

Blow to Glenmark: HC restrains it from making Zita & Zita-Met

PTI ■ NEW DELHI

In a blow to Indian drug firm Glenmark Pharmaceuticals, Delhi High Court on Wednesday restrained it from making, selling, advertising, distributing or exporting its anti-diabetes drugs Zita and Zita-Met on the ground that it violated the patent of US pharma major Merck Sharp and Dohme (MSD).

Justice AK Pathak, while permanently injunctioning Glenmark from making and selling the two drugs, also said there was no public interest in the matter as there were other chemical compounds, other than the one invented by MSD, which were used in anti-diabetes drugs.

"Arguments of the defendant (Glenmark) about public interest does not have much force in the facts and circumstances of the present case.

"Sitagliptin (invented by MSD) is not the only DPP-IV inhibitor (oral anti-diabetes drug) for treatment of type II diabetes in the market and

there are several other DPP-IV inhibitors, including the one manufactured and marketed by the defendant, that is, Teneligliptin," it said.

The court also said that merely because Glenmark was selling its drugs at a rate lower than that of MSD cannot be a ground for not stopping it from making them.

"The invention of plaintiffs (MSD), that is, Sitagliptin improves the efficient management of the condition of a patient suffering from type II diabetes by inhibiting the DPP-IV enzyme.

"Merely because defendant (Glenmark), who is manufacturing generic version, is selling a tablet at a lower price than that of plaintiffs cannot be made ground to decline injunction against the defendant, who has been found to have been infringing the invention of the plaintiffs, is as much as, a competitor of the plaintiffs," the court said.

While MSD's anti-diabetes drug Januvia costs Rs 43 a pill, which is roughly 1/5th of its price in the US, according to market sources,

Glenmark's version costs around 30 per cent less.

Reacting to the verdict an MSD spokesperson said the company was pleased that the High Court "has found Glenmark to have infringed the patents of our Sitagliptin products Januvia and Janumet and have restrained Glenmark by decree of permanent injunction from making, using, selling, distributing, advertising, exporting, offering for sale or dealing in SPM or any other salt of Sitagliptin in any form, alone or in combination with one or more drugs."

Referring to various documents and testimony of experts, the court also concluded that Glenmark by using Sitagliptin phosphate monohydrate salt in Zita and Zita-Met, "clearly infringed" the patent of MSD.

The court, however, did not say anything about the sale of existing stock. In its 133-page judgment, the court said that on perusing the product inserts of Glenmark's two drugs, it found that they were a "repli-

ca" of product inserts of MSD's products "with minor and insignificant variations".

"...It emerges from the comparison of the product inserts of the plaintiffs' (MSD) product and that of defendant (Glenmark) that they are same and contain same compound, that is, Sitagliptin phosphate monohydrate, inasmuch as, the drug is DPP-IV inhibitor and used for treatment of type II diabetes," it said.

It also said that "use of Sitagliptin salt in Zita and Zita-Met, by itself, amounts to infringement of patent" as per the Indian Patents Act, 1970.

It also observed that MSD's Sitagliptin phosphate monohydrate "exhibits potent DPP-IV inhibitory properties and is particularly useful for prevention of type-2 diabetes".

"Defendant is restrained by a decree of permanent injunction from making, using, selling, distributing, advertising, exporting, offering for sale or dealing in Sitagliptin phosphate mono-

hydrate or any other salt of Sitagliptin in any form, alone or in combination with one or more other drugs thereby infringing patent of the plaintiffs.

"...Plaintiffs shall, however, be entitled to actual costs of the proceedings," the court said.

MSD in its plea had sought permanent injunction against Glenmark alleging that the Indian pharma company had violated its IPR over its anti-diabetes medicines, Januvia and Janumet, by coming out with their own drugs containing the same salts.

The US firm had said it had invented 'Sitagliptin' salt used in its anti-diabetes drugs and has patent over molecule.

Glenmark, on the other hand, had contended that it has used 'Sitagliptin Phosphate' in its anti-diabetes drugs, Zita and Zita-Met, and US firm has no patent right over this salt. Glenmark had said that Sitagliptin Phosphate has been a distinct product from Sitagliptin and due to this, MSD had obtained separate patent for Sitagliptin Phosphate in the US.

Patent/Company