

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 0649

As previously reported in the *Current Patents Gazette* issue 0646 the PDJ has now published the SPC application for a live attenuated varicella-zoster virus (VZV), particularly the Oka strain made by Merck & Co. Based on **EP651789**, the SPC covers **Varivax**, which was disclosed as a product by granted **EP261634**. Merck & Co in collaboration with **Aventis Pasteur MSD** (now sanofi-aventis) have co-developed and launched Varivax for the treatment of chickenpox using the Oka strain of the varicella virus licensed from the **Biken Institute at Osaka University** in Japan. Whilst the product has been launched to treat paediatric VZV it only entered registration in the US for adult VZV in May 2006. **CSL Ltd** market Varivax in Australia. The *Strategic Drugs Database (SDdb)* anticipates sales of Varivax to continue to rise until at least 2010. If granted this SPC should afford further protection until July 2018.

Prior to publication in the PDJ, we can report that two new SPC applications have been filed at the UK Patent Office. The first SPC application by **Pfizer**, covers **cefovecin**, (**Convenia**) a third generation cephalosporin antibiotic used in veterinary medicine for the treatment of skin, soft-tissue and urinary-tract infections. The SPC, on **EP540609**, which was originally filed by **SmithKline Beecham** and re-assigned to Pfizer in 1997, will expire around July 22, 2016 if granted.

The second SPC application was filed by the **Southern Research Institute** and covers **clofarabine**, a purine nucleoside antimetabolite now developed and launched as **Clolar**, **Clofarex** or **Evoltra** by **Genzyme Corp** in the US and Canada and by **Bioenvision Inc.** in Europe. Available as an injectable solution for iv infusion, clofarabine is indicated in the US for the treatment of pediatric patients aged 1 to 21 years with relapsed or refractory acute lymphoblastic

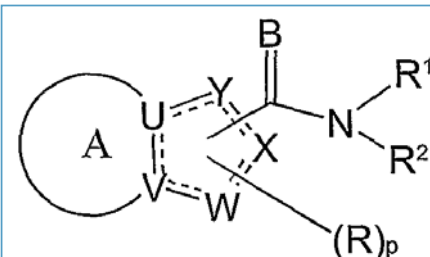
leukemia (ALL) after at least two prior regimens and is also being developed for the potential treatment of acute myelogenous leukemia (AML) and B-cell lymphoma. Under an August 1998 deal, the Southern Research Institute granted Bioenvision worldwide rights, excluding Japan and South East Asia (which were acquired later), to develop and commercialize clofarabine. Bioenvision subsequently sold the exclusive rights for the US and Canada to **ILEX** who were acquired by Genzyme in December 2004. Our Strategic Drugs Database (*SDdb*) analysts, expect sales of clofarabine to grow to around \$168 million by 2010. If granted the SPC application on **EP473708**, should expire May 22, 2015.

The Japanese Patent Gazette for November, which we received this week, contained no new granted patent extensions although new applications were reported for one veterinary and three human drugs and consisted of 18 applications on 13 patents. **Tulane** (US) and **Zentaris GmbH** each have one extension application covering **cetorelix acetate**. **Takeda** have 10 applications on 7 patents covering **lansoprazole** used in the treatment of unerosive gastroesophageal regurgitation, mostly of three years nine months and 10 days. **Novartis** have four extension applications requesting a five year extension on two patents, JP2653958 and JP07025690, for **cyclosporine**. Cyclosporine is marketed as **Neoral** and **Sandimmun**, Neoral being an improved formulation of Sandimmun with sales of around \$950 million in 2005. The veterinary application by **Astellas Pharma** requests just over four years extension for the **Profender** spot-on formulation of **emodepside** and **praziquantel**.

In the light of last weeks discontinuation by **Pfizer** of the development of **torcetrapib**, including the combination with **atorvastatin**, the timing of this week's publication of **WO2006129167** by Pfizer for a solid

amorphous dispersion of the two is rather interesting.

Chroma Therapeutics Ltd filed a UK initial ("A0") patent application this week, seeking protection for eight enzyme inhibitor applications this week: **Mek**, **PDE-4**, **PI3 kinase**, **c-Met** and four applications claiming Plk inhibitors. These continue a series of applications from Chroma, eg **WO2006123121** and **WO2006117548** (HDAC inhibitors), **WO2006117570** (aurora kinase inhibitors) and **WO2006117567** (eg HDAC, aurora kinase, DHFR, PI3 and p38 MAPK inhibitors). As of December 2006, Chroma's drug development pipeline includes CHR-3520 (multi kinase inhibitor in the preclinical phase), CHR-4432 (PI3 kinase inhibitor) and CHR-3620 (p38 MAPK inhibitor), both for targeted local inflammation and both about to enter the preclinical phase.



