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# Ranbaxy may have to pay huge fine, again

**SUSHMI DEY**  
New Delhi, 13 April

Ranbaxy Laboratories, set to be merged with Sun Pharmaceutical Industries, might again have to pay a hefty penalty to the US authorities for alleged violations at its Toansa factory in Punjab. The facility is currently banned from supplying products to the American market.

According to a regulatory source, an administrative subpoena issued recently to Ranbaxy's active pharmaceutical ingredient (API) manufacturing unit in Toansa has been triggered through an investigation into alleged fraud and violation of manufacturing norms. "If the company fails to satisfy the authorities that there were no wrongdoings, it might again lead to a fine and other strin-

gent action by the federal authority," the source, in the know of developments, told *Business Standard*.

Last year, Ranbaxy had to pay a fine of \$500 million to the US authorities after it pleaded guilty to fraudulent activities and misrepresenting data to seek fast approvals.

However, Sun Pharma, which last week agreed to buy Ranbaxy in a proposed \$4-billion deal, including a debt of \$800 million, might not have to bear an additional brunt. "In connection with the transaction, Daiichi Sankyo has agreed to indemnify Sun Pharma and Ranbaxy for, among other things, certain costs and expenses that might arise from the subpoena," a spokesperson for Sun Pharma said.

Daiichi Sankyo and Ranbaxy

did not respond to some questions sent by *Business Standard* in relation to the subpoena.

While announcing the proposed transaction with Sun Pharma last week, Daiichi Sankyo had said Ranbaxy had recently received a subpoena from the US Attorney for the District of New Jersey.

According to the notice, Ranbaxy must produce certain documents relating to issues previously raised by the Food and Drug Administration (FDA) with respect to the company's Toansa facility.

Ranbaxy, which was acquired by Japan's Daiichi Sankyo in 2008 from Malvinder Mohan Singh and family, the promoters, is currently facing the US FDA's import alert on four of its key facilities in India.

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## TROUBLED PAST

2006: US FDA issues warning letter to Ranbaxy's Paonta Sahib facility

2007: Whistle-blower's lawsuit alleges the firm defrauded federal programmes

Jun 2008: Daiichi Sankyo acquires a majority stake in Ranbaxy

Sep 2008: US FDA imposes import alert on Ranbaxy's Paonta Sahib and Dewas factories; bans 30 drugs

May 2013: Criminal charges filed; Ranbaxy agrees to pay a fine of \$500 million

Sep 2013: US bans imports from Ranbaxy's new formulations factory in Mohali

Jan 2014: US FDA bans imports from Ranbaxy's main API factory in Toansa

Apr 2014: Sun Pharmaceutical acquires Ranbaxy in a \$4-billion deal



Company.

## Ranbaxy may...

While its formulation manufacturing plants at Poanta Sahib (Himachal Pradesh) and Dewas (Madhya Pradesh) are under the US drug regulator's scanner since 2006, its newly-commissioned factory in Mohali was barred from supplying to the American market in 2013. The company's largest API-manufacturing unit at Toansa, which faced import alert in January this year, was the last and the latest to face an enforcement.

Following the US FDA enforcement on the Toansa factory, the Ranbaxy management had initiated a third-party investigation to find out the guilty. Chief Executive Arun Sawhney had ruled out any scope of sabotage leading to disruptions at the plant.

Contd.