

Zyprexa's SPC reaches end of the road

In several western European countries, September brings the expiry of supplementary protection certificates (SPCs) for Eli Lilly's blockbuster olanzapine schizophrenia treatment Zyprexa (see Figure 1). As various generics firms in several major European territories already hold marketing authorisations for olanzapine tablets, immediate generic competition upon SPC expiry appears likely. This will potentially bring a swift decline in sales of Zyprexa that exceeded US\$5 billion globally in 2010, half of which came in the US, where the key patent constraint expires next month.

Indeed, in Europe's largest market of Germany, several generics firms launched olanzapine tablets some years ago. They had to withdraw them from the market, however, at the end of 2008. At that time, Germany's federal court of justice, the *Bundesgerichtshof*, reversed a patent court's decision that Lilly's olanzapine compound patent – and its associated SPC – was invalid (*Generics bulletin*, 16 January 2009, page 17).

The first generic olanzapine products had reached the German

market in November 2007. By the time they were forced from the market just over a year later, the generics had captured 56% of the country's market for the schizophrenia treatment, according to local generics industry association, Pro Generika. And olanzapine continues to cause controversy in Germany, with Pro Generika having recently complained that the molecule was included in the list for which the AOK health insurance fund was inviting bids, even though olanzapine's SPC had not yet expired (see page 12).

In Spain, Zyprexa has faced competition since April this year, with companies including Ranbaxy and Stada seizing on the brand's patent expiry (*Generics bulletin*, 6 May 2011, page 13). The relatively early generic entry in Spain came after local authorities refused to grant Lilly an SPC.

Patent intelligence expert GenericsWeb observes, however, that Lilly's patent portfolio for olanzapine is extensive, with specific protection remaining for olanzapine pamoate, the active ingredient in the Zyprexa extended-release injectable formulations that Lilly markets for intramuscular administration.

In certain European countries, data exclusivity is due to expire for the prostate-cancer agent Plenaxis (abarelix) in those states that offered six years of exclusivity prior to harmonisation (see Figure 2). In the remainder of European Union member states, exclusivity extends to September 2015.

GenericsWeb has also identified potential targets for future generic development (see Figure 3). The recent Canadian approval of Boehringer Ingelheim's combination antihypertensive Twynsta (amlodipine/telmisartan) led two Canadian patents to be included in Health Canada's Patent Register.

Although the US Food and Drug Administration (FDA) recently approved Vertex Pharma's direct-acting antiviral agent Incivek (telaprevir) – which is indicated for treating chronic hepatitis C when used in combination with peginterferon alfa and ribavirin – no patents are currently listed against the brand in the FDA's Orange Book. However, GenericsWeb believes it has identified the key molecule patent protecting telaprevir.

SPCs expiries in September

INN	Country
Danofloxacin	Switzerland
Dolasetron	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Sweden, UK
Latanoprost	Switzerland
Olanzapine	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Romania, Sweden, UK

Figure 1: Molecules for which supplementary protection certificates (SPCs) expire in certain markets in September 2011 (Source – GenericsWeb)

Data exclusivity expiries in September

INN	Country/Region
Abarelix	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Turkey
Erlotinib	Turkey
Levocetirizine	Switzerland
Posaconazole	US
Ranibizumab	Israel
Ribavirin	Switzerland
Sorafenib	Australia
Sunitinib	Australia

Figure 2: Molecules for which data or market exclusivities expire in certain markets during September 2011 (Source – GenericsWeb)

Molecules in the spotlight

INN	Event
Amlodipine/telmisartan	First Canadian patents listed in Health Canada Patent Register following approval of Twynsta in August 2011
Cimicoxib	SPC applications published in Belgium, Finland, Norway and Sweden
Indapamide/perindopril	Newly-issued Canadian patent listed in Health Canada Patent Register for Coversyl Plus
Phentermine	First US Orange Book patent listed following the FDA's approval of Suprenza in June 2011
Telaprevir	FDA approval of Incivek

Figure 3: Molecules in the spotlight, based on recent regulatory or litigation events (Source – GenericsWeb)

Want more? This data is extracted from the monthly update for Pipeline Scope, an online intelligence tool that provides fast access to reliable information on key patent, SPC and data-protection expiries, covering 44 countries and over 1,500 INNs.

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