**Ranbaxy Sues US FDA for Revoking Nod to Generics**

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Says FDA has overstepped jurisdiction by revoking approvals given years back Ranbaxy Laboratories has sued the US Food and Drug Administration (FDA) in an American court for revoking approvals the company had to market generic versions of patented drugs exclusively for six months in the US market - Astra Zeneca's anti-ulcer pill Nexium and Roche's anti-viral Valcyte. Ranbaxy's marketing opportunity from this has been estimated by analysts at upwards of $200 million. Of this, they estimated revenue from generic Nexium to top $160 million.

In a petition filed at the District Court of Columbia last week that was reviewed by ET, Ranbaxy contended that the FDA had overstepped its jurisdiction by revoking approvals granted to the company years back. Dubbing the decision as “arbitrary, capricious and contrary to law“, Ranbaxy said: “FDA has no power to correct an alleged `mistake'' it made six years ago“. The company didn't respond to queries sent by ET as of press time.

Earlier this month, the FDA struck down its earlier approvals to Ranbaxy, saying it had erred in granting them, given the “compliance issues“ related to the plant making the drugs. Ranbaxy had sought approval of the drugs made at its Paonta Sahib facility, which has been blacklisted by the US regulator since 2008 for lapses in prescribed manufacturing practices and other data flaws.

Ranbaxy argued that the FDA's decision to grant approval was not a mistake but a well-thought-out position that senior officials arrived at after considering the matter despite the known compliance issues. While striking down its approvals, FDA said Ranbaxy forfeited its eligibility for 180-day exclusivity for generic Valcyte but was silent on whether the company had also surrendered its exclusivity rights for generic Nexium. Ranbaxy in its plea has assumed that its exclusivity for Nexium is most likely to meet a similar fate. It said the FDA “must treat like cases alike“ and its conclusion for one should extend to the other.

Ranbaxy was expected to launch the Nexium generic in May and market it exclusively until November, but it has failed to do so till date. In an investor call early this month, Ranbaxy CEO Arun Sawhney said the company believes it still has the exclusivity opportunity for Nexium.

The stock fell 1.9% on BSE on Tuesday as it became clear that Ranbaxy doesn't have an alternate plan to launch generic Nexium. Analysts were hoping that it could still do so from its US-based plant, which is the only FDA-approved Ranbaxy facility that can still supply drugs to that market.

The delay in launching a low-cost version had prompted states in the US, rival generic drugmakers, consumer groups, drug retailers and wholesalers to step up pressure on Ranbaxy to either launch it immediately or step out of the way to allow other generic drugmakers to do so.

In September, Connecticut attorney general George Jepsen had urged the FDA to either make Ranbaxy deliver on its promise or scrap its drug application and allow other generic drugmakers to make low-priced Nexium, which earns Astra Zeneca over $5 billion yearly in US sales alone. Ranbaxy has been facing the heat from the US drug regulator and all its India-based plants have been banned from shipping to that market. In April, rival drugmaker Sun Pharma agreed to take over Ranbaxy from Japanese parent Daiichi Sankyo for $3.2 billion.