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## Recent Changes In Indian Patent Office Practice With Respect To Biological Resources

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The potential of bio-technology in providing new and better medicines has been realised worldwide, including in India. As a result many start-ups are entering into this new promising field of technology. With emerging technology comes new intellectual property, and the requirement to protect it in order to maintain a competitive edge and sustainable growth. Protecting such new inventions by obtaining patents is one of the ways to secure competitive advantage, but unlike regular chemical and pharmaceutical inventions, biological inventions have their own challenges.

Indian patents law has some unique provisions putting a bar to patentability of some inventions and requiring the applicants of patents to comply with certain requirements. One such requirement which an applicant for patent in India has to comply with is obtaining approval from the

National Biodiversity Authority, for seeking IPR protection, if the invention uses an Indian biological resource. In this article, we have analysed the provisions of the Biological Diversity Act, 2002 (hereinafter 'BD Act') and related provisions of the Indian Patents Act, 1970 on this requirement, and the practice of the Indian Patent Office (hereinafter 'IPO') in dealing with such requirements. We have also analysed the steps which the potential applicants should consider for protecting their inventions in India using Indian Biological resources.



The Biological Diversity Act, 2002 came into effect from 1 October 2003. However, it is interesting to note that the provisions of this statute have gained extensive attention only after the IPO issued guidelines for examination of biotechnology inventions. The IPO issued "Guidelines for Examination of Biotechnology Applications for

Patent" on 25 March 2013, to bring uniformity and consistency and also to assist the examiners and controllers during the examination of biotechnology related patent applications and allied subjects under the Patents Act, 1970. However, these guidelines do not constitute rule making and in case of any conflict between these guidelines and provision of the Patents Act, 1970 and Patents Rules, 2003, the provisions of the Act and Rules would prevail. Although these guidelines are exhaustive, all the aspects could not be covered. In this article we discuss the recent changes being implemented by the examining division at the IPO to ensure that biotechnology related patent applications comply with BD Act. Specifically the effect of BD Act is discussed because it's only post-issuance of guidelines that the IPO is now raising queries on the origin and source of biological material during the examination of biotechnology related patent applications. Further we also discuss the challenges that are being faced by applicants and the implications in not complying

with the requirements of BD Act.

The BD Act governs the conservation of Biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of use of Indian biological resources and community knowledge associated therewith. Under the ambit of BD Act, the National Biodiversity Authority (hereinafter 'NBA') was constituted, which is empowered to enforce and regulate the provisions of the BD Act.

The Indian Patents Act, 1970 as amended in 2005, under section 10 makes it mandatory for an applicant to disclose the source and geographical origin of biological material in the patent application. Further as per the Patents Rules, 2003, Form-1 mandates the applicant to declare regarding the permission required from the competent authority in respect of the Biological material used in the invention. This requirement fulfils two conditions; firstly, it ensures unauthorised use or abuse of any biological material

from India and/or its consequent benefit sharing with the community. Secondly, the patent office ensures that national or the public interest of India is protected.

The BD Act as discussed broadly provides for use and/or protection of biological resources [Section 2 (c)], Bio-survey and Bio-utilisation [Section 2(d)]; commercial utilisation [Section 2(f)]; Research [Section 2(m)]; Transfer of research (Section 4) and application of IPR (Section 6). The Section 6 of the BD Act (came into force on July 1, 2004) specifically states that “No person shall apply for any intellectual property, by whatever name, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of NBA before making such application”: provided that if a person applies for a patent, permission of the NBA may be obtained after the acceptance but before the sealing of the patent by the patent authority concerned. Further, if an applicant applies for the approval of NBA, then the said authority will dispose of the

*application for permission made to it within ninety days from the date of receipt.*

Thus lately, Indian Patent Office has taken cognisance of this fact and asking the applicant to clarify on the source and origin of Biological Material/Resource in their Patent applications. For the applicants whose application originates from India i.e. Indian Companies or Indian Individuals or Foreign Companies conducting R&D in India, this is a major concern, because they need to obtain prior approval from NBA for their patent applications.

This provision of BD Act also gives a breather to the applicant, such that the applicant does not need to withhold its application till the approval of NBA, rather the provision provides that the applicant should obtain such permission, if needed, before the issuance of Letters Patent Document (hereinafter ‘LPD’). Thus, such applicant can file the patent application and while the application is pending can apply for NBA approval. But for foreign applicants, who are entering into

India through a national stage or convention application need not apply for this permission if the biological resources mentioned in their application does not originate from India. However, Indian Patent Office sometimes may ask to include a disclaimer in the specification stating that the Biological material mentioned in the application is not originating from India.

Although, there are no guidelines provided by the Indian Patent Office on the non-compliance of this provision but one could anticipate refusal of grant of patent on non-compliance of section 10. Further, the BD Act under Section 55 provides penalties, if a person contravenes or attempts to contravene or abets the contravention of the provisions of Section 6. In such case the penalty can include imprisonment for a term which may not exceed five years or a fine which may extend to 10 lakh rupees (approx. US\$16,000) and where the damage caused exceeds 10 lakh rupees such fine may commensurate with the damage caused, or with both. Further the act also incorporates that offences

under the provision of this act under Section 58 are cognisable and non-bailable.

Thus the challenges for an applicant who is using biological resources originating or occurring from India are many-fold considering the IPO has not provided any specific guidelines as to how it is going to deal with such applications which are already under examination, or which have reached the grant stage. But as of now the IPO has been quite accommodating in giving time to applicants in obtaining NBA approval for patent applications which has reached its grant stage without issuing the LPD. However, for new applications it will be advisable to initiate this process either at time of filing the application or during the pendency of the application.

In view of aforesaid, it is quite explicit that going forward the Indian Patent Office is going to practice issuance of queries/objections relating to origin and source of biological material in respect of biotechnology related inventions during the

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examination process. Although the above discussion only provides a general and broad perspective to the compliance of BD Act with respect to biotechnology related patent applications, however it is recommended to seek appropriate advice and guidance from local attorneys to ensure suitable legal compliance.

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