

# Current Patents Gazette

## Patenting in Context

### News & Highlights from week 0810

The UK Patents and Designs Journal (PDJ No. 6198) does not contain any Supplementary Protection Certificate events this week. However, several Special Notices are of interest. Several weeks ago, the Current Patents Journal (CPG 0805) reported that following ratification by France in January, the **London Agreement** regarding translation of patents would enter into force on May 01, 2008. The UK has also implemented transitional arrangements for those patents granted prior to the entry into force of the legislation. The PDJ contains a Notice detailing the effect of this agreement on European Patents entering into force in the UK. In summary, this means that:

- From May 01, 2008 a translation of an EP (UK) granted in French or German will no longer be required.
- For an EP (UK) granted from February 01, 2008, patentees will not need to file a translation for the patent to enter into force (taking advantage of the 3 month prescribed period for filing a translation).
- For an EP (UK) granted between December 01, 2007 and January 31, 2008, a two month extension may be requested to the prescribed period. Provided that the request is filed before April 30, 2008 this will automatically be granted (as per current practise) and so no translation will need to be filed.

More details are available on the UKIPO website.

A further Notice reminds us that from April 02, 2008 the PDJ itself will no longer be published, being replaced by a free, web-based searchable database updated on a weekly basis every Wednesday. Additional Web pages will also be published to manage Official Notices and Designs data.

The Japanese Gazette published on February 25 was received this week and contains details of eight granted extensions.

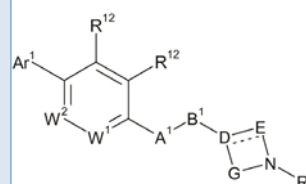
Amongst these, two 5 year extensions have been granted on **JP06062623** for **valaciclovir HCl (Valtrex)**, used in suppression of genital herpes. Similar extensions had already been granted for use in treatment of herpes simplex (HSV), so the expiry date of August 12, 2013 is unchanged. Valtrex, the L-valyl ester prodrug of the antiviral **aciclovir**, has been developed and launched by **GSK** for the treatment of herpes zoster (shingles) and herpes labialis (cold sores), and for the treatment or suppression of genital herpes. Further indications have also been approved in the EU. Worldwide sales of Valtrex reported by GSK for 2007 totalled around \$1.9 billion, representing a growth of 18%. These are expected to peak at around \$2.1 billion in 2008, after which falls are predicted due to generic competition. SPCs have been granted in the UK and other designated states on equivalent **EP308065**, mostly

expiring December, 2009. In the US, **Ranbaxy** and GSK reached an agreement in July 2007 settling their litigation, whereby Ranbaxy would launch a generic formulation in late 2009 and would be granted 180 days exclusivity as the first to file. In October 2007, the FDA granted **Teva** tentative approval of its generic version with final approval anticipated for December 2009.

A further extension of four years and three months has been granted on **JP2851480** for the use of **lamivudine** in treating B type liver cirrhosis which will expire September 02, 2016. An extension of 2 years and 17 days has previously been granted to **GSK** on JP2851480 for the combination of lamivudine with **adefovir dipivoxil** for use in treating chronic Hepatitis B (HBV) and B type liver cirrhosis. An extension of 1 year 10 months and 8 days was also granted earlier on this patent for lamivudine.

Five year extensions have also been granted to **Kirin-Amgen**

for **darbepoetin alfa (Aranesp)**, a closely related recombinant form of **erythropoietin**, on **JP2938572** and **JP3073905** for use in treating gastric anaemia in patients undergoing dialysis. These will expire August 16, 2019 and October 09, 2015 respectively. An SPC has been granted in the UK and other EU states for Aranesp using **EP0640619**, which expires June 2016, except in Switzerland where the SPC expires September 2017. Despite the extended IP protection, **Amgen** posted worldwide Aranesp sales of \$3.6 billion in 2007, a 12% decrease on 2006. In October 2007, analysts at Lazard Capital Markets believed proposed EU label changes for Aranesp and the entry of biosimilars could put pressure on Amgen's EPO sales in the EU. Two additional biosimilars were expected to receive EU approval in the coming months, following EU approval of **Sandoz's Binocrit (epoetin alfa)** in August 2007 putting further pressure on sales.



**First patenting to emerge from Biovitrum on G protein-coupled receptor 119 (GPR119) agonists**

# UK Initial Applications

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A0 applications filed January 28th – February 3rd 2008 – expected to see publication in early August 2009

• **Cellpharco** has filed a patent application (GB0801410) relating to **therapeutic intervention**. This appears to be a re-filing or development of a document first lodged in January 2007, which **Thomson Scientific** analysts believed to originate from a Porto-based pharmaceutical consultancy. During the intervening year nothing further seems to have emerged from the company.

• **Circassia** is seeking protection for **peptides from Factor VIII** (GB0801513). The handful of patents to date from this **Imperial College** spin-off are primarily concerned with immunotherapeutics, so this newest application seems to represent the start of work in a new therapeutic area. In November 2007, the company completed an in-licensing program in support of its current focus on immune response control, especially in allergy, acquiring IP rights from **Monash University** and **BioMay**.

**Imperial Innovations** does not seem to have a background in the field of blood clotting, so it remains to be seen whether this topic will achieve similar importance in Circassia's activities, requiring the in-licensing of supporting technology.

• **Oxagen** appears to have filed two UK applications (GB0801671, GB0801672) with claims to **compounds having CRTH2 antagonist activity**. However, the same PDJ issue includes a third application with an identical title (and near-adjacent serial number, GB0801674) in the name of an individual "inventor", **Alison C Roberts**. It seems most likely that all three originate from the same drug discovery program. Key to understanding how the "Roberts invention" comes to be associated with those filed by Oxagen is recognition that Alison Roberts is in fact a freelance attorney, who completed her training with the

London-based law firm of **Kilburn & Strode**, then worked for a time for **Zeneca Agrochemicals** near Wokingham. Oxagen has already accumulated a substantial portfolio of cases protecting CRTH2 antagonists, including for example **WO2005040114** on which Roberts' name appears as an attorney acting on behalf of Kilburn & Strode. The Oxagen program, stretching back to 2003 and based on technology from **Evotec**, has produced a clear lead, designated **ODC-9101**. This is probably the indoleacetic acid derivative salt described in **WO2007107772**, which has potential in PGD2-mediated disorders including asthma and allergies; the original new compound corresponding to ODC-9101 seems to be covered by **WO200504426**, filed by the same attorney.

• **Summit**, formerly known as **VASTox**, is claiming the use of

**compounds for preparing antituberculosis agents** (GB0801288). Such agents are already prominently featured by CEO **Dr Steven Lee** in the company's May 2007 review but have not so far appeared in any of the company's patent publications. However, the **Oxford University** spin-off includes among its scientific advisors **Professor Edith Sim**, a co-founder of **VASTox**, who heads the University's Department of Pharmacology; her special interests include arylamine N-acetyltransferases (NAT), a potential therapeutic target for tuberculosis and other diseases. Prof Sim's own publications in this field include **WO9961625** filed in the name of **Isis Innovation**; this case was allowed to lapse in 2005 but Summit now, no doubt, has access to the know-how that underlies this discovery technology.