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Ranbaxy faces more trouble in US

Joe C Mathew / New Delhi March 04, 2010, 0:10 IST

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Local arm faces lawsuit for alleged marketing of products with false patent claims.

In addition to the US drug regulator, Food and Drug Administration (FDA), and rival pharma majors that appear keen to launch litigation against Indian company Ranbaxy, a US citizen has joined the bandwagon by filing a case in the world's biggest drug market.

The petitioner — Bentley A Hollander — filed a case in a district court in Pennsylvania on February 23, complaining that Ranbaxy's US arm — Ranbaxy Laboratories Inc — is marketing some products with false patent claims. Hollander wants Ranbaxy to be fined for “falsely marking articles with expired patents, as well as using these expired patents in advertising in connection with such articles, all for the purpose of deceiving the public into believing that such articles are covered by these expired patents”.

The complaint arises from Ranbaxy's use of a patent (number 4,619,921) on the label of Ultravate, a skin care brand, which the company acquired from Bristol Myers Squibb along with 12 other dermatology products three years ago.

The petitioner argued that the patent rights over that product had expired about five years ago, much before the brand was acquired by Ranbaxy and the company had no right to continue its mention on the product labels.

Ranbaxy, which is now owned by Japan's Daiichi-Sankyo, did not respond to an emailed query on Hollander's petition.

Bigger troubles

Despite the latest development, the issue could be the least serious among the problems being faced by Ranbaxy in the US. On Tuesday, for instance, Ranbaxy lost an opportunity to launch the generic version of the urinary drug Flomax due to lack of requisite approval from the US drug regulator. An unimpeded launch would have helped the company earn up to \$50 million in the sale of generic Flomax alone in the next two months, according to industry analysts.

The rejection of Ranbaxy's application happened after the US FDA said it was not confident of the good manufacturing practices (GMP) being followed in Ranbaxy in its US manufacturing facility, analysts said. The product was initially planned to be manufactured in the company's Paonta Sahib facility in Himachal Pradesh, from where exports to the US were banned by the FDA. Ranbaxy's US manufacturing facility — Ohm Laboratories — was seen as an alternative production base by the company, until the USFDA pulled up Ohm also for GMP lapses in December 2009.

Analysts say 'Sell'

HDFC Securities has given a sell call on the stock and projected a price of Rs 230 for a Ranbaxy share. This is almost half the price at which the company's stock closed Wednesday's trading session on the Bombay Stock Exchange — Rs 473.1.

“The six per cent sales growth guidance given by the company last week itself was an indication of its muted performance during the year ahead,” HDFC Securities analyst Ranjit Kapadia said.

He added the ongoing limited exclusivity opportunity for the generic version of Valtrex and the now lost opportunity for a similar exclusivity for a generic version of Flomax, along with some raw material supply agreements with multinational drug major Astrazeneca, had all indicated growth opportunities.

Angel Trading, in its investor note, said it would review the Ranbaxy stock, though the financial impact of the development would be minimal.