

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 0637

There are no SPC events reported in the UK PDJ (No. 6121) this week. However we have recently received the Japanese Gazette for August, which contained details of eighteen granted extensions on nine patents covering six pharmaceutical products.

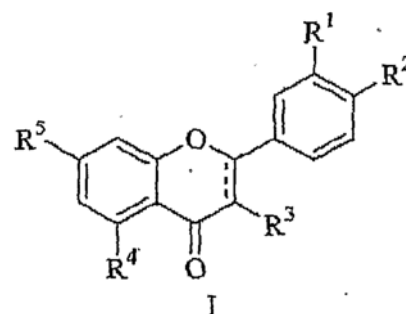
Six extensions covered **AstraZeneca's Crestor (rosuvastatin calcium)** product which was developed under license from **Shionogi**, who retained the commercial rights for Japan. Shionogi received three extensions of five years for the use of rosuvastatin calcium in treating hypercholesterolemia and familial hypercholesterolemia on JP2648897 which now expires May 2017. AstraZeneca also received three extensions for the same use, of three years seven days, on JP3267960 which expire August 2023. Originally, both sets of three extension applications specified Crestor 10mg, 5mg and 2.5mg tablets respectively, although this is not mentioned in the grant entries in the gazette. Crestor continues to gain market share as worldwide sales, which were over US\$1.34 billion in 2005, increase rapidly. Whilst some analysts believe that AZs aim of achieving a 20% market share is unrealistic, according to our Strategic Drugs database (*SDdb*), they still believe a market share of over 13% (over US\$3.5 billion) is possible by 2008. This is partly due to a strong year on year performance in the USA and other markets and partly due to dissipating safety concerns together with strong growth in new prescriptions and in the overall statin market. In addition, the potential for an increased role for potent statins in reducing arterial inflammation has led analysts to raise their long-term Japanese sales estimates for Crestor.

Actemra (tocilizumab) launched in Japan for the treatment of Castleman's disease by Chugai, together with parent company **Roche**, also received six extensions. Chugai

received two extensions of two years five months and four days on JP3370324 (which now expires September 2014) for tocilizumab and its use. **Prof. Tadamitsu Kishimoto** also received two extensions of almost five years on each of JP2865300 (which will now expire December 2013) and JP2998976 (which will expire June 2015) for the product and its use. As reported in our Dolphin database, Prof Kishimoto of **Osaka University**, has been cited as inventor on several of Chugai's patents relating to IL-6 monoclonal antibodies and is currently visiting Professor at the Osaka University Graduate School of Frontier Biosciences' Collaborative Institute between the Laboratory of Immune Regulation and Chugai. In the press release advertising the launch of Actemra, Chugai stated that tocilizumab was a co-development of Osaka University and Chugai. Approval for Actemra is also being sought in the US for this indication, whilst trials are underway worldwide for use of tocilizumab in treating rheumatoid arthritis (RA), Crohn's disease (CD) and other IL-6 related disorders.

Novartis were granted two five year extensions for **letrozole** and its use in treating post-menopausal breast cancer on JP2018112 which will now expire March 2012. Marketed as **Femara**, letrozole is comarketed by **Chugai** in Japan and achieved worldwide sales of over US\$ 500 million in 2005. *SDdb* reports that 2005 sales benefited from increased penetration of the extended adjuvant setting after five years of tamoxifen therapy, whilst future sales of the product would likely be boosted by the December 2005 US approval for use as an initial treatment immediately after surgery in patients with hormone-sensitive early breast cancer (adjuvant setting). This made it the only medicine in its class approved in the US for use as an initial therapy as well as after five years of tamoxifen therapy. **The University of Tulane Medical School**

received two extension of just over 3½ years on JP3179489 for **pralmorelin hydrochloride (KP-102)** and its use in treating growth hormone hyposecretion. This extends the life of the patent to February 2016. In 1992 **Kaken Pharmaceutical**, who had received an exclusive license from Tulane had granted a license to **Wyeth** to codevelop the product in North America. The product, released in Japan in February 2005, had been undergoing phase II trials in the US for the treatment of GH deficiency with Wyeth; however, it appears that Wyeth has discontinued development and Kaken were reported to be seeking other partners.



Neuprotech's first application pertains flavonoid antioxidants; the Australian company is a spinout of the Univ of Melbourne and the Howard Florey Institute.

UK initial ("A0") applications filed August 2nd - 7th 2006

Advanced Protein Systems Limited is seeking protection for gels used in wound management, having previously claimed a protein polymer wound dressing in **WO2005079877**. This seems at first to represent a departure from the company's previous exclusive focus on colostrum products as food supplements. However, it becomes apparent that the latter topic is associated with **APS LLC of Arizona**, whereas the present invention emanates from **APS Limited of Cambridge UK**, probably based on work carried out at **BioCity Nottingham**. Unwisely perhaps, the UK-based company adopted this potentially confusing APS name relatively recently, having previously operated as **BioTranSys Ltd** and **BioVectors Ltd**, in the field of polymer-based drug delivery technology. APS Ltd uses the name **Albigel** for its wound healing product, which is being developed in collaboration with Brightwake. The company's IP rights probably extend to cases filed from the mid-1990s onwards in names that include **Andaris Group**, **Quadrant Technologies** and the **University of Nottingham**.

