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Ranbaxy Faces Multi-pronged Battle on Nexium in US

FACING HEAT Attorney General of Connecticutasks USFDA to pull up Ranbaxy for failing to launch drug, wants co to deliver or let other pharma cos produce the drug

Soma.Das1
@timesgroup.com

New Delhi: Ranbaxy Laboratories is facing increasing pressure from different states in the US, rival generic drugmakers, consumer groups, drug retailers and wholesalers to either immediately bring to market the first generic version of British-Swedish innovator AstraZeneca's blockbuster heartburn drug Nexium (esomeprazole magnesium) or bow out to allow other companies to launch the drug.

The Gurgaon-based drugmaker, which was acquired by Sun Pharma in April, was scheduled to launch in late May the generic version of the second-best selling drug in the US under a six-month exclusive marketing opportunity, but it has failed to do so till date.

Attorney General of Connecticut George Jepsen last week urged the US Food and Drug Administration to either make Ranbaxy deliver on its promise or scrap its drug application and allow other generic drugmakers in the queue to make low-priced version of the drug which earns its parent firm over $5 billion a year in the US alone.

In another statement, Jepsen said, "Ranbaxy's actions have stalled FDA approval of any other generic drug alternatives to AstraZeneca's Nexium." He added that consumers should not suffer as a result of the company's manufacturing problems — problems that "Ranbaxy may not be motivated to resolve as it continues to profit under its deal with AstraZeneca".

After fighting a patent battle to launch the first generic drug, Ranbaxy had in 2008 settled its litigation with AstraZeneca, a common industry practice, to delay its generic launch until May 27 this year for commercial benefits. It also got into a tie-up with AstraZeneca to supply raw materials for the same drug, through which Jepsen has alleged that Ranbaxy continues to profit.

Jepsen's request to the FDA follows a citizen's petition filed by an unnamed 'generic drugmaker' in May, reviewed by ET, which argues that the FDA should have scrapped Ranbaxy's drug applications seeking generic exclusivities, including Nexium, because it had originated from Paonta Sahib and Dewas, units blacklisted by the US drug regulator for manufacturing lapses and generating falsified data.

The petition claims that the scale of fraudulent activities at Ranbaxy makes it implausible that drug applications filed at that time from affected facilities were not fraught with flawed data. If Ranbaxy has renewed its application for the same drugs from another site, that should be treated as a new application and the company should lose its status as the first generic applicant and forego the 180 days exclusive marketing opportunities it is holding on to.

Ranbaxy has been reeling under prolonged regulatory troubles in the US and all its India-based plants have now been banned from shipping to that country. Five months ago, rival drugmaker Sun Pharma agreed to buy it from Japanese parent Daiichi Sankyo for $3.2 billion.

A Ranbaxy spokesperson refused to comment on the matter but in its response to the US FDA in July, reviewed by ET, the company claimed that these charges were built on an unsubstantiated conjecture that all its applications from select manufacturing sites were fraught with "unreliable data", which cannot be assumed as true.

"The citizen's petition is premised on numerous factual errors, gross mischaracterisations and rank speculation which cannot form the basis of any reasoned decision," Ranbaxy said in its response. The company added that changing of site for a drug application was not an uncommon practice and did not make its drug application 'new'. It also argued that the consent-decree it had signed with the FDA was a court-approved agreement, which the US drug regulator could not alter unilaterally to revoke any first-to-file opportunities.

Ranbaxy and a few other drugmakers are also defending a suit in the district court of Massachusetts with regard to the same drug, brought upon by consumer groups and drug retailers which have accused it of conspiring with AstraZeneca to delay the generic and deprive American consumers of a cheaper alternative.

Analysts expect Ranbaxy to earn $180-250 million in the first six months if it manages to successfully launch a generic Nexium in the US.

Drug Delay May Cause Trouble

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$5 billion
Earnings the drug gives its parent firm in the US alone

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Ranbaxy has a six-month exclusive marketing opportunity, but it has failed to do so till date

$180-250 million estimated earnings Ranbaxy would reap in the first six months if it manages to launch a generic Nexium in the US