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Zydus arm, Irish co in patent dispute

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AHMEDABAD: The Rs 3,700-crore Zydus Group's US subsidiary Zydus Pharmaceuticals USA has challenged the Irish company Shire Pharmaceuticals over its patented gastro drug Lialda. The Ahmedabad-based company, that ranks fifth in India, on Tuesday sent a Para IV notice to Shire, which owns the blockbuster drug Adderall XR used to treat hyperactive disorder among kids; pointing out that it has filed an abbreviated new drug application (ANDA) for a generic version of Lialda.

Zydus has come up with a generic version of Lialda's 1.2 gm mesalamine delayed release tablets, thus challenging Shire's formulation. Shire with \$3-billion revenue is one of the leading global speciality biopharmaceutical company with operations in the UK & the US and has presence in Europe, South America, Canada and the Pacific Rim.

According to the Hatch-Waxman legislation in the US, if a generic company successfully challenges the patent holder under Para IV, it gets 180 days of generic market exclusivity. Indian pharma companies such as Ranbaxy and Dr Reddy's have challenged innovators through this route in the past. Shire now has 45 days to decide if it wants to file a patent infringement suit against the Indian major.

If it decides to bring in the suit, the Food and Drug Administration (FDA) can impose a 30-month stay on Zydus's ANDA.

In its statement, Shire has maintained that Lialda drug is protected under the FDA Orange Book (patented products) list and that the patent expires in 2020. The Irish pharma added that it was reviewing the details of Zydus' Para IV notice letter.

According to Shire's annual report, the sales of the gastro-intestinal product Lialda stood at \$235.9 million in 2009 in the US market, up from \$140.4 million a year back. The drug holds 18% market share in the segment.

As per a study, Ulcerative Colitis, a disease of the intestine, was estimated to have affected 1.2 million patients worldwide in 2007 and Lialda was the only oral once-a-day treatment. Meanwhile, Shire is also carrying out Phase 3 global trials to determine the efficacy of Lialda for the treatment of diverticulitis.