

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 0629

The UK Patents and Designs Journal this week (No. 6113) reports the entry into force in June 2006 of an SPC granted to **Novo Nordisk** for **tiagabine**. The SPC is based on EP236342 and will expire 13th June 2011, calculated from the French marketing approval. Novo Nordisk developed tiagabine, a GABA reuptake inhibitor, as a treatment for severe epilepsy and in 1990, licensed the drug to **Abbott Laboratories** for development in the US, Canada and Mexico and later Latin America. Novo Nordisk licensed its worldwide rights, excluding the US and Japan, to **Sanofi** in 1997 and in November 2000, Abbott followed suit by licensing its US rights to **Cephalon**, to investigate tiagabine for further indications. Cephalon subsequently initiated phase II trials of tiagabine for the potential treatment of neuropathic pain, generalized anxiety disorder (GAD) and insomnia after acquiring rights to the drug (excluding Canada, Latin America and Japan) from Sanofi in January 2002. Cephalon reported 2005 revenue of \$1.2 billion, a 19% increase over 2004. SPCs have also been granted for tiagabine based on EP236342 in a number of other European countries due to expire June 2011 and equivalent US5010090 has also been granted an extension of 1255 days, set to expire 30 September 2011.

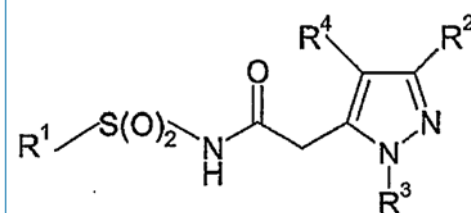
Forest Laboratories and **H.Lundbeck** have filed suit against **Caraco Pharmaceuticals** over **Lexapro** (escitalopram). Lexapro, an S-enantiomer of citalopram is indicated for the treatment of major depressive disorder and panic disorder. Forest Laboratories obtained US licensing rights to escitalopram in March 1998, and by March 2006 Forest filed suit against Teva for infringing the US reissue patent, RE34712. Forest won the suit this month, as a federal judge ruled that the reissue patent, covering the active ingredient in Lexapro is valid, enforceable and infringed by proposed generic competition. Invalidating Lexapro's

patent would have allowed **Ivax** and **Cipla** to sell a generic version of the drug. Analysts commented that had the ruling gone in favor of Teva it would have been "devastating" for Forest as escitalopram represents nearly 70% of the company's 2006 revenue.

Janssen, Ortho-McNeil Neurologics and **Synaptech** have filed suit against **Barr Pharmaceuticals** in relation to patent protection for the drug **Razadyne**, an extended release capsule formulation of the acetylcholinesterase inhibitor **galantamine**. Shire and Janssen acquired worldwide rights to the drug and licensed rights to the use of galantamine in Alzheimer's disease under patents held by Synaptec. In February 2005, Barr filed an ANDA containing a Paragraph IV certification with the FDA for Razadyne. Barr then notified Janssen, the NDA holder, and patent owner Synaptech, of its challenge to Razadyne patents.

On Jul 12, 2006 **Critical Therapeutics, Inc** (CTI) announced that **US20030113323**, the equivalent of **WO00047104**, which is reported in **ThomsonPharma**, was granted as **US7060504**. The patent relates to "antagonists of HMG1 for treating inflammatory conditions" and covers a method of measuring the concentration of the protein High Mobility Group Box 1 (HMGB1) using an antibody (Ab) in the diagnosis of several inflammatory conditions, including arthritis and lupus. The PCT application (**WO00047104**) was originally assigned to **Picower Institute for Medical Research**; however, in August 2001 the EPO received notification that this application was to become part of **North Shore-Long Island Jewish Health System's** patent portfolio, who also appear as the assignee for the granted US7060504. CTI, claimed rights to three granted US equivalents to WO00047104 in a December 2002 press release; conversely,

EPOline does not report a change in ownership to CTI. CTI is collaborating with **MedImmune** regarding **HMGB1 antagonists** with potential in rheumatoid arthritis and sepsis therapy, likely to have been screened using the diagnostic technique disclosed in US20030113323. In December 2005, CTI developed fully human monoclonal Ab that protected against RA and sepsis in preclinical models. At that time, the company expected identify a clinical candidate Ab in 2006, which would be followed by additional preclinical studies to support the submission of an IND application. In February 2006, preclinical data exploring the program's anti-inflammatory activity and synergy with TLR ligands were presented at the European Molecular Biology Organization Workshop, "Innate Danger Signals and HMGB1," in Milan, Italy.



