

Lupin receives favorable ruling for generic Yaz

18 April 2013 | News | By BioSpectrum Bureau

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Lupin, the third largest Indian pharmaceutical company by sales announced that the US Court of Appeals for the Federal Circuit has ruled in its favor regarding its appeal of a previous judgment by a lower court for Bayer AG's Yaz oral contraceptive product.

The company noted in a release that on April 16, 2013 the United States Court of Appeals for the Federal Circuit has ruled that United States Patent No. RE 37,564 (the RE '564 Patent) is invalid thereby reversing the district court's decision of validity.

Confirming the same a Lupin spokesperson stated, "We are pleased with the ruling which paves the path for entry of generic product which would immensely benefit customers." Lupin is currently seeking approval from the US FDA for its generic and is working out its commercialization plan.

Lupin's Generic Drospirenone and Ethinyl Estradiol Tablets (3 mg + 0.02 mg) of Bayer AG's Yaz tablets are indicated for prevention of pregnancy, to treat the symptoms of premenstrual dysphoric disorder (PMDD) for women and to treat moderate acne for women at least 14 years old only if the patient desires an oral contraceptive for birth control. The total sales for Branded and generic sales for the product stood at \$361 million (IMS MAT Dec 2012).

Lupin is the fifth largest and fastest growing generics player in the US (5.1 percent market share by prescriptions, IMS Health). The company is also the fastest growing top 10 generic pharmaceutical players in Japan and South Africa (IMS). For the financial year ended March 2012, Lupin's consolidated total income and Profit after Tax were \$ 1.49 billion and \$ 182 million respectively.