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US MARKET

Ranbaxy may lose exclusivity on Nexium generic

Pressure mounts on US regulator on account of a five-month delay by Indian drug maker in launch of its version

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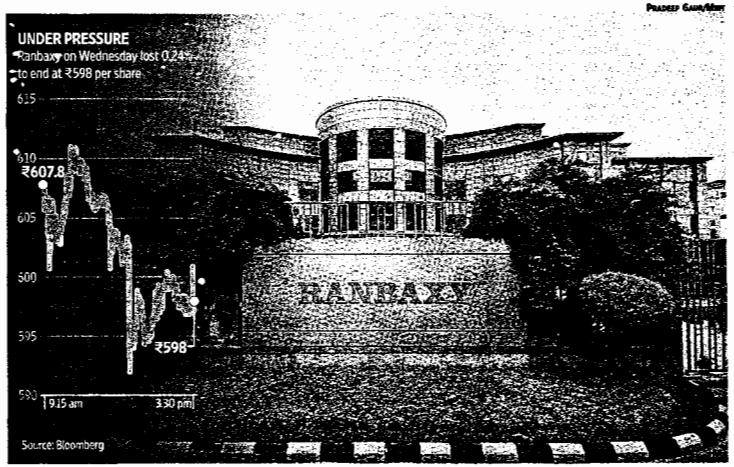

Ranbaxy Laboratories Ltd is likely to miss out on a windfall from the launch of the first generic copy of AstraZeneca Plc's blockbuster heartburn drug Nexium in the US market.

The Indian drug maker may lose the six-month market exclusivity for the Nexium copy in the US as there is pressure mounting on the US Food and Drug Administration (FDA) to look at other generic applicants on account of a five-month delay in Ranbaxy's launch of its version of Nexium.

Ranbaxy was expected to launch its low-cost version in May, when the Nexium patent expired. It had a 180-day exclusivity period as per US law as it was the first to file a generic application, known as abbreviated new drug application (ANDA) with the FDA for Nexium.

The FDA has been under pressure from US citizens forums to speed up the launch of the low-cost version since May. This intensified last week when the attorney general of the state of Connecticut, George Jespen, wrote to the FDA seeking immediate action to either expedite Ranbaxy's launch or approve other drug companies that have also applied for the generic launch in the US market.

For Ranbaxy, it's a $170 million sales opportunity if it is successful in launching the drug with market exclusivity. But the company is in a difficult situation, having had to move the manufacturing site for this product twice in the last six years after the original sites—Poanta Sahib in Himachal Pradesh and Mohali in Punjab—came under an FDA ban. The company is now trying to move the product registration and manufacturing site to its US factory in Pittsburgh, but this has not been cleared by the FDA.

"The FDA is under pressure to look at alternate options using provisions under the recently amended medicine modernization Act of the country, but in that case Ranbaxy may lose its exclusivity and it will have to either transfer the right to another company or allow others to enter the market," said an ex-FDA official in the know of the development, requesting anonymity.

Both Ranbaxy and the FDA were tight-lipped about the generic launch plan.

Ranbaxy declined to comment in response to a query emailed to the company on Tuesday.

"Under federal law, we were not able to comment on any pending drug applications, that is confidential," Sandy Walsh, press officer at the FDA, said in an emailed response.

The medicine modernization Act allows the regulator to recall the exclusivity rights for a generic drug maker if the first filer or the right holder delays the launch of the low-cost version beyond 40 days of the expected launch.

"But the first-filer exclusivity was granted to Ranbaxy before the new amendment in the FDA modernization Act. So there is no certainty on how the law will work on a previously granted exclusivity," said Hitesh Mahida, an analyst with Antique Stock Broking Ltd.

Ranbaxy filed the ANDA for esomeprazole, the generic name of Nexium, in 2008. Dr Reddy's Laboratories Ltd, Aurobindo Pharma Ltd, Sun Pharmaceutical Industries Ltd are the other generic drug makers from India who have filed the ANDA for the Nexium copy for the US market.

The patent-holder AstraZeneca and Ranbaxy had signed a settlement in 2008 regarding the generic launch of the drug, following a patent litigation on the drug after Ranbaxy filed the generic application for it.

US pharma industry journal *FiercePharma*, which first reported on the Connecticut attorney general's appeal to the FDA on 10 September, had cited him as saying: "The delay (in launch of low-cost generic of Nexium) further compounded by the fact that Ranbaxy and AstraZeneca are working together to manufacture and market branded Nexium—a provision that was part of their 2008 patent settlement."

"Ranbaxy and AstraZeneca should be competing—instead, they are working together to defeat competition and harm consumers," *FiercePharma* reported attorney general Jespen as saying.

AstraZeneca posted $2 billion sales for Nexium in 2013. A generic launch upon the expiry of the patent on the product directly cuts the cost of the medicine to the patient by at least 30-40%. The US government encourages generic companies to enter the market soon after the expiry of the patent on drugs, especially expensive ones, by providing the first generic applicant with a six-month market exclusivity.