

# 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 0638

The PDJ this week (No.6122) reports that **Novo Nordisk's** SPC for **insulin aspart (NovoLog®; NovoRapid®)** entered into force on 29 August 2006. Based on **EP214826**, the SPC is due to expire on 28th August 2011. Insulin aspart, a rapid, short-acting human insulin analog was developed and launched by Novo Nordisk for the treatment of both type 1 and type 2 diabetes. The company retains exclusive rights in most markets worldwide with sales of the drug totalling \$1121 million in 2005. An SPC has also been granted in the UK for the NovoMix formulation of insulin aspart, **NovoMix® 30** (insulin aspart + protamine). The SPC, based on **EP705275**, is due to expire in June 2015. Novo Nordisk filed for two further SPCs, based on EP705275, relating to suspensions comprising soluble insulin aspart and protamine in a 70/30 ratio (**NovoMix® 70**) or 50/50 ratio (**NovoMix® 50**).

The PDJ also reports that **E R Squibb & Sons Inc** (now **BMS**) has filed an SPC for **entecavir (Baraclude®)**, a viral replication inhibitor, developed and launched by BMS for the treatment of chronic hepatitis B virus (HBV) infection. As we reported three weeks ago (*Current Patents Gazette 0635*), the filing is based on **EP481754** and if granted, is expected to expire in October 2016. Sales of entecavir reported by Bristol-Myers Squibb (BMS) for 2005 were \$12.0 million and according to our Strategic Drugs Database (*SDdb*), its market share with respect to the HBV franchise is predicted to increase from around 2% (2005) to approximately 26% in 2008.

An SPC has been filed by **E.I. du Pont de Nemours and Co** for plant protection products comprising **proquinazid**. The SPC is

based on **EP698013**, disclosing fungicidal fused bicyclic pyrimidinones, and if granted is estimated to expire in May 2019.

A defining moment in **Altana's** history: In September 2006, Altana announced its plans to sell **Altana Pharma AG** to **Nycomed**, to focus on its specialty chemicals business **ALTANA Chemie**. The transfer, planned for January 1, 2007, is pending approval by the competent antitrust authorities in the EU and the US.

This merger is likely to expand upon Nycomed's R&D efforts, particularly in the gastrointestinal and respiratory fields and according to the Danish company's CEO, Dr. Håkan Björklund, will also provide a leadership position in its EU home markets and create a strong platform in some of the world's fastest growing pharmaceutical markets, including Russia-CIS and South America.

Altana Pharma AG has several key candidates that may form part of the acquisition agreement along with the associated intellectual property. Should Nycomed acquire **Alvesco (ciclesonide)** claimed in **US05482934** it would raise the question: will Nycomed seek to continue the collaboration with **sanofi-aventis** to utilize its **ultrahaler device technology** in the development of a dry powder inhaler (DPI) formulation of ciclesonide? Another candidate of note is **pantoprazole** claimed in **EP00166287** (see **ThomsonPharma**). Interestingly Nycomed, which will now take ownership of this H<sup>+</sup>/K<sup>+</sup> ATPase inhibitor, was one of 12 companies with a distribution license for this product, for which the US equivalent **US4758579** is listed in the FDA orange book and for which a term

extension has been granted for pantoprazole (marketed as **Somac**) on the AU equivalent, now due to expire in Jan 2010. Altana's Phase III PDE4 inhibitor, **rofumilast**, presumably is also part of the agreement and although this will not affect the collaboration with **Pfizer**, which returned all rights to the candidate in July 2005, this may have consequences for the current licensing agreement with **Tanabe Seiyaku Co Ltd**. Most recently Altana advanced its HDAC inhibitor, **Byk-357666**, into preclinical testing in September 2006; this is likely to be covered by **WO2005087724**, Altana's only published application pertaining **HDAC**, to date.



