

# Current Patents Gazette

ISSUE 0631

4th August 2006

## 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 0631

The Patents and Designs Journal this week (No. 6115) reports that **Shire Pharmaceutical's** Supplementary Protection Certificate (SPC) for **balsalazide disodium (Colazide)** expired on 6<sup>th</sup> July 2006. The SPC, based on GB2080796 (assigned to Biorex), provided the maximum 5 years protection. Developed by **Salix Pharmaceuticals Inc**, under license from **Biorex**, balsalazide is an oral 5-aminosalicylic acid (5-ASA) prodrug, indicated for the treatment of ulcerative colitis. In May 2000, Shire and Salix entered into a marketing and distribution agreement for balsalazide in a number of EU countries. European sales of balsalazide reported by Shire for 2005 totalled \$8.6 million, representing a 5% year-on-year growth. According to our Strategic Drugs Database (SDdb), total sales of balsalazide are predicted to increase to \$156.5 million by 2008, but its market share with respect to the ulcerative colitis franchise is predicted to decrease slightly, due to future competition from **mesalazine MMX**. However, mesalazine MMX is the subject of collaboration between **Shire** and **Giuliani**. This oral sustained-release, multimatrix formulation of mesalazine (Mesavance), which utilizes **Cosmo SpA's MMX technology**, is being developed for the potential treatment of ulcerative colitis. Shire filed for US approval in December 2005, and in February 2006, a Marketing Authorization Application was filed in Europe.

The PDJ also reports the entry into force of **Pharmacia's** SPC for **exemestane (Aromasin)**, a steroidal aromatase inhibitor for the treatment of advanced breast cancer in postmenopausal women whose disease had progressed following tamoxifen therapy. Based on GB2177700, the SPC entered into force on 8<sup>th</sup> July 2006 and is due to expire on 7<sup>th</sup> July 2011.

Ahead of publication in the PDJ, we report the filing of three SPCs. **Alza Corporation** has

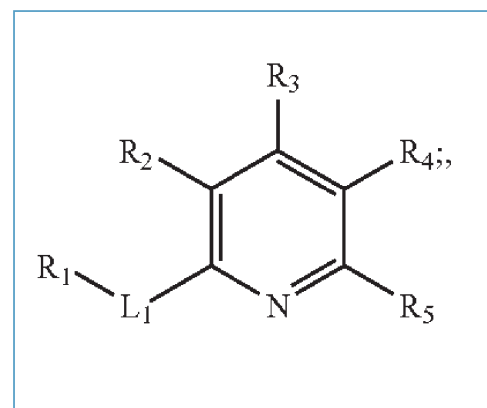
filed an SPC for its **IONSYS Fentanyl Iontophoretic Transdermal System**, which is indicated for the management of acute pain. The filing is based on EP836511, which discloses a device for the transdermal electrotransport delivery of fentanyl and sufentanil. If granted, we estimate that protection for this transdermal system will be extended until January 2021.

An SPC for **daptomycin** has been filed by **Cubist Pharmaceuticals**. **Cubist** (under license from Lilly) and its licensee **Novartis** developed and launched an iv formulation of the cyclic lipopeptide antibiotic, for the treatment of complicated skin and skin structure infections caused by susceptible strains of Gram-positive micro-organisms. The SPC is based on EP1115417 and if granted, is estimated to expire in January 2021.

**LTS Lohmann Therapie-Systeme** and **Schwarz Pharma Ltd** have filed an SPC application for **rotigotine**. This follows an agreement between Schwarz and LTS for manufacturing the transdermal patch product. The filing is based on EP1033978, assigned to LTS Lohmann and **Discovery Therapeutics** (now **Aderis Pharmaceuticals**), claiming a transdermal therapeutic system containing a D2 agonist for the treatment of Parkinsonism. If granted we expect the SPC to expire in February 2021, based on the UK marketing authorization. Schwarz Pharma, under license from Aderis, has launched a once-daily transdermal patch formulation and a nasal formulation of rotigotine for the treatment of Parkinson's disease. In August 1998, Discovery Therapeutics signed a licensing agreement with Schwarz for the development of rotigotine in a once-a-day transdermal patch and under a revised agreement Schwarz gained full worldwide rights to rotigotine.

**Vicuron Pharmaceuticals** has filed a PCT application (**WO2006080920**) for a lantibiotic

named Antibiotic 107891 and its Factors A1 and A2 this week. This follows on from **WO2006075988**, published on July 20<sup>th</sup>, and **WO2005014628**. Both 2006 applications definitively claim the structure of Factors A1 and A2, with this week's application disclosing further supporting NMR data. The original 2005 application claims tentative structures for the two Factors based on NMR, IR and mass spec data. It appears that Vicuron was unsure of the structure for Factor A1 and Factor A2 in 2003 but wanted to make a patent application, and therefore included only a tentative structure. Subsequently, more structural data became available and the two 2006 applications were filed before the publication of WO2005014628 on 17<sup>th</sup> February 2005, consolidating the patent protection for these antibiotics. Until one or more of these applications is granted, the precise basis for Vicuron's monopoly will not be entirely clear.



