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Sanofi's Eloxatin pact could join FTC's pay-for-delay tally

Jonathan Gardner

The US Federal Trade Commission is probably the least happy reader of the news that Sanofi-Aventis has struck a deal to get generic versions of the chemotherapy agent Eloxatin off the market for more than two years. The pacts look to reverse massive erosion in sales of the French company's fifth-biggest drug in 2008, which in the view of the US regulator will likely cost consumers hundreds of millions of dollars.

Whilst Sanofi's sales of Eloxatin, known generically as oxaliplatin, have collapsed in the months since its main US patent expired, the new agreements to withdraw generic versions between June 30, 2010 and August 9, 2012 will likely re-ignite US sales of the branded version. US sales of branded Eloxatin plummeted 97% to just $10m in the fourth quarter in 2009 compared to the same period the previous year, following the August 11, 2009 patent expiry. As the new agreements only prop up sales in the US it is unlikely that Eloxatin will return to former blockbuster glories, but any additional sales will prove to be useful for a company such as Sanofi, which is facing a precipitous patent cliff in the coming years.

Projected US annual sales for Eloxatin, ($m) pre-agreement				
2008	**2010**	**2012**	**2014**	**2016**
1,393	164	79	74	72

Six-way deal

Bookending the holiday weekend, Sanofi announced agreements with Teva, Fresenius and Sandoz on Thursday, and then today announced agreements with Hospira, Par Pharmaceuticals and Actavis. In return for agreeing to take their unauthorised generic products off the market, the companies will be authorised to sell generic oxaliaplatin under a license before expiry of some later patents.

The remaining terms of the agreement were kept confidential, although it seems more than likely that the companies received some type of compensation of the type that would cause the FTC to decry it as a "pay for delay" deal.

Curiously, the Sanofi statement includes a cryptic sentence stating that it also has a settlement agreement with Sun Pharmaceuticals that remains enforceable, although it is subject to appeal, and that Sanofi will ask the US District Court for the District of New Jersey to also order Sun to withdraw its generic oxilaplatin on June 30. It was a statement that had analysts scratching their heads as to its meaning, and Sanofi's press office did not return a call seeking clarification.

Just as curiously, shares in Sanofi fell 1.4% today, an unexpected market reaction given the benefit the company is likely to see as a result of the agreements. Given that generic oxilaplatin is on the market already, and that end-users will have three months to stock up on their cheap supplies, it is possible that investors do not see it as a particularly positive settlement in terms of its effects on branded Eloxatin sales.

Government scrutiny

The FTC, which lost a bid to include a ban on "pay for delay" patent settlements in health care reform, will review the Sanofi agreements along with the US Justice Department (*US health care reform limits further pain for pharmaceutical industry, March 19, 2010*). Its legal capacity to block them, however, has suffered blows in recent years given that its ability to challenge such agreements as *per se* violations of antitrust law has been successfully fought in courts (*Obama healthcare reform puts new focus on 'pay for delay' deals, February 26, 2010*).

In a January report, the regulator said it has recorded 66 such deals since 2004, with the number rising from three in federal fiscal year 2005 to 19 in 2009. In the past month, Watson Pharmaceuticals agreed with Takeda to delay its launch of generic diabetes drug Actos until August 2012, another pact that could increase prices and sales for the patent owner to the tune of hundreds of millions of dollars (*Can Takeda prolong*

Actos' life?, March 11, 2010).

To block these type of deals would likely yield significant saving. In evaluating a ban, the Congressional Budget Office estimates five year federal government savings of $800m, and the FTC itself estimated that the agreements cost US consumers in general $3.5bn a year.

Both branded and generic manufacturers oppose a ban, and given both the significant opposition to other aspects of health reform and the closeness of the final vote, the ban on patent settlements did not make the final cut in health reform.

Potential government savings of $800m is no small amount, even in vast budget of nearly $4tn, and with the federal government running a deficit of more than $1tn it is conceivable that Congress would return to such a proposal in a quest for savings. It may be even more likely if the number of settlements continues to accelerate as the patent cliff drops from beneath the industry, making deals such as Sanofi's Eloxatin pact extinct.