

# Current Patents Gazette

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## DOLPHIN



The records appearing in this Gazette will be added to DOLPHIN, the database Of all pharmaceutical inventions in the next week. Based on the INPADOC database produced by the European Patent Office, it covers all national and international patents with relevance to pharmaceutical research and development published from 1968 onwards and selected patents from earlier years. DOLPHIN contains information on bibliographic data, contents, associated products, legal status, licensees and context of patents, which is presented in a format to convey all aspects of a patent at a glance.

## News & Highlights from Week 0645

The UK Patents and Designs Journal (PDJ No. 6129) contains no SPC events this week but we can report the filing of two new SPC applications ahead of publication in the PDJ. **Shire Pharmaceuticals** have filed for an SPC covering **Fosrenol**, which is used for the oral treatment of hyperphosphatemia in dialysis patients, on EP817639. Fosrenol (**lanthanum carbonate**) was developed under exclusive license from **AnorMED**. If granted, the SPC should expire March 2019 – three years after the normal patent expiry – based on the earliest EU approval in Sweden, which was exactly 8 years after the patent filing date. 2005 sales of Fosrenol were around \$53.5 million, still considerably behind the market leader, **Renagel (sevelamer)**.

The second SPC application was filed by **Merial** on EP379341 and covers the **selamectin** veterinary product developed and marketed by **Pfizer** as **Stronghold**. Unusually, the centralised EU Marketing Authorisations are all 1999 numbers, whilst the first authorisation date submitted by Merial is January 18, 2006. Pfizer's granted SPC on EP677054 quotes a first authorisation date (based on the same approval numbers) of November 25, 1999 and expires November 24, 2014 – 15 years later. Using the date quoted by Merial the SPC, if granted, would expire January 17 2015, 5 years after entering into force. It appears that on the date quoted by Merial the MA was amended to include flea control in areas to which the affected animal has access. It will be interesting to see if the Patent Office considers the amendment sufficient reason for using the new approval date when determining the duration of the SPC should it be granted. In this case the difference is only around 2 months, however if Merial's application is successful it could open the way to new strategies for considerably extending the life of future SPC applications.

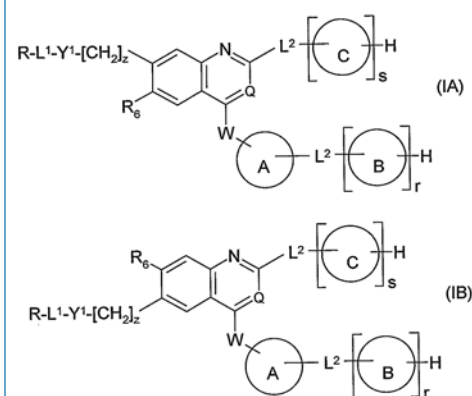
In last week's Current Patents Gazette (CPG Issue 0644), we reported on granted Japanese patent extensions published in the October 25 JP gazette. Also recorded in that issue were 15 new extension applications on 13 patents covering seven drug products.

**Pfizer** led the way with six applications on four patents. Two applications of 4.75 years were filed on JP3176630, the product patent, which if granted would protect **linezolid** until around June 2, 2019. Linezolid, which has been extensively launched and marketed as **Zyvox**, is the leading iv antibiotic treatment and is also available in tablet and oral suspension formulations, enabling a smooth transition from hospital to home treatment, according to analysts for our Strategic Drugs database (SDdb). Consequently sales, which were \$618 million in 2005, are expected to exceed \$1 billion by 2009. Two extension applications were filed for another market leader, **tolterodine tartrate (Detrusitol)**, with a five year extension requested on JP2664503 and a 17 month extension requested on JP3616011. If granted JP2664503, the product case, will expire January 2014, whilst the extra 17 months on JP3616011 appears to give protection until April 2021 for the sustained release form marketed as **Detrusitol or Detrol LA**. Sales of tolterodine were \$988 million in 2005. Pfizer also filed two extension applications on JP3533179, which describes a process for making the antidepressant **sertraline (Zoloft)**. Sales of Zoloft totalled \$3.256 billion in 2005, representing a 3% decline which is expected to accelerate with generics now entering the US market.

**Chugai** filed a five year extension request on JP3068033 which if granted would protect **Roche's epoetin beta**, marketed as **Epogin, Recormon or Neorecormon**, until April 2022 in Japan. Roche are unable to market the

product in the US, due to **Amgen's** successful patent litigation, but worldwide sales were still around \$1.8 billion in 2005.

**Gilead Sciences** applied for an extra five years protection on JP06015475 and JP2958774 for **Ambisome**, a liposomal, injectable formulation of **amphotericin B**. **Kyowa Hakko** requested five year extensions on JP07116174, JP3068858 and JP05086925 for **Patanol** eyedrops (**olopatadine HCl**) and **Meiji** requested extensions of five years on JP2911674, over 4.5 years on JP3238485 and almost 2.5 years on JP3490468 for the oral contrast agent, **Bothdel**.



