Beware of the Indian Biological Diversity Act, 2002

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This article is an attempt to educate the reader regarding the statutory compliances under the Indian Biological Diversity Act, 2002 (“Act”), and to provide concise advice in order to avoid unintended non-compliance.

The Indian Biological Diversity Act, 2002

The Act received the Presidential assent on February 05, 2003 and seeks to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. The Act also reinstates to respect and protect knowledge of local communities traditional knowledge related to biodiversity and to conserve and develop areas of importance from the standpoint of biological diversity by declaring them biological diversity heritage site.

Regulations and requirements

The regulatory authorities constituted under the Act are the National Biodiversity Authority (“NBA”), the State Biodiversity Boards (“SBB’s”) and the Biodiversity Management Committee’s (“BMC’s”).

The NBA regulates the grant of approval –

a) for obtaining Indian biological resources or knowledge associated thereto for commercial utilization, bio-survey or bio-utilization by foreign citizens, or foreign corporations, or non-resident Indians (as defined by the Indian Income Tax Act) or Indian corporate bodies having non-Indian shareholding or management (refer to Section 3 of the Act);

b) for transfer of results of research relating to Indian biological resources by any person to any foreign citizen, or non-resident or Indian corporate bodies containing foreign shareholding or management (refer to Section 4 of the Act);
c) for applying for intellectual property protection including patents by any person in or outside India (refer to Section 6 of the Act).

d) To regulate activities of, approve and advice the Government of India on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits.

e) To notify areas of biodiversity importance as biodiversity heritage sites under this act and perform other functions as may be necessary to carry out the provisions of the Act.

f) To take measures to protect biodiversity of the country as well as to oppose the grant of intellectual property rights to any country outside or any biological resources obtained from India.

The SBB’s regulate the grant of approvals for obtaining Indian biological resources for commercial utilization, bio-survey or bio-utilization by Indian citizens or Indian corporate bodies (refer to Section 7 of the Act).

The local BMC’s provide consultation to the NBA and SBB’s regarding the use of and the imposition of fees for accessing or collection of biological resources by any persons, whether legal or natural.

Further, the NBA deals with the requests for access to the biological resources as well as transfer of information of traditional knowledge to foreign nationals, institutions and companies. The recent developments relating to NBA implementation include the establishment of designated National Repository (DNR) under Section 39 as an important aspect of infrastructure for biodiversity conservation. This DNR provides service providers for preserved specimen consisting all faun, herbarium (dried plant material for research), living cells, genomes of organisms and information relating to hereditary and function of biological system.

**Penalties and Offences**

The Act stipulates that all offences shall be cognizable and non-bailable, which means that all offences under the Act shall be punishable with imprisonment for 3 years or more and that a police officer may arrest any alleged offender without a warrant.
Any contravention of the provisions of Sections 3, 4 and 6 of the Act, or attempt or abetment thereof attracts an imprisonment term of 5 years, or fine of INR 1 million (note: in case the damage caused is greater than INR 1 million, then commensurate with such damage caused), or both.

Any contravention of the provisions of Section 7 of the Act, or attempt or abetment thereof attracts an imprisonment term of 3 years, or fine of INR 0.5 million, or both.

Furthermore, in case the offender is found to be a company, the directors and key managerial personnel of the company shall be deemed to be guilty of such offence, unless they prove that they the offence was committed without their knowledge.

**Typical objections/violations under the Act**

Based on recent experiences in advising on this Act, the typical non-compliance or statutory violations found are as below –

a) Objection from the Indian Patent Office (“IPO”) with regards to failure in providing disclosure with respect to the use of biological resources for arriving at the invention for which a patent application has been made.

b) Objection from the IPO with regards to the need for seeking approval of the NBA prior to receiving grant of the patent application.

c) Notice from the NBA alleging violation of Section 3 of the Act on account of failure to seek approval of the NBA prior to accessing Indian biological resources for carrying out research.

d) Notice from the NBA alleging violation of Section 6 of the Act on account of failure to seek approval of the NBA prior to receipt of grant of patents in countries outside India on inventions which are based on research or information on Indian biological resources.

**Measure to avoid objections/violations**

In light of the above, it is amply clear that the access to Indian biological resources is heavily regulated and contains extremely harsh penalties for unregulated access. In view thereof, it is critical that in-house compliance teams in R&D organizations devise effective measures to
contain statutory risks. Briefly outlined below are some steps that can be taken by those concerned-

a) Pre R&D (for foreign individuals, NRI’s, foreign corporations and Indian corporations having non-Indian shareholding or management)
   i. Gather information from research teams regarding the material proposed to being obtained for a research project.
   ii. Identify whether such material is a “biological resource” or a “value added product”. If there is no clarity, seek opinion of expert outside counsel.
   iii. Gather details regarding the date of procurement and details of vendors from who such material is procured.
   iv. Apply to the NBA for approval prior to obtaining the Indian biological resource.

b) At the time of filing a patent application (for any person, whether legal or natural, whether Indian and non-Indian)
   i. Intimate your patent counsel regarding use of a biological resource in the invention, if in case there is no clarity, seek opinion of the patent counsel.
   ii. Provide undertaking regarding use of an Indian biological resource in the invention to the Indian Patent Office.
   iii. Provide adequate disclosure of the source and geographical origin of the biological resource used in the invention.
   iv. Apply to the NBA for approval prior to receiving grant of a patent whether inside or outside India.

Conclusion

Although, the Act is a noble attempt to protect the rich biological diversity of India, there are a number of reasons why it is a complex one to navigate, some of which are outlined below –

a) Inadequate explanations of the difference between key terms such as “by-products” and “value added products” has caused a lot of confusion, since “by-products” are included in the definition of “biological resources” whereas “value added products” are
excluded; thus, causing unnecessary difficulty in ascertaining whether one lies under the purview of the Act, or not. Coherent and detailed examples from the concerned authorities will go a long way in getting rid of such confusion.

b) Non-adherence of the mandatory 90 day period for disposal of NBA applications, coupled with the denial of grants of patents by the Indian Patent Office ("IPO") until receipt of NBA approvals, has lead to massive increase in the bureaucracy, timelines and costs of the patent approval process. Since, India is well known for inordinate delays in patent approvals, this added burden could lead to a situation whereby filing a patent application is no longer worth the trouble. Delinking the NBA approvals to patent approvals would be a welcome move by the concerned authorities.