

2010 Business Agenda : Patents vs Patients

There is need to develop a conducive system

Dr Milind Antani, Head, Pharma-Life Science Practice and Gowree Gokhale, Partner & Co-Head, Pharma Practice, Nishith Desai Associates present certain recommendations in the hope that the day is not far when India will have an IP regime with excellent infrastructure, backed by skilled experts and balanced to encourage innovation and accessibility to affordable medicines

Indian pharmaceutical industry has witnessed fast growth in the recent years and global industry players are noticing India as a major player. The protection of Intellectual Property Rights (IPR) in India, was one of the biggest concerns of global pharma companies seeking to enter India in the past. The landscape is changing post-implementation of Trade-related Aspects of Intellectual Property (TRIPS) provisions. However, there are still concerns about the full implementation of the product patent regime. It was feared that indigenous industry could receive a set back after the advent of the product patent regime, while attracting many multinational companies into India. The scene is not quite as expected.



The will on India's part to bring in change is evident from the recent statement by Controller General of Patents, Designs and Trademarks, P H Kurian that on an average, Indian filings contributed only 20 percent to the total number of applications, the lion's share of 80 percent coming from overseas. He further mentioned that in five years, about 13,000 patents have been granted in the drugs and agro-chemicals sector. The statistics from the Patents office say that over 35,000 patent applications were filed in 2007-08, of which over 15,000 were granted, which showed significant increase from 12,000-odd patent applications in 2003-04.

Currently, though there are well-established statutory, administrative, and judicial frameworks to safeguard (IPR) in India, there is need to develop a conducive system delivering excellent services to the applicants apart from addressing certain issues and concerns that have surfaced especially patentability criteria, incremental innovation, patent linkage system, enforceability, misuse of opposition provision and need for skilled patent examiners and need for well functioning patent office providing easy accessibility to the data.

Issues, concerns and recommendations:

Section 3 (d): Section 3(d) has grabbed the attention of the industry because patents for drugs have been rejected under this provision even though they have received patents in other countries e.g. Glivec of Novartis and recently Boehringer Ingelheim's anti-AIDS drug Nevirapine. The word 'efficacy' is given significant importance and it is essential for the applicant to demonstrate the enhancement of therapeutic efficacy, as increased bioavailability may not suffice to be eligible for the grant. The definition and interpretation of the terms 'efficacy', 'enhanced efficacy', 'therapeutic efficacy' and 'significant increase in the efficacy' are crucial elements in judging the patentability.

Recommendations: This interpretational controversy is best set to rest by the amendment to Section 3(d).

Apart from formulating guidelines for examination of patent applications involving micro-organisms, and avoiding ever-greening of patents, as recommended by the Mashelkar Committee, the Patent Office should also play a vital role in setting out parameters for measuring 'enhanced efficacy' as is required by Section 3(d).

The patent office should also provide guidance on how to apply the test of inventiveness in relation to pharma product patents, thus balancing national interest with India's international obligations.

Oppositions

Many companies are facing issues due to the pre grant and post grant opposition to the applications. The pre-grant opposition can be filed anytime after the publication of the patent application but before a patent is granted. The post-grant opposition can be filed within a



period of one year from the date of publication of the granted patent. The grounds on which pre-grant opposition and post-grant opposition can be filed are similar. Opposition at two levels is creating delays in patent grant procedure.

Recommendations: The Government should re-look at this two stages of oppositions, specially in view of the fact that the Patents Act already provides for the revocation under Section 64. Patent office should be more judicious in accepting pre-grant oppositions.

Data Exclusivity

Though the Government has accepted the recommendations by Satwant Committee report partially, it needs to take steps for implementation of the data exclusivity regime in India.

Administrative Infrastructure:

Patents: The Indian patent database is not an online searchable one, and the Journals of the Office that are meant to publish the patent application or granted patent, publish only the bibliographic information and abstract; not the entire specification and claims. Having no access to the database is a disadvantage that also restricts the ability of IP practitioners to conduct Freedom-to-Operate searches for Indian patents.

Trademarks: Some of the departments in the Office have not been functioning smoothly due to which documents are not taken on record for unreasonably long periods of time.

Enforcement: There has been tremendous improvement in the enforcement of IP rights in India. However, there still exists a large scope for improvement. Recovery of damages in a civil action is still difficult since cases take a number of years to reach a conclusion. An injunction is much easier to obtain. There is also room for improvement on the criminal enforcement front. Training of the police and judicial officials on matters dealing with IP rights is underway and we hope to see much better trained resources soon.

Recommendations: Unless there is proper and more effective and well equipped patent and judicial infrastructure, it would be very difficult to implement the law. There is a need to professionalize the patent office by recruiting techno-legal people, providing excellent and state of the art facilities to access the data and simplify the process at the office.

Pricing of medicines: Another very important issue that affects the people of India is the concern regarding the price of the medicine and access to the affordable medicines. Indian healthcare system is at a stage where significant increase in the price of medicines may hamper the basic motive of providing good healthcare to the people of India at large. A fear of the increased drug price in the mind of a common man is valid and needs to be addressed. The Patents Act has provided certain measures to control or limit patent rights in specific situations. Use of patents by the Government, compulsory licensing, and certain exceptions like parallel import and Bolar provisions are such measures. The exercise of these measures will balance the patent rights and provide access to affordable medicines.

Recommendations: Having a strong board to review price of patented medicines, preparing a list of ailments that are fatal and life threatening, use of compulsory licensing provisions, encouraging people of India to be more aware towards health insurance, facilitating health insurance, implementation of special access program for Anti cancer and Anti HIV medicines, are some of the measure that may lead to access to affordable medicines. It is equally important that the people of India have access to quality medicines and judicious and effective use of patent system and implementation of certain provisions to avoid misuse and encourage would ensure adequate balance between innovation, control and access.

Awareness Program: Apart from the issues and concern over the Patents Act and its implementation, India needs to carry out an extensive awareness program regarding intellectual property especially the patents. The students of science especially pharmacy, biotechnology needs to get exposed to the applied knowledge of patents, various procedures and processes to encourage them on the lines of creating an invention. Another sector that needs to be made aware of the patents is of medical professionals who are very active in research or are involved in developing innovations in their practice of profession. The students and professionals should be encouraged to file patent applications.

A day is not far when India will be on global map with IP regime that is implemented by excellent

infrastructure backed by skilled experts and is balanced to encourage innovation and accessibility to affordable medicines.



© Copyright 2001: The Indian Express Limited. All rights reserved throughout the world. This entire site is compiled in Mumbai by the Business Publications Division (BPD) of The Indian Express Limited. Site managed by BPD.