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

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

NEW DELHI: The **Delhi High Court** has ruled that Indian companies Alembic and **Natco** NSE -0.48 % Pharmaceuticals can export generic versions of two of German drug maker **Bayer** NSE 0.88 %'s life saving medicines for research and regulatory pu W

Indian makers of generic drugs embroile inventors.

Bayer had approached court in 2016 to stop **Alembic Pharmaceuticals** NSE -1.16 % from exporting its generic of the German company's blood thinner brand 'Xarelto' (Rivaroxaban), used to prevent and treat dangerous blood clots.

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 com 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

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purposes which I… eption under TRIPS (Agreement on Trade-Related Aspects o… perty Rights)," Pratibha Singh, counsel for Alembic, told ET.

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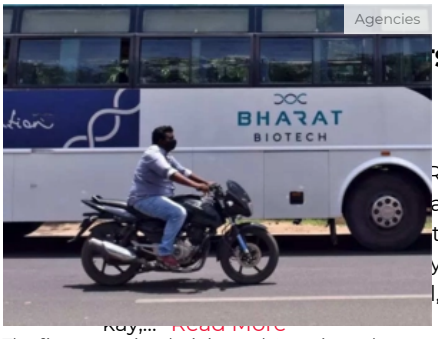
By Teena Thacker, ET Bureau Last Updated: Oct 14, 2021, 07:15 AM IST

Synopsis

"The trials are ongoing, and we expect to submit data by the end of this year," a company insider said. The trials, including over 600 participants, are being conducted by dividing the volunteers into three groups.



The first group is administered Covaxin as the first dose and intranasal vaccine as the second dose.

After receiving positive recommendations from the expert committee on **Covaxin** use for children, **Bharat Biotech** is now looking to submit the trial results of its Covid-19 **intranasal vaccine** by end of this year, people in the know told ET.

"The trials are ongoing, and we expect to submit data by the end of this year," a company insider said. The trials, including over 600 participants, are being conducted by dividing the volunteers into three groups.

The first group is administered Covaxin as the first dose and intranasal vaccine as the second dose. The second group will get both doses in the form of intranasal vaccine.

The third group will get the intranasal vaccine as the first dose and Covaxin jab as the second dose. The doses are given 28 days apart. The intranasal vaccine can be game changer in the vaccination drive because it offers the convenience of administration.

The drug regulatory authority had in August given its approval to Hyderabad-based Bharat Biotech to conduct phase-2/3 trials on its intranasal vaccine.

The adenoviral intranasal vaccine BBV154 is the first of its kind **Covid-19** jab which has been undergoing human trials in India. The phase-1 trial in healthy volunteers of age om 18 to 60 years was well tolerated, the ministry of scienc said in a statement earlier.

It also said the vaccine was found to be safe, immunogenic and well-tolerated in the preclinical toxicity studies and was able to elicit high levels of

neutralizing antibodies in animal studies.

The development of Bharat Biotech's intranasal vaccine has been supported by the department of biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC). The company strategised to fast-track research and development efforts, especially for vaccine development, diagnostics, drug repurposing, therapeutics and testing.

Bharat Biotech's Covaxin had demonstrated 77.8% efficacy against symptomatic Covid-19 and 93.4% against severe illness during the phase-3 clinical trials.

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