## Abbott filed its first NCE claim for JNK inhibitors

## UK initial ("A0") applications filed June 20<sup>th</sup> - June 27<sup>th</sup> 2006

**Electrophoretics limited**, a subsidiary of **Proteome Sciences plc**, is seeking protection for a diagnostic assay for spongiform encephalopathies. **DOLPHIN**, our Database of All Pharmaceutical Inventions, holds a recent application from Proteome Sciences (**WO2006061609**) co-assigned to **University College London** and **Medical Research Council**, disclosing a method of diagnosing neurodegenerative diseases. See also **WO2004040316**, a diagnostic method for transmissible spongiform encephalopathies.

Salisbury-based, **Murvus Technology Ltd** has filed for DNA molecules and methods. Founded in April 2004, as a result of a management buy-out from **Protherics PLC**, Murvus is developing products for use in medicine, public health and veterinary care. This is the first application from the company, whose directors have expertise in the areas of cell targeting, programmed cell death and novel methods of cancer therapy.

**Friedrich Miescher Institute for Biomedical Research**, **INSERM** and **Ecole Superieure de Lyon** have filed an application for the prevention of muscle atrophy. Several applications are assigned to INSERM relating to muscular atrophy, two of which concern the survival motor neuron (SMN) gene eg see **WO0021553**.

**Alza Corporation** has filed an application on methods of reducing alcohol-induced dose dumping for opioid sustained release oral dosage forms. This appears to be related to Alza's fentanyl iontophoretic transdermal system (IONSYS), approved by the FDA in May 2006 and indicated for the short-term management of acute post-operative pain in adult patients requiring opioid analgesia during hospitalization. In January 2006, the European Commission approved the use of IONSYS in the 25 member states of the European Union.

**Arrow International Ltd** has filed three applications with **Chongqing Shenghuaxi Pharmaceutical Co Ltd** claiming crystalline duloxetine hydrochloride. This collaboration was previously highlighted in *Current Patents Gazette in July 2005*, where the companies jointly filed for the synthesis of famciclovir and other purine derivatives, however this apparent collaboration still appears to be unreported. Chongqing Shenghuaxi Pharmaceutical Co Ltd is an API manufacturer that specialises in antibiotics, hormones and synthetic substances.

**Nihon Medi-Physics Co. Ltd** and **GE healthcare** have co-filed an initial UK application entitled "novel compound with affinity with amyloid". Nihon Medi-Physics was founded in 1973 as part of a joint venture with Sumitomo Chemical Co. Ltd and in October 1996 a 50:50 partnership between **Sumitomo Chemical** and **Amersham International** was established; as a result of take-over of Amersham, GE Healthcare became a shareholder of Nihon Medi-Physics by proxy, while Sumitomo Chemical presumably retains its 50% share in the company. This co-filing indicates that the subject matter is of particular interest to GE healthcare over Sumitomo Chemical, although the latter has also made previous patent applications relating to amyloid modulation. While **DOLPHIN** does not report Nihon Medi-Physics as having had any previous interest in this area, GE Healthcare appears to have last worked on benzothiazole derivatives for in vivo imaging of amyloid plaques, see **WO03068269**.

Lone inventor, **Petrie, Stuart**, is seeking protection for a "topical anti-pruritic, anti-herpetic and anti-inflammatory pharmaceutical compositions". **DOLPHIN** reports just one application that is potentially from the same inventor see **AU04389189** on a new method of achieving appetite reduction. This is possibly the same Stuart Petrie who received a national teaching award alongside Professor Thomas Rades, both of the **Univ of Ontago**, New Zealand. However, Petrie appears to be associated with the school of surveying, although colleague Prof. Rades is associated with the Pharmacy dept. and specializes in formulations?

**Prolysis Limited** has filed an initial UK application on "antibacterial agents". The antimicrobial specialist was incorporated in April 1998 appears to be a spin-out from **Oxford Univ** and has previously traded under the names **Inhoco763 Ltd** (until May 1998) and **Microgenics Ltd** (until June 1999). The company's founder and chief scientific officer, **Professor Jeffery Errington FRS**, appears on **WO0246461** (a method of identifying transcription modulators) assigned to **Isis Innovation**, the IP arm of Oxford Univ; Prof Errington has patented of cephalosporins while at the **Sir William Dunn School of Pathology**, Univ of Oxford. The company lists **GYR-767** (a series of DNA supercoiling inhibitors) and **CDI-936** (a series of Cell division inhibitors) as its key projects; the former being the most advanced. Other potential projects in lead evaluation status are **CDI-538**, a FtsZ-mediated GTPase inhibitor; **MUR-807**, targeting glutamate racemase and the conversion of L-glutamate to D-glutamate, an essential cell wall component and thus inhibiting cell wall synthesis; finally **ANN-855**, targeting RNA biosynthesis. The company also has a number of partnerships including **BioFocus Key Organics**, **Jubilant Chemsys**, **Univ of Sheffield** (Prof D Rice and team) and **Amura**, from which Prolysis has in-licensed the ligand design technology, **ProtoDiscovery**, for *de novo* design and virtual screening. The company appears to have a long-standing collaborative agreement with the Univ of Oxford as well as with the **Univ of Newcastle** where Prof Errington had worked as the Director of the Institute for Cell and Molecular Biosciences.

Due for publication in December 2007