

Source: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/delhi-high-court-favours-natco-alembic-allows-them-to-export-generics-of-bayers-drugs/articleshow/57534420.cms>

## Delhi High Court favours Natco, Alembic; allows them to export generics of Bayer's drugs

The Delhi High Court has ruled that Indian companies Alembic and NatcoBSE 0.73 % Pharmaceuticals can export generic versions of two of German drug maker BayerBSE 1.07 %'s life saving medicines for research and regulatory purposes. The court's ruling on Wednesday is yet another victory to Indian makers of generic drugs embroiled in court battles against the drugs' inventors.

Bayer had approached court in 2016 to stop Alembic PharmaceuticalsBSE 1.44 % from exporting its generic of the German company's blood thinner brand 'Xarelto' (Rivaroxaban), used to prevent and treat dangerous blood clots.



Alembic and Natco are required to give an undertaking that they will not export their drugs for any other purpose than those in Section 107A of the Indian Patents Act, 1970.

The company also sued the government in 2014 to stop Natco's export of 'Sorafenat', the Indian company's generic brand of Bayer's cancer drug 'Nexavar' (Sorafenib) used to treat three types of cancers. Natco was granted a compulsory licence to manufacture the generic of Nexavar in 2012--a decision that the Supreme Court upheld in 2014 when Bayer appealed the move and asked for the compulsory licence to be set aside.

In a setback to the German drug giant, the court has ruled in favour of the Indian companies, allowing them to continue with the exports for clinical development and regulatory purposes.

"I've held their exports to be permissible," stated Justice Rajiv Sahai Endlaw while pronouncing the judgment.

Alembic and Natco are required to give an undertaking that they will not export their drugs for any other purpose than those in Section 107A of the Indian Patents Act, 1970.

Section 107A includes acts that would not be considered an infringement of a company's patent rights. Under this provision, companies can make, use, sell and import a patented invention solely for purposes reasonably related to the development and submission of information required under any law in force in India or another country.

According to Bayer, Alembic was infringing its patent on the blood thinner by exporting and dealing in the drug, Rivaroxaban. Alembic had argued that exporting its version of the drug was well within the provisions of Section 107A. Bayer, however, claimed that Alembic had exported 90 kgs of the drug worth Rs3 crore and that the export of such a large quantity was not as per this section.

In Natco's case, Bayer took objection to the Indian company's export of Sorafenat and said that compulsory licence conditions clearly stipulate that the licence has been granted for the sale of the drug within Indian territory. Natco sought permission from the court to send samples of the active ingredients of the drug to other countries for experimentation and generation of clinical trial data for submission to Drug Controlling Authorities.

"The court has reiterated that the growth of the pharma industry in India cannot be stunted in such a manner by stopping exports for exploratory purposes which is a recognised exception under TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights)," Pratibha Singh, counsel for Alembic, told ET.