Glenmark made their first NCE application for cannabinoid receptor ligands this week, see WO2006129178

UK initial ("A0") applications filed October 23rd - 31st 2006

Advanced Biomedical Ltd has filed an application entitled solid liposomes:solidification and stabilisation of water/oil structures. This may be related to **WO9938009**, claiming detection of analytes using liposomes and signal modification, utilising technology licensed from the UK Ministry of Defence. Advanced Biomedical specialises in manufacturing and designing liposomes for customer end use.

The Cambridge-based biotech company **Antitope Ltd**, founded in 2004 and focused on the pharmaceutical industry, has filed what appears to be its first application, claiming Tcell assays. Antitope specializes in immunogenicity testing and protein engineering, particularly with therapeutic monoclonal antibodies. Current areas of importance for Antitope include its **EpiScreen™** and Composite Human Antibodies technologies to develop novel anticancer agents with broad-range solid tumor specificity; also as a complement to its ex vivo EpiScreen™ technology, Antitope is developing a novel technology to predict immunogenicity using transgenic mice bearing critical human genes for accurate prediction of human immune responses.

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Domantis Limited is claiming novel polypeptides and uses thereof. The company is focused on developing human Domain Antibodies (dAb) for treating disorders including inflammation (eg asthma, Crohn's Disease) cancer (eg haematological and solid tumors) and autoimmune diseases (eg rheumatoid arthritis). In 2003 Domantis in-licensed, from the **Medical Research Council**, a novel polymerase technology, to accelerate the search for therapeutic polypeptides including dAbs, and allow the development of better diagnostics and research reagents. The company is focused on developing human. **DOLPHIN** holds a series of applications from the company disclosing direct and matrix screening methods.

Fermentas UAB, a biotechnology company dating back to 1975 and located in Vilnius (Lithuania) has filed an application for the use of DNA polymerases. The company is engaged in the manufacture of high quality molecular biologicals and providing services to the international research community. Taq DNA polymerase and Pfu DNA Polymerase (recombinant) are in its product list, which only can be used for research purposes; patents owned by **Roche** protect these products.

Genomica SA is seeking protection for an assay and kit for the identification of *legionella* in a sample. The company a molecular diagnostics leader in Spain, was founded in 1990 and 100% owned by **Zeltia**. The company established a strategic alliance with the German company **Clondiag** and plans to extend its activities in the area of molecular diagnostics in Europe by means of the design, development and commercialization of new diagnostic applications with our innovating in vitro diagnosis platform, **Clinical Arrays®**. **Genomica** is developing systems to detect therapeutic activity, with the aim to identifying compounds for the treatment of Obesity, Diabetes, and Arteriosclerosis, together forming the ODA project. **DOLPHIN** database holds several applications from the company.

NuPharm Laboratories Limited is seeking protection for spray formulations of both **clobetasol** and **betamethasone**. The only other application filed by this Deeside company relates to a foam formulation of **minoxidil**, now published as **US20050079139**, a case apparently not yet formally assigned to the company in the US even though its UK and Canadian equivalents are.

Owman Investment Limited, since patenting the **heptahelix receptor** in 1997, has been transformed into **Heptahelix AB**, which has now filed an initial UK application entitled simply "Compounds". Given the specialism of the firm's founder, **Professor Christer Owman** of **Lund University**, these molecules are likely to be active at a receptor from the leukotriene-like (**LTXR**) or fatty acid cell-surface (**FFAR**) families, both types of heptahelix.

Oxitec Limited has filed an application simply entitled "expression system". Oxitec is an ISIS innovations spinout based on technology developed by molecular biologist **Dr Luke Alphey** and colleagues at **Oxford University's Department of Zoology**; Dr Alphey appears as a key inventor on many of the applications reported in **DOLPHIN** as assigned to Oxitec. The company's main focus appears to be agricultural and predominantly pesticides; however, its most recent application on a mathematical model useful for controlling parasitic infections, has a particular slant towards the protozoan *Plasmodium falciparum* the key culprit responsible for **malaria** see **WO2005042751**. Also see **WO2005012534** for similarly entitled "insect gene expression systems....", which this application may relate to.

Pastel Biosciences Limited has lodged an application pertaining polypeptides and libraries comprising them. This would appear to be the first application to emerge from Pastel BioSci, which was founded in September 2002. CEO of the company **Dr. Stephen Osborne** developed the **Epimer technology** that enables the extremely rapid selection of capture molecules having high affinity and specificity for target proteins and polypeptides. Dr Osborne appears to have been named on one prior application on **HCV peptides** assigned to **SORIN BIOMEDICA DIAGNOSTICS**. Pastel Biosci operates from laboratories within the **Centre for Biomolecular Design and Drug Development at the University of Sussex, Brighton**.

Due for publication in early May 2008