

Astellas US sues Wockhardt for alleged patent infringement of Adenoscan

Tuesday, October 06, 2009 08:00 IST

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Astellas US LLC, the US subsidiary of the Japanese drug major Astellas Pharma, has sued the Mumbai-based Wockhardt Ltd and its US subsidiary for alleged infringement of its patent on pharmacological stress agent Adenoscan - adenosine injection - as the latter has filed an abbreviated new drug application (ANDA) for generic version of the product.

In a petition filed by Astellas in District Court of New Jersey, last month, the company alleged that Wockhardt has infringed its US Patent No 5,731,296 for selective vasodilation by continuous adenosine infusion, issued in March 24, 1998, which is valid till March 2015. In July, Wockhardt has filed an ANDA seeking nod from the US Food and Drug Administration (FDA) to manufacture and sell adenosine injection, USP, 3mg/mL in US.

Astellas has requested the Court to prohibit any approval by the FDA to Wockhardt's adenosine injection, USP on any effective date prior to the date of expiration of the '296 patent and to declare that the latter will infringe one or more claims of the said patent if the ANDA is approved and the product is sold in the US.

Adenoscan (adenosine injection), licensed and sold by Astellas in the US, is a pharmacologic stress agent indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately, and is a market leader in the segment in US. The product has one more patent, US Patent No 5,070,877, which has expired in May 2009 even as the patent for '296 is still valid.

Astellas currently sells three adenosine injection brands for myocardial perfusion scan in US - Adenocard, Adenoscan and Lexiscan - in which the Lexiscan has been introduced in the market in June 2008. The company has reported a combined sales of USD 400 million for Adenoscan and Lexiscan and with the advantages reported on Lexiscan over Adenoscan, the company expects a major market potential Lexiscan, according to announcement of Astallas, earlier.

Astellas has a marketing tie up with King Pharmaceuticals for sales of Adenoscan in countries other than US. Astellas and King Pharma, in 2007 has also settled a patent litigation with Teva Pharmaceuticals on the product. Under the terms of the settlement agreement, Teva will be able to launch their generic version of Adenoscan pursuant to a license in September 2012, or earlier under certain conditions. The product has contributed a major share of King Pharma's royalty revenues of USD 15 million during the second quarter of 2009, according to King Pharma announcement.

The pharmacological stressors are used in nearly 50 per cent of the 10 million patients

who undergo pharmacologic stress myocardial perfusion imaging (MPI) in North America, (the current leading market) which makes more than 5 million studies performed annually, as per a report in 2007. In 2007, MPI stressor sales over USD 350 million in the United States. Studies further states that the annual growth of the market is between 10 to 15 per cent per annum and is expected to reach over a billion USD market in five years' time.