**LINKING BIODIVERSITY WITH PATENT LAW**

The Indian Patent Office has attempted to bridge the gap between the laws on patents and biological diversity, but instead, it created a maze of problems. The issuance of guidelines (in 2012) for processing of patent applications relating to traditional knowledge and biological material by the Indian Patent Office has led to more chaos at the patent office and dissatisfaction among patent applicants instead of streamlining the process.

The major objective of bringing in said guidelines was to lay down an adequate process for examining and granting applications relating to biological resources obtained from India by observing the mandate of the Biological Diversity (BD) Act, 2002.

The guidelines were supposed to be the missing link between the Patents Act, 1970 and the BD Act. However, they ended up creating a labyrinth of procedural requirements. This article discusses the effects of the guidelines.

India joined the Convention on Biological Diversity (‘CBD’) on February 18, 1994, becoming part of the movement to promote conservation of biodiversity and the equitable sharing of benefits arising out of the use of genetic resources.

To conform to the national laws regarding the mandate of the CBD, the Indian Parliament passed the BD Act, 2002. Section 6(1) of the Act lays down the provision of obtaining prior permission from the National Biodiversity Authority (NBA) for applying for any IP in or outside India for any invention based on any research or information on a biological resource obtained from India.

In case the patent has already been applied for, the permission of the NBA may be obtained after the acceptance of the patent but before the sealing of the patent. The section further provides that the NBA shall dispose of the application for permission made to it within 90 days from the date of receipt thereof. The BD Act also has penal provisions for the contravention of the provisions of section 6.

The patent laws of India complements this provision of the BD Act by making it mandatory for the applicant of a patent to submit a declaration on the application form to the effect that “the invention as disclosed in the specification uses the biological material from India and the applicant shall submit the necessary permission from the Competent Authority before the grant of the patent.” Moreover, the Patents Act places a mandatory obligation on the applicant to disclose the source and geographical origin of the biological material used in the invention.

Despite having specific provisions in the patent statute, there was a severe lack of uniform implementation as most of the applications filed and examined flouted the provisions of disclosing the source and geographical origin of the biological material used. The patent offices did not require prior permission under section 6 of the BD Act for the use of the biological resource.

Thus, the guidelines were brought in to lay down the systematic procedure for identification, screening, and classification of the applications relating to biological materials.

The guidelines made it mandatory for the Controller General to object to the office action about the requirement of permission from the NBA in the matter, if not already submitted. If the objection was not raised in the office action, the same might be raised at any stage after that.

In any case, the patent shall not be granted to an invention which uses biological material from India unless the applicant submits the NBA permission. This led to a flood of office actions from the patent office requiring the applicant to obtain permission from the NBA.

According to the statistics from the NBA, the number of applications filed for seeking prior permission to obtain IP rights from 2004 until March 2013 was 537, which grew to 821 by March 2016. This increase in the number of applications is attributed to a change in practice at the patent offices.

The situation became worse when the approvals were not received from the NBA within the statutory period of 90 days. Instead, applications remained pending at the NBA for more than five years. Delays on the part of the NBA in granting permission have the effect of stalling the grant of a patent. Given the limited term of 20 years for a patent, delay in grant becomes commercially critical. Such delays at the NBA are attributed to lack of resources. According to annual reports, in the year 2015/16, the NBA had executed only 18 access and benefit-sharing agreements.

There has been widespread criticism for lack of collaboration between the two offices. The NBA is a statutorily autonomous body under the Ministry of Environment and Forests, and the patent office is a government agency under the Ministry of Commerce and Industry, so the two agencies function independently of each other, and there is no linkage between the two.

The Controller General of Patents has also issued an official notification providing instructions to streamline the process relating to patent applications that deal with biological material from India. According to the notifications, the Controllers have been directed to refrain from raising objections on obtaining approval from the NBA concerning inventions which reside in:

* Value-added products and not the biological material;
* Bio-waste which is generated after the economical use of the biological material is exhausted; and
* Biological material prepared synthetically.

The inventions which come under the category of ‘value-added products’, following section 2(p) of the BD Act, are exempted from the provisions of the Act. According to the BD Act, “value-added products” means products which may contain portions or extracts of plants and animals in unrecognisable and physically inseparable forms. Therefore, inventions which relate to herbal formulations or compositions involving the use of oils or extracts of the plants and animals in the indistinct and physically intimate way do not require NBA permission.

In cases where the applicant has made a declaration that the biological material used in the invention is neither obtained nor sourced from India, the patent office is now merely granting such an application without requiring the applicant to obtain permission.

In cases where all the objections have been complied with except submission of NBA approval, the Controller shall mark the application in the examination module as ‘NBA approval pending, but for a grant’ and the system administrator will tag such cases so that the claims can be treated as disposed of by the Controller.

The procedural changes for dealing with patent applications are very welcome and have come as a respite for patent applicants. Several patent applications which were gathering dust for a long time could now finally see the light of the day.

However, the actual linkage of the Patents Act and the BD Act has still not happened. Issues such as delays, dealing with different forums, a single-window system, etc., remain unaddressed. However, we hope the same to be resolved soon.