

Anastrozole arrives as its SPC expires

Generics companies throughout western Europe will be turning their attention to anastrozole this month as the supplementary protection certificate (SPC) protecting AstraZeneca's blockbuster breast-cancer treatment Arimidex expires in mid-February.

As can be seen from Figure 1, information supplied by patent intelligence experts GenericsWeb – for our inaugural Pipeline Watch – shows that a six-month paediatric SPC extension for anastrozole expires during February in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Sweden and the UK.

The SPC extends the duration of national counterparts to European patent EP0,296,749. However, AstraZeneca also holds European patent EP1,455,781, which covers using anastrozole to treat early-stage breast cancer in post-menopausal women. Alfred Tiefenbacher, Helm, Hexal, Stada and Teva have all filed oppositions to the patent with the European Patent Office (EPO), which has set 6 April this year as the date for oral proceedings.

However, the picture regarding anastrozole has been further clouded by AstraZeneca having filed a divisional patent application

EP1,997,492, for reducing the rate of recurrence of cancer.

If the US can be taken as a model, competition in Europe's anastrozole market will be fierce. More than a dozen players surged into the market after a US paediatric patent-extension for Arimidex expired on 27 June last year (*Generics bulletin*, 16 July 2010, page 12).

Meanwhile, SPCs for eptacog alfa are set to expire this month in seven European states. These SPC expiries are based on the centralised European marketing authorisation date of February 1996. However, some states elected to reference earlier Norwegian and Swiss authorisations, meaning SPCs elsewhere already expired last year.

In the European Union, two recombinant enzymes – rasburicase and tenecteplase – lose their 10-year data exclusivity, enabling generics firms to file dossiers (see Figure 2). Treprostinil, a treatment for pulmonary arterial hypertension, also loses exclusivity in several states.

By monitoring approvals, patent litigation and applications for SPCs or similar extensions, GenericsWeb also maintains a list of potential generic candidates. For example, vernakalant and bilastine are now the subject of SPC applications in the UK (see Figure 3). **G**

Potential filing opportunities for products whose data exclusivity expires in February

INN	Country/Region
Alendronic acid/colecalciferol	Canada*
Anidulafungin	US
Bortezomib	Australia
Capecitabine	European Union
Choriogonadotropin alfa	European Union
Fluvoxamine	US
HIV AG-AB combined	Switzerland
HIV-1 antigen; HIV-2 antigen	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Ivermectin/praziquantel	Canada*
Menthol/methyl salicylate	US
Mometasone	US
Nicotinic acid/simvastatin	US
Nimesulide	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Rasburicase	European Union
Solifenacin	Canada*
Tenecteplase	European Union
Treprostinil	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Iceland, Lithuania, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Spain

* in practice, Canada had not implemented its previous data protection legislation in a manner that automatically prohibits this type of reliance for a minimum period of time

Figure 2: Molecules for which data exclusivity expires in certain markets during February 2011 (Source – Pipeline Scope)

Potential launch opportunities for products whose SPC expires in February

INN	Country/Region
Anastrozole	Austria**, Belgium**, Denmark**, Finland**, France**, Germany**, Ireland**, Italy**, Netherlands**, Sweden**, UK**
Eptacog alfa	Belgium, Finland, France, Germany, Italy, Luxembourg, Netherlands
Ioversol	Italy
Lamivudine	Austria, Belgium, Germany, Ireland, Latvia, Norway, Slovenia, Switzerland, UK
Mycophenolic acid	Belgium, Italy, Luxembourg, Latvia, Sweden
Penciclovir	Austria, Denmark, Luxembourg

** indicates expiration of six month paediatric extension to SPC

Figure 1: Molecules for which supplementary protection certificates expire in certain markets in February 2011 (Source – Pipeline Scope)

Potential target molecules

INN	Event
Aspirin/bisoprolol	First extension application published in UK
Bilastine	First extension application published in UK
Conestat alfa	First extension application published in Belgium and Netherlands
Iron oxide	First extension application published in Netherlands
Pegloticase	First extension application published in US
Vernakalant	First extension application published in Italy, Netherlands, Norway and UK

Figure 3: List of potential generic target molecules, based on regulatory or litigation events (Source – Pipeline Scope)

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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