

Current Patents Gazette

Patenting in Context

News & Highlights from week 0814

This week see the first week of publication of the new web-based UK **Patents Journal** as scheduled. The numbering of the Journal continues on from the Patents and Designs Journal (PDJ), so the first edition published on April 02, 2008 is Patents Journal No. 6202. This contains news of five Supplementary Protection Certificate (SPC) Applications, SPC/GB08/011 through SPC/GB08/016, and the entry into force of Plant Protection SPC, SPC/GB01/027, awarded to **Ishihara Sangyo**. All the SPC applications have been reported previously in the Current Patents Journal. These consist of applications by **Wisconsin Alumni Research Foundation (WARF)** on **EP1185615** based on the **Focetria** approval and by **Pharma Mar** for **Yondelis** on **EP1702618** as reported in CPG 0811, by **Uriach & CIA** for **rupatadine** on **EP0577957** as reported last week in CPG 0813. Also reported is the application by **Pfizer** for **maraviroc** on **EP1284974** and the first of **Eli Lilly's** pair of applications on **EP0561639** for Pfizer's **anidulafungin** as reported two weeks ago in CPG 0812.

Not yet reported in either the PDJ or the new Patents Journal is the SPC application by **Vertex Pharmaceuticals**, filed by **GlaxoSmithKline (GSK)**, for **fosamprenavir calcium** on **EP0933372**. If granted, this will give Vertex and licensee GSK protection until July 2019,

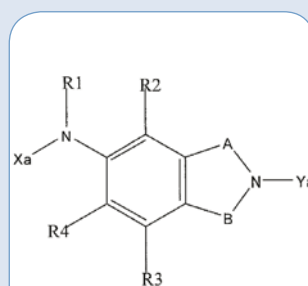
fifteen years after the earliest EU marketing approval. Fosamprenavir, marketed as **Lexiva** or **Telzir** is a prodrug of HIV protease inhibitor **amprenavir** and has been developed and launched by GSK, under license from Vertex. Available as oral tablets, it is indicated for the treatment of HIV infection in adults, in combination with other antiretroviral agents. Sales of the fosamprenavir/amprenavir franchise reported by GSK for 2007 totaled \$282.3 million, a year-on-year growth of 8% at actual exchange rates, according to Thomson-Pharma analysts.

GSK has also been in the news this week because of two Court hearings. The first of these saw the publication of the UK Court of Appeal judgement regarding the revocation of **Genentech** and **Biogen Idec's EP1176981**. The patent is currently being opposed at the European Patent Office (EPO) by a number of companies, including GSK and **Wyeth**. A claim for revocation of EP1176981 was also filed on February 19, 2007 at the UK High Court by the **Glaxo Group** with a further claim for revocation being filed May 31, 2007, by Wyeth. The date of the UK proceedings was set for February 2008, but the patentees applied for a judicial stay, pending resolution of the EPO Opposition proceedings. The judge declined the request, citing GSK's need for commercial certainty regarding potential launch of **ofatumumab**, but

referred the question to the Court of Appeal for a precedential ruling on the general issue of staying proceedings whilst parallel proceedings are pending at the EPO. In a decision of January 31, 2008 the Appeals Court published its decision that it was within the judge's discretion to refuse the stay in such cases and ruled that in this case there was no reason to interfere with his judgment, especially as since the hearing of the Appeal, Genentech had agreed to a revocation of the patent, presumably only in the UK as Opposition proceedings appear to be ongoing at the EPO. GSK and licensor **Genmab** are developing ofatumumab, an anti-CD20 human monoclonal antibody, for the potential treatment of non-Hodgkin's lymphoma and autoimmune diseases, such as rheumatoid arthritis and multiple sclerosis.

The second court case in which **GSK** was involved was the case heard at the District Court for the Eastern District of Virginia,

which aimed to prevent the **USPTO** from implementing its proposed new rules governing the examination of patents. In a twenty-six page opinion, Judge Cacheris granted GSK's and Tafas's Motions for Summary Judgment, finding the PTO's proposed limitations to the number of continuation applications and claims per patent to be an improper extension of PTO authority. In his ruling of April 01, 2008, he stated "Because the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2) does not extend to substantive rules, and because the Final Rules are substantive in nature, the Court finds that the Final Rules are void as 'otherwise not in accordance with law' and 'in excess of statutory jurisdiction [and] authority.'" The Judge also issued an order instructing the USPTO and its employees not to implement the proposed rules. It is possible that the USPTO will appeal the ruling, but industry commentators do not expect the appeal to succeed.



First NCEs claimed by Lectus Therapeutics are Kv1.x channel modulators

UK Initial Applications

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A0 applications filed February 25th – March 2nd 2008 – expected to see publication in early September 2009

• **Katholieke Universiteit Leuven (KUL)** has filed GB0803173 to protect **PPAR agonists**. This application was filed just two weeks before publication of **WO2008028888**, in which Life Sciences Research Partners **VZW** and **Flanders Interuniversity Institute for Biotechnology (VIB)** jointly claim treatment of muscle wasting disease based on the TGF signaling pathway. **Thomson Scientific** patent analysts noted that one of the inventors, Dr Peter Carmeliet, is a Professor of Molecular and Cellular Medicine at KUL, and that his slightly earlier **WO2008006819** claims the use of PPAR- α agonists in a similar context, focusing on **fenofibrate**. This inventor link between KUL and the other Belgian institutions, though somewhat oblique, may offer the best clue as to the origin and object of the new PPAR agonist filing.

• **MUBio Products** has filed GB0803192 relating to an **SCLC biomarker panel**. The Maastricht-based company's only previous international patent application seems to be **WO2007104511** with claims to a cancer vaccine. The company spun out from the local university in 2000 in order to exploit the research of Dr René Vleugels and Professor Dr Frans Ramaekers, and has recently merged with **NovoVacs**. Diagnosis of small cell lung cancer is the stated object of the new invention, appearing to tie in with the principal uses of the NCAM-180 gene specific antibodies which form the basis of the earlier invention.

• **Anant Sharma** has filed UK initial patent application GB0803515 with claims to a **medicament and method of treatment**. On the assumption that Mr Sharma's research interests have not changed

radically over the past three years, this new invention could well follow on from **WO2006095178**, which was concerned with treatment of herpes simplex virus, using alkaloids such as **colchicine** and **vinblastine**, especially in the context of preventing eye socket infections. A consultant ophthalmologist associated with the **Bedford Hospital NHS Trust**, Mr Sharma has published in this field with colleagues at the **Birmingham and Midland Eye Centre**.

• **Arecor** has filed GB0803594 to protect a **protein formulation**. This seems to be a sequel to **WO2007003936**, originally published in the name of parent company **Insense**, based on the protein formulation work of Dr Jan Jezek. As part of a larger team, Dr Jezek also contributed to the radiation-based protein stabilization work described in **WO2007034198**,

now also assigned to Arecor. Based on the Colworth Science Park, and with links to **Unilever**, Arecor uses the names **Arestat-T** and **Arestat-R** respectively to refer to its heat and radiation protection technology for proteins. Among the applications listed for Arestat are differentiation of biosimilars, progressing otherwise unstable preclinical drug candidates, and stockpiling of vaccines.