

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 0707

No SPC events were reported in the UK Patents and Designs Journal (PDJ No 6143) published on the 14th February 2007. However, we can report the filing of four new SPC applications ahead of publication in the PDJ, including one to **Pfizer** for their veterinary drug, **maropitant**.

The first was filed in January by **Takeda Pharmaceuticals** for a combination comprising **pioglitazone** and **metformin**, marketed as **Actoplus Met (Competact)** under collaboration with **Andrx**. Based on **EP0861666**, this SPC should provide additional protection until July 2021 if granted. The drug was launched in the US in November 2005, receiving European approval in July 2006 before being launched in the UK in October 2006 for type 2 diabetes. Sales of pioglitazone were expected to be around \$3 billion in 2006.

Watson Laboratories also filed a UK SPC application in January for a **testosterone containing transdermal patch** based on **EP0712303**, which if granted, should provide the maximum five years protection expiring July 2019. Watson and **Procter & Gamble** are developing a TheraDerm-MTX enhanced transdermal testosterone patch (**Intrinsa**) with and without **estradiol**, as a treatment for female sexual dysfunction; and by August 2002 had entered Phase II for the treatment of FSD in the US. In June 2006, the CHMP gave a positive opinion with regard to an initial marketing authorization application for the drug, which was followed by approval on July 28.

In February 2007 **EPIX Pharmaceuticals** filed an SPC application for **gadofosveset trisodium** based on **EP0806968** which should provide protection until October 2020, based

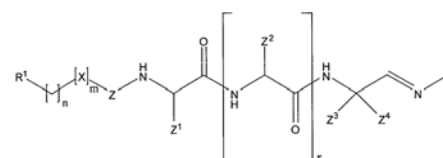
on the October 03, 2005 marketing authorization, if granted. **EPIX** and **Bayer Schering** (formerly Schering AG) have developed and launched **Vasovist**, an albumin-binding gadolinium-based intravascular MRI contrast agent for the imaging of blood vessels and blood flow, particularly in patients with peripheral vascular disease (PVD). By June 2006, gadofosveset was launched in the EU for visualization of abdominal or limb vessels in patients with PVD. In July, regulatory hurdles were encountered in the US, following two approvable letters issued by the FDA; EPIX's appeal for approval, however, was rejected in August 2006 as was EPIX's request for an Advisory Committee to review gadofosveset, with the agency suggesting that for future approval two additional clinical trials would be required. In November, Epix was planning to appeal against this decision in 1Q 2007. Although discussions are ongoing regarding US regulatory approval, gadofosveset was approved in Canada by November 2006.

February's Icelandic Gazette reports the grant to Pfizer of an SPC for their veterinary product **tulathromycin**. Two SPCs were also granted to **AstraZeneca**, which means that approximately 15 SPCs have now been approved in the country. However, the SPCs were granted for AstraZeneca's **Exanta** products (**melagatran** and the prodrug **ximelagatran**) which were withdrawn from all markets one year ago due to the risk of severe liver damage, so the grant of the SPCs is unlikely to be meaningful.

The UK PDJ records that Claims for Revocation against three patents assigned to **Chiron** and parent **Novartis** had been discontinued by "Consent Order" of the High Court on January 15 whilst two further notices recorded that SPCs granted on two of the patents had

been revoked. Both cases had been brought against Chiron by **Roche** and we can presume that following the Novartis acquisition of Chiron, the company moved to end this litigation involving Roche, in which they have a 33.3% holding. The SPCs revoked were EP0153114, covering Roche's **Herceptin (trastuzumab)** product and EP0181150 covering **Fuzeon (enfuvirtide)**.

Two PCT applications, **WO2007019266** and **WO2007019267**, received this week were filed by **MiNeuT Therapeutics** and appear to the first patenting by the company, which was founded in 2005 by **Dr Mia Levite**, a researcher based at the **Weizmann Institute**. Dr Levite has four previous applications assigned to her or to Yeda R&D (the commercial arm of the Weizmann Institute). The European rights to the first patent application on which she is cited as inventor (WO03037247) have been passed to her by **Yeda** while two more recent applications published in 2005 and 2006 were filed under her name.



