Pharmaceutical Patents in India

Compulsory Licensing

Health Emergency & Affordable Healthcare

A Publication of

TECH CORP LEGAL LLP

AN INTRO TO

PATENT LAWS

An introductory guide to Pharmaceutical Patent Laws in India

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India is facing tremendous pressure from US for enforcement of Intellectual Property Rights (IPR) since last few months, specifically with regards to concerns over violations of pharmaceutical patents in India.

Recent Issue – Dasatinib [Bristol-Myers Squibb (BMS)'s Cancer drug]

Dasatinib, an anti-cancer drug produced by pharma major Bristol-Myers Squibb (BMS), is used to treat chronic myeloid leukemia. Recently, the health ministry of India is exploring various options to revoke the patentee's rights for Dasatinib, arguing that such move is required to deal with an "emergency".

Recent Issue – Dasatinib [Bristol-Myers Squibb (BMS)'s Cancer drug]

Although the health ministry is confident about revocation of Dasatinib's patent, it is bound to attract stringent criticism from global pharmaceutical companies. However, such step by the health ministry of India can be attributed to the strong pressure exerted by public health groups, who usually reprimand the public authorities of being non-responsive to their concerns regarding affordability and availability of medicines for life-threatening diseases.

As per news reports, the health ministry is in communication with the department of industrial policy and promotion (DIPP), wherein it is being discussed that the cost of the drug produced by Bristol-Myers Squibb (BMS) will be met through government schemes.

Revocation of Patent by Government – Indian Patent Laws

In accordance with various provisions of the Indian Patents Act, the government can revoke a granted patent under following circumstances:

Revocation of Patents by Controller for Non-working, Non-availability at Reasonable Price

As per Section 85, any person interested, or the Central Government can approach the Controller to pass an order revoking the patent on the ground that ***the patented invention has not been worked in the territory of India*** or that ***reasonable requirements of the public with respect to the patented invention has not been satisfied*** or that the ***patented invention is not available to the public at a reasonably affordable price.***

However, as mentioned in section 85 of the patents act, this is only applicable if a ***compulsory license has been granted in respect of a patent***, and such ***application can only be made to the Controller after the expiration of two years*** from the date of the order granting the first compulsory license.

In addition, if such an application is made by an individual or a legal entity, other than by the Central Government, the applicant is required to set out the nature of the applicant's interest, along with the facts upon which the application is based.

Alternatively, if the Controller is satisfied:

that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

that patented invention has not been worked in the territory of India, or

that the patented invention is not available to the public at a reasonably affordable price,

an order revoking the patent can be passed.

(ii) Revocation of Patent in Public Interest

In accordance with Section 66 of the Indian Patents Act, where the Central Government is of opinion that a patent or the mode in which it is exercised is ***mischievous to the State*** or ***generally prejudicial to the public***, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the ***patent shall be deemed to be revoked***.

(iii) Revocation by High Court on Petition of Central Government

According to Section 64(4), a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of Government within the meaning of section 99 upon reasonable terms.

Going by the limited information available in the public domain with regards to communication between the ministry of health and DIPP (public body governing IPR), it is yet to be seen under which provision the government intends to revokes Dasatinib's patent granted to BMS. As the government has already turned down health ministry's request to issue a Compulsory License under Section 84, the ministry is expected to file an application with the Patents Office under Section 85, which will provide an opportunity to BMS to put forward its objections as its right to be heard under principles of natural justice.

Compulsory Licensing in India – Controversial for Pharmaceutical Patents

Rejection of Compulsory License for Dasatinib

Compulsory licensing is one of the most debatable provisions of the Indian Patents Act. In October 2013, the Patents Office rejected an application from BDR Pharma to make a generic version of BMS's Dasatinib.

The proposal was rejected on the grounds that the Indian company did not make enough efforts to obtain a voluntary license for the anti-cancer drug.

As per the application made by BDR Pharma, BMS responded with number of queries asking BDR to answer, when BDR applicant requested BMS for issuance of a voluntary license. It shall be noted that making such request for voluntary license is mandatory under patents act, before an application for compulsory license is made to the Controller. BDR alleged that BMS used these queries as delaying tactics, while the Controller General of Patents held that prior to deciding on the merits of the case, the threshold requirement of establishing a prima facie case must be satisfied.

The CG of Patents held that BDR had not really made any credible attempt to procure a license and therefore could not be said to have satisfied the statutory requirement that the applicant must have negotiated in good faith for 6 months at least.

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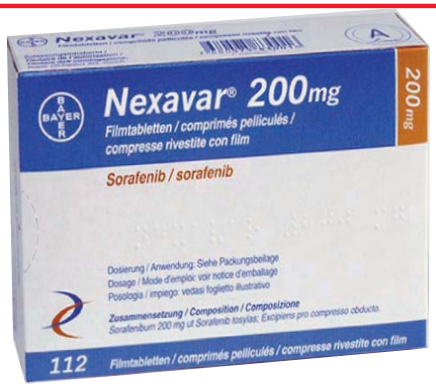

India allows compulsory licensing of Bayer's Nexavar

The decision is likely to open up the field for the generics industry or force innovative companies to make drugs more affordable. But will it also affect innovation? *BioSpectrum* explores the two sides of the story

Compulsory License Granted for Bayer's Nexavar in 2012

In March 2012, the Indian Patent office granted first compulsory license to NATCO pharma to make anti-cancer drug sorafenib for the India market. However, the compulsory license is subject to certain conditions, such as maintaining account of sales, and payment of royalty at six percent of the net sales on a quarterly basis to Bayer. The order also makes it obligatory for NATCO to supply the drug free-of-cost to at least 600 needy and deserving patients per year.

More details can be seen here.

“India's IPR decisions have hit pharma sector the most”

-John J Castellani, CEO, Pharmaceutical Research and Manufacturers of America
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