

Current Patents Gazette

ISSUE 0736 7th September 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 0736

No Supplementary Protection Certificate (SPC) events were reported in the **UK Patents and Designs Journal (PDJ No.6172)** this week. However, ahead of publication in the PDJ, we can report the filing of five SPC applications. **Cerus Corp** has filed two SPC applications covering the **INTERCEPT Blood System for platelets and plasma**. Both are based on **EP0707476** and if granted, will provide protection until May 2017. The INTERCEPT System is based on Cerus' proprietary **Helinx technology** for pathogen inactivation. The system employs the unique properties of **amotosalen HCl** to block the replication of DNA and RNA, preventing the proliferation of susceptible pathogens. **Amotosalen HCl (S-59)** is a positively charged amino-psoralen that intercalates into helical regions of DNA and RNA. In the absence of photoactivation, S-59 remains in a dark equilibrium with the nucleic acid. With UVA illumination, covalent monoadducts are formed between S-59 and pyrimidine bases. Addition of a second photon results in the formation of covalent diadducts or crosslinks. Viruses, bacteria, protozoa, and leukocytes containing sufficient numbers of monoadducts or crosslinks are unable to replicate or undergo repair.

An SPC application was filed by **SmithKline Beecham** for **rosiglitazone + metformin**, based on **EP996444**, and if granted will provide protection until November 2018. **GlaxoSmithKline** has developed and launched **Avandamet™**, a combination of rosiglitazone maleate and metformin hydrochloride, for the oral treatment of type 2 diabetes. GSK is also developing an extended-release formulation of the combination (**Avandamet XR™**).

Merck has requested an SPC for **sitagliptin** based on **EP1412357**, which will expire March 2022 if granted. Merck's **Januvia™** (sitagliptin phosphate) is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes, either as monotherapy or in combination with metformin or a PPAR-gamma agonist when the single

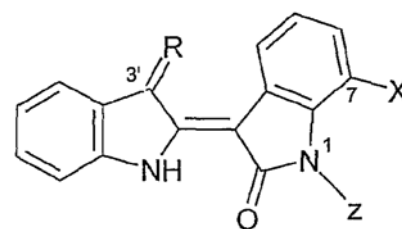
agent does not provide adequate glycemic control. The drug has been launched in several major markets worldwide.

Finally we can report that **Celgene** has filed an SPC application on **EP0925294** for **Revlimid™ (lenalidomide)**, with an estimated expiry of June 2022. **Lenalidomide**, an oral TNF-alpha inhibitor thalidomide derivative, developed for the treatment of patients with transfusion-dependent anemia due to low- or immediate-risk myelodysplastic syndromes (MDS) is also indicated in combination with dexamethasone for the second-line treatment of multiple myeloma. By January 2006, lenalidomide was available in the US for the treatment of MDS and in June 2006, the FDA approved the drug for second-line MM treatment in combination with dexamethasone. EU approval for MM was granted in June 2007 and it is this approval which has triggered the SPC application.

On September 05, the US Court of Appeals (CAFC) upheld the validity of US Reissue 34712 covering **Forest Laboratories' Lexapro**, affirming a 2006 Delaware District Court decision against **Teva** and **Cipla**. The decision is expected to block the sale of generic equivalents until March 2012, when the 6 month pediatric exclusivity on the patent expires.

Molecular Vision Limited (MVL) has filed two UK initial applications to protect a **detection apparatus and method**. The Imperial Innovations spin-off entered into a development deal with **Acrogenomics Inc** in May 2006 aimed at commercializing low-cost point-of-care diagnostic devices, based on the proprietary **BioLED** technology. The company's co-founders include Imperial College professors Andrew de Mello and Donal Bradley, and Dr John De Lello. The three are named as inventors on Imperial's **EP1336089**, which is concerned with a detection system. A subsequent case concerned with analysis of cancer cells involved collaboration with Cancer Research UK, but most recently they have reverted to the

engineering aspects of their subject with a second PCT application published in May 2007 relating to a **microfluidic device (WO2007054710)**. Whereas these PCT applications remain in the name of Imperial or IC Innovations as applicant, Molecular Vision is now named as the owner of the European application, which itself began life as **WO0242747**. As well as its formal change of ownership, the application has a colorful history in terms of prosecution, having been initially refused by the EPO in May 2005, on the grounds of lack of inventive step. The basis for this decision was a series of articles that had appeared in *Science* and *Nature* between 1995 and 1999 describing the construction and use of photovoltaic diodes. However, by May 2007 an Appeal Board had accepted that grant could go ahead, and MVL's persistence with this appeal is indicative of the importance of this invention to the company's BioLED technology; grant was achieved in the US in February 2006 (**US6995348**). Judging by the timing, it is likely that the successful European appeal prompted filing of the present applications.



