THOMSON

Current Patents Gazette

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Patenting in Context

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 0647

This week, the UK Patents and Designs Journal (PDJ No. 6130) reports only one SPC that entered into force covering an agricultural composition; no pharmaceutical SPC events were reported.

Rhone-Poulenc Agriculture Ltd's SPC for a combination comprising **diflufenican** and **terbuthylazine** entered into force on October 28th 2006 with the effective period of expiry published as the 10th September 2010. Based on **EP0223449**, which was originally assigned to **May & Baker Ltd**, covers the respective herbicide and fungicide as part of a combination product for use as a weed killer.

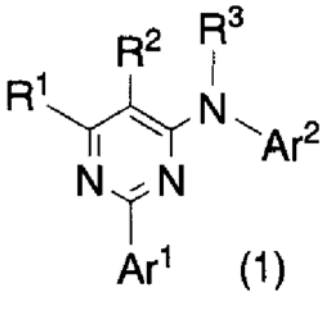
The German Patent Gazette for this week (Patentblatt 2006/47), however, contains two pharmaceutical SPC applications and four granted pharmaceutical SPCs as well as four agrochem applications. **Novartis** received the first of the granted certificates for **darifenacin** (as the **hydrobromide**) on **DE69626397**, which now expires October 22, 2019. DE69626397 is the national filing of **EP0850059** and was originally filed by **Pfizer**. However, the patents covering darifenacin were reassigned to Novartis following the merger of Pfizer and **Pharmacia**. SPC applications have now been granted in most of the designated states for this EP, although the UK application is still pending. Approved for OAB and urinary incontinence darifenacin was launched in Europe (as **Emselex**) and the US (as **Enablex**) in early 2005 and achieved sales of around $46 million. These are expected to grow significantly.

NPS Pharmaceuticals were granted an SPC for **cinacalcet**, a first-in-class calcimimetic for treatment of secondary hyperparathyroidism (sHPT), which was outlicensed to **Amgen**. According to our *Strategic Drug database* (*SDdb*) analysts, Amgen, who have developed and marketed cinacalcet as **Sensipar** (US) and **Mimpara** (EU), posted sales of $157 million for it in 2005, its first full year of launch, up from $37 million in 2004. The granted SPC on DE69533948, which is the national filing of EP1203761 also expires October 22, 2019. (The reason for this coincidence is that the EU authorisations for darifenacin and cinacalcet were both granted on October 22, 2004.)

Expiring earlier in 2019 is the granted SPC for **palifermin** (**Kepivance**) awarded to **Chiron** on DE69434053, which expires April 28, 2019. Launched in the US by **Amgen** in April 2005 and in Europe at the end of 2005 for the treatment of oral mucositis caused by chemotherapy and radiotherapy in patients with hematological malignancies, Kepivance is expected by analysts to achieve sales of around $250 million by 2010.

The biggest drug gaining SPC protection was **etanercept**, co-marketed by b (formerly **Immunex**) and **Wyeth** as **Enbrel**, which gained the full 15 years from the earliest approval in Europe. This was the Swiss/Liechtenstein approval, which occurred two days earlier than the EU approval, Consequently, the SPC on Wyeth (formerly **AHP**)'s DE59010933 expires February 1, 2015. As Enbrel achieved sales of around $3.7 billion in 2005, including around $1.1 billion non-US sales, it is perhaps fortunate for Wyeth, who has the marketing rights outside North America that the difference between Swiss and EU approvals was not greater than two days, especially as sales are predicted to grow to over $6.5 billion by 2010.

Orion Genomics has announced a notice of allowance of a key patent application covering the company's **MethylScope technology,** by the USPTO, and which Orion expects to be granted early on in 2007. The technology is a broad approach to discovering and quantifying the DNA methylation status on each and every gene in the human genome; errors in DNA methylation accumulate with age at a far greater rate than errors in the DNA sequence, it is therefore a major factor in the presence of disease such as cancer, and is a rich source of biomarkers for novel diagnostic tests. The work was authored by Orion co-founder, Rob Martienssen, Zachary Lippmann (both from **CSHL**), Eric Richards (**Washington University**) and Vincent Colot (**CNRS**); although the patent number itself was not divulged in the press release, **DOLPHIN** reports just the one application naming all four inventors, **WO2004046313** (assigned to CSHL and Washington Univ), it seems likely, therefore, to presume that the US equivalent is the subject of this pending grant. Also see WO2005040399 for associated technology (assigned to Orion Genomics).



