

## Fresh opportunity to Patent Applicants for complying with Biological Diversity Act, 2002

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The Government of India has in order to provide an opportunity for complying with the Biological Diversity Act, 2002, issued an Office Memorandum dated September 10, 2018 providing directions to the National Biodiversity Authority in this regard.

The National Biodiversity Authority (NBA) was established by the Government for implementing the Biological Diversity Act, 2002. The NBA addresses issues of conservation and sustainable use of biological resources and fair and equitable sharing of benefits from its use by way of benefit sharing fee or royalty or sharing of financial benefits arising out of the commercial utilisation of such rights. At the local level the NBA's functions include documentation of biological diversity including preservation of habitats, conservation of landraces, folk varieties and cultivators, domesticated stocks and breeds of animals and microorganisms besides chronicling of knowledge relating to biological diversity.

Under section 6 of the Biological Diversity Act, prior approval has to be obtained from the NBA before applying for any intellectual property right in or outside India for any invention based on any research or information on a biological resource obtained from India. If a patent application is filed without prior permission of the NBA, the same may be obtained up to grant of patent. The penalty for contravening section 6 is set out in section 55(1) of the NBA which provides that, whoever contravenes or abets the contravention of the provisions of section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees.

Under the Patents Act and Rules, while filing application for grant of patent in Form 1, the applicant is required to make a declaration that *"the invention as disclosed in the specification uses the biological material from India and the necessary permission from the Competent Authority shall be submitted by me/us before the grant of patent to me/us"*. For inventions not involving use of biological material, this declaration is to be cancelled out. Further, the complete specification should correctly disclose the source and geographical origin of any biological material used in the invention. Failure to meet these requirements is a ground for pre-grant and post-grant opposition u/s 25(1)(j) and 25(2)(j) of the Act, respectively. A patent is liable to be revoked u/s 64(1)(j) if a false declaration is made regarding use of biological material from India or u/s 64(1)(p), if the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material.

It has been noted by the Government that a large number of entities though not fully aware of the provisions of the Biological Diversity Act, are desirous of complying with the same. To meet this need and to facilitate and enhance implementation of the Biological Diversity Act, the Government has via Office Memorandum no. F.N. C-12025/8/15-CS-III dated September 10, 2018 issued directions that all such cases where prior approval was required but a person/entity has not obtained such approval, shall be heard by the Authority, which shall then pass appropriate orders with respect to acts that may have occurred in past. The NBA is required to take decisions in such cases within a period of 100 days from the date of issuance of the Office Memorandum, including course of action for past matters. The NBA is required to be guided by the principles of natural justice and relevant judgments of Hon'ble Courts in similar matters. The NBA has also been directed to continue to spread awareness about the Biological Diversity Act to various stakeholders.

These initiatives of the Government will help provide stakeholders who were either unaware of the NBA approval requirement or have delayed in obtaining said approval, with an opportunity to complete the formalities required to process their patent applications further. Additionally, the benefit sharing between the stakeholders and the Government on mutually agreed terms will help in meeting the objectives of the Biological Diversity Act, including monetizing India's biological resources and securing its conservation and sustainable use.

In cases where application has been filed with the NBA but approval has not been received, the patent office has to keep applications pending for grant, even when all other requirements of patent grant have been met. The Government's directions to the NBA to taken action in such cases within a period of 100 days will result in reducing the pendency in the patent office to this extent.