The Biological Diversity (Amendment) Bill 2023: a balancing act of rights and obligations

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The Biological Diversity (Amendment) Bill, 2023 was approved by both houses of the Indian Parliament in August 2023. The Bill introduces major changes compared to the National Biological Diversity Act, 2002 and the subsequent Rules, 2004. The amendments ease the process of patent filing for Indian citizens and support the livelihood of indigenous people associated with biodiversity-related activities. The introduction of a new term, 'codified traditional knowledge' will make few activities distinct from 'traditional knowledge'. The Bill has provisions to protect the nation's rich biological wealth, including that deposited in the International Depository Authority. It is a positive move to protect the larger interest of India while honouring the international obligations under various treaties and conventions.

The Biological Diversity Act (BDA), 2002 enacted by the Indian parliament, has its genesis in the Convention on Biological Diversity (CBD), 1992, to which India is a signatory. The Act is based on three canonical principles, viz. conservation, sustainable utilization, and fair and equitable sharing of benefits. After two decades, the BDA Act 2002 has undergone some major amendments, which both houses of parliament approved during the last monsoon session. The Bill, originally introduced in the Lok Sabha in 2021, was referred to the Joint Committee for discussion. The report of the Joint Committee, which was placed in both houses in August 2022, eventually led to the approval of the amended bill in its present form. While keeping the basic fabric of the 2002 Act almost intact, the 2023 amendment introduced a few changes that invigorate research, invention, and patent filing associated with bioresources and ensure their effective management.

Patent filing made easy

Section 6 (1) of BDA, 2002 insisted that prior approval of the National Biodiversity Authority (NBA), Chennai, is mandatory to get any form of Intellectual Property Rights granted by the Indian Patent Office, pertaining to any research or information involving a biological resource obtained from India. Subsequently, under Patent Rules 2003, Form 1 of the patent application was modified to the extent of incorporating a declaration from the applicant. Accordingly, the applicant gives a declaration affirming that the invention, as disclosed in the complete specification (Form 2) uses biological material from India, and the necessary permission from the competent authority shall be submitted by him/her before the grant of the patent. In other words, patents related to biological resources will be granted by the Patent Office only after approval from the NBA. The Act provided 90 days for the competent authority (NBA) to act upon the applicant's request for approval. This has its share of burden on the NBA to clear applications adhering to the timeline, as every approval is accompanied by an Memorandum of Agreement on non-judicial stamp paper between the applicant and NBA, specifically highlighting the technical and legal aspects of the agreement with provision for benefit-sharing mechanism. The whole exercise is not only time-consuming but also often futile, as every patent application does not culminate in granting the patent. During processing of patent application, technically referred to as patent prosecution, the invention mentioned in the patent application may not pass the essential criteria of novelty, non-obviousness and potential for commercialization. Therefore, there exists a considerable gap between the number of patent applications filed with complete specifications and those getting sealed or granted. Whereas, in the amended bill, prior approval from the NBA is mandatory only for those who are scheduled under section 3(2) of BDA (foreign nationals and entities) and is not binding to Indian citizens and entities residing in India. They only have to register with the NBA before the grant of patent (u/s 6(1A) (ref. 1). However, it is mandatory for Indian citizens and entities to obtain prior approval at the time of commercialization of the patent (u/s 6(1B) (ref. 1). Unsurprisingly, for obvious reasons, the number of granted patents translated for commercial activities, including technology transfer/licensing is meagre. Therefore, only those who are serious and desire commercialization need to seek approval from the NBA. This indeed benefits both parties, saving considerable time and effort.

Safeguard to biological materials deposited in repositories

The Act was silent about the access to microorganisms, including plant and animal cells, cell lines, algae, fungi, etc. originated from India and deposited in the International Depository Authority (IDA) across the globe. India became a contracting party to the Budapest Treaty in 2001, which meant the mandatory deposition of these biological materials in internationally recognized IDAs for patenting. Subsequently, subsection (ii) (4) of section 10 was incorporated in the Indian Patent Act, 1970, making it compulsory to deposit biological materials related to the invention in any IDAs. However, the Act did not have a provision to safeguard the materials deposited in these repositories. The Bill is now more vigilant that section 6(1) (ref. 1) declares that those materials deposited in the repositories outside India and traditional knowledge associated thereto are also an integral part of the Indian bioresource. In essence, all except Indian citizens and entities residing in India will have to seek prior approval from the NBA to access biological materials of Indian origin deposited in the repositories before the grant of a patent. The move is certainly another checkpoint to prevent biopiracy and safeguard our bioresources both within and outside the country. Furthermore, the introduction of a new section 36A is expected to ensure the monitoring and regulation of biological resources obtained from other countries, with respect to their access and utilization in India by an appropriate agency like the NBA or a similar organization.

