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Teva’s $1bn Copaxone blow

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Teva’s efforts to extend the lifecycle of its multiple sclerosis therapy Copaxone have finally run out of steam. Yesterday’s US district court ruling means that a generic version of the 40mg formulation could be on the market as soon as February, several months earlier than expected.

The worst-case scenario for Teva now looks likely; it previously said Copaxone sales could fall by $1-1.2bn if two generic 40mg competitors emerged next month, and there are already several waiting in the wings. Teva had better news in the shape of approval of its generic version of Glaxosmithkline’s Advair, but this was not enough to stop its shares opening down 6% on the New York stock exchange this morning.

Copaxone copycats

Among the generic Copaxone pack are Novartis and Momenta, whose version of the 40mg dose is under FDA review. The companies launched a 20mg version, called Glatopa, in 2015, and their 40mg product is the only one so far to show bioequivalence to Copaxone’s active ingredient, Leerink analysts said.

Meanwhile, Mylan said it was one of the first companies to challenge Teva’s patents with its ANDA; if its claim holds up it could get 180 days of market exclusivity on approval.

The Leerink analysts forecast a three-horse race between Momenta/Novartis, “another generic competitor and a Teva-authorized generic”. Others with a 40mg product include Dr. Reddy's Laboratories and Amneal Pharmaceuticals.

Whichever copycat comes out on top, Teva’s forecast 2017 Copaxone sales of $3.8-3.9bn look set to take a big hit after the latest ruling, in which the US District Court of Delaware invalidated claims covered by the ’250, ’413, ’776 and ’302 patents based on obviousness.

This follows a December 2016 decision by the Patent Trial and Appeal Board that the ’250, ’413 and ’302 patents were invalid for the same reason.

The rulings scupper Teva’s strategy of switching patients from the original 20mg once-daily version of Copaxone to the newer 40mg, thrice-weekly version – unless its appeal succeeds. However, Evercore ISI analyst Umer Raffat, for one, believes that there is not much hope of this, adding: “The court sees the ’250, ’413, ’302, and ’776 patents as nothing more than lifecycle management.”

A separate patent, extending the 40mg dose to 2035, is also the subject of an ongoing court case. But the writing looks to be on the wall for Copaxone, and the rest of Teva’s pipeline will have a hard time filling the gap.

Teva’s top five products in 2022

			Estimated sales ($m)	
Product	**Indication**	**Status**	**2016**	**2022**
SD-809	Huntington's disease	Filed	-	1,019
Copaxone	Multiple sclerosis	Marketed	3,958	1,006
TEV-48125	Migraine	Phase III	-	1,003
DuoResp Spiromax	Asthma/COPD	Marketed	98	494
QVAR	Asthma/COPD	Marketed	470	478

Source: EvaluatePharma.

At least Teva can now boast of having an FDA-approved version of Advair, called Airduo Respiclick, as well as a

generic copy of Glaxo's Flovent, named Armonair Respiclick. Both use Teva's Respiclick inhaler.

But even this news, while positive, is not as emphatic as it could have been: Airduo Respiclick is not an exact copy of Advair as it delivers a lower dose of salmeterol. Furthermore, Teva's product is only approved in asthma, while Advair also has the go-ahead in COPD.

There are more Advair generics on the horizon, including one from Mylan, with a GDUFA date of March 28, and one from Vectura and Hikma Pharmaceuticals, with a decision set for May 10. If these are deemed equivalent to Advair they could have an edge over Teva's version.

Glaxo's drug was pulling in over $8bn at its peak in 2013, so there is a large market to go after. But, when the Copaxone defeat is weighed against the Advair generic victory, Teva appears to have lost more than it has gained.

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