US seeks injunction on Indian drug firm Ranbaxy

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US officials sought a "groundbreaking" injunction against Indian drug giant Ranbaxy on Wednesday, saying the maker of the first generic version of cholesterol-lowering Lipitor has failed to meet US safety guidelines.

The filing, which would require Ranbaxy to stop selling drugs made at four of its manufacturing plants until it remedies deviations from current good manufacturing practices, could trigger multi-million-dollar repercussions as Ranbaxy's drug had been one of the most hotly anticipated rollouts of a generic when it hit the US market late last year.

The Justice Department, citing manufacturing and data integrity shortcomings, said that US food safety authorities want to block the company from doing business here because its actions made "many of Ranbaxy's drugs adulterated, potentially unsafe and illegal to sell in the United States."

The US Food and Drug Administration (FDA) gave the Indian firm the go-ahead last November to make a generic version of Lipitor, which was the best-selling drug of all time and earned US pharma giant Pfizer $100 billion after coming on the market in 1997.

Pfizer's patent on Lipitor -- atorvastatin calcium -- expired at the end of November.

Ranbaxy, which is majority owned by Japan's Daiichi, had faced delays

in gaining FDA approval due to problems with quality control at some of its Indian and US factories.

Those problems came into sharp focus Wednesday with the department's filing, made at the request of the FDA, against India's Ranbaxy Laboratories -- and its US subsidiary Ranbaxy Inc -- in US District Court outside the capital Washington.

"This action against Ranbaxy is groundbreaking in its international reach," Tony West, assistant attorney general for the Justice Department's Civil Division, said in a statement.

"It requires the company to make fundamental changes to its plants in both the United States and India," he added.

"Our commitment to ensuring that the drugs the American people rely on are safe, effective and manufactured according to the FDA's standards extends beyond our borders."

If and when the decree is approved by the court, "it becomes a court order with which Ranbaxy must comply or face contempt," the Justice Department said.

The Justice Department listed several problems, including "inadequate testing of drugs to ensure that they kept their strength and effectiveness until their expiration date."

In addition, "Ranbaxy submitted false data in drug applications to the FDA, including the backdating of tests and the submitting of test data for which no test samples existed," it added.

According to the consent decree, Ranbaxy must hire a third party expert to conduct an internal review at the facilities; implement procedures and

controls to ensure data integrity; and withdraw any applications found to contain untrue statements or data irregularities that could affect application approval.

In a separate statement, FDA said it took action to protect consumers.

"This company continued to violate current good manufacturing practice regulations and falsify information on drug applications," said Dara Corrigan, the FDA's associate commissioner for regulatory affairs.

"The FDA continues to be committed to protecting consumers from potentially unsafe products that may be offered on the market."

It said notably that Ranbaxy's drugs would be barred from the US market as well as inclusion in the US President's Emergency Plan for AIDS Relief (PEPFAR) program "until drugs can be manufactured at such facilities in compliance with US manufacturing quality standards."

Ranbaxy said it had signed the consent decree in December ahead of the filing, and that the company was committed to strengthening procedures and policies.

"Separately, Ranbaxy also announced that it intends to make a provision of $500 million in connection with the investigation by the US Department of Justice, which the company believes will be sufficient to resolve all potential civil and criminal liability," it said.

In the United States, anti-cholesterol drugs account for 255 million prescriptions a year, and about nine million people are taking Lipitor.

US-based Watson Pharmaceuticals announced its launch of a generic version of Lipitor under an exclusive supply and distribution agreement with Pfizer, whereby Pfizer manufactures the drug and Watson sells it,

sharing net sales with Pfizer until 2016.

The FDA said it recommends that patients taking Ranbaxy-produced drugs maintain their drug therapy, but speak with their doctors.

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