

Current Patents Gazette

Patenting in Context

News & Highlights from week 0817

The UK Patents Journal (No 6205) this week records the lodging of SPC/GB08/018 by **Vertex** for **fosamprenavir**, which is marketed as **Lexiva** and **Telzir**. This was first reported by us three weeks ago in Current Patents Gazette 0814 and if granted, will give Vertex and licensee **GSK** protection based on **EP0933372** until July 2019 for their HIV infection treatment.

Also reported in the Journal is the grant of two Plant Protection SPCs in the UK to **E.I. Du Pont de Nemours (Dupont)** for **proquinazid** (on EP0698103) and **indoxacarb** (on EP0565574).

At the opposite end of the SPC lifecycle, we also have the expiry of two SPCs reported in the Journal. The first relates to **iodixanol**, which was granted to **Amersham Health AS** (formerly **Nycomed**, now part of **GE Healthcare**) on **EP0108638** and expired on March 30, 2008. Iodixanol is a dimeric, isomolar, non-ionic, water-soluble, radiographic contrast medium, marketed as **Visipaque**. Intra-arterially it is indicated for digital subtraction angiography, angiocardio-graphy (left ventriculography and selective coronary arteriography) and peripheral, visceral and cerebral arteriography. Intravenously, it is indicated for Contrast Enhanced Computer Tomography (CECT) imaging of the head and body, excretory urography, and peripheral venography. **Daiichi Seiyaku** (now **Daiichi Sankyo**) holds the marketing rights in Japan.

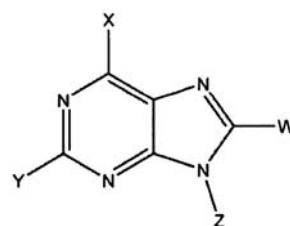
SPCs have also expired in most European states, except for Switzerland, where the SPC does not expire until November, due to a later marketing approval. The equivalent US patent, **US5349085**, however does not expire until September 2011, the term being based on 17 years from the grant of the patent rather than 20 years from the filing of the original parent application (November 1983) or the original convention priority (November 1982).

The second SPC which is reported as expiring on March 29, 2008 was awarded to **Istituto Gentili** on **GB2118042** for **alendronate (Fosamax)**. However, in a November 2003 decision, the UK Court of Appeal dismissed the appeal by **Merck & Co Inc** and **Gentili** against an earlier Chancery Division decision which declared both GB2118042 and **EP0998292 (Merck)** invalid. In this action brought by **Teva, Arrow Pharmaceuticals** and **Generics (UK)** both patents had been declared invalid, GB2118042 for anticipation and obviousness. The High Court order of November 2003 was stayed pending an appeal to the House of Lords, which was refused February 2005. The order for revocation with an effective date of 23 January 2003 was published in the UK PDJ of 2 March 2005. EP0998292 was also revoked by the EPO's Opposition Board in July 2004. Merck appealed this decision but the appeal was dismissed following oral proceedings on March 14, 2006, so the decision to revoke the patent stands.

Merck has also been active in filing new SPCs, with an application being lodged with the UKIPO on March 26, 2008. This application is based on **EP1441735**, which is owned by Merck subsidiary **IRBM** and covers **raltegravir (Isentress)**, Merck's oral tablet formulated HIV-1 integrase inhibitor used for the treatment of HIV-1 infection in treatment-experienced adult patients. Launched in the US late in 2007, Isentress achieved sales of \$40 million in 2007. These are expected by analysts to rise to around \$750 million in 2011. If the SPC is granted, it will expire December 19 2022 – giving around two months extra protection for the drug, although a further six months could be obtained through the new European pediatric exclusivity, if Merck completes the necessary procedures.

At around the same time Merck was filing its new SPC application, **Boehringer Ingelheim** received approval from the EMEA for **dabigatran etexilate (Pradaxa)**, an orally active prodrug of the thrombin

(Factor IIa) inhibitor **dabigatran** as an antithrombotic agent. This was widely reported in the UK press early this week, following its licensing for NHS use in hip and knee surgery patients. The BBC reported that hip and knee surgery patients were to start being given Pradaxa, which is "available as a daily tablet and needs less monitoring than other drugs". Pradaxa is covered by a number of Boehringer patents, including granted European and US patents based on PCT application **WO9837075** (which claims dabigatran itself), **WO2005028468** (which claims polymorphs of dabigatran etexilate and **WO2005018615** which claims a tablet formulation. These patents will protect the product until at least February 2018 and probably until August 2024, based on the later PCT application, with other patenting for formulations and crystal forms giving even longer protection. Boehringer remains confident in the potential for Pradaxa as it continues to invest in an extensive clinical trial programme investigating Pradaxa across four further therapeutic areas.



