

PATENT LAW PROVISIONS GOVERNING RESEARCH ACTIVITIES OF GENERIC DRUG MANUFACTURERS PRIOR TO PATENT EXPIRY

Patent tussle between generic drug manufacturers and innovation companies is commonplace in the highly competitive pharmaceuticals industry. Friction between generic drug manufacturers and innovation companies typically begin when generic drug manufacturers initiate research using a patented product to submit information to regulatory bodies to seek approval for introducing a generic version of a patented product. While the generic drug manufacturers intend to introduce the generic version once the patent expires, research is carried out when the patent is still in force. Several countries, including India, have provisions governing such research activities. The instant article provides an overview of provisions governing such research activities in India.

The Indian Patent Act (“Act”) includes provisions that facilitate research and development using patented product/process without being liable for infringement. Such an exemption from patent infringement is known as Bolar Exemption. The instant exemption is in favour of the generic drug manufacturing industry, and it helps the generic industry flourish in India. Generic drug manufactures use patented products (prior to expiry of the patent) to carry out research and experimentation to develop and submit information to the Drug Controller General of India (DCGI) for approval of the generic version of the patented drug. Such acts of generic drug manufactures are not considered infringement. The Bolar provision has been incorporated in the Act under Section 107A(a). The provision not only extends to pharmaceutical products, but also extends to any product/process that may require regulatory approvals.

Governing statute:

107A. Certain acts not to be considered as infringement. – For the purpose of this Act,

(a) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;...

shall not be considered as a infringement of patent rights.

The exemption allows generic drug manufacturers to introduce generic drugs within a short time subsequent to patent expiration. India being an under developed nation, majority of the population cannot afford drugs at higher prices. Therefore, expedited entry of generic drugs into the market provides access to drugs at affordably price.

An attempt to dilute the effectiveness of the above discussed provision was made when Bayer filed a case against Cipla.

Bayer vs Cipla:

Bayer was granted a patent for a drug “sorafenib tosylate”, which it marketed under the brand name Nexavar in India. Cipla had filed an application to DCGI seeking marketing approval for a drug “Soranib”, which was a generic version of “sorafenib tosylate”. Bayer contented that DCGI should not grant marketing rights to Cipla. Bayer attempted to create a link between regulatory approval (governed by Drug and Cosmetic Act) and patent status (governed by The Patent Act) to support its contention. Such linkage between patent status and regulatory approval is commonly known as patent linkage, and such linkage does exist in some countries.

The court in its judgement dismissed Bayer’s appeal. It was reasoned that India has signed TRIPS, and patent linkage is a “TRIPS Plus” concept, which India has not signed. Hence, patent rights in India will have to be enforced under The Patent Act, and not under any other law, such as the Drug and Cosmetic Act. Therefore, in India, as provided by The Patent Act, and further reinforced by the instant case, act of making, constructing, using or selling or importing a patented product/process solely for uses reasonably relating to the development and submission of information required under any law for the time being in force is not considered patent infringement.

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