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Copycats trip as patent holders hawk variants, tweak dosage

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Mumbai, April 15

GENERIC drug players like Natco Pharma and Lupin are finding it tough to launch new products, as innovator companies offer different versions of existing drugs before patent expiry, in effect prolonging the patent period and stymieing plans to launch copycat drugs in lucrative markets. With generics eating up about 80% of a branded drug's market share after launch, innovators are using variants to hold on to market share.

Natco and its US-based marketing partner Mylan are fighting Teva Pharmaceutical Industries over a generic version of the latter's blockbuster drug Copaxone used to treat multiple sclerosis. In February, Teva launched a 40 mg three-times-a-week version of the drug, replacing the once-daily 20 mg formulation, by the end of May.

Mylan was expecting approval for the generic version in May but with the courts agreeing to hear Teva's appeal on the validity of the Copaxone patent, it can only do so at risk.

Lupin received a jolt when the US-based Warner Chilcott launched the oral contraceptive pill Lo Loestrin 24 Fe, with comparatively lower levels of estrogen to replace the earlier version that was set to lose patent protection in July 2014. This product now goes off-patent only in February 2029, according to a class-action lawsuit launched against Chilcott.

In January 2014, the US district court of New Jersey upheld Chilcott's patent of the new Loestrin. While Lupin had agreed not to launch a generic before the patent expiry, it is unlikely to gain market share since patients may not switch to a generic version.

In another instance, Chilcott had entered into a settlement with Lupin for Asacol, a treatment for a type of inflammatory bowel disease. However, in March 2013, the US company replaced Asacol with Delzicol and discontinued the former drug.

"Warner Chilcott has successfully managed to switch about 100% Rx to new variants in case of two of its brands i.e. Asacol and Loestrin Fe. This has been a negative surprise for Lupin, which planned to launch Loestrin Fe in July 2014 and had a settlement to launch Asacol authorised generic," IDFC Institutional Equities director (equity research) Nitin Agarwal observed. Warner Chilcott was acquired by Actavis in 2013.

Both companies had taken a leaf out of Abbott Laboratories' book. Abbott launched Tricor, generically known as fenofibrate in 1998, almost five years after US Food and Drug Administration gave its approval in 1993.

In November 2000, Novopharm USA — which was later acquired by Teva — filed an ANDA for approval of a generic version of Tricor.

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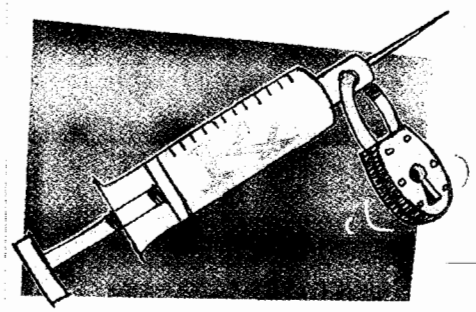

MEDICINE CHEST

- Abbott launched Tricor-2, a branded reformulation of the original drug Tricor
- Teva altered the dosage of its blockbuster multiple sclerosis drug Copaxone
- Warner Chilcott launched Lo Loestrin 24 Fe, with less estrogen to replace earlier version
- Changes in formulation, dosage practically increase the patent period, putting generics firms at a disadvantage

Patent

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Patents...

The filing automatically triggered a patent infringement lawsuit by Abbott, which in turn imposed a 30-month stay on approval of any generic versions of the drug by the USFDA.

Eighteen months into the stay, Abbott launched Tricor-2, a branded reformulation of Tricor in the dosages of 54 mg and 160 mg. The company submitted studies showing that the new dosages had the same pharmacologic properties as the original 67 mg, 134 mg and 200 mg versions, based on bioequivalence studies and zero clinical trials.

The strategies adopted by the majors is paying off. Teva's new

Contd.