

## Otsuka sues Zydus for Para IV patent infringement of blockbuster drug Abilify

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The Japanese drug major Otsuka Pharmaceuticals has filed a Para IV patent infringement suit against Zydus Pharmaceuticals USA, Inc, the wholly owned subsidiary of the Ahmedabad-based Cadila Healthcare (Zydus) in US for alleged attempt to manufacture and market the generic version of its patented antipsychotic drug Abilify (aripiprazole) before the expiry of patent.

In a complaint filed with the US District Court for the District of New Jersey, Otsuka Pharma alleged that the Zydus' filing of an Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA) to manufacture and sell the generic version of Abilify for treating bipolar disorder and schizophrenia, will infringe the patent rights of the company.

Otsuka's US Patent No. 5,006,528 ('528), entitled Carbostyryl Derivatives, issued initially on 1991, has received an extension from the US Patent and Trademark Office (USPTO) in 2005 and has exclusivity rights upto April 20, 2015, including six-month period of paediatric exclusivity.

Zydus has filed ANDA with the US FDA to sell generic products containing 5, 10, 15, 20 and 30 mg of aripiprazole in US market, according to the complaint. Otsuka has appealed the Court to enjoin Zydus from the commercial manufacture, use, import, offer for sale and sale of Zydus USA's generic products with the said strengths until the expiration of the '528 patent, or such later date as the Court may determine.

Abilify a blockbuster anti-depressant and anti-psychotic medication, jointly developed by Bristol-Myers Squibb (BMS) and Otsuka Pharmaceuticals and approved for treating schizophrenia by the FDA in November 2002, according to Frost & Sullivan reports. The product has brought in an estimated revenue of US \$2.4 billion for BMS in 2009, according to reports. Abilify is manufactured and marketed in US by Otsuka Pharma.

While the marketing agreement between BMS and Otsuka was expected to expire in November 2012, the companies extended the partnership on the drug until the date of patent expiry through a deal in the beginning of April, 2009. As per reports at the time, Bristol has agreed to pay Otsuka US \$400 million cash up front. The deal is expected to support the BMS to absorb the financial blow when patent for its top selling blockbuster blood thinner, Plavix, gets expired in a couple of years, says experts.