Decriminalization of violations

The offences made under the Act, 2002 were cognizable and non-bailable under section 58 of the Act, and hence included both imprisonment and fine (in rupees) or both[2]. This impeded research as scientists and students, not conversant with the provisions of the Act, were hesitant to access the bioresources even for biosurvey due to fear of attracting criminal charges. The amended bill revoked section 58 and replaced section 55 with a new provision imposing a hefty sum, ranging from INR 100,000 to 10 million, as a penalty commensurate with the gravity of the offence. Unlike the Act, the offences made u/s 55 of the Bill will be adjudicated for penalty by an officer not below the rank of Joint Secretary to the Government of India (GoI) or a Secretary to the State Government (u/s 55 A(1)). Any person aggrieved by the decision of the adjudicating officer can approach the National Green Tribunal for an appeal.

Codified traditional knowledge vs traditional knowledge

In a marked deviation from the Act, the Bill has introduced the terminology 'codified traditional knowledge' in lieu of traditional knowledge in several places. It is defined in the Bill as knowledge derived from authoritative books specified in the First Schedule to the Drugs and Cosmetics Act, 1940. The first schedule comprises nearly 100 books listed under Ayurveda, Siddha and Unani Tibb systems. This differs from the definition given by WIPO, wherein traditional knowledge in any systemic and structured form which is ordered, organized, classified and categorized in some manner constitutes codified traditional knowledge. The definition in the Bill has wider implications as (1) it prohibits the sharing or transferring of codified traditional knowledge to any person or entity defined under section 3(2) but reserved only for Indians, and (2) Indian citizens and entities accessing the codified traditional knowledge for commercial utilization are exempted from sharing benefits with the local communities.

The latter raised apprehensions from a few quarters that all traditional knowledge and practices associated thereto, which are either in the digital format available in the Traditional Knowledge Digital Library (TKDL) or in the Peoples Biodiversity Register (PBR), will now be exempted from the purview of benefit-sharing. TKDL is an initiative taken by the Council of Scientific and Industrial Research (CSIR) after successfully revoking the US patent on turmeric and the European patent on neem, while PBR is a grassroot-level people's participatory effort initiated after the implementation of BDA, 2002. It is alleged that the rights of tribal people on forest produce and their traditional knowledge will be now commercialized by Indian companies for which, neither do they have to seek permission from the respective State Biodiversity Boards nor will the communities be compensated through fair and equitable benefit-sharing mechanisms.

On close scrutiny, it is evident that the apprehensions are misplaced and unfounded, as traditional knowledge and codified traditional knowledge are not synonymous but defined differently with contextual and functional properties. As mentioned, TKDL is an ambitious collaboration of GoI agencies implemented by CSIR, which has more than 4.54 lakh formulations/practices associated with the Indian systems of medicine, collected from ancient texts and documents. The knowledge is classified in compliance with international standards and made available to major patent offices across the globe for the exclusive purpose of search and examination by the patent examiners. PBR, on the other hand, documents the traditional knowledge and practices associated with the ethnic/local communities, which are mostly in oral form and firmly held family secrets, compiled in a written format. Fortunately, neither of these documents comes under the definition of codified traditional knowledge but retains the status of traditional knowledge. Therefore, any product/process derived from them for commercial activity is open to the principles of access and benefit sharing (ABS), as envisaged in the Nagoya Protocol. In brief, only the codified traditional knowledge is exempted under section 7(1) and not the traditional knowledge per se. Therefore, even the Indian citizens and companies who want to access any biological resource or associated traditional knowledge for commercial utilization will have to seek the permission of the respective State Biodiversity Boards according to sections 23(b) and 24(1), (2) mentioned in the Bill, and highlighted in section 7(1) (ref. 1). Whereas, only Indian citizens and entities are privileged to access the codified traditional knowledge for commercial utilization without seeking prior approval from the respective State Biodiversity Boards, and are exempted from sharing the benefits of such commercial activities.

This Act of benevolence will safeguard the interest of local communities, including traditional practitioners known as vaids, hakims and registered AYUSH practitioners, who can continue with their profession and associated commercial activities to sustain their livelihood. Arguably, it provides equal opportunity for all others not covered under section 3(2) to use this provision in the Bill to start commercial activities based on codified traditional knowledge. However, in the post-TRIPS Agreement era, with India recognizing and granting product patents on drugs and with the JNTBGRI-Jeevani episode of the 1990s fresh in mind, it is unlikely that any business entity or citizen in India would venture into commercial activities associated with codified traditional knowledge without seeking patent protection to the product. In such a scenario, the possibility of granting a product patent is largely remote either in India or elsewhere in the world because the invention lacks novelty as the knowledge is available in the public domain in India.

Conclusion

The principles of ABS are not diluted in the Biological Diversity (Amendment) Bill, 2023, but strictly adhere to the provisions of the Nagoya Protocol. Therefore, apprehensions, if any, are unfounded. However, few checks and balances have been put in place to prevent biopiracy and related issues, essentially to protect the national interest while honouring obligations under international treaties and conventions. Apparently, certain provisions in the TRIPS Agreement on patent protection and those on conservation and sustainable utilization of bioresources under CBD are inherently in conflict. Hence, such a balancing act between rights and obligations is inevitable while framing national laws.

1. The Biological Diversity (amendment) Act 2023. *The Gazette of India*, 3 August 2023, No. 10 of 2023.
2. GoI, The Biological Diversity Act, 2002 and Biological Diversity Rules, 2004, National Biodiversity Authority, Government of India, 2004, p. 74.

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