First patenting to emerge indicating a collaboration between CNRS, Univ Athens, Univ Pierre et Marie Curie, Univ Rennes and Univ of Lleida on indirubins.

UK initial ("A0") applications filed July 23rd – July 29th 2007

Acacia Pharma is a hospital-based pharmaceutical company established as recently as September 2006. It has filed a UK initial application this week entitled **new therapeutic use**. Cancer supportive care appears to be its therapeutic focus with a specific focus on cancer cachexia, cancer-related fatigue, postoperative nausea and vomiting, postoperative pain and oral mucositis.

Crusade Laboratories Limited is claiming **viruses** in an initial UK patent application (GB0714578). More than half of the company's patenting to date involves at least one other party, most frequently Glasgow University and the Medical Research Council (MRC). Crusade focuses on herpes simplex virus and in particular the oncolytic use of a modification, **HSV1716**. The original patents protecting HSV1716 are reported to have been filed by Glasgow University, but by February 2000 the virus had been licensed to researchers at the University of Pennsylvania and the Wistar Institute. All of Crusade's patents name **Professor Moira Brown** as an inventor, but her earliest invention is **US6423528**, which first appeared in the name of Glasgow University, its January 1991 priority date being almost nine years before the company's incorporation. That early patent is now formally reassigned to Crusade, and could well provide the basic protection for HSV1716.

Eldrug has filed a UK initial patent application (GB0714603) entitled **compound**. From the applicant's name it seems likely that the invention relates to a pharmaceutical product, but virtually nothing on the public record offers any clues as to what the innovation involves. The one hard fact is that there is a Greek company of that name **based on Patras Science Park**, and it is possible that in future more information will become available concerning the activities undertaken there.

GW Pharma, the cannabinoid therapeutic specialist company, has filed a UK initial application (GB0714447) pertaining to the **use of cannabidiol for the treatment of neurodegenerative conditions**. Neurodegenerative disease appears to be a relatively new area of interest for GW Pharma, which recently claimed the use of cannabinoid-containing plant extracts for the treatment of neural degeneration and neurodegenerative diseases in **WO2007083098**, particularly extracts containing tetrahydrocannabinol or cannabidiol as the predominant cannabinoid. GW Pharma is developing high ratio cannabidiol for the treatment of psychosis, epilepsy, schizophrenia and movement disorders.

Ineos Healthcare has filed a UK initial application (GB0714584) aptly entitled **use**. The Cheshire-based renal and GI specialist company was spun-out of the Ineos Group and formally incorporated in December of 2002. Ineos Healthcare, also known as Ineos Silicas Healthcare, is named on equivalents to Crosfield's **WO9915189** application relating to metal compounds as **phosphate binders for the treatment of hyperphosphatemia**. Crosfield, a specialist in silica-related products, was acquired by Ineos in 2001, which is when Ineos Silicas was formed. This application may well relate to the company's proprietary **Alpharen™** product which seems to be the focus of the few pharmaceutically relevant applications assigned to either Ineos Healthcare or Ineos Silicas thus far.

John Ellacott has filed an initial UK patent application (GB0714410) claiming a **self-powered chemical dosing system**. A person of this name does appear on the internet as a graduate of Cambridge University, now living in Harrogate and a Partner with KPMG, interested in alternative medicine, so possibly this is the inventor who has filed. However, there seems to be at least one further John Ellacott with a record of patenting various valves, in the context of environmental control, and therefore less likely to be directly involved in pharmaceutical innovation.

NovaThera has filed a UK initial application (GB0714602) entitled simply **process**. Spun-out of Imperial College London in 2003, NovaThera is involved in the development of products in the field of **tissue engineering and regeneration**. Current products in development include the Advance Bio-Technology wound care range which utilizes the company's proprietary **TheraGlass** technology for controlled delivery of bacteriocidal silver. Also the company is presently engaged in a strategic alliance with **Pharming Group** to develop a suite of products based on the **application of TheraGlass in the delivery of recombinant human proteins**, including rH C1-inhibitor, rH fibrinogen, rH collagen and rH lactoferrin.

PLIVA has filed a UK initial application (GB0714489) claiming a process for **preparing a viral vaccine**. Established in 1921, PLIVA has headquarters in Zagreb, Croatia, and is a subsidiary of Barr Pharmaceuticals (acquired by Barr as of October 25th 2006). PLIVA is a global generic pharmaceutical company with a portfolio of more than 1200 products including the **macrolide antibiotic azithromycin** (see **US04517359**) indicated for bacterial infections including pneumonia and Haemophilus. This application comes from the Zagreb arm of PLIVA's R&D; according to its web site the Zagreb R&D team concentrates on the development of new generic products for the US market, biosimilar products, improved chemical entities and complex generic formulations.

Due to be published in late January 2009.