Valsartan SPC expires in top EU markets

In mid-November, Novartis' Diovan (valsartan) – "the top-selling branded antihypertensive medication worldwide" – lost supplementary protection certificate (SPC) exclusivity in four of western Europe's five largest markets. The SPC expiries in France, Germany, Italy and the UK came several months after Diovan had first faced generic competition in Spain (**Generics *bulletin***, 20 May 2011, page 20). Furthermore, Diovan has also just lost SPC protection – following six-month paediatric extensions – in several smaller European markets, namely Austria, Belgium, Denmark, Finland, Ireland, Luxembourg, Latvia, the Netherlands and Sweden (see Figure 1).

According to Novartis, brand sales down by 3% to US$4.35 billion in the first nine months of this year gave Diovan – including the Co-Diovan combination with hydrochlorothiazide – a 13.5% share of the global antihypertensives market. Of that nine-month sales total, US$1.79 billion was achieved in the US, where a six-month paediatric extension to the valsartan compound patent runs until September 2012.

The six-month paediatric SPC extensions in the European Union (EU) have proven vital to Novartis in protecting not only its Diovan brand, but also its Co-Diovan combination with hydrochlorothiazide.

SPC expiries in November

INN	Country
Atorvastatin	Finland, Norway
Pasteurella vaccine	Italy, Portugal
Remifentanil	Switzerland
Tasonermin	Spain
Testosterone	Italy, Luxembourg
Topotecan	Denmark, France, Italy, Luxembourg
Valsartan*	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Latvia, Netherlands, Sweden, UK

* expiry of six-month paediatric extensions

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

However, the extent to which Novartis' SPCs protect the combination has divided national courts. Right up until SPC expiry this month, Novartis and generics companies have been arguing in national courts over how the EU's SPC regulation should be interpreted (see page 25).

Just a few weeks ago, a commercial court in Vienna, Austria, insisted it had the answer. Ruling that Novartis' Austrian valsartan SPC also covered the combination with hydrochlorothiazide (**Generics *bulletin***, 1 November 2011, page 13), the Vienna court insisted the SPC regulation "leaves so little room for doubt that – at least at a first-instance stage – there is no reason to seek a preliminary ruling from the European Court of Justice (ECJ)". However, that is exactly the course of action that the High Court of England and Wales chose in referring a similar case (**Generics *bulletin***, 3 October 2011, page 17).

At around the same time, a French Court of Appeals decided that Actavis' valsartan/hydrochlorothiazide tablets did not infringe Novartis' valsartan SPC (**Generics *bulletin***, 14 October 2011, page 13). This went against the position taken by other courts, including in Germany.

Meanwhile, Pfizer has ensured that it enjoys a lucrative extension to its monopoly for Lipitor (atorvastatin) blockbuster by obtaining six-month paediatric extensions to national SPCs that stretch protection until May 2012. As **Generics *bulletin*** went to press, patent intelligence expert GenericsWeb had identified paediatric SPC extensions for the cholesterol-lowering brand in most major EU countries, with the exceptions of Finland and Norway. As the Finnish and Norwegian SPCs were based on a process patent, they proved an inadequate barrier, and Lipitor has already faced generic competition for several months.

In terms of data exclusivity (see Figure 2), November brings the expiry of 10-year protection in the majority of EU member states for Novartis' oncology agent Gleevec (imatinib) and Alcon's glaucoma treatment Travatan (travoprost). In Australia, five-year exclusivity for Biogen's multiple-sclerosis treatment Tysarbi (natalizumab) ends.

GenericsWeb also monitors intellectual-property developments around potential targets for generic development. European centralised approvals in 2011 have led to the filing of SPC applications for Bristol-Myers Squibb's anticoagulant agent Eliquis (apixaban); Pfizer's Xiapex (collagenase) treatment for Dupuytren's disease; and Virbac's CaniLeish (leishmania infantum) veterinary vaccine. G

Data exclusivity expiries in November

INN	Country/Region
Fumagillin	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovenia, Slovak Republic, Spain, Turkey
Imatinib	European Union
Natalizumab	Australia
Travoprost	European Union
Urinary tract infection immunostimulating agent	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK

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

Molecules in the spotlight

INN	Event
Apixaban	First SPC applications for patent family (Finland, Netherlands, UK) following European approval of Eliquis in May 2011 and first extension application following Australian approval of Eliquis in July 2011
Collagenase	First SPC applications for patent family (France, Sweden, UK) following European approval of Xiapex in February 2011
Leishmania Infantum	First SPC applications for patent family (Italy, Netherlands, Spain, UK) following European approval of Bluevac BTV8 in April 2011

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