BRIDGING THE GAP

The Indian Patent Office has issued guidelines aimed at bringing together the intentions of the Patents Act and the Biological Diversity Act, but this has posed serious challenges in obtaining patent protection, say Ranjna Mehta-Dutt and Neha Srivastava of Remfry & Sagar.

Section 10(4)(ii)(D) of India's Patents Act, 1970 mandates the disclosure of the source and geographical origin of biological material whenever it's mentioned in a patent specification but not sufficiently described in it or made available to the public.

The provision is supplemented by the requirement to declare in the application form 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 before the grant of patent".

The above requirement was introduced in 2005 to complement the provisions of the Biological Diversity Act, 2002 (BDA), which stems from the Convention of Biological Diversity (CBD). The CBD acknowledges its signatories' sovereign rights to their genetic resources, and mandates that any access to a country's genetic resources or any intellectual property derived from them be subject to the equitable sharing of benefits.

Specifically, section 6 of the BDA requires obtaining prior approval from the National Biodiversity Authority (NBA), an independent body, before applying for a patent for inventions that use biological material from India. The statute also provides for penalties/sanctions in cases of non-compliance with this requirement.

Although the Patents Act was amended to meet the objectives of the BDA, in practice section 10(4)(ii)(D) and the requirement to obtain NBA approval was not being strictly complied with. Therefore, the Patents Act had failed to serve as a useful check in ensuring the effective implementation and enforcement of the BDA provisions.

In the wake of this missing link, the Indian Patent Office (IPO) has issued guidelines for the processing of patent applications related to biological material. The guidelines have reaffirmed the requirement to obtain NBA approval before securing the grant of a patent.

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The guidelines have also required the disclosure of source and origin under a separate heading in the specification body—irrespective of whether the biological material was obtained from India or not.

Beyond the statutory provisions

Although the intention of the IPO guidelines is to bridge the gap between the Patents Act and the BDA, in practice it has posed serious challenges in obtaining patent protection. To begin with, the mandatory disclosure of the source and origin of the biological material under a separate heading in the description goes beyond the statutory provisions of the Patents Act.

The statute requires such disclosure only when the biological material is not sufficiently described in the specification and/or is not available to public. By making this requirement independent of such a clause, and even applying it to cases where the biological material has not been obtained from India, the IPO has tried to establish a link that not only looks beyond the Patents Act, but is likely to impose an undue burden on the applicant.

The impact of the guidelines can already be felt in practice, as the requirement is being raised by default in all applications disclosing biological material, regardless of whether such a requirement is applicable.

Another challenge created is obtaining prior approval from the NBA. By itself, it is an extremely cumbersome and time-consuming process, and making it a mandatory prerequisite to the grant of a patent magnifies the challenge, as it is expected to result in inordinate delays in the granting of patents.

Interestingly, in appreciation of the objectives of the CBD, the NBA, while granting the approval, is required to impose a benefit-sharing fee and/or a royalty arising from the commercial use of such patent rights. However, the paradox here is that, unless such patent rights are granted and commercially worked, economic benefits arising from them cannot be predicted.

Therefore, a patent applicant is placed in a 'Catch 22' situation, where on the one hand without the prior approval of the NBA a patent application cannot proceed to grant. On the other, without the grant of a patent the benefits arising from its commercial working cannot be declared in order to seek NBA approval.

Adding to the plight of applicants, the NBA also appears to be unequipped to handle the burden that is likely to arise from the increase in the number of applications. The data published by the NBA reveals the small number of applications that have been approved so far.

Amid the challenges, there is a separate NBA permission required by 'foreign' applicants for access to biological material (from India) before they can seek permission to apply for an IP right. The IPO has failed to design any procedure for such prior permission and has shifted the entire responsibility concerning this to the NBA.

The NBA, on the other hand, has chosen to remain silent on the validity of such applications. They clearly contradict the very objective of 'prior approval' and put a foreign applicant in a position where it seeks permission for access to biological material after, not only has it been accessed, but also used to conceptualise the invention for which patent protection is sought.

Therefore, a foreign patent applicant can find itself in a quandary as, technically, it would be required to go through a formal procedure for seeking permission for access to biological material before gaining NBA permission to apply for IP.

In summary, the linking of patent applications with prior approval from the NBA cuts both ways. While it serves to bridge the gap between the BDA and the Patents Act, it fails to steer itself away from emerging as a stumbling block.

Therefore, there is a need for further deliberation and a multi-faceted approach that not only confines the requirements of a patent application to the patent statute, but introduces a kind of 'NBA approval highway' that promises the vigorous and speedy grant of approvals. ■

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