

# Latanoprost SPC ends in top EU markets

In mid-January, Pfizer's blockbuster treatment for glaucoma and ocular hypertension, Xalatan (latanoprost), loses supplementary protection certificate (SPC) exclusivity following the expiry of six-month paediatric extensions (see Figure 1). The end of Pfizer's SPC exclusivity will occur in western Europe's largest markets, namely France, Germany, Italy, Spain and the UK, as well as in the majority of the region's smaller markets, including Austria, Belgium, Denmark, Finland, Greece, Ireland, Luxembourg, the Netherlands and Sweden.

Reporting its results for the third quarter of 2011, Pfizer noted that the loss of latanoprost protection in the US in March 2011 had contributed to turnover by its Specialty Care division falling by 5% on an operational basis to US\$3.80 billion. Immediately following US patent expiry on 22 March, the Food and Drug Administration (FDA) awarded final approvals for generic latanoprost to Alcon, Apotex, Bausch & Lomb, Luitpold and Mylan. Pfizer responded by launching an authorised generic through its Greenstone unit (**Generics bulletin**, 8 April 2011, page 22). Paddock has since also secured FDA clearance to market a rival to Xalatan.

Patent intelligence expert GenericsWeb believes such intense competition on latanoprost is likely to be mirrored in the European Union following SPC expiry.

In the first nine months of 2011, Pfizer's US sales of Xalatan and its sister brand Xalacom (latanoprost/timolol) tumbled by two-thirds to US\$159 million. The two brands' turnover in 'developed Europe' – defined by Pfizer as western Europe and Scandinavia – declined by a tenth to US\$385 million.

January also brings the end of SPC protection in much of western Europe for Janssen's Reminyl (galantamine) Alzheimer's disease treatment. Hexal has already introduced a generic version in Germany, several weeks ahead of SPC expiry (see page 19).

Meanwhile, Bristol-Myers Squibb has followed up last year's

European Union (EU) centralised approval for its Nulojix (belatacept) immunosuppressant by filing an SPC application in Belgium (see Figure 2). The first US patents have been listed in the FDA's Orange Book against Horizon Pharma's Duexis (famotidine/ibuprofen) combination brand for relieving arthritic pain with a reduced risk of developing ulcers, as well as against Incyte's Jakafi (ruxolitinib) treatment for myelofibrosis.

## Data exclusivity expires for Sprycel

In terms of data exclusivity (see Figure 3), January brings the expiry of five-year protection in Australia for Bristol-Myers Squibb's Sprycel (dasatinib). However, GenericsWeb points out, patent protection for the leukaemia treatment extends beyond data exclusivity in all major territories. Therefore, launches of generic dasatinib are likely to remain constrained by intellectual property.

The patent-intelligence expert also says it has identified a "key patent family" protecting Pfizer's Vyndaqel (tafamidis). The originator secured an EU approval for the brand in November last year as an orphan drug for treating transthyretin amyloidosis, a hereditary condition caused by abnormal protein accumulation in body tissues. **G**

Molecules in the spotlight	
INN	Event
Belatacept	First SPC application published in Belgium after European Union approval of Nulojix in June 2011
Famotidine/ibuprofen	First patents listed in US Orange Book following FDA approval of Duexis in April 2011
Ferric carboxymaltose	First extension application published in Australia following approval of Ferinject in April 2011
Ruxolitinib	First patent listed in US Orange Book following FDA approval of Jakafi in November 2011
Salmon pancreas disease virus	First SPC application published in Norway after European Union approval of Norvax Compact PD in August 2011
Tafamidis	Key patents identified following European Union approval of Vyndaqel in November 2011

Figure 2: Molecules in the spotlight, based on recent regulatory or litigation events (Source – GenericsWeb)

SPC expiries in January	
INN	Country
Cisatracurium	Switzerland
Gadobenic acid	Austria, Belgium, France, Germany, Greece, Italy, Luxembourg, Netherlands, Spain, Sweden, Switzerland, UK
Galantamine	Austria, Belgium, France, Germany, Greece, Italy, Luxembourg, Netherlands, Spain, Sweden, Switzerland, UK
Gatifloxacin	Germany, Netherlands
Hvt Ibd vaccine	Austria, Belgium, France, Italy, Luxembourg, Netherlands, Sweden, UK
Latanoprost*	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Spain, Sweden, Switzerland, UK

\* six-month paediatric extension expires

Figure 1: Molecules for which supplementary protection certificates (SPCs) expire in certain markets during January 2012 (Source – GenericsWeb)

Data exclusivity expiries in January	
INN	Country/Region
Daptomycin	Turkey
Dasatinib	Australia
Galsulfase	Turkey
Ivermectin/praziquantel	Switzerland
Pegaptinib	Switzerland

Figure 3: Molecules for which data exclusivity expires in certain markets during January 2012 (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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