

# Ropinirole rolls into focus of EU players

Generics players in most of the European Union's (EU's) major markets should soon be able to market ropinirole for its main use after supplementary protection certificates (SPCs) covering the Parkinson's disease indication expire this month. "The imminent expiry of these SPCs," commented patent intelligence expert GenericsWeb, "suggests that generics companies will no longer be limited to ropinirole's secondary use – treating restless-legs syndrome." Other SPCs that protected the ropinirole molecule – which forms the basis of GlaxoSmithKline's Requip brand – expired in late-2008.

Novartis's Femara (letrozole) breast-cancer agent also faces SPC expiry in much of Europe towards the end of this month. GenericsWeb said it had identified several paediatric SPC extensions for Pfizer's

Xalatan (latanoprost) that would extend protection for the ocular antihypertensive until January 2012. However, it has not as yet recorded any such paediatric extension in Luxembourg, so the local SPC runs out this month (see Figure 1).

Data exclusivity for Pfizer's Caduet (amlodipine/atorvastatin) expires during July in those European states that offered six years of exclusivity prior to harmonisation (see Figure 2). "In the remainder of EU states, exclusivity extends to July 2015," GenericsWeb noted.

GenericsWeb observed that US patents for compounds including the prostate-cancer agent abiraterone, the hepatitis C drug boceprevir and the HIV-inhibitor rilpivirine had been listed in the Orange Book maintained by the US Food and Drug Administration (see Figure 3). **G**

Potential launch opportunities for products whose SPC expires in July	
INN	Country
Exemestane	Belgium, Czech Republic, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Portugal, Slovenia, Sweden, Switzerland, UK
Latanoprost	Luxembourg
Letrozole	Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Latvia, Netherlands, Norway, Romania, Sweden, UK
Miglitol	Austria, Denmark
Pasteurella vaccine	UK
Ropinirole	Austria, Denmark, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Sweden, UK
Yttrium-90	UK

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

Molecules in the spotlight	
INN	Event
Abiraterone	First US Orange Book patent listed following FDA approval of Zytiga in April 2011
Iron chelates	Litigation alert on US member of family following an infringement suit filed by Albion and Breckenridge against PruGen
Boceprevir	First US Orange Book patent listed following FDA approval of Victrelis in May 2011
Ipilimumab	First extension applications published in US following approval of Yervoy in March 2011
Pentetreotide	US members of families listed in Orange Book
Rilpivirine	First US Orange Book patents listed following FDA approval of Edurant in May 2011
Tranexamic Acid	Newly issued US patent listed in Orange Book for Lysteda

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

Potential filing opportunities for products whose data or market exclusivity expires in July	
INN	Country/Region
Alemtuzumab	European Union
Amlodipine/atorvastatin	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain
Antitrypsine alpha-1 human	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain
Butenafine	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Mineral salt solution (Navstel)	US*
Cytarabine	European Union
Deferasirox	Australia
Fexofenadine/pseudoephedrine	US*
Gemcitabine	US*
Ivermectin/praziquantel	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Natalizumab	Israel
Nitenpyram	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Peginterferon alfa-2a	Switzerland
Rupatadine	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Telithromycin	European Union
Zolpidem	Australia

\* 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 or market exclusivities expire in certain markets during July 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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