

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 0516

You may have noticed the decision of the **US Patent and Trademark Office** to stop publishing filing dates (§371 dates) of PCT entries with immediate effect. This decision has generated a considerable stir among patent information providers (including the **European Patent Office** as provider of **Esp@cenet** and **INPADOC** data) and, unless the **USPTO** reverses its decision, will undoubtedly have the same effect among patent information end users once the implications become clear. Whilst being relatively insignificant from a legal perspective, almost all patent information providers use this date (or at least the year component of the date) to identify US application numbers unambiguously. Many patent databases will simply not accept records without an application date. Apart from difficulties with entering and processing the data, the **USPTO's** decision may potentially have significant effects on the correct generation of patent family information. The *Current Patents Gazette* has also been affected by these issues and therefore, we are unable to provide US patent data in this current issue. However, information about this week's publications from the USPTO will be included into next week's Gazette and we hope to re-establish the regular pattern of publication within the next two to three weeks.

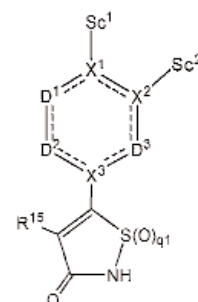
No SPC events were reported by the UK PTO this week. However, an important judgement was released by the European Court of Justice (ECJ) on April 21st, regarding two SPC related cases referred to them (C-207/03 and C-252/03). These involved whether Swiss Marketing Authorisations (MAs) should be treated as the first Community approval for purposes of determining the duration of an SPC, in cases where the Swiss Authorisation is earlier

than other European approvals. In such cases the UK PTO and the Luxembourg Minister for the Economy had taken the view that because a Swiss authorisation counts as an approval in Liechtenstein, a Swiss authorisation should be considered as the first community authorisation.

The ECJ agreed with the UK and Luxembourg authorities and the Advocate General's opinion, as expressed in September 2004 (see *Current Patents Gazette 0446* published November 12, 2004). In short, where a Swiss MA is the earliest approval, this should be taken as the first Community approval for purposes of calculating the SPC duration. Interestingly, the ECJ side-stepped a second question posed by the UKPTO, which was whether a "competent authority within the EEA" was obliged to rectify any existing SPCs, the duration of which had been erroneously calculated. The ECJ did not answer the question on the grounds that because the UKPTO had correctly interpreted the rules, there was no need for them to reply to the question. This means that there is no ruling as to whether patent offices in the EEA which did not previously accept a Swiss MA as a first authorisation would be obliged to recalculate the dates of SPCs currently granted. (The Advocate General had previously given the opinion that they would be obliged to recalculate the duration of existing SPCs.)

The result of this decision means that the for case C-207/03 the SPC for **basiliximab** expires April 6, 2013 rather than October 8 2013 and the SPC for the **artemether / lumefantrine** combination expires January 21, 2014 respectively rather than November 29, 2014 as requested by **Novartis** and their partners.

In case C-252/03 the drug in question was **Millenium Pharma's eptifibatid** for which the Swiss authorisation was February 27, 1997 compared to July 1, 1999 for the first "community" authorisation and so should expire February 26, 2012 rather than June 30, 2014. Interestingly, in this latter case a UK SPC has been granted based on the EU marketing authorisation, rather than the earlier Swiss one and so highlights the need for an answer to the 2nd question in the linked case, which the ECJ declined to answer. It will be interesting to see if the UKPTO recalculates the expiry of this SPC based on EP477295 or whether it is referred back to the ECJ for a further judgment on the unanswered question.



Incyte discloses novel 3-Oxo-thiazolidine derivatives the first small molecules to emerge from a new PTP1B inhibitor program.

UK initial ("A0") applications filed March 12th - 18th 2005

The Health Protection Agency (HPA) and **Allergan** have jointly filed on re-targeted conjugates. The HPA was formed on 1st April 2003 from various component parts of the UK healthcare system including the Centre for Applied Microbiology & Research (CAMR). CAMR and Allergan are investigating CAMR's novel neurotoxin-based technology for the potential treatment of acute and chronic pain conditions. CAMR's technology arose from its research into the neurotoxins produced by *Clostridium botulinum*: the binding portion of the neurotoxin is removed and ligands are attached that target peripheral nerves. The DOLPHIN database of all pharmaceutical inventions holds two patents assigned to CAMR naming Allergan as a licensee.

Insense Ltd has submitted an A0 application on improvements relating to skin dressings. Insense Ltd is a spin-out from Unilever and was founded by Professor Paul Davis. It is located on the Colworth Science Park at Sharnbrook in Bedfordshire and holds 6 PCT applications. The company is concentrating on its wound-healing technology platform. Its innovative wound dressings incorporate active biochemistry in such a way that they transport oxygen into the wound environment. "Oxyzyme" the first product to be developed from this platform, is a sophisticated dressing that produces low-dose iodine and hydrogen peroxide when exposed to oxygen.

