EXPERT COMMENTS

IPR Provisions and Amendment of Indian Patent Act 1970: Impact on Access to Medicine

Dr. Subhash C. Mandal*
Chairman, Regulatory Affairs Division (RAD),
Indian Pharmaceutical Association (IPA), Kalina, Santacruez (East), Mumbai-400098
Correspondance : subhash.mandaldr@gmail.com

PREAMBLE:

Indian Patent act that been amended in 1970 was a paradigm shift from pre-independence Patent act regime, which had allowed process patent and duration of patent was only for 7 years. On the basis of this act Indian pharmaceutical industry started to grow and reached about 2.40 lakh crores presently, which was only 10 crores during 1940. Presently India is exporting more than 1 lakh crores of medicines to more than 250 countries round the world including developed countries.

This has not only made India self-sufficient in production of Drugs and medicines, but it also is a life line for poor countries and presently India is called as "Dispensary of the world".

As a result of WTO agreement, India was forced to be a part of WTO by signing in December 1994. Thereafter, Patent act has been amended with effect from 1st January 2005 in India. Experts opined that though there is ample scope of protecting the interest of our country utilizing several Articles of TRIPS agreement, it was not utilized properly. The objective of the Article 7 is "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Principles of Article 8 state that "1. Members may in forming or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.

2. Appropriate measures, provided that they are consistent with the provisions of the Agreement may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unnecessarily restrain trade or adversely affect the international transfer of technology".

Article 30 and 31 of IPR agreement are two mechanisms in which the patented object can be used without the permission of the rightful owner.

The action:

Patents are supposed to represent a balance between the rights and obligations of a patent holder. Patent laws are required to ensure that the products of new research are available to the largest number of people, while providing a fair return to the innovator. Keeping this objective in mind Indian Patent Act 1970 has been amended with some provisions for protecting the health of the people, which are as follows-.

1. The Indian Act denied granting of a patent retrospective to the mailing date of the submission. Thus, Indian companies that had

been producing and selling patented medicines could not be subjected to patent infringement claims. The Act also provided that even after a patent had been granted, Indian companies would be able to continue production subject to payment of reasonable royalties to the patent holders. Sub section 2 of section 5 of the act specifies the term "reasonable", but no explanation is given.

2. A most significant feature of the Act is that it provides protection from secondary patenting of the same chemical/pharmaceutical molecule incorporating sec 3(d) of the act. It forbids patenting of 'salts, esters, polymorphs, metabolites, pure forms, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances unless they differ significantly in properties with regard to efficacy.'
3. The Act also provides for pre- and post-patent objection of patents and describes 11 areas where one can raise objections on the granting of a patent. This includes objection to a patent based upon existing knowledge in the public domain (prior art). This holds good for domestic inventions and also for imported materials and according to the following "That if the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of the claim"[sec.25 (d)] such an application is not patentable.
4. The Act has now made a provision under section 107 a (b), for the import of patented commodities from any part of the world, where it is cheaper, even though it is patented in India. This is known as parallel import. For this purpose, it will also not be required to obtain any authorization from the patentee. The Act simply says that 'who is duly authorized under law to produce and sell or distribute the product' will become the source for Indian importers.
5. One of the most important areas of the Act is its provisions for compulsory licensing. The act clearly directs that a '(Compulsory) license is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product'. The license shall also be granted to remedy a practice determined after judicial or administrative process to be anti-competitive. This particular clause may be carefully used to control exorbitantly high prices of patented products.

In the greater interest of a country, the compulsory license process empowers and allows a domestic company to produce a particular medicine if the patent holder company does not produce or supply the medicine. In contrast to this the Indian Act has designed the provisions of compulsory licensing, in a manner that is more suitable to the needs and traits of the Indian industry. Section 92A (1) of the Act states that a "Compulsory license will be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public heath problems, provided a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India". In other words, a country simply needs to announce, by notification, the need for importing any patented medicine from India. Such products can then be ordered from any Indian company for manufacturing and exporting if a compulsory license was granted to that company. The other important section of the Act is that a compulsory license may be requested on the grounds that the establishment or development of commercial

activities in India is prejudiced. For such purpose, the applicant has to make efforts to obtain a license from the patent holder on reasonable terms and conditions and when such efforts have not been successful within six months, he will be granted a compulsory license.

Outcome:

Besides Indian patients, Indian manufacturers are also saving millions of lives in poor countries especially in Africa by supplying low cost antiretroviral drugs. One Indian company has supplied one year's ARV medicine at a price of $250, whereas a multinational is supplying the same at a price of $10,000 in 2001.

Case study-1

India has denied patenting a new polymorph of imatinib mesylate an anti-leukemic drug to a multinational in 2006, who are marketing one month's medicine at a price of Rs. 120000, whereas the same drug is being supplied by Sun Pharma at a price of Rs. 8000. The company went to court and challenged the section 3 (d) of Indian patent act and lost the case. Thereafter they again went to court with a plea that section 3 (d) has wrongly interpreted and the verdict is again going against them.

Case study-2:

Very recently India has granted compulsory licensing as per the section 84 to Natco for Sorafenib, which is a patented drug of Bayer. Sorafenib has been shown to extend survival rates among those suffering from liver cancer and renal cell carcinoma.

The Supreme Court of India refused to entertain Bayer's appeal to set aside the compulsory license (CL) on Sorafenib (Nexavar). The Supreme Court's dismissal of Bayer's Special Leave Petition against the Bombay High Court's decision upholding of the CL concludes the legal proceedings on the first ever CL issued in India.

The grant of Compulsory license (CL) to NATCO for the anti-cancer drug – sorafenib tosylate – and the litigation ensuing around it is the first of its kind in India. Sorafenib tosylate is a crucial drug for patients living with kidney and liver cancer. Bayer was selling the product under the brand name Nexavar for Rs. 2,84,000 per patient per month which is unaffordable to most patients in India. On 9 March 2012, the Patent Controller granted a CL to Natco Pharma to market a more affordable generic version of Nexavar at around Rs. 8, 800 per person per year. Bayer unsuccessfully challenged the order before the Intellectual Property Appellate Board (IPAB) and later at the Bombay High Court.

Though compulsory licensing have been granted earlier by several countries like Thailand this is the first instance that India granted compulsory licensing first time. The fact that this is the first CL issued in India is in itself a major step and can be a precedent for many more compulsory licensings in the future. The compulsory licensing on sorafenib is not only helping cancer patients but is also extending a scope towards building domestic manufacturing capacity and developing know how in a new range of anti-cancer drugs. Sorafenib is one of the first in a group of new drugs that specifically target cancer cells. Similar drugs with better results are likely to be available over time, and it is important that generic manufacturers develop capacity to manufacture these.

It appears that the newly amended Indian patent act has adopted some mechanisms like - compulsory licensing to protect the interest of the ailing people, though this is not the only measure to improve access to medicines. There are several areas need to be sorted out by the policy makers for improving access to medicines.

Conclusion:

The Indian Patent Act 1970 helped Indian pharmaceutical Industry to grow with tremendous pace, which not only met the need of India but contributed immensely for the global need. One school believe that the amended version of Indian Patent Act 2005 has provided some measure to protect interest of public health care, but the other school opined that it will be deterrent for conducting research as pharmaceutical industry may not be interested to put money for new innovation. It is widely believed that judicious utilization of the IPR provisions will strike a balance between the interest of public health and innovations in the field of Pharmaceuticals.