

Biodiversity and IP - filing and prosecuting patent applications that use biological resources

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Indian Law requires patent applicants to seek approval from the National Biodiversity Authority (NBA) before filing patent applications that use biological resources, under The Biological Diversity Act, (BDA), 2002. For more details on this please see our previous article titled "Biodiversity and IP: The Struggle is Real". The following article discusses some important aspects that must be kept in mind while applying for and prosecuting patent applications that include biological resources.

1. Who is the Applicant?

First and foremost, it must be determined who will access/obtain the biological resource and apply for the patent application. This is because under BDA different provisions are applicable for Indian and foreign nationals/company for accessing biological resources.

Applicant is Indian National or Company: As Indian Citizens and Indian Companies are not required to seek prior approval for accessing biological resources for research, such applicants are only required to seek approval of NBA for filing a patent application. Such a request may be filed and obtained after the acceptance of the patent but before it is sealed. However, as this may cause delays, it is advisable to seek permission of NBA, prior to filing of patent application or as soon as possible after filing the patent application.

Applicant is a foreign citizen, foreign corporation, Non-resident Indian (as defined by the Indian Income Tax Act) and Indian corporate body having non-Indian shareholding or management:

In addition to seeking approval from NBA for filing patent application, such applicants must seek approval from NBA before commencing any research project, so as not to contravene Section 3 of the BDA. Although, the request for filing patent application may be filed and obtained after the acceptance of the patent, it is advisable to seek such permission, prior to filing of patent application or shortly after filing the patent application.

2. What is the source of Biological Resource Used?

Another aspect that must be considered while filing such a patent application is the source of biological resource i.e., from where did the applicant obtain the biological resource mentioned

in the patent application. In case the patent application mentions a biological resource that is not of Indian origin, approval is not required to be obtained from NBA. In such cases, if the Indian Patent Office raises an objection during examination, the applicant can overcome such an objection by stating that the source of the biological resource is not Indian. Applicant may however also be required to submit a declaration to that effect at the Indian Patent Office in response to said objection. The Indian Patent Office, for example in 2937/DELNP/2009 has withdrawn the objection and allowed the application for grant, on a statement by the applicant that the biological resource used in the patent application was not obtained from India. Applicants should bear in mind that in case a false declaration is provided, the patent will be liable to be revoked.

3. Does the Invention relate to a biological resource defined under the BDA.

Several patent applications are based on inventions that relate to material that does not come under the definition of “Biological Resources” under the BDA act. Thus, if patent application is in respect of the following, excluded subject matter, then approval from NBA before filing patent application is not required.

Value Added products: Section 2 of BDA explicitly excludes value added products from the purview of “Biological resources”. Value added products are defined as “*value added products means products which may contain portions or extract of plants and animals in unrecognizable and physically inseparable form.*”. For example, products such as wheat flourⁱ, tobacco dustⁱⁱ, allicin-enriched garlic extractⁱⁱⁱ, were considered as value added product by the Indian Patent Office.

Bio-waste: NBA approval is also not required for, inventions that use/ disclose Bio-waste. Bio-waste is generated after the economic use of the biological resource/material is exhausted and is therefore not covered under the definition of “Biological resources”.

Synthetically prepared biological material: Inventions that use synthetically prepared biological material, can also be filed without seeking prior approval from NBA. Such material for example includes materials such as enzymes, pigments, gums, sucrose etc.

Office Circular of IPO – Procedure for Handling Patent Applications

As a matter of practice, the Indian patent office required every patent applicant for an invention based on biological resources to obtain NBA approval before the patent is allowed to proceed for grant. As a result, a significant number of such patent applications were stuck at the patent office pending approval. To address the difficulties faced by patent applicants in prosecuting patents applicants that involve the use of biological material and difficulties faced by them due to delay in obtaining NBA permission the Office of The Controller General of Patents, Designs & Trademarks has issued an Office Circular (CG/Office Circular (P)/2017/451). The Office Circular streamlines the procedure for handling applications that involve the use of biological material. The following guidelines have been provided in the circular:

1. Approval from NBA is not required for applications where the invention does not relate to a biological resource defined under the BDA, such as (a) value added product, (b) Bio-waste or (c) Synthetically prepared biological material. The circular clarified that the Controller must verify from the disclosure in the patent specification if the claimed invention resides in a “Biological resource” or comes within the ambit of the exclusions before raising any objection in the examination report.
2. When an applicant makes a declaration in application for patent that the biological material used in the invention is neither obtained from India nor sources from India, then Examiners/Controllers should consider such a declaration during examination and should avoid raising an objection in the examination report.

Thus, it is useful to keep in mind the approvals required under the Biological Diversity Act while prosecuting patent applications to ensure such applications proceed to grant in a timely manner.

ⁱ [Controller decision India Patent Application No: 1920/DEL/2009](#)

ⁱⁱ [Controller decision India Patent Application No: 1827/DEL/2006](#)

ⁱⁱⁱ [Controller decision India Patent Application No: 2937/DELNP/2009](#)