

Levofloxacin leads launches during June

In the majority of western European countries, supplementary protection certificates (SPCs) protecting Sanofi's blockbuster antibiotic Tavanic (levofloxacin) expired during June. Patent intelligence expert GenericsWeb has not identified any other European patent families that would prevent generic competition upon expiry of these SPCs. Indeed, the first levofloxacin launches started on 'day one' after SPC expiry, led by companies including Hexal in Germany as well as Actavis in the UK, where Mylan had failed to invalidate the SPC (**Generics bulletin**, 27 November 2009, page 17).

Generic competition to Tavanic in western Europe coincided with the US Food and Drug Administration (FDA) approving the first levofloxacin rivals to Johnson & Johnson's Levaquin (see page ??).

Two anthracycline oncology agents – doxorubicin and idarubicin – also face SPC expiries in several countries this month (see Figure 1). Protection also runs out for the Boniva (ibandronic acid) blockbuster marketed by GlaxoSmithKline (GSK) and Roche. But GenericsWeb

has identified several other patent families covering formulations and uses of the osteoporosis treatment.

In terms of data exclusivity, GSK's anticoagulant Argatroban faces expiry in those European Union member states that offer six years of exclusivity before harmonisation. GenericsWeb observed that 10-year exclusivity in several other markets would last until June 2015.

Canadian five-year exclusivity expired during June for a number of products, including the antibacterial drug dapson and the antiviral agent entecavir (see Figure 2). But in both cases, Canadian patents could protect the products beyond the exclusivity term, GenericsWeb said.

GenericsWeb has identified two new potential targets for generic development. The recent FDA approval of the thyroid-cancer treatment vandetanib in April 2011 led to two patents being listed in the FDA's Orange Book (see Figure 3); while newly-issued for combinations of chlorphenamine, ibuprofen and pseudoephedrine have triggered listings in the US and Canada. **G**

Potential launch opportunities for products whose SPC expires in June

INN	Country
Doxorubicin	Austria, Belgium, Denmark, Finland, Greece, Italy, Luxembourg, Netherlands, Sweden, UK
Estradiol	Luxembourg
Ibandronic acid	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Romania, Sweden, UK
Idarubicin	Finland, Italy, Switzerland
Levofloxacin	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Slovenia, Sweden, Switzerland, UK
Stavudine	Switzerland
Tiagabine	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Switzerland, UK

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

Molecules in the spotlight

INN	Event
Chlorphenamine/ ibuprofen/ pseudoephedrine	Newly issued Canadian and US patents listed in Health Canada Patent Register and Orange Book for Children's Advil Cold Plus Suspension and Advil Allergy Sinus formulations respectively.
Vandetanib	First US Orange Book patents listed following FDA approval of vandetanib.

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

Potential filing opportunities for products whose data exclusivity expires in June

INN	Country/Region
Argatroban	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Iceland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain
Copper/manganese sulfate	Canada**
Dapson	Canada**
Darbepoetin alfa	European Union
Darunavir	US*
Dasatinib	US*
Desloratadine	Switzerland
Doxycycline	US*
Dronabinol	Canada**
Entecavir	Canada**
Ethinylestradiol/etonogestrel	Australia
Glutamine	US*
Human papillomavirus vaccine	Australia
Imatinib	Switzerland
Ioflupane	Switzerland
Methyl aminolevulinic acid	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Methylphenidate	US*
Palonosetron	Australia
Ropinirole	US*
Tipranavir	Australia
Zolpidem	US*

* Generics firms can file a paragraph IV certification one year before five-year new chemical entity (NCE) exclusivity expires.
 ** In practice, Canada did not implement its previous data-protection legislation in a manner that prohibited reliance on proprietary data during the exclusivity term.

Figure 2: Molecules for which data exclusivities expire in certain markets during June 2011 (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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