



Compulsory Licences in India

Many countries have provisions which allow for compulsory licences to be granted under exceptional circumstances. However, in recent years, these provisions have only rarely, if ever, been used.

An exception arose in India in 2011, when the Indian Patent Office granted a compulsory licence to the generics company Natco. The compulsory licence allowed Natco to manufacture and sell Bayer's product Nexavar, which was protected by Indian Patent No. 215758. The compulsory licence was issued on the basis that (a) the price of Nexavar was too high and thus the drug was "*not available to the public at a reasonably affordable price*", and (b) Nexavar was imported into India and this did not constitute working "*in the territory of India*".

The grant of a compulsory licence under these circumstances attracted significant criticism, especially from outside India, and seemed to set a worrying precedent. Some pharmaceutical companies have since been reluctant to commercialise new products in India, due to the legal uncertainties and the aggressive approach adopted by generic competitors in light of Bayer vs Natco.

However, there is perhaps now a glimmer of hope in India. In particular, a recent application by BDR Pharma for a compulsory licence for the Bristol Myers Squibb (BMS) drug Dasatinib has been rejected by the Indian Patent Office, on the basis that BDR Pharma did not make a credible effort to secure a voluntary licence prior to filing the request for a compulsory licence.

Specifically, BDR Pharma applied to BMS for a voluntary licence for Dasatinib on 2 February 2012. BMS replied to the request with a series of questions on 13 March 2012, but did not refuse the request. BDR Pharma did not reply to the questions from BMS, but instead filed a request for a compulsory licence on 4 March 2013. This step was taken nearly one year after the reply from BMS.

The Indian Patent Office considered that BDR Pharma had not complied with Section 84(6)(iv) of the Indian Patents Act, 1970. This provision requires that the applicant for the compulsory licence has made efforts to obtain a voluntary licence from the patentee and that those efforts have not been successful within a period of six months. In other words, the applicant for a compulsory licence must have negotiated with the patentee in good faith for six months prior to filing the request for the compulsory licence.

On that basis, the Indian Patent Office concluded that BDR Pharma did not make a *prima facie* case for the grant of a compulsory licence, and the application was rejected without considering its merits further.

This decision from the Indian Patent Office is a small positive development for innovator companies active in India, and suggests that Indian tribunals will consider each application for a compulsory licence on its merits and are prepared to reject applications which do not meet the statutory requirements. It also highlights the importance of seeking to negotiate in good faith with companies that apply for a voluntary licence.

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