



Dr Reddy's said in a BSE filing that the company remains confident in its legal positions on this patent. (Image: Reuters)

Indian pharma major Dr Reddy's Laboratories said today that a US District Court has issued a temporary restraining order on the sale and commercialisation of its generic Buprenorphine and Naloxone sublingual film in the American market. It is indicated for treatment of opioid dependence. Dr Reddy's said in a BSE filing that the company remains confident in its legal positions on this patent. "The court order does not include a prohibition on commercial manufacturing of the product," it added.

The company said that following the launch of its generic Buprenorphine and Naloxone sublingual film in the US market, "the US District Court for the District of New Jersey has received and reviewed an emergency application from the plaintiffs in the current patent litigation for a temporary restraining order and preliminary injunction against Dr Reddy's".

The Hyderabad-based firm added that pending a hearing and decision on the injunction application, the court has issued a temporary restraining order against the company for further sales and commercialisation of the product. "The plaintiffs will be required to post a bond or other security totalling USD 18 million to satisfy any losses or damages incurred by Dr Reddy's during the period of the temporary restraining order," it added.

The court has scheduled an expedited hearing of the preliminary injunction for June 28, and a ruling is expected soon thereafter, it added. The proceeding only involves one patent. The company “remains confident in its legal positions on this patent and believes it will prevail on the issues raised with respect to the application for injunction,” Dr Reddy’s said.

The company had said yesterday that it has received final approval from the US Food and Drug Administration (USFDA) and is launching Buprenorphine and Naloxone Sublingual film, (2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg) — a generic version of Indivior UK’s Suboxone sublingual film in the US market.

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