

# Rivastigmine and nateglinide show up

In many of Europe's largest markets, supplementary protection certificates (SPCs) for the Alzheimer's drug rivastigmine – the active ingredient in Novartis' Exelon brand – expire this month. "These SPCs are based on a limited European patent which does not specify molecule stereochemistry," comments patent intelligence expert GenericsWeb, which monitors SPC expiries through its Pipeline Scope service. "A later family of national patents also exists which claims the S-enantiomer of rivastigmine tartrate and has SPCs due to expire in 2012 and 2013 in certain countries," it observes.

As can be seen from Figure 1, SPCs for nateglinide – the active ingredient in Novartis' Starlix diabetes treatment – expire in France, Germany, Switzerland and the UK this month. However, European

data exclusivity prevents generic filings until 3 April this year, and expiry of a subsequent patent family claiming crystalline nateglinide is extended by SPCs that run until 2015 and 2016.

GenericsWeb has identified SPC paediatric extension applications for Pfizer's Lipitor (atorvastatin) in France, Ireland, Netherlands and the UK. "If granted, these extensions would provide Pfizer with an additional six months of SPC protection, which could be very lucrative given that Lipitor is the world's best-selling branded drug," it notes.

This month sees several molecules lose the benefit of 10 years of European data exclusivity, including Abbott's Kaletra combination of the antiretrovirals lopinavir and ritonavir, and Novartis' Zometa (zoledronic acid) bisphosphonate blockbuster (see Figure 2).

Four patent term extension applications have been identified in Japan relating to Daiichi-Sankyo's antiviral agent laninamivir (see Figure 3). The recent US approval of Trovis' Viibyrd (vilazodone) antidepressant has led to the Orange Book listing of two US oral formulation patents. Lundbeck's schizophrenia candidate ziconapine is the subject of US litigation over a patent-term adjustment. **G**

## Potential filing opportunities for products whose data exclusivity expires in March

INN	Country/Region
Atazanavir	US
Avobenzone/ecamsule/ octocrilene/titanium dioxide	US
Bexarotene	European Union
Calcium levofolinate	US
Cinacalcet	US
Clobetasol	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Iceland, Lithuania, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Spain
Dalfopristin/quinupristin	Switzerland
Ferucarbotran	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, Switzerland, UK
Fulvestrant	Australia
Histrelin	Canada*
Hydroxyethyl starch/ sodium chloride	Canada*
Lopinavir	European Union
Lopinavir/ritonavir	European Union
Moxidectin/praziquantel	Canada*
Posaconazole	Australia
Rotavirus vaccine	Australia
Sirolimus	European Union
Sulfur hexafluoride	European Union
Tepoxalin	European Union
Timolol/travoprost	Canada*
Unoprostone	Switzerland
Zoledronic acid	European Union

\* In practice, Canada did not implement its previous data-protection legislation in a manner that prohibited reliance on proprietary data during the exclusivity term.

## Potential launch opportunities for products whose SPC expires in March

INN	Country
Alendronic acid	Cyprus
Diclofenac	Italy
Moxidectin	Latvia
Nateglinide	France, Germany, Switzerland, UK
Nonacog alfa	Switzerland
Rivastigmine	Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Sweden, Switzerland, UK
Sertindole	Austria, Belgium, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Sweden, Switzerland, UK

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

## Molecules in the spotlight

INN	Event
Laninamivir	First extension application published in Japan
Vilazodone	First patents listed in US Orange Book
Ziconapine	Litigation initiated in the US

**Figure 2: (left) Molecules for which data exclusivities expire in certain markets during March 2011 (Source – GenericsWeb)**

**Figure 3 (above): 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.

For further information, visit [www.genericsweb.com](http://www.genericsweb.com), or contact:

Europe: +44 870 879 0081 North America: +1 704 665 1986

Or e-mail: [info@genericsweb.com](mailto:info@genericsweb.com)

