

Current Patents Gazette

ISSUE 0701 5th January 2007

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 0701

The January 3rd edition of the Patents and Designs Journal (No 6137) reports no SPC information this week.

Ahead of publication in the PDJ, however, is the filing of four SPC applications, one of which is agrochemical. **SPC/GB07/001**, lodged by **Encysive Pharmaceuticals Inc** and based on **EP0819125**, covers **sitaxentan**. If granted this should provide patent protection until at least April 2021. The endothelin A (ET-A) antagonist was launched in the UK in November 2006, and then launched in Germany the following month, both for the same indication, pulmonary hypertension.

Novartis AG has lodged a UK SPC based on **EP0914118** for **deferazirox (deferasirox)** and marketed as **EXJADE**. If granted this should provide an additional five years patent protection expiring in June 2022, based on the marketing approval date provided on the application. The iron-chelating agent has not yet been launched in Western Europe since the marketing approval was received in August 2006, although it has already been launched in Switzerland and the US for treating iron overload.

Syngenta Participation AG filed **SPC/GB07/003**, based on **EP0580553** originally assigned to **Ciba-Geigy AG**, covering the broad-spectrum pesticide **thiamethoxam**. If granted this should mean that the patent term should be extended until July 2018.

Finally, in December 2006 **Bayer Pharmaceuticals** lodged a UK SPC (**SPC/GB07/004**) for **sorafenib** based on **EP1140840**. Approximately two months earlier Bayer lodged a French SPC application based on the same EP, published in the December 8th issue of the **BOPI** (06/49). However, there appears to be a discrepancy

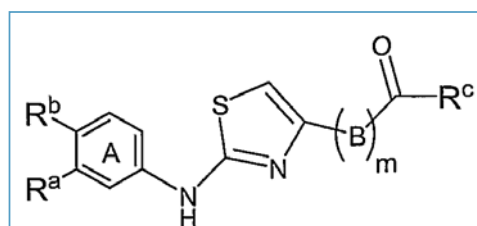
between these two applications regarding the marketing approval provided, resulting in a potential difference in patent term extension granted of one day. The UK SPC application uses a local authorisation date of 20th July 2006 providing further patent protection until at least 19th July 2021, while the FR SPC application uses the centralized EU marketing authorization date of 19th July 2006 and hence patent term extension should expire a day earlier. Bayer and **Onyx**, the owner of the underlying technology, have already launched sorafenib in the US for renal tumor in December 2005. A year later in December 2006, Merrill Lynch regarded sorafenib's failure to reach its primary endpoint in advanced melanoma Phase III trials, and any delay in label expansion, as a delay to the drug's time to profitability. Consequently, the analysts expressed concern regarding renal cancer data scheduled for mid-2007, as "the historical success rate for drugs in this disease is lower than melanoma"; Merrill Lynch believed that this indication had little opportunity. However, Merrill Lynch noted that better efficacy has been demonstrated as a first-line melanoma treatment. Overall, Merrill Lynch anticipated a flattening or declining trend in sorafenib sales, mostly due to competition from sunitinib (Sutent), temsirolimus and bevacizumab (Avastin), as well as a decline in sorafenib's off-label use following the results of this Phase III trial.

In Current Patents Gazette 0648 we reported on the **Merial** SPC application, which contained an anomalous first authorisation date of January 18, 2006 for a 1999 approval of veterinary product **selamectin**. The 2006 date was a minor amendment to the authorisation and if used rather than the 1999 date would have resulted in two months extra duration for any granted SPC. Although not published as a correction in the PDJ, the SPC application now shows the earlier November

1999 authorisation date on the Patent Office web-site.

Just shortly before Christmas, **Advitech Inc** announced the grant of **US7141262**. This patent covers the company's manufacturing process of its platform technology known as **XP-828L (Dermylex)** based on previous work of **Pierre Jouan Biotechnologies**, a French biotechnology company from which Advitech obtained a licence back in May 2003. Dermylex is a growth factor (TGF-beta) based compound for the treatment of psoriasis. Earlier in the year, in June 2006, Advitech had patent applications of its own published in the US and Europe which related to Dermylex and which claimed compositions comprising TGF-beta and proteins for treating psoriasis.

