the BDA has become even more aligned with international treaties and modern biotechnological and research practices. This article critically examines the scope and impact of the amendments, with particular attention to the categorization of foreign and domestic entities, eliminating the need for prior approval (for Indian entities) by the regulatory bodies such as the National Biodiversity Authority (NBA), thereby expediting the grant process for patent applications. The amendments strike a practicable balance between conservation priorities and sustainable commercial benefits.

Refined Definitions and Clarified Scope

A major thrust of the 2024 amendments lies in the elaboration/inclusion of critical legal definitions. Absent from the earlier Act, the term “access” has now been included as a new Section 2(a), meaning the collection, procurement, or processing of any biological resource occurring in or obtained from India or associated traditional knowledge for purposes such as research, commercial utilization, or bio-surveys.

The definition of “biological resources” under Section 2(c) has replaced the term “by-products” with “derivatives” and reads as: “plants, animals and micro-organism or parts thereof, their genetic material and **derivatives** (excluding value added products¹) with actual or potential use or value but does not include human genetic material.”

Further, the term “*derivative*” is now separately defined in Section 2(fa) as “a naturally occurring biochemical compound or metabolism of biological resources, even if it does not contain functional units of heredity.” Section 40 of the Act substituted by the 2024 amendments vests the Central Government with a non-obstante power to notify a list of biological resources for which the NBA permission shall not be required. The said section clarifies that any

¹ “Value added products” means products containing portions or extracts of plants and animals in un-recognizable and physically inseparable form. Examples of extracts – biocosmetics such as soaps, lotions, and creams, utilizing ingredients derived from plants, animals, or microorganisms; Ayurvedic health supplements like Chyawanprash and Pudina Hara to enhance their medicinal properties;

biological resources when normally traded as commodities or items derived therefrom including agricultural wastes, medicinal plants and their products etc. are exempt from the NBA approval. However, this exemption is applicable only in respect of Indian entities. Foreign entities are still required to seek the NBA approval.

“**Folk Variety**” means a cultivated variety of plant that was developed, grown and exchanged informally among farmers.

Regulation of Access: Foreign Entities

The BDA places strict controls on who can access the country’s biological resources and traditional knowledge. Under Sections 3 to 5, foreign individuals and companies including those registered in India but under foreign ownership or control must secure prior approval from the NBA before collecting or using any such resources. The same approval is required to share research findings with foreign entities, unless the information involves codified traditional knowledge² or is being shared for non-commercial academic purposes. One notable exception is for joint research projects between Indian and foreign institutions, which are permitted without prior approval, as long as they follow guidelines set by the Central Government.

Regulation of Access: Indian Entities

Section 7 of the BDA requires Indian individuals and organizations to notify their respective State Biodiversity Boards (SBBs) before accessing any biological resource for commercial use. However, not all uses are treated equally. Exemptions apply in several cases, including the use of codified traditional knowledge and the collection of cultivated medicinal plants by traditional practitioners such as vaidas, hakims, and AYUSH professionals³ as long as it supports their livelihood. Additionally, Indian entities engaging in commercial use involving cultivated medicinal plants or their products are also exempt from prior notification on proof of a certificate of origin from the relevant Biodiversity Management Committee (BMC).

IPR Rules Tightened and Streamlined Under Amended BDA

The amended BDA has introduced significant changes to how intellectual property rights (IPRs) linked to India’s biological resources and associated traditional knowledge are regulated. The amendments, especially to Section 6, are aimed at reinforcing sovereign control over biological resources while simultaneously easing compliance for Indian researchers and innovators.

Stricter Control for Foreign Entities

Under the revised **Section 6(1)**, foreign individuals or entities (regardless of whether they operate through Indian-registered companies) must now obtain prior approval from the NBA before the **grant** of any IPR. Previously, this approval was required **before even applying** for

² Section 2(ea): “codified traditional knowledge” means the knowledge derived from authoritative books specified in the First Schedule to the Drugs and Cosmetics Act, 1940.

³ AYUSH professionals are practitioners of traditional Indian systems of medicine, encompassing Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy.

an IPR. The shift is intended to bring regulatory scrutiny at a more consequential stage of the IPR process and prevent misappropriation of Indian bio-resources.

New Compliance Pathway for Indian Applicants

In contrast, the newly inserted Section 6(1A) creates a distinct and more facilitative pathway for Indian applicants. Indian individuals and institutions must now **register with the NBA before the grant** of IPRs based on research or information derived from biological resources originating from India. This applies even if the resource has been deposited in repositories **outside India**. Importantly, this registration requirement replaces the earlier **mandatory approval process**, offering a simplified compliance route, encouraging domestic innovation and patenting activity.

Commercialization Still Regulated

The amendment also introduces Section 6(1B), which requires Indian applicants to obtain NBA approval before commercializing any IPRs that involve biological resources or associated knowledge from India. However, this clause carves out an exemption for plant variety rights, which are governed under the Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act.

Powers and Responsibilities of the NBA (Sec 21)

The NBA has significant authority:

- to oppose the grant of IPRs abroad on Indian biological resources or knowledge.
- to determine the benefit-sharing mechanism which may include:
 - Joint ownership of IPR
 - Technology transfers
 - Financial or non-financial compensation to benefit claimers
 - Inclusion of local scientists and communities in R&D

Funds from benefit-sharing to be deposited to the **National Biodiversity Fund** or directly to the claimants.

Legal Recourse and Penalties

- **Appeals:** Disputes arising from NBA or SBB decisions can be appealed before the **National Green Tribunal (NGT)**. Pre-existing High Court cases remain unaffected.
- **Penalties:** The 2024 amendment decriminalizes violations by removing imprisonment. Instead, it introduces steep financial penalties ranging from ₹1 lakh to ₹1 crore.

Conclusion

The Biological Diversity Act, 2002, particularly after its 2024 amendments, reinforces India's commitment to protecting its rich biological heritage. It balances the interests of local communities and researchers, ensures sustainable use, and promotes ethical access and benefit-sharing. By integrating international standards and modern regulatory practices, the BDA remains a cornerstone of India's environmental legal framework.