

# Biocon, Mylan Challenge Ban on Using Roche Data

Delhi HC's interim order barred use of the data  
in selling biosimilar version of Trastuzumab

## Case in Capsule

Innovator company Roche sells breast cancer drug  
Trastuzumab under the brand name Herceptin

Biocon and Mylan  
got nod to sell the  
biosimilar version of  
the drug under the brand names  
Canmab and Hertaz, respectively

Roche sued Biocon  
and Mylan earlier  
this month for  
launching the  
brands & DCGI for giving  
permission for the launch

Roche argues that claims  
made by Biocon and Mylan  
in their package insert are a  
"slavish copy" of its version

Biocon & Mylan insist  
that the package insert is duly  
approved by the drug authority

HC has restrained Mylan & Biocon from "referring to  
Herceptin" or any data related to it for selling or promoting  
Canmab & Hertaz until the next hearing scheduled for Feb 28

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NEW DELHI

Bangalore-based Biocon and US generic drugmaker Mylan have challenged Delhi High Court's interim order which barred them from using Swiss drug innovator Roche's data to sell their jointly developed biosimilar version of breast cancer drug Trastuzumab.

In a relief of sorts for Biocon and Mylan, the court on Friday said it was not taking an immediate position on whether the two firms had the drug regulator's approval for the package insert they were using to sell their biosimilar version. "At present, there are two versions of the parties which are contrary to each other," said the court order.

Roche has argued in the court that claims made by Biocon and Mylan in their package insert are a "slavish copy" of the innovator's version and go much beyond, and even contrary to, what the drug regulator originally approved. Biocon and Mylan have contested Roche's assertion, insisting that the package insert is duly approved by the drug authority. "Thus, unless the main approval or the approval (for) package insert is revoked or cancelled," the companies have claimed, they are "entitled to use the same in their packaging while marketing the drug".

Roche, which unexpectedly gave up its patent on the \$6-billion breast cancer drug Trastuzumab (sold under the brand name Herceptin) in India last year, sued Biocon and Mylan earlier this

month for launching the world's first biosimilar version of the original drug in India. The company also sued the Drug Controller General of India for giving permission for such a launch.

The court had restrained Mylan and Biocon from "relying upon" or "referring to Herceptin" or any data related to it for selling or promoting their brands Canmab (Biocon) and Hertaz (Mylan) until the next hearing scheduled for February 28. In its order on Friday, the court made it clear that the part of the order which stopped these firms from using Roche's trademarks — Herceptin and Herclon — will continue to hold.

Trastuzumab was being considered for a compulsory licence, but Roche pre-empted the move by not renewing the patent in India.

Roche has told the court that the drugs of Biocon and Mylan are being misrepresented as 'biosimilar Trastuzumab' and 'biosimilar version of Herceptin' without following the due process in accordance with the guidelines on similar biologics for getting approvals in India. The Swiss company has argued that there is no public record available in the clinical trial registry of India or elsewhere to show that these firms actually conducted phase-I or phase-II clinical trials for the drug. The companies could not be reached for comment over the weekend. While Biocon is represented by Harish Salve and Prathibha Singh, Mylan's counsel is Abhishek Manu Singhvi. Roche is being represented by Neeraj Kishan Kaul and Rajiv Nayar.

*Patent*