

Medicis files another patent infringement suit against Glenmark

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The US-based Medicis Pharmaceutical Corp, the specialty pharmaceutical company focusing on dermatological and aesthetic products, has sued the Mumbai-based Glenmark Generics Ltd and its US subsidiary in the District Court of New Jersey for alleged infringement of its patent rights on antifungal agent – Loprox Gel (ciclopirox gel).

In its complaint filed in the end of October, Medicis alleged that Glenmark has attempted to manufacture and market a generic version of Loprox through an Abbreviated New Drug Application (ANDA) filed with the US Food and Drug Administration (FDA). The allegation is that the latter's attempt to manufacture and market the product will be an infringement of its US Patent No. 7,018,656 ('656) for antimycotic gel with high active substance release, issued by the US Patent and Trademark Office on March 28, 2006.

Loprox (ciclopirox) is a topical anti-fungal to treat dermatomycoses, which includes ringworm and other fungal skin infections. The company also holds US Patent No. 7,026,337 ('337) which covers the use of the product in treatment of dermatomycoses, such as tinea pedis and tinea corporis. Both the patents are exclusively licensed to Medicis, and have a life time till 2018, according to Medicis reports.

The product has been facing competition from generic players for a number of years. Medicis, which acquired the Loprox 1 per cent topical cream brand from the former German lifesciences firm Hoescht, later reformulated it into 0.77 per cent cream, and has introduced gel, suspension and shampoo form to tackle the generic competition.

According to a report published earlier in 2007, in a period of six years following the loss of patent exclusivity to the 1 per cent cream brand, the annual prescription volume of the product fell from 700,000 Rx/year to 200,000 Rx/year, a clear 72 per cent loss of market share due to generic competition. However, the non-acne product regained and even doubled the prescription volume with Medicis' reformulation strategy.

Even as Medicis regained the market, the product has shown a downward growth in sales in the last nine months, according to the company report. The company recorded revenues of approximately US\$ 35.5 million associated with its non-acne products for the three months ended September 30, 2009, representing an increase of approximately 4.2 per cent from the previous year. "This increase is due primarily to increased sales of Restylane and the launch of Dysport in the quarter, offset by a decrease in Loprox sales," says the company report. Medicis non-acne products include primarily Dysport, Loprox, Perlane, Restylane and Vanos.

Earlier, in June, 2009, Medicis has filed another patent infringement lawsuit against Glenmark for the latter's alleged attempt to manufacture and market generic version of

Vanos (fluocinonide cream) in the District Court of New Jersey. Vanos, which contains fluocinonide 0.1% as active ingredient in a cream base is used to relieve inflammation and itching caused by certain skin conditions that respond to corticosteroids. Vanos is also used in psoriasis and atopic dermatitis.