PHARMABIZ.com
india's most comprehensive pharma portal

Takeda sues Wockhardt for para IV patent infringement on diabetes drug, Actos

Tuesday, August 03, 2010 08:00 IST
Our Bureau, Mumbai

The Japanese drug major Takeda Pharmaceuticals and its US subsidiary has filed a Para IV patent infringement litigation in US against the Mumbai-based Wockhardt Ltd and its US subsidiaries, Wockhardt USA LLC and Morton Grove Pharmaceuticals Inc, for alleged initiatives to manufacture and market the generic version of the oral type-2 diabetes drug, Actos.

In a lawsuit filed with the Southern District Court of New York, USA, in the end of July, 2010, Takeda has complained that the Wockhardt's move seeking approval for Abbreviated New Drug Application (ANDA) with respect to generic version of pioglitazone hydrochloride tablets 15 mg, 30 mg and 45 mg, infringes the patent rights of the company's pioglitazone hydrochloride brand, Actos.

The patents-in-suit are the US Patent Nos. 5,965,584 (the `584 patent), 6,329,404 (the `404 patent), 6,166,043 (the `043 patent), 6,172,090 (the `090 patent), 6,211,205 (the `205 patent), 6,271,243 (the `243 patent), and 6,303,640 (the `640 patent), issued between a period of almost two years from October 1999 to October 2001.

Actos is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes as a monotherapy. It is also indicated for use in combination with a sulfonylurea, metformin, or insulin when diet and exercise plus the single agent dose does not result in adequate glycemic control.

The Japanese drug major and its US subsidiary has recently completed settlement agreements with six out of eight defendants in patent infringement litigation, including the India-based drug manufacturers, Ranbaxy Pharmaceuticals, Inc and Torrent Pharmaceuticals Ltd on Actos and Acto Plus met (pioglitazone HCl and metformin HCl).

The other companies which entered into the agreement are Mylan Pharmaceuticals, Inc, Watson Pharmaceuticals, Inc, Alphapharm Pty Ltd and Sandoz, Inc and their respective affiliates, to settle patent infringement litigation brought against them relating to their ANDAs for generic ACTOS.

According to an announcement issued by Takeda in the end of April, 2010, the company has granted Mylan, Watson and Ranbaxy licenses to enter the United States market with generic pioglitazone on August 17, 2012 or before, under certain circumstances. These three companies were the first-filers of ANDAs with Para IV certifications for generic Actos in US. Takeda has granted Alphapharm, Sandoz and Torrent licenses to enter the U.S. market with generic ACTOS 180 days after Mylan, Watson and Ranbaxy.

With this series of settlements the company is continuing patent suit with two – The Isreal-based Teva Pharmaceutical Industries, Ltd and the Indian generic firm Aurobindo Pharma Limited, which sought to market generic versions of ACTOS and ACTO plus met before the expiration of several Takeda patents in mid-2016.

The Actos reported sales of US$ 3.4 billion in 2009, according to IMS Health. The market for the product is expected to grow, as its major rival, Avandia from Glaxo SmithKline Pharma is marked by the federal drug regulators as with serious drug safety concerns.