

# Teva sues Dr Reddy's, two others on patent

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ISRAELI drugmaker Teva has sued Indian generics company Dr Reddy's along with two others, Sandoz and Momenta, for 'intending to violate' the patent of its brand Copaxone. The drug, used to treat multiple sclerosis, has been a favourite for a handful of companies looking to make a copycat version.

Teva had received a notice from Dr Reddy's on August 6 this year, as it wanted to make the drugs before the expiry of patents 413 and 250. Later that month, Sandoz also notified the company after filing an abbreviated

## Bitter medicine

■ Copaxone accounts for 21% of Teva's revenues, with sales of \$4.3b in 2013 globally

■ Teva had appealed to the FDA to not grant approvals for copycat versions of the drug

■ Hyderabad-based Dr. Reddy's had hoped for permission before expiry of the patent

new drug application (ANDA) with the US drug regulatory authority, FDA.

Mid-August, Teva had confirmed receiving Para IV notice for its Copaxone (40mg/ml dosage drug)

which is administered to patients three times a week. "Teva will continue to vigorously defend its Copaxone intellectual property rights against infringement wherever they are challenged. Teva intends to file a lawsuit for patent infringement against Dr Reddy's within the 45-day period provided under the Hatch-Waxman Act," the company had then (in August) said.

The blockbuster drug which accounts for 21 per cent of the company's revenues, with sales of \$4.3 billion (in 2013) globally, will lose patent protection by 2015, in the US.

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Patent

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US sales of the drug Copaxone stood at \$3.2 billion in 2013. For the European markets, the patent would expire in 2025.

Filed in the district court of New Jersey earlier this month, the lawsuit is likely to attract a 30-day stay on FDA approval for Copaxone's ANDA of Dr Reddy's. Teva earlier had been filing petitions with the FDA to not grant approvals for copycat versions, taking some desperate measures to save the money-spinner drug from losing to low-cost generics.

"It is a long-drawn legal battle and based on Para IV certifications, it may take time before companies could launch the drug. There could be shared exclusivity," said Sarabjit Kaur Nangra, vice-president, research (pharma), Angel Broking.

While Mylan and Natco had joined hands for the launch of this drug, Momenta and Sandoz did too. Copaxone could be one of the biggest launches for Dr Reddy's too, and the Hyder-

abad-based company had hoped it would launch the drug by FY16, as it has been the third filer for approval. The brand Copaxone is said to cost more than \$60,000 for a patient every year.

"When the generic drug is going to be launched is a billion-dollar question. Although we had filed for the drug that was set to expire on May 23 this year, even after four months it has not happened, as the expiry has been challenged. The Supreme Court of the USA will hear a review petition in November now," said an official from Natco Pharma.

Caught in a similar legal tangle is Aurobindo Pharma, that now has to fight a legal battle to market and make and issued by Reckitt Benckiser's copy version of Guaifenesin sustained release formulation and tablets, which is used to treat chest congestion. The brand Mucinex comes under patents 252 and 032 issued in 2005 and 2010 respectively.

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