

## Novartis settles Gleevec as other patent fights continue



Amy Brown

News that Novartis has managed to delay the inevitable launch of generic versions of Gleevec for a mere six months in the US will provide small comfort for the Swiss pharma giant, which is going through a painful period of patent losses.

However, as one of the biggest looming losses facing the industry, the settlement represents a small win for big pharma against low-cost rivals. Most of the other big expiries on the immediate horizon have already been fought over and decided in the world's biggest drugs market, but there are a few that remain to be resolved whose outcomes are closely watched. One is Teva's ongoing battle to prevent Copaxone copycats, which saw another development unfold yesterday (see tables below).

### Boost to sales

Gleevec's basic compound patent expires on July 4, 2015, but Novartis was hoping that IP around certain polymorphic forms of the drug would extend exclusivity until 2019. Sun Pharmaceutical had been fighting this, and the Swiss group announced a deal that would allow Sun to sell a generic version from February 1, 2016.

Sun has already received tentative approval for its copycat pill, but no other generic appears to have filed with the FDA. As such, branded Gleevec will not see a massive erosion of sales until more competitors enter. However, analysts had been expecting a generic launch at patent expiry next year and, considering the maturity of the product, these extra few months will be highly profitable for Novartis.

UBS estimates that the company will receive a \$1.2bn boost to sales, while Bernstein calculated that earnings per share would receive a 6% lift in 2015.

Gleevec NPV calculation	
Current NPV	\$6.1bn
New NPV	\$7.2bn (+17%)
Implied share price rise	+0.50%
Actual share price rise	+0.25%

According to *EvaluatePharma's NPV Analyzer*, pushing out the patent expiry to February 2016 causes the value of the drug to rise by 17%, equating to a 0.5% share price lift; Novartis stock was little changed yesterday.

### Approaching cliffs

As the table below shows, Gleevec is one of the biggest-selling products facing US patent loss over the next few years. Generating peak sales of \$4.7bn in 2013 – almost half in the US – the leukaemia drug was a prime target for generic drug makers.

Otsuka's Abilify is projected to be approaching an even bigger cliff. To date the Japanese drug maker has fended off generics companies seeking to invalidate its April 2015 US patent, and it is clear from the sales forecasts below that this patent is expected to hold.

Others have had to settle – last month Pfizer struck a deal with Teva and Actavis over its blockbuster pain drug Celebrex, allowing both firms to launch in December – six months after the patent was due to expire, but a year earlier than Pfizer was hoping.

And AstraZeneca has long settled with generics firms over its two ageing blockbusters, Nexium and Crestor;

the impending loss of the statin in particular will punch a big hole in the company's finances.

### Ongoing battles

Legal wrangling is ongoing, however, over Daiichi Sankyo's blood pressure pill Benicar. Mylan has 180 days' exclusivity for its generic version after expiry of the patent in October 2016, although Apotex has been trying to win the right to launch early as well.

Also very much still in the courts is Teva with Copaxone, one of the most closely watched and contested patent fights. Last month a US Supreme Court agreed to hear Teva's appeal of a case it is fighting against rival generics firms, and a ruling is not expected until well into 2015 ([Copaxone not dead yet as Teva appeal lives on, April 1, 2014](#)).

Generics firms could launch "at risk" when the main patent expires later this year – Teva is fighting to extend the protection to a later patent that goes in 2015 – but few expect this to happen. Much of the sales erosion is seen coming from competition from novel therapies rather than copycats.

Yesterday, a US district court threw out another of Teva's cases – this one against the FDA – suggesting that the Israeli drug maker will fight this battle to the end.

The twists and turns of patent battles means surprises are always possible. Only yesterday, Eli Lilly saw a UK court rule against it over a patent that was assumed would hold until 2021 in Europe. And after years of regulatory foot-dragging over the approval pathway for generic versions of combination inhaled drugs, guidance from the FDA last year appeared to clear the path for Advair copycats ([GSK moat breached as FDA issues generic Advair guidance, September 10, 2013](#)).

And, further out, there are other big battles over blockbuster brands waiting to happen. Lilly's Cialis looks a likely candidate; the erectile dysfunction drug has a November 2017 patent that analysts reckon will hold – judging by sales forecasts – but Synthon won tentative approval for its generic version back in 2012, and a 30-month stay on FDA approval lapses in May 2015. So it seems likely that a deal of some sort will emerge.

But, with these settlements increasingly attracting the scrutiny of competition watchdogs, big pharma cannot be expected to deliver the surprisingly long extensions that have been seen in the past. And the extra six months that Novartis got for Gleevec come to be seen as a respectable win.

#### Big patent expiries of the next few years

Product	Company	Patent expiry	US sales in yr before expiry (\$bn)	Sales lost in following year (\$m)	% lost in following year
Lunesta	Dainippon Sumitomo	May 2014	0.5	(413)	(80%)
Abilify	Otsuka	Apr 2015	4.1	(3,011)	(74%)
Evista	Eli Lilly	Mar 2014	0.8	(565)	(73%)
Benicar	Daiichi Sankyo	Oct 2016	0.6	(415)	(70%)
Nexium	AstraZeneca	May 2014	2.1	(1,210)	(57%)
Crestor	AstraZeneca	Jul 2016	2.5	(1,241)	(49%)
Gleevec*	Novartis	Feb 2016	2.0	(850)	(42%)
Copaxone	Teva	May 2014	3.1	(866)	(28%)
Advair	GlaxoSmithKline	Aug 2016	3.7	(966)	(26%)
Celebrex	Pfizer	Dec 2014	1.9	(488)	(25%)

\*estimates predate patent ruling

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