Avidex Ltd is seeking protection for a UK application claiming polypeptides. This is likely to follow closely on from **WO2006125963**, having the same title and claiming high affinity polypeptides against **MHC Class I peptides**, useful for treating and diagnosing autoimmune diseases. **MediGene AG** completed acquisition of Avidex in Sept 2006. Avidex's leading drug candidate, **RhuDex**, is being developed as a disease-modifying and antiarthritic agent, designed to block T cell co-stimulation via the CD80 pathway.



The first patenting to emerge from Dr Reddy's Labs AMPK activator program.

UK initial ("A0") applications filed November 21st - 28th 2006

AcurePharma AB has filed an application entitled use of a compound as a **VEGF inhibitor**. The company's only other UK initial ("A0") application, filed in October 2006, relates to **neurological therapy**. As of 3rd Jan 2007, **AcurePharma** expected to have low molecular weight melanocortin and adenosine receptor ligands in Phase 1 and the clinical development phase respectively for rheumatoid arthritis and osteoarthritis by Q2, and development of its spinal cord injury program is expected to reach Phase II by Q4.

F2G Ltd is seeking protection for **antifungal agents**. The company based in Manchester specializes in research and development of new treatments for serious fungal infections. In June 2002 F2G LTD entered into an agreement with **Genome Therapeutics Corp**, in which F2G was said to use Genome Therapeutics' proprietary in-house compound library and F2G's antifungal whole-cell assay screening capabilities to identify specific compounds with potent activity against medically important fungal human pathogens. **DOLPHIN** holds 5 patent applications from the company.

Karus Therapeutics Ltd has filed what appear to be its first two applications this week, both entitled chemical compounds. In July 2005, **Karus** became the 15th company to be spun out of the **University of Southampton** since 2000, and its focus is on the development of a new generation of potent and selective **histone deacetylase inhibitors** for the treatment of **cancer, inflammation and heart disease**.

Mallinckrodt Inc is seeking protection for an application entitled **^{99m}Tc (I) tricarbonyl complexes with tridentate chelators** for myocardium imaging. Previous work by the company related to imaging using **^{99m}Tc** includes **WO2005079864, WO0189586 and US6359119**.

Paradigm Therapeutics Ltd has filed an application for a receptor. Paradigm focuses on key gene families such as **G-protein coupled receptors (GPCRs)**, ion channels and proteases to find therapies for pain, CNS disorders, hormone dependent diseases such as prostate and breast cancer and metabolic diseases and has about 40 applications in **DOLPHIN** most of which are about receptors, silicon compounds or ion channels.

Progenika Biopharma S.A. has filed an application for a diagnostic method. There are 9 applications in **DOLPHIN** from this company and most of them are for in vitro diagnosis of bladder or pancreatic cancer. This company is focused on high-throughput genetic screening technologies.

reMYND NV's most recent published PCT application, **WO2005005640**, relates to a model for **neurodegenerative disease**, based on a yeast with modified oxidative stress response. It is therefore not surprising that the company's project has now progressed to the stage where novel therapies for neurodegenerative diseases have been identified, and accordingly an application has now been filed claiming **thiadiazole derivatives**. The Belgian biotech company, a spin-off from **Leuven University**, currently lists nine Alzheimer's and/or Parkinson's disease candidates, two in particular with sub-nanomolar EC50 values.

The University of Warwick has filed for a **Down's Syndrome** Assay. This may be connected to a paper published in 2003 by inventors based at the University with the title "Evaluation of molecular prenatal diagnosis for Down syndrome, Health Technology Assessment".

UCB SA has filed two applications this week for **bicyclic and heterobicyclic derivatives**, processes for preparing them and their uses.

University College Cardiff Consultants Limited has filed an application this week with **K U Leuven** entitled 'chemical compounds'. This appears to be the first joint patent application from the universities. This application appears to be the result of ongoing collaboration between **Chris McGuigan** at University College Cardiff and **Jan Balzarini** at Leuven into antiviral drug discovery. The **Welsh School of Pharmacy** (a Cardiff University subsidiary) and the **Rega Institute** (an interfaculty biomedical research institute of the K.U.Leuven) are investigating a series of **stavudine (d4T)** analogs, including **SO-324**, as potential prodrugs for the treatment of HIV infection.

Due for publication in May 2008