

# Strong Opposition to HC Ban on Biocon, Mylan Cancer Drug Sale

**OUR BUREAU**  
NEW DELHI

Public health groups on Friday lashed out at the Delhi High Court order that stopped Bangalore-based Biocon and US generic drug giant Mylan from selling biosimilar versions of breast cancer drug Herceptin (Trastuzumab) till next hearing on appeal of Swiss innovator drugmaker Roche.

Campaign for Affordable Trastuzumab called the court's move "unwarranted and inexplicable" while Biocon termed the development "extremely shocking" and said it was an attempt by Roche to protect its monopoly in India.

"The court has also restrained Biocon from relying upon any data relating to Trastuzumab's manufacturing process, safety, efficacy and sales. This is contrary to the provisions of The Drugs and Cosmetics Act of India, which does not allow any exclusive protection of data (data exclusivity) including manufacturing process, safety and efficacy of a drug to any originator company," a statement from the patient-interest group said on Friday.

Roche has sued Biocon, Mylan and the Drug Controller general of India over cancer drug Trastuzumab, alleging that there is no public record to show that compa-

nies conducted phase-I and phase-II clinical trials.

The Swiss firm also claimed that the approvals for biosimilar came in much faster than the prescribed guidelines in the country.

"Roche was a member of the drafting committee for the biosimilar guidelines. This move by Roche bears out our contention that the guidelines are weighted against innovators in developing countries, and are likely to be used by big pharma to protect its own interests rather than ensure the safety and efficacy of biosimilars," it added.

A Biocon spokesperson said, "We are confident that once we are heard by the court, this injunction placing certain limits on promotional activities will not stand."

*Patent*