

Pharma & Healthcare Update

June 24, 2015

PHARMA ALERT

- Supreme court bars Glenmark from manufacturing allegedly infringing copies of MSD diabetes drug
- State bans online sale of prescription drugs
- Advertising prescription drugs is now prohibited without prior government permission

SUPREME COURT BARS GLENMARK FROM MANUFACTURING ALLEGEDLY INFRINGING COPIES OF MSD DIABETES DRUG

The Supreme Court of India has barred Glenmark Pharmaceuticals (Glenmark) from making and selling alleged infringing copies of Merck, Sharp and Dohme's (MSD) diabetes drug until further order.

MSD filed a patent infringement suit in 2013 against Glenmark before a single judge of the Delhi High Court for using its patented product, Sitagliptin, as an active pharmaceutical ingredient without permission in its product portfolio. It also applied for a temporary injunction restraining Glenmark from manufacturing and selling the allegedly infringing drugs, Zita and Zitamet. The temporary injunction was refused by the single judge. MSD appealed against the single judge's order before a Division Bench of the Delhi High Court and was able to obtain a favourable order restraining Glenmark from manufacturing and selling the allegedly infringing drugs. Glenmark appealed against the order of the Division Bench before the Supreme Court and was able to obtain a stay on the order of the Division Bench.

On 15 May 2015, the Supreme Court lifted its stay on the Division Bench's order on the ground of maintaining balancing equities between the parties, while also maintaining public interest. Glenmark can no longer manufacture the allegedly infringing drugs, but was permitted to continue to sell drugs which were already on the market.

This is a positive decision by the Supreme Court, as it has attempted to balance the interests of all the parties in a patent infringement suit.

STATE BANS ONLINE SALE OF PRESCRIPTION DRUGS

The State Drug Licensing Authority of the State of Telangana (the Telangana FDA) has reportedly banned the online sale of prescription drugs.

The Telangana FDA has reportedly issued a press release banning the operation of the online sale of prescription drugs.

Under applicable law, prescription drugs have to be dispensed under the supervision of a registered pharmacist and against an original prescription of a registered medical practitioner. The reason behind the ban was non-compliance with these conditions.

These legal requirements of sale of prescription drugs are laid down under the Drugs and Cosmetics Rules, 1945 (made, centrally, under the Drugs and Cosmetics Act, 1940) which is administered in all the States of India by the State level drug licensing authorities.

The business of online pharmacies is likely to be adversely affected if other state licensing authorities replicate the decision of the Telangana FDA..

ADVERTISING PRESCRIPTION DRUGS IS NOW PROHIBITED WITHOUT PRIOR GOVERNMENT PERMISSION

An amendment in the law has prohibited manufacturers who produce prescription drugs from advertising the drugs without prior central government approval.

The Ministry of Health and Family Welfare has amended the Drugs and Cosmetics Rules, 1945 (Rules) which regulate the manufacture, import, distribution and sale of drugs. After the amendment, a manufacturer of drugs listed under Schedules H, H1 and X to the Rules is required to obtain prior approval of the Ministry of Health and Family Welfare to advertise the drugs.

Schedule H sets out all prescription drugs. Schedule H1 sets out various antibiotics. Schedule X sets out a number of narcotic and psychotropic drugs.

It is believed that this step may have been taken to curb self-medication by consumers.

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– **Khushboo Baxi & Anay Shukla**

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