AstraZeneca claim endothelin converting enzyme 1 (ECE1) inhibitors, the first NCEs from this program for the treatment of COPD

UK initial ("A0") applications filed June 7th - June 13th 2006

A.M El-Tawil, seemingly based at the City Hospital in Birmingham has filed an application on a novel treatment for inflammatory bowel diseases. He has written several papers relating to inflammatory bowel diseases including 'Zinc deficiency in men with Crohn's disease may contribute to poor sperm function and male infertility' which appeared in *Andrologia* and 'High incidence of Crohn's disease in pre-menopausal women: *Escherichia coli* may be contributing' which appeared in the *International Journal of Colorectal Disease*. He appears new to patenting.

Cambridge Consultants Ltd has filed two applications relating to dry powder inhalers (DPI) this week, continuing on from WO2006061637 published on 15th June 2006, having the same title. In April 2006, the company presented their new generation DPI, **NEXT**, for improving the treatment of asthma and chronic obstructive pulmonary disease. Designed in conjunction with **Chiesi Farmaceutici**, the NEXT DPI is a medium resistance, breath-activated device holding up to 120 doses, consistently achieving 60% fine particle fraction and having successfully completed pharmacokinetic clinical studies.

Daniolabs, the Cambridge based biotech company, has filed a string of applications relating to treatments, which reduce sebum (an oily based substance excreted from the sebaceous gland) production and excretion. This appears to be a new area of interest for Daniolabs.

Evolutec lodged an application relating to a histamine binding protein. Evolutec are currently developing rEV-131 (EV-131), a recombinant histamine-binding protein derived from the saliva of ticks, for the potential intranasal treatment of allergic rhinitis. rEV-131 is currently undergoing phase II trials. Evolutec are also developing rEV-598, a novel histamine and serotonin binding protein at the preclinical development stage.

Kaizen Matsumoto made four GB applications this week for solvents for the removal of carcinogens and pharmaceutical agents from systemic circulation. This London based inventor has previously made two GB applications for solvents for carcinogen extraction, WO2006059063 (currently under Ex Parte review) and GB2379608.

NovaBiotics Ltd has filed on compounds and their uses. This Aberdeen based biotech company only has one published patent application to their name, WO2006018652, claiming antimicrobial peptides and peptide variants, useful for treating onychomycosis and mucosal infections. The company, founded in 2004 by Dr Deborah O'Neil, hopes to be trading on AIM by the end of this year.

Optinose AS has submitted an application on intranasal administration. In February 2005, OptiNose and **MedPharm Ltd** formed a collaborative agreement to develop intranasal sedatives. MedPharm would use its expertise in formulating poorly soluble drugs and OptiNose would combine the drug with its bidirectional nasal delivery technology.

Oxford Genome Sciences (UK) Ltd (OGeS), a virtual beginner in the world of patenting has filed on proteins. Currently, the company has signed a number of collaborations in the area of colorectal cancer. OGeS and **Medarex Inc.** have formed a strategic collaboration to discover and develop new human antibody therapeutics for the treatment of cancers. OGeS is also collaborating with **Biosite Inc.** in the evaluation of protein-based disease markers for colorectal cancer and the **Oxford University-GE Healthcare consortium** to develop a range of novel molecular tools that will allow earlier detection of colorectal cancer.

Plethora Solutions, established in 2005 and based in central London, UK, specializes in the treatment and management of urological disorders. The company has filed on a composition following the theme set by WO0247676, which claimed a topical formulation of phenylephrine, their PSD-503 drug candidate.

Among the more explicit titles on initial UK patent applications filed during the second week of June is "Plasmid RK2-based broad-host-range cloning vector useful for transfer of metagenomic libraries to a variety of bacterial species." This case was filed by **Sinvent AS**, a wholly-owned subsidiary of **SINTEF Holding**, based in **Trondheim**. Though the SINTEF group as a whole has diverse interests, there are already more than a dozen patents and applications published relating to biomedical topics, including for example WO0159126 in which novel genes encoding a nystatin polyketide synthase are claimed. That application was filed jointly with **Alpharma** and the **NTNU** technology transfer agency. The present work is probably from scientists at the **Gemini Center for Microbiology**, associated with **St Olav's Hospital** and the **University of Trondheim**.

Syntopix Group plc is a relatively new drug development company (spun-out from University of Leeds in 2003) focusing on prescription and OTC products for the treatment of common inflammatory skin conditions. Syntopix appears new to patenting and are developing new topical therapeutics for the treatment of skin diseases, particularly acne and MRSA infections. This year the company was awarded with the 'Young Company of the Year Award' at the 3rd annual Yorkshire Bioscience Awards in Leeds.

The Queens University of Belfast has submitted an application helpfully entitled FKBP-L: a novel inhibitor of angiogenesis. This research may be part of that undertaken by Dr T Robson in the School of Pharmacy, who recently gave a presentation on the "Characterisation of a novel HSP90 interacting protein, FKBP-L/DIR1; implications for pathways controlling cell growth and survival" at the IACR & ISMO Joint Cancer Research Meeting, Ireland.

Due for publication in mid-December 2007