**WO2006117552 and WO2006117570 are the first patents to emerge from Chroma's aurora kinase program**

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## UK initial ("A0") patent applications filed September 26<sup>th</sup> – October 3<sup>rd</sup> 2006

Almac Sciences Limited has filed what appears to be their first application, claiming reduction of  $\alpha$ -halo ketones and soluble diazoalkane precursors. Almac provide cytotoxics, peptides, oligonucleotides, proteins and chirals to the pharmaceutical industry, and launched its radiolabelling services for clinical and pre-clinical supplies in November 2005.

Antitope Limited has an application this week entitled T cell assays. A previous application by **Antitope, WO2006056769** claims a method for testing the immunogenicity of variant mammalian antigens in an MHC-II transgenic mammal. The Cambridge-based company, formed in 2004, offers its *ex vivo* EpiScreen for predicting immunogenicity.

**Argenta Discovery Ltd** has filed two applications this week, one entitled heterocyclic compounds and the other cyclic amine derivatives and their uses. These may be related to **WO2006082412** (claiming heterocyclic human neutrophil elastase inhibitors) and **WO2005075469, WO2005075466** and **WO2005014588** (all claiming amine derivatives having histone deacetylase inhibitory activity). In Nov 2006, **Argenta** initiated its first clinical trial with ADC4022, for the treatment of chronic obstructive pulmonary disease and severe asthma.

**Avidex Ltd** adds to its patent portfolio this week with an application claiming T-cell therapies. This may continue on from **WO2006103429** (claiming high affinity HIV T-cell receptors) or **WO2006056733** (claiming  $\gamma\delta$  T-cell receptors) or **WO2006037960** (claiming T-cell receptors containing a non-native disulfide interchain bond). In Sept 2006, **Avidex** became a wholly owned subsidiary of **MediGene AG**.

Cambridge University Technical Services Ltd has an application this week relating to the treatment of conformational disorders. This follows on from **WO2004089369**, which claims the use of autophagy stimulation for treating protein conformational disorders.

Forum Bioscience Holdings Limited has filed what appears to be its first application claiming treatment of wounds. Previous applications filed are WO2005094904 (disinfectant solutions), WO2005006891 (sweetener), and WO2004056380 (for treating bacterial infection). As can be seen from these applications, the company has a broad profile of life science products.

**Glaxo Group Ltd** has filed a series of seven applications for novel compounds this week and has recently had a series of PCT applications published with the same title relating to pyridopyrimidinone derivatives as p38 kinase inhibitors. Also this week from Glaxo is an application for a process and an influenza vaccine. Glaxo has launched **Fluarix** for the treatment of influenza virus.

KU Leuven Research & Development has one application this week for oligonucleotide arrays. This appears to be the first application by the University in this area. The research may relate to predicting susceptibility to cystic fibrosis, see **WO2006058395**.

**Lectus Therapeutics Ltd** has filed an application for ion channel modulators and uses thereof. This may follow on from previous applications filed in 1999 about the use of phenylpropionic acids and ester compounds as beta-blockers for treating coronary artery diseases such as myocardial infarction and hypertension. Lectus Therapeutics Ltd is a UK-based company specializing in the discovery and development of ion channel therapeutics for urinary bladder disorders, pain and angina.

**TheRyte Ltd**, a spin-off from the University of Liverpool is seeking protection for treating cancer. This appears to continue the patent portfolio from the company who have up to 4 published PCTs to date, claiming CDK hydrophobic region mimetic peptide lead compounds, and theranostic' biomarkers to predict treatment response.

The University of Dundee is seeking protection for the manufacture of **rimcazole** this week. Led by Barbara Spruce in the Surgery and Molecular Oncology department, Burroughs Wellcome trialed the sigma receptor ligand rimcazole as a potential anti-psychotic approximately two decades ago, however development was discontinued in 2002 due to poor performance in the clinic. However, rimcazole an oral drug and appears to be showing promise as a cancer therapeutic, particularly in cancer types with high unmet need and scaleable GMP manufacturing process for rimcazole dihydrochloride is in place by the university. The drug is on track to enter human cancer trials in Q1 2007.

The University of Liverpool together with the **Liverpool School of Tropical Medicine** has filed an application this week on dispiro tetraoxane compounds. This appears to be related to the work of Richard Amewu and co-workers who have recently design and synthesized orally active dispiro 1,2,4,5-tetraoxanes synthetic antimalarials with superior activity to artemisinin. Dr P O'Neill at the University of Liverpool has been granted an award to be shared with **Romark Pharmaceuticals** in the development of new direct synthetic routes to potent synthetic 1,2,4 – trioxanes.

**VASTox plc** has filed three applications for the treatment of duchenne muscular dystrophy. VASToc plc is the licensee for development and marketing of Isis Innovation's utrophin modulators for treating Duchenne muscular dystrophy, see WO00125461 filed in October 1999.

Due for publication early in April 2008