

# Natco Pharma Applies for India's First Compulsory License

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Economic times [reports](#) that [Natco Pharma](#) has applied for a compulsory license to sell a generic version of Bayer's drug [Nexavar](#). Nexavar is used for treating liver and kidney cancer and costs about Rs 2.85 lakhs (10lakhs = 1 million) for a month's course in India. The high cost of Rs 2.85 lakhs for a month's course is unaffordable for an average Indian. Natco has claimed that it can sell its generic version of Nexavar, [sorafenib tosylate](#) for Rs. 8, 900 for the same course.

Natco had sought a voluntary license from Bayer in December, 2010. However, the request to grant the Voluntary license to Natco was refused by Bayer. Consequently, Natco went ahead and applied for a compulsory license. The Indian Patent law (Section 89(4)) allows an interested party to apply for a compulsory license when a voluntary license has been refused to the interested party by the company holding the patent. On grant of a compulsory license, the licensee has to pay some royalty (usually 5% of sales) to the patent owner.

## Further information about compulsory license in India

Under the provisions of Indian Patent Act, an interested party may apply for a compulsory license after expiry of 3 years from grant of patent. The request for compulsory license can also be made by a party that has availed a license for the patent from the patent owner. The conditions under which a compulsory license is granted by the controller of Indian Patent office is covered under section 84, section 92(1) and 92(3), and section 92(A). Section 84 is related to preventing the abuse of patent as monopoly and to make way for commercial exploitation. Section 92(1) and 92(3) are related to situations calling for national emergency and section 92(A) is related to export of drugs/medicines to foreign countries with public health problems and lack of resources and infrastructure to produce the necessary drugs required by the public. Article 30 and 31 cover compulsory licensing provisions in TRIPS. The relevant sections have been added at the end of the article from the Indian Patent Act.

This is the first instance of a company applying for compulsory license in India. Till date, no compulsory license has been issued by the controller or the government of India. There have been a few occasions (three) where parties have applied for compulsory license under section 92(A); however, such applications were withdrawn later by the parties themselves.

#### Section 84

- (a) The reasonable requirements of the public with respect to the patented invention have not been satisfied;
- (b) The patented invention is not available to the public at a reasonably affordable price.
- (c) The patented invention is not worked in the territory of India.

Section 89 further explains the rationale of granting compulsory license under Section 84.

#### Section 89

- (i) That the patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;
- (ii) That the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

Subsection 6 of Section 84 specifies the factors while considering the application under section 84.

- (1) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patent or licensee to make full use of the invention;
- (2) The ability of the applicant to work the invention to the public advantage;
- (3) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;
- (4) As to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.

#### Sections 92 (1) and 92 (3)

These sections enable the Central Government and the Controller to deal with situations demanding national emergency related to public health crises by granting relevant compulsory licenses.

Section 92 A

Provides for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

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