Intercytex Ltd an emerging healthcare company developing cell therapy products for the woundcare and aesthetic medicine markets, has submitted two applications on a skin equivalent culture and skin composition treatment. Intercytex's lead product is ICX-PRO, which is designed to actively stimulate repair in chronic wounds and has completed Phase IIb trials with Phase III trials planned for the first half of 2005. Intercytex commenced operations in 2000 and has raised over £19 million in three private equity-funding rounds. It has over 50 employees and is headquartered in Cambridge, UK with GMP clinical production facilities and research located in Manchester, UK and additional research laboratories in Boston, MA. Intercytex's founder Paul Kemp is named on several patents related to various regenerative medical therapeutics including the wound repair stimulant Apligraf® (an Organogenesis product).

Isogenica Ltd has filed an application on a method for stable ligand selection. Isogenica was launched in December 2000, and is applying molecular evolution technologies to accelerate and rationalize the drug discovery process. Isogenica aims to initiate a number of its own discovery programs the first of which would be in the field of antibacterial peptides. The company's core technology, CIS display, can be applied to the discovery of new antibody, peptide and polypeptide drug candidates. In May 2004 Isogenica announced that it had entered into a research collaboration with AstraZeneca. The collaboration will assess the utility of Isogenica's CIS display technology for the discovery of biologically active polypeptides that are specific for targets provided by AstraZeneca. DOLPHIN holds one PCT application for the company (WO 2004022746), which disclosed an *in vitro* peptide expression library.

Oxagen has submitted an A0 application entitled compounds with PGD2 antagonist activity. Oxagen Ltd was formed in April 1997 as a spin-out genomics company from the Wellcome Trust Centre for Human Genetics. Oxagen was initially focused on GPCR targets. However, by January 2003, Oxagen had become a biopharmaceutical company with a full drug pipeline for treatment of metabolic diseases, such as type II diabetes, osteoporosis and endometriosis, and inflammatory diseases, such as rheumatoid arthritis, inflammatory bowel disease, psoriasis and asthma. In September 2004, Current Patents Gazette reported two A0 initial applications were filed by Oxagen based on research in collaboration with Incyte, California. The inventions disclosed methods for identifying novel matrix metalloproteinases (MMP2) as prognostic and diagnostic markers for disease treatment.

Domantis was launched in 2000 by Sir Gregory Winter and Dr Ian Tomlinson from the UK Medical Research Council's Laboratory of Molecular Biology (MRC-LMB). The company has filed for antibodies. The Investigational Drugs database reports that Domantis is collaborating with Argenta and Peptech to develop small-molecule, fully human domain antibody (dAbs) therapeutics for the potential treatment of chronic obstructive pulmonary disease and inflammatory conditions respectively.

Biotica has filed two applications, describing novel compounds and the other describing the use of a compound. It focuses on developing novel polyketide pharmaceuticals through the targeted alteration of polyketide biosynthetic pathways. The majority of its portfolio is anticancer therapeutics such as mTOR inhibitors, Hsp90 inhibitors and angiogenesis inhibitors. In February 2005 Biotica and Cambridge University announced the funding of a three-year program of research into new heterologous expression systems for the production of polyketides.

Anant Sharma, Consultant Ophthalmic Surgeon and Research and Development Director at Bedford Hospital has filed two applications claiming medicament and treatment for Herpes Simplex and other infections and ophthalmic apparatus and method. This applicant has two earlier applications disclosing intraocular pressure sensor (GB2374925) and *in vivo* imaging antibodies, particularly labelled antibodies for diagnosis of ocular disease mediated by Herpes Simplex (GB2285862).

Spectrum Medical LLP has an application disclosing monitoring of predetermined substances in the blood. Spectrum Medical focuses on developing products and vaccines for the prevention and treatment of disease and identification of parameters of protective immunity to intracellular parasitic infections. Spectrum's lead project is an engineered vaccine against meningococcal meningitis in collaboration with Finland's National Public Health Institute (KTL) and an American research institute. The company's discovery research aims at developing a vaccine against *Chlamydia pneumoniae* disclosed in an earlier application (WO0003731).

The University of Nottingham has filed an application claiming methods and compositions relating to the diagnosis and treatment of progressive neurodegenerative disease. The university has an earlier application disclosing dipeptide derivatives that are transglutaminase inhibitors for treating neurodegenerative disorders. The university has won a grant of over half a million pounds from the Alzheimer's Research Trust to fund a five-year major research programme into Alzheimer's related disorders.