

MNC drugs set to lose mkt monopoly

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THE legal battles triggered by the provisional market monopoly granted to Novartis' cancer drug, Glivec, and Eli Lilly's 'entertainment' pill, Cialis, are set to end in favour of their local rivals. Patent lawyers and experts said the new patent law provides for protection from infringement suits to companies copying drugs before the new Act came into force, which will work in favour of those who have challenged the provisional monopoly granted to Glivec and Cialis.

At least six Indian companies are fighting Novartis' exclusive marketing right (EMR) for Glivec, while Eli Lilly is trying to keep nearly 14 local firms from selling copies of its erectile dysfunction treatment. These EMRs were granted as per the law that existed before the third amendment to the Patents Act came into force early this year. The amended act will protect generic players against infringement action if they have been selling the copy before January 2005 and were still making them when patents were granted to the innovator's brand. Accord-



ing to Supreme Court advocate V Lakshmi Kumar, although EMRs have not been specifically mentioned in the act, it comes in the same section as product patents and will get the same protection. However, the fact that reasonable royalty for the patent holder may not be reasonable for the generic firm seeking a licence can lead to another round of litigation.

While Eli Lilly is now fighting Indian copiers like Ajanta Pharma and Ranbaxy in the Delhi and Calcutta high courts, Novartis is fighting companies like Natco Pharma, Ranbaxy, Cipla, Hetro, Sun and Intas in various courts, including the Chennai and Mumbai high courts and the Supreme Court.

The Supreme Court on Monday admitted Natco's special leave petition challenging the Delhi HC's refusal on jurisdictional grounds to hear the Hyderabad-based company's objections to the Novartis EMR, a Natco spokesperson told ET. Earlier this month, the Bombay High Court had refused to ask Natco to stop selling the generic copy of Glivec (imatinib mesylate beta crystalline form) but asked the company to record the revenue from the product separately as Novartis had asked for a damage in its petition. Earlier, the Chennai HC had restrained other Indian companies from selling the product.

The court had also asked Novartis to give the drug free to patients with a monthly salary less than Rs 3.26 lakh considering the drug's price. Sources said Cipla is now selling the alpha crystalline form of the drug and Sun Pharma the gamma crystalline form.