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Feb 28 to be deciding date for Biocon, Mylan

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Indian Biotechnology major Biocon and US generic drug maker Mylan, who have been selling their jointly developed biosimilar version of Roche's breast cancer drug, have now challenged the interim order. Both companies that released their biosimilar version of breast cancer drug Trastuzumab, have challenged the Delhi High Court's interim order that barred them from using Swiss drug innovator Roche's data to sell their biosimilar.

Meanwhile, the court last week said that 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 of Trastuzumab. The order further read, "At present, there are two versions of the parties which are contrary to each other."

In its argument, Roche pointed out that the claims made by Biocon and Mylan in their package insert are a "slavish copy" of the innovator's version. It further explained that it goes much beyond, and is even contrary to, what the drug regulator had originally approved.

Biocon and Mylan on the other hand have insisted that the package insert was duly approved by the drug authority. They argued, "Unless the main approval or the approval for package insert is revoked or cancelled, we are entitled to use the same in their packaging while marketing the drug."