

Santarus suffers heartburn from Zegerid patent loss



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Santarus was left suffering severe heartburn following a decision by a US district court yesterday to invalidate its key patents over Zegerid, Santarus' unique formulation of omeprazole, which generated sales of \$119m last year and accounted for 69% of the company's total revenues.

Although there remains uncertainty over the timing and nature of the launch of a generic version by Par Pharmaceutical, Santarus shares slumped 36% in early trade to \$3.43 as investors appear prepared to accept the worst case scenario that a generic launch will be imminent and aggressive. A copycat version within the next few months, instead of 2016 when the patents were set to expire, will almost completely erode the net present value of Zegerid, down to just \$23m from \$144m, according to *EvaluatePharma's NPV Analyzer* (see table below).

In the balance

Santarus have said they will appeal the court's decision, which ruled against five patents listed in the FDA Orange Book over Zegerid, on the basis the patents were "obvious".

Assuming the litigation process continues, any launch by Par would be "at risk", although the court's decision to invalidate all the patents should give it the confidence to go ahead. First, however, Par needs to receive final FDA approval for its generic versions, having so far only gained tentative approval from the regulator.

Par is thought to be the only company to have filed an ANDA for generic versions of Zegerid and is therefore set to receive 180 days of marketing exclusivity for its product. However, the company has so far shied away from making any launch decisions, only saying it "intends to review its options".

Nevertheless, the following table illustrates the impact an imminent generic launch would have on Zegerid's value to Santarus. Changing the patent expiry date to June this year, pretty much a worse case scenario, would cause a 39% decline in share price to \$3.28, similar to the market reaction so far.

EvaluatePharma's NPV Analyzer: Zegerid			
	Default	My NPV	Change
Share Price (13 Apr 10)	5.36	3.28	-39%
Market Cap (\$m)	313	191	-121
NPV (after-tax) (\$m)	144	23	-84%
NPV Per Share (\$)	2.47	0.39	-2.08
% of Share Price	46%	7%	
Shares Outstanding (m)	58		
Patent Expiry (USA)	16-Jul-16	30-Jun-10	

Zegerid is an immediate release formulation of omeprazole and sodium bicarbonate for the short-term treatment of gastric ulcers and heartburn; essentially one of many variations and spin offs from AstraZeneca's phenomenally successful development of omeprazole as one of the first proton pump inhibitors (PPI).

Claim for damages?

Aside from the potential generic erosion of its most valuable product, what may also be hurting Santarus today is concern that Par may also claim for damages.

On February 1, 2010, the two companies signed a deal whereby Par agreed to delay the launch of its generic version until the outcome of the court case, despite the fact the 30-month stay expired on February 3. In return, Santarus agreed to post a bond that could be charged if Par won the litigation battle.

Although the size of this bond and extent of potential damages has not been revealed, Par is within its rights to make this claim. Santarus could therefore be set for a double hit from the court's decision.

Given the potentially crippling impact this could have on Santarus, it seems only a so-called "pay for delay" deal with Par can save them now.

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