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Roche Sues Biocon over Cancer Drug

Pharma Co has also sued Mylan for launching biosimilar version of the original breast cancer drug, Herceptin, and DCGI for allowing the launch

SOMA DAS
NEW DELHI

The Indian arm of Swiss pharma major Roche, which unexpectedly gave up its patent on it s $6 billion breast cancer drug Herceptin (Trastuzumab) in India last year, has sued Bangalore based Biocon and US generic giant Mylan Inc in Delhi High Court (HC) for launching world's first biosimilar version of the original drug in India.

It has also sued the Drug Controller General of India for giving permission for such a launch.

The Delhi High Court has restrained Mylan and Biocon from "relying upon" or "referring to Herceptin" or any data relating to it for selling or promoting their brands Canmab (Biocon)and Hertaz (Mylan) till the next hearing, according to an order reviewed by **ET**. Trastumab was being considered for a compulsory license, but Roche pre-empted the move by not renewing the patent here.

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 argues that there is no public record available, in the clinical trial registry India (CTRI) or elsewhere to show that these firms actually conducted phase-I or phase-II clinical trials for the drug.

Roche further contests that guidelines on similar biologics were only issued in 2012, which laid down 'a detailed and structured process for comparison of biosimilar with the original product and "all the applications for manufacturing and marketing authorization" of biosimilars have to follow that path before getting an approval. Roche also claims that DCGI has approved Biocon's "protocol and design study for testing" related to the proposed drug even before its own regulatory guidelines were firmed up.

"As per the annual report for the year 2012 of the defendant No 2 (Biocon), in June 2012 much before the guidelines became effective, the defendant No 2 was already conducting Phase III clinical trials (for the drug candidate)" Roche has pleaded, according to a copy of the Delhi HC order.

Roche has cast doubts in its submission saying the Indian drug regulator's approval for biosimilars couldn't have come about in 'such a short period' when its 'prescribed procedure' in the guideline is so long.

Three months after Roche announced that it would no longer pursue a patent on breast cancer drug Herceptin in India, Biocon in October last year got an approval for making the drug from the central drug regulator.

The journey of this blockbuster drug, which earns its parent company over $6 billion in annual sales globally, has been particularly intriguing in India as it was the first drug candidate, which was being considered for grant of a compulsory license by the government under section 92 of Indian Patents Act. The case for grant of compulsory license was buried after Roche in August unexpectedly dropped claims for a patent on drug by not applying for a renewal of its existing patent in India.

While Roche and Mylan couldn't be reached for their comment immediately, a Biocon spokesperson refused to comment saying the company was not appraised of the matter yet.

Biocon has developed this biosimilar in partnership with US generic giant Mylan and both launched their brands early this year with much fanfare.

Roche which markets Trastuzumab in India under the 'Herceptin', commands a near monopoly in this market here. Roche had launched the drug at over 1 lakh per vial. However, following India's decision to grant its first compulsory licence on liver cancer drug Sorafenib (Nexavar), Roche in March 2012 announced a cut of over 15% in the price of Herceptin per dose to 92,000. It also tied up with Indian drug maker Emcure Pharma, which started offering the drug under brand Herclon at 72,000 per dose. While Roche, known for aggressively defending its patents, it didn't give a specific reason for dropping its patent on this drug here, sector analysts read this as a change in its India strategy.

Patient groups, however, alleged that the company made such a move because it was on weak ground with regards to this drug patent in India.

A Shocking Ailment

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THREE MONTHS AFTER Roche dropped the patent on Herceptin, Biocon got an approval from the central drug regulator

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