

Quetiapine expiry creates a lot of noise

Late March brought the expiry of supplementary protection certificates (SPC) across much of the European Union (EU) for quetiapine, the active ingredient in AstraZeneca's antipsychotic drugs Seroquel and Seroquel XR. The two blockbuster brands generated global sales of US\$4.34 billion and US\$1.49 billion respectively in 2011, including turnovers of US\$546 million and US\$490 million in western Europe.

AstraZeneca is not only experiencing fierce generic competition in major European markets (see Figure 1), but also in the US, where a six-month paediatric extension to US patent 4,879,288 ended on 26 March. US sales of immediate-release Seroquel were US\$3.34 billion last year. Quetiapine immediate-release tablets have been on the market for some time in several European countries after generic competitors circumvented patents – and associated SPCs – that only claim processes for preparing the active ingredient.

“Patents protecting the quetiapine sustained-release formulation extend until May 2017, but it is likely generic competitors have taken significant steps to circumvent these patents as many generic companies hold licences to market both formulations and will seek to launch both simultaneously,” observes patent intelligence expert GenericsWeb.

The originator is fighting hard to maintain market exclusivity for both formulations. But a UK patent court has just ruled that its extended-release patent is invalid due to obviousness (see front page). And in the US, a Columbia district court has thrown out AstraZeneca's bid to secure a preliminary injunction that would have prohibited the US

Food and Drug Administration (FDA) from granting final marketing approval to any abbreviated new drug application (ANDA) referencing Seroquel, although the extended-release patent has survived.

AstraZeneca's US paediatric exclusivity for Seroquel expires on 2 June 2013, GenericsWeb observes, so generic challengers have to carve out such indicated uses from their labels.

In terms of data exclusivity (see Figure 2), March brought the expiry of 10-year protection in the majority of EU member states for several drugs, including GlaxoSmithKline's anticoagulant Arixtra (fondaparinux sodium). “Key patent protection for fondaparinux has already expired, and with data exclusivity potentially being the only remaining constraint, generic competitors may now be able to submit applications for marketing authorisations for their generic versions in Europe,” GenericsWeb comments.

SPC expiries in March	
INN	Country
Bordetella vaccine	Austria, Belgium, Luxembourg, Sweden, UK
Dermatan sulfate	Italy
Lepirudin	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, UK
Letrozole	Cyprus
Naratriptan	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Luxembourg, Latvia, Netherlands, Norway, Slovenia, Spain, Sweden, UK
Quetiapine	Austria, Belgium, Bulgaria*, Cyprus, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Romania, Spain, Sweden, Switzerland, UK
Raltitrexed	Switzerland
Tolcapone	Austria, Belgium, Finland, Germany, Greece, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain
Ziprasidone	Romania
Zolmitriptan	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Slovakia, Slovenia, Spain, Sweden, UK

* the SPC remained an application at expiry, so never entered into force

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

Data exclusivity expiries in March	
INN	Country/Region
Alglucosidase alfa	Turkey
Aliskiren	US
Apomorphine	Switzerland
Arsenic	European Union
Atovaquone/proguanil	US
Attenuated feline panleucopenia vaccine, Felv vaccine	European Union
Bimatoprost	European Union
Darunavir	Australia
Dexketoprofen	Austria, Belgium, Cyprus, Czech Rep.
Duloxetine	Australia
Epoetin delta	European Union
Fondaparinux sodium	European Union
Galsulfase	Australia
Lapatinib	US
Levonorgestrel	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Parecoxib	European Union
Paricalcitol	Australia
Phleum pratense allergen	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Iceland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey
Pimecrolimus	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Sitaxsentan	Australia
Voriconazole	European Union

Figure 2: Molecules for which data exclusivity expired in certain markets during March 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.

For further information, visit www.genericsweb.com, or contact:

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

Or e-mail: info@genericsweb.com