Asahi Kasei have made their first NCE application for PDE4 inhibitors this week in WO2006123639

UK initial ("A0") applications filed October 9th - 16th 2006

Antitope Limited has a pair of new applications on file concerned with **T cell assays and epitope databases**.This follows two cases published earlier this year on the same subject, namely **WO2006056769** and **WO2006082406**. The patent portfolio on which the Cambridge-based company relies is, however, far more extensive than this, being derived from those of **Biovation** and **Merck KGaA**, with whom the company's CEO/CSO, **Matthew Baker**, was previously associated. Antitope's EpiScreen technology is used to predict drug-induced allergic reactions, and hence is used in screening potential drug candidates. **Serono**, **MedImmune** and **Elusys Therapeutics** are among the companies said to have taken up this screening technique

BioXell SpA, with more than a dozen PCT applications published already, is now seeking protection for an unspecified novel method. Despite the lack of detail in this title, it is highly likely that this latest invention is related to vitamin D in some way, since that is the theme underlying virtually all of the company's patenting to date. A notable exception is **WO2006056492**, which claims **TREM-1 protein**, and is probably implicated in the septic shock treatment licensed to **Merck & Co** in May 2005.

Fusion Antibodies Limited has filed two applications entitled assay method and antibody and its uses thereof. Fusion, established in 2001 as a spin-out from **Queen's University** Belfast, is a biotechnology company focusing on the discovery, development and commercialization of antibody-based therapeutics for cancer, as well as providing associated recombinant protein engineering services to the bioscience industry. **DOLPHIN** holds three applications with the same titles, **WO2005012568**, **WO2006109045** and **WO2006117538**.

Karo Bio AB is seeking protection for a application claiming novel **estrogen receptor ligands**. Previous work on estrogen receptor modulators by the company includes **US20050202440** (naming the **University of California** as co-Applicant), **WO2004037792**, **WO2004037792** and **WO0001716**. At the Neuroscience meeting held in Atlanta, USA in October 2006, Karo Bio presented new research indicating that its estrogen receptor-? agonists have antidepressant effects in a number of animal models, with the agonists able to increase the serotonergic tone in the brain.

KU Leuven Research & Development is seeking protection for two applications, entitled mRNA quantification and the other claiming an intensive care unit system. This appears to be the company's first application in the area of mRNA analysis, and previous work on diagnostics has included **WO0170798**, claiming the novel gene nuclear spindle-associating protein (NuSAP) for use in diagnostics.

Mario Iobbi has this week filed his third application, claiming a regulated drug delivery system. His previous applications claimed a device and method for automatically regulating supplemental oxygen flow-rate (**WO2006110812**) and a minimally invasive heart valve with cusp positioners (**EP1603493**). Iobbi is associated with the Center for Biomedical Engineering at the **University of California at Irvine**, and has recently been involved in modelling reaching impairment after stroke using a population vector model of movement control that incorporates neural firing-rate variability.

Mologic Ltd has filed its first application, claiming nitric oxide and related metabolic diagnostic. This diagnostic company, previously known as **Kelbank Limited**, was registered as Mologic in June 2003. Based in Colworth Science Park, alongside the large **Unilever R&D** establishment, the company is mainly focussed on wound diagnostics and contract R&D in the areas of diagnostic device design and antibody development.

Reckitt Benckiser (UK) Limited/Reckitt Benckiser N.V. has filed an application vaguely titled "compositions". The company's recent applications relate to topical compositions having primarily antimicrobial properties but also skin-cleansing properties. Prior to this most of their recent filing relate to insecticide or surface cleaning compositions.

Due for publication in April 2008