An application from **Ares Trading SA** concerned with VIT domain containing protein presumably relates to the vault protein inter-a-trypsin domain. Though it is recognized as being related to the von Willebrand/Integrin A (vWA) domain, it seems that its function may still not have been fully explained. Ares (Serono) seems not to have any previous involvement with VIT, and possibly the most relevant earlier work lies in the company's established collaboration with **Inpharmatica**, which has yielded **WO2004096856** relating to the von Willebrand Factor type C (vWFC) domain.

Cesare Peschle and **Gianluigi Condorelli** have filed an application entitled 'uses and compositions comprising miRNAs'. The first inventor is the research director at **Instituto Superiore di Sanita** with links to the **Thomas Jefferson University**, Philadelphia and the second inventor has links with **San Raffaele Biomedical Science Park of Rome** and **University of California San Diego**. The inventor's work to date comprises stem/progenitor cell types and its use for the regeneration of the infarcted heart, methods of manipulating cardiomyocyte cell growth *in vitro*, and methods of isolating hard-to-find hematopoietic stem cells for transfusions and innovative approaches for bone marrow transplants and gene therapy. This application appears to be related to the team's discovery of microRNAs 221 and 222 inhibiting normal erythropoiesis and erythroleukemic cell growth via kit receptor down-modulation, with a potential role of these miRNAs in cancer therapy.

Transdermal drug delivery with temporal control is the subject of an initial application filed by **Dewan Chowdhury**, and this is undoubtedly a sequel to two earlier cases in the same name, **WO2005120471** and **WO2006037954**. There, we noted inventorship links with **3M**, another pending patent application (concerned with nanotubes), and a UK Trade Mark registration for the name "memspatch".

Haemostatix Ltd, a drug design and development company focussing on unmet clinical needs in haemostasis, has filed an application for a therapeutic agent. The company was founded in 2003 by Sarah Middleton and Professor Alison Goodall as a **University of Leicester** spin-out. Dolphin holds **WO2005035002**, which is assigned to the University of Leicester and names the company founders, and the equivalent EP is assigned to Haemostatix. The applications, which disclose fibrinogen targeting microparticles for promoting haemostasis, cover the company's lead product, artificial platelets (**HaemoPlax™**).

NovaUCD, the technology transfer centre associated with **University College Dublin**, makes an indirect appearance among the UK initial patent applications published at the beginning of August 2006. The application, in the name of **Celtic Catalysts Limited**, is simply entitled "compounds", but almost certainly has relevance to the pharmaceutical industry because of the background and specialisms of those involved in the relatively new enterprise. The founders and advisory board bring experience from such organizations as **The Scripps Institute**, **Janssen Pharmaceutica** and **Solvay**. Celtic itself seems to have no previous patent applications, but may well have access to such cases as UCD's **WO2005118603**, which is concerned with chiral phosphine compounds and names the company's two co-founders among its inventors.

Prolmmune Ltd has filed an application relating to an MHC oligomer and its components and preparation. This continues on from an application last month, **WO2006082387**, which claims an MHC oligomer having a peptide binding groove, also from three earlier applications (**WO2005051983**, **WO2005035567** and **WO2004018520**) by the same inventor, Nikolai Franz Gregor Schwabe.

The Secretary of State for Defence is seeking protection for an application entitled immunogenic proteins and uses thereof. This is likely to continue on from **WO2005012339** of the same title and relating to outer layer proteins of *Bacillus anthracis*. The only named inventor on **WO2005012339** is Caroline Redmond, and this appears to be her first application.

Sterix Limited is seeking protection for an application entitled compound. This may relate to two previous applications of the same title for treating cancer: **WO2006032885** (new steroid sulphatase inhibitors) and **WO2004085457** (new 17 β -hydroxysteroid dehydrogenase inhibitors). In February 2004, the UK biotechnology firm was acquired by **Ipsen Ltd**, along with Sterix's oncology portfolio including **STX-64** and **STX-140**. **STX-64**, renamed as **BN-83495**, has completed a Phase I clinical trial for sulphatase inhibition in post-menopausal breast cancer expressing oestrogen receptors.

Bernard M. Turner has filed four applications this week, all with different titles but relating broadly to chemotherapy of cancer and infectious diseases. These appear to be the first applications by Turner. There are several inventors of this name to be found in related literature, although it is unclear which individual these applications relate to.

Due for publication at the end of February 2008