

Mylan, Biocon move HC against order on biosimilar drug trials

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New Delhi, Feb 14

THE Delhi High Court on Friday reserved its order on a plea filed by pharma majors Biocon and Mylan seeking a vacation of an earlier order barring the companies from relying upon or otherwise referring to any clinical trial data relating to the biosimilar version of Roche's drug Herceptin. The high court's February 5 order had put a roadblock in these pharmaceutical companies' plans to enter the \$6.4 billion global breast cancer drug market.

The court said it will deliver its judgment on the

THE DELHI HIGH COURT HAS RESERVED ITS ORDER ON THE PLEA. IT WILL DELIVER ITS JUDGMENT BY FEBRUARY 18

plea by February 18.

Bangalore based-Biocon and US based-Mylan have jointly developed the Herceptin biosimilar and were expected to start selling it in India as CANMAb™ and HERTRAZ™, respectively, this month. They had also planned to use the clinical trial data generated in India to support regulatory filings in other countries.

Herceptin (scientific name Trastuzumab), which is currently the standard

treatment for metastatic breast cancer worldwide, earned \$6.4 billion in global revenues for Roche in 2012 while India sales amounted to \$21 million. The drug loses patent protection in Europe in 2015 and in the US in 2019.

During the proceedings, senior counsel Harish Salve appearing on behalf of the two aggrieved pharma companies told the court that there is no bar in law that prevents the companies from using the clinical trial

data of Roche as the material is already in public domain. He added that since the data are already in public domain, Roche cannot claim the drug's data to be confidential.

On the other hand, counsel appearing on behalf of Roche told the high court that Mylan and Biocon are required to carry out trials of their own and rely on the data that are extracted from such trials. He argued that Roche was not preventing them from using the data but it was necessary, as per law, that the two companies should carry out their own trials and publish the same in their medicine boxes.

Regulatory