

Drug MNCs stall generics with RTI Use Info To Move Courts, Obtain Stay To Protect Patents



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Mumbai: A huge spurt in infringement suits (stay orders) against domestic drug companies recently highlights that multinational firms are increasingly using the right to information (RTI) route to enforce intellectual property and block entry of affordable generics. Domestic companies like Glenmark, Biocon, Cadila and Alembic are facing a fresh attack from MNCs like Novartis and Astra Zeneca, the impact of which will be critical for development and expansion of the domestic pharma industry, experts say.

Recently, Novartis filed injunctions against half a dozen companies to prevent them from launching generic versions of its blockbuster anti-diabetic drug, Galvus (vildagliptin) — see chart.

Legal sources say that in over a dozen cases the RTI route has been deployed by MNCs to seek information on regulatory dossiers of generic firms on patented drugs. Though the trend of deploying RTIs by MNCs started three-four years back, there is a huge spurt in cases now to

LEGAL SPANNER

Product	Companies in Litigation
 Rivaroxaban	Bayer vs MSN
	Bayer vs Symed
	Bayer vs Intas
 Vildagliptin	Novartis vs Wockhardt
	Novartis vs Biocon
	Novartis vs Cadila
	Novartis vs Alembic
	Novartis vs Bajaj Healthcare
Saxagliptin	Novartis vs Glenmark Generics
Copaxone	Astra vs Glenmark
	Teva vs Natco

aggressively safeguard against competition.

"The impact of such actions can be critical for generic companies and will affect the expansion of India pharma industry as also affect filings internationally. The use of RTIs to stop the launch of the product itself will also seriously affect the development of affordable generics as it fastens the burden of proving non-infringement upon the generics," senior advocate Prathiba Singh told TOI.

Ranjit Shahani, VC and MD of Novartis India, says "Respect and protection of intellectual property ensures that patients receive benefits

of future discoveries to conquer unmet medical needs. There are over 5,000 medicines under development by the pharma industry. Systematic undermining of patents by discriminatory rulings does not help the patient in the long run."

MNCs fear that the generic companies are trying to bust patents and would launch the drug in the market, while domestic companies say that the approvals sought may be for exports to lucrative markets like the US.

"Law firms representing MNCs file urgent applications seeking ex-parte injunctions against generic producers of

low-cost versions of expensive originator medicines. The generic company is not present on the first day and the MNCs' version is taken as true and ex-parte injunctions granted. After ex-parte injunction, even if the generic company appears in the matter, and files its defence, the damage is done with delayed hearings and the court not keen to hear the patent dispute frequently. With rising litigation costs — and no resolution in sight — pressure builds on the generic company; some even break down and give up the pharmaceutical product all together. Also, failure by the courts to look at principles such as irreparable harm to patients and legal safeguards in the patent law such as 'bolar' is leading to the violation of basic rights of patients who are left with no low-cost versions of expensive medicines," says Leena Menghane, India Coordinator, Access Campaign, Medecins Sans Frontieres.

In March, Novartis had obtained quia-timet injunctions from the Delhi high court against two other drugmakers, Biocon and Wockhardt, accusing them of infringement on vildagliptin.

Patent

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