First Cathepsin S inhibitors to emerge from 4SC's program relating to inhibition of cancer cell, T-cell and/or keratinocyte proliferation

UK initial ("A0") applications filed January 4th - 10th 2007

Avidex has filed a UK initial application for **T cell receptor-based hypersensitivity therapies** (GB0700312). This is likely to be related to two previous applications useful for treating autoimmune disorders and hypersensitivity, see **WO02102840** (claiming **MHC class I multimers**) and **WO02102852** (claims a **modified CD8** molecule with enhanced binding to MHC). As of February 2007, Avidex had several drug candidates derived from its monoclonal T cell receptor (**mTCR**) technology at the research stage. In December 2006, signed an agreement with the vaccines arm of **Sanofi Pasteur** to use this mTCR technology to directly validate presentation of specific T cell epitopes important in vaccine development and clinical trials.

Britannia Pharm has filed a UK initial application for the use of **phospholipids** as a selective **pulmonary barrier layer** (GB0700366) This is likely to be related to **WO2006125970** which claims the use of a mixture of phospholipids (termed **Pumactant, AP-0016**) for the treatment of **allergic inflammatory conditions**, where Pumactant does not interact with the tissue to which it is applied. In Nov 2004, Britannia signed an agreement with **AirPharma**, whereby AirPharma was to develop a dry powder formulation of AP-0016 for seasonal allergic asthma. By Feb 2007, Pumactant, which also inhibits the production of endogenous hyaluronic acid, was in the early development stage for **wound healing**.

Prosidion files six UK initial patent applications, one entitled compounds and the other five entitled **GPCR agonists**. Prosidion is a subsidiary of **OSI Pharmaceuticals** concentrating on the development of treatments for **type 2 diabetes** and **obesity**. Prosidion is developing **PSN-632408**, a **GPR119** agonist apparently for these indications. See **WO2007003960**, **WO2007003962** and **WO2007003964** for previous applications from Prosidion disclosing GPR119 agonists.

Serentis has filed two UK initial patent applications. One entitled the treatment of **fibrotic disorders** and the other entitled use of **opioid compounds** in **wound healing**. This appears to be the first sign of patent activity from this company which describes itself as an emerging bio-pharmaceutical company and is based in Cambridge, UK. Serentis received capital in 2006 from **Novo Ventures**, the life science venture capital arm of the **Novo Nordisk Foundation**. A partner at Novo Ventures is a director of Serentis. Serentis was co-founded by **Tim Sharpington** who is COO.

Smith & Nephew has filed an initial UK application (GB0700152) for an **analgesic**. This appears to be the company's first application that refers to an analgesic and it will be interesting to see how it will be used because the applicant's global business units are Orthopaedic Reconstruction, Orthopaedic Trauma & Clinical Therapies, Endoscopy and Advanced Wound Management.

The University of York has filed an initial UK application for **methanogenic prokaryotes** (GB0700274). Researchers from the Chong Lab at the university recently published an article with researchers at the **Slovak Academy of Sciences**, Slovakia, in the online journal on Blackwell Synergy with the title "Isolation and characterization of an amiloride-resistant mutant of *Methanothermobacter thermautotrophicus* possessing a defective NA⁺/H⁺ antiport" (FEMS Microbiol Lett. 2007 Feb 2).

Vernique Biotech has filed what appears to be its first initial UK application (GB0600134) with the title "Use of **epoxidised compounds**". Vernique Biotech is a UK based company developing pharmaceutical and industrial markets for **Vernonia Oil**, a naturally epoxidised oil contained in the seeds of **Vernonia galamensis**. A plant native to Ethiopia and claimed to be the world's only natural source of **Epoxy Resin**. **The Government of Ethiopia** has given Vernique Biotech the exclusive global rights to its vernonia oil in an agreement which complies with the **Convention on Biological Diversity** (CBD).

Due for publication in early July 2008