**First patenting to emerge on Hdm2 inhibitors; the named assignee, Lutz Weber, is the executive director of NexusPharma.**

## UK initial ("A0") applications filed August 8th - 15th 2006

**Ardana Bioscience Ltd** and the **Medical Research Council (MRC)** have filed a joint application entitled agents, methods and uses. Previous collaborations include **WO2005044298** (use of a tolerising cell and a prostaglandin to increase cAMP levels in the treatment of degenerative diseases) and **WO02092064** (use of PDE<sub>4</sub> inhibitors and 19-hydroxy PGE derivatives for inducing cervical ripening). Since inception in July 2000, **Ardana** has held exclusive rights to commercialise research by the **MRC's** Human Reproductive Sciences Unit (HRSU) in Edinburgh. This arrangement gives **Ardana** the right to assess and obtain a license or assignment of all existing unencumbered IP and unencumbered patent applications emerging from HRSU research.

**B&A for Scientific Research Ltd** is seeking protection for two applications relating to herbal compositions. Little information is available relating to the company, and this appears to be its first application. The company may be connected with Gothenburg-based **B&A Exportrade AB**, which exports the Body Cure range of products offering ecological products made from organic barley grass juice and cold-pressed rapeseed oil.

**Bernard M Turner** has filed an application on chemotherapy of viruses. This follows a series of initial filings over the past year from this inventor disclosing agents to treat HIV-1 and cancer; however this inventor does not appear to have any published applications.

**Biotechgen Ltd** has an application entitled modification of enzymatic action for the treatment of microbes or diseases. This also appears to be the first application from the Oxford-based biotech company, incorporated in 2000 and developing IP in the area of cancer diagnostics and therapeutics. Its drug development program appears to concentrate on inhibitors of angiogenesis.

**Cambridge University Technical Services Ltd** and **Massachusetts Institute of Technology** have filed what appears to be their first joint application, entitled biomaterial. This may relate to current joint projects creating novel implant materials and tissue scaffolds with enhanced lifetimes or effectiveness. One project is looking at bone substitute materials with a focus on substituted calcium phosphates, advanced biocomposites and bone mineralization and apposition to biomaterials, while the other is researching tissue engineering, focussing on novel scaffolds, cell incorporation into scaffolds, cell-substrate mechanical interactions and functional tissue replacements using primary cells or stem cells.

**ChemBiotech** is seeking protection for an application entitled nanoparticle nucleic acid binding compound conjugates forming I-motifs. This appears to be the first application from the Birmingham-based scientific consultancy company, which has close research links with the **University of Birmingham**. Professor **John F. Kennedy**, the founder and Managing Director of **ChemBiotech**, is a leading researcher at the **University of Birmingham** and is also Professor of Applied Chemistry at the **North East Wales Institute**, specializing in the fields of carbohydrate and protein chemistry and biotechnology.

**Coressence Ltd** has filed an application relating to a prebiotic composition. **Coressence** is a fairly new company, having been incorporated in May 2005, and confusions exist as to their location. Their website is currently under development, and lists their address as Pontesbury in Shropshire; however Companies House lists it as Bristol. Research indicates that **Coressence** may currently be researching the production of "green electricity", from pure alcohol derived from apples and other sugar-producing crops.

The **Desiré Collen Research Foundation** is seeking protection for a novel therapy for immune disorders. This may be related to **WO2005032572**, which claims the use of plasmin modulators for enhancing or inhibiting the recruitment of bone marrow stem and/or progenitor cells.

**University of Southampton** has filed an initial application on a novel peptide for the treatment of asthma. This may be related to the University's discovery of ADAM33 gene in collaboration with **Schering-Plough**, which has a close relationship to the way that airways in the lungs respond to environmental stimuli and its link to asthma. The University's asthma project hopes to identify new treatments to prevent the disease rather than 'damping down the inflammatory response'. See **WO2006030241** from the University claiming use of a growth factor selected from epidermal growth factor and a keratinocyte growth factor, for the prevention and treatment of asthma.

**K U Leuven R&D**, the spin out from the **University of Leuven** has filed an application for novel formulations to treat skin disorders. The company only has three previous applications relating to dermatological conditions including **WO2005113571** relating to compositions comprising oligonucleotides for the treatment of psoriasis.

Due for publication in February 2008