Sulfamoyl purine derivatives and their analogs are claimed in Wyeth's first patenting for Hsp90 inhibitors

UK Initial Applications

Current Patents Gazette

A0 applications filed March 17th – March 23rd 2008 – expected to see publication in mid September 2009

AcureOmics has made two filings (GB0805081 and GB0805084) to protect **biomarkers**. AcureOmics was established in October 2007 based at the **Umea Biotech Incubator at Umea University** in Sweden, developing point of care diagnostics. Their biomarker research program is aimed at distinguishing disease states from healthy individuals, with initial promising results for arthritis. The founders of the company, Torbjörn Lundstedt, Thomas Moritz and Johan Trygg are all named inventors on filings related to Umea University and several other Umea University-related companies like **Action Pharma** and **AcurePharma**. In January 2008, AcureOmics entered into a collaboration with **Gottfries Clinic** targeted at Chronic Fatigue Syndrome and Fibromyalgia. This is the first filing from this company.

David Sancho-Madrid has filed a UK initial patent application (GB0805159) on the subject of **immune modulation via C-type lectin**. There is evidence of national patenting in Spain on related subjects, but **WO2005078081** serves to link this inventor directly to work on regulators of HDAC6 tubulin deacetylase being carried out at the **Universidad Autonoma de Madrid**. Prior to that however, he was named in a team of

seven filing on the subject of immune regulation for **Albor Biologics** – see **WO2004069183**. Analysts researching this earlier invention noted a second academic link, to the **University of Barcelona**. Beyond its location in Westwood, Massachusetts, and its association with Roy Lobb, not a great deal is known about Albor or its association with these Spanish academics. Prior to 2002 Lobb was patenting on such subjects as VLA antibodies and integrins for **Biogen**, but even there it was possible to infer links with academic institutions, including for example **Imperial College London**, the **Schepens Eye Institute, Massachusetts General Hospital**, and the **New England Medical Center**. From **WO9416094** there are indications that **Merck & Co** was at one time licensed in relation to the recombinant VLA4 antibody work.

IP4 Business has lodged two new applications at the UK intellectual property office covering **hand held nebulisers** (GB0805077 and GB0805079). The company, an IP advisory and consulting service, was incorporated in November 2002 with a registered address in Huntingdon, Cambridgeshire but appears to operate out of offices in York and Scarborough. IP4 Business has previously filed two similar applications in 2003

and 2006 (GB0301441 and GB0602286) but neither applications were continued at the end of their respective Convention years. Little else is known of this company or its founder, James Hodgson, with its corporate website only revealing contact details and a list of services.

Nandi Proteins has filed an application for a **process for modifying proteins**. Nandi Proteins is a spin out company from **Heriot-Watt University** and was set up in January 2001 to exploit know how to improve the functional properties of common proteins such as whey, egg and soya proteins. A recent filing, **WO2008032039**, discloses a method for monitoring the degree of protein denaturation during the course of heat treatment and is applicable to the food processing industry; the current application appears to be a continuation of this, possibly disclosing method of modifying proteins for use in foods to, for example, decrease their allergenicity or to increase their shelf life.

Summit has filed a new UK initial application claiming a **treatment of myelination diseases** (GB0805119). The present application appears to represent a new target for Summit, whose recent patenting seems to have been

focused around the use of urotrophin modulators for the treatment of Duchenne muscular dystrophy, see **WO 2007091106**, **WO 2007091107**, **WO2008029152** and **WO2008029168**; lead compound, **SMT-C1100**, in currently in preclinical investigations.

TheRyte has filed an initial application to protect a companion diagnostic for cancer. TheRyte, based in Surrey as a spin off from the **University of Liverpool** and established in June 1998, is an anticancer drug discovery and diagnostics company which claims **THR-53**, a CDK hydrophobic region mimetic, as a lead candidate anticancer compound and which it is offering for licensing. In an article in Int J Oncol April 2008, TheRyte's Chief Medical Officer & Director of R&D, **Professor Hilmar Warenius**, disclosed that the authors had noted relationships between proteomic expression and drug efficacy when Ras, cyclin B1, cyclin D1, Cdk1 and Cdk4 were examined; the current application may be related to the determination of susceptibility to anticancer treatment using these proteins as diagnostic markers. See also **WO9942835**, **WO03081239** and **WO2005123760**.