

Current Patents Gazette

Patenting in Context

News & Highlights from week 0807

The **UK Patents and Designs Journal** (PDJ 6195) this week reports the expiry of two SPCs. **Shell's** Plant Protection SPC for the antifungal combination of **dimethomorph + mancozeb**, which is marketed as **Invader**, expired January 21, 2008, whilst **Novartis'** SPC for veterinary product, **lufenuron**, a flea control insecticide marketed as **Program**, expired January 18, 2008.

Not yet reported in the PDJ is the SPC application by **GlaxoSmithKline (GSK)** for **nelarabine** which was filed on **EP0294114** on January 11, 2008. This European patent, which claims nelarabine, is due to expire in May 2008, so the SPC filing at this time is crucial as the product was only approved in the EU in August 2007. Nelarabine, marketed as **Arranon** and **Atriance**, is indicated for the treatment of patients with T-cell acute lymphoblastic leukemia (ALL) and T-cell lymphoblastic lymphoma. If granted the SPC will extend the protection based on the Product patent by a full five years until May 26, 2013. Use of nelarabine in the treatment of tumours and T-cell lymphoproliferative disorders is also claimed in **EP0539479**, which expires July 2011 – almost two years before any granted SPC on the product case. However, the marketing exclusivity on nelarabine as a NCE, is likely to be the

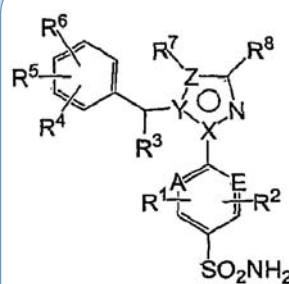
constraining factor in Europe as this could extend 10 or 11 years from the August 2007 approval date to a maximum of August 2018.

Also filing for further protection was **Pfizer** which submitted an application on January 16, in the names of **Sugen** and **Pharmacia & Upjohn**, for an SPC on **EP1255752** to protect **sunitinib (Sutent)** which is an orally active inhibitor of VEGFR2, PDGFR-beta, Kit and Flt3 tyrosine kinase signaling pathways. The product is indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression or intolerance to **imatinib** and for the treatment of advanced renal cell carcinoma (RCC). If granted the SPC will extend protection for sunitinib based on this patent by around five months to July 2021. Sales for sunitinib (Sutent) reported by Pfizer for 2007 totaled \$581 million, up 166% on 2006, and almost 6% of the anticancer protein kinase inhibitors franchise currently dominated by **Novartis'** imatinib. According to our **Thomson-Pharma** analysts, in March 2007, **Cowen & Co** spoke with renal cancer experts who viewed Sutent as best-in-class for the treatment of renal cell carcinoma, a \$1 billion market opportunity, and noted that Pfizer believed that the combined worldwide opportunity for Sutent in

multiple cancers could reach a \$1.5 billion peak.

Novartis is the third company which has filed an SPC application in January that has not yet been published in the PDJ. This application was filed on **EP1137635** for **vildagliptin (Galvus)**, which is one of a series of orally active dipeptidyl peptidase IV (DPP IV) inhibitors that modulates glucagon-like peptide (GLP) metabolism, for the treatment of type 2 diabetes. If granted the SPC will expire September 2022, 15 years after the EU marketing approval. In July 2004, **OSIPharmaceuticals** UK subsidiary, **Prosidion**, acquired **Probiodrug's** DPP IV technology and intellectual property. Part of this portfolio was **EP0896538** on which opposition was filed at the EPO by **Bristol-Myers Squibb (BMS), Novo Nordisk, GSK, Pfizer, Novartis, Tanabe Seiyaku, Takeda** and **Boehringer Ingelheim**. In July 2004, following the initial opposition proceedings, the

patent was ordered to be revoked. Prosidion appealed, with oral proceedings expected March 2008. Since that time, almost all of the opponents have withdrawn their opposition. In the latest of these notices, the EPO Register Plus reports that Novo-Nordisk withdrew its opposition on January 21, 2008, leaving only TanabeSeiyaku(now**Mitsubishi Tanabe Pharma**) to continue the opposition. There would still appear to be time, however, for Tanabe and Prosidion to come to terms and stop the proceedings, before the scheduled hearing in March. It would seem likely that licenses have been granted to the former opponents and of the 12 licensees of this technology published to date, stated licensees include **Merck, BMS, Novartis**, a "large UK Pharma" (GSK?) and a "large Japanese pharma" company (Takeda?). Since that time, Prosidion has filed for SPC protection on **EP0896538** for Novartis' vildagliptin and Merck Inc's **sitagliptin (Januvia)**.



First patenting to emerge from Pfizer on carbonic anhydrase inhibitors.

UK Initial Applications

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A0 applications filed December 24th – January 2nd 2007 – expected to see publication in early July 2009

Onclmmune has filed (GB0725239) in order to protect a **calibrator for autoantibody assay**. The company was established in 2003 in order to exploit the work of **Professor John Robertson** at the **University of Nottingham**, and its first international patent application appeared as **WO2006126008**, concerned with improved immunoassay methodology. However, there is also University of Nottingham tumor marker patent property naming Prof Robertson as inventor, including for example **WO9958978**, and his spin-off company probably has access to this too. In November 2006, Onclmmune established a US presence in **Lexena**, close to **Kansas University's** Lawrence and Medical Center campuses, with the intention of collaborating with cancer researchers there. CEO of the US enterprise is **Dr Tony Barnes**, who features alongside Robertson as an inventor on the first Onclmmune published patent application. Sharing premises with Onclmmune is an established **KU enterprise** known as **IBT Laboratories**, whose activities extend beyond cancer immunology into allergy and conducting clinical trials on a contract basis. Onclmmune's original inspiration is said lie in the early Nobel prize-winning work on PCR reactions by **Kary Mullis**, as described by **Cetus**

Corp in **EP200362**. Already at the Lexena site, however, are renowned breast cancer researchers **Carol Fabian** and **Bruce Kimler**, who together with protein chemists **Christian Schoenich** and **Russ Middaugh** are expected to work with Onclmmune on the development of cancer diagnostics.

Pronostics is patenting **improved microparticles** (GB0725306). The Babraham-based diagnostics company was formed in June 2006 by the merger of **FingerPrint Diagnostics** (FPD) and **SmartBead Technologies** (SBT), with the aim of commercializing UltraPlex barcode molecules. Of the two component companies, both traceable back to **Cambridge University** research from the late 1990s, it at first seems that only SBT has been systematically seeking patent protection for its inventions, having accumulated half-a-dozen PCT applications since 2001. However, twice that number have appeared naming as inventor the founder and former CSO of FPD, **Dr David Grainger**, many of them naming **Cambridge University Technical Services** (CUTS) as the formal applicant. Though these CUTS inventions are mostly from Dr Grainger's work in the Department of Medicine on inflammation and cardiovascular disease, it is

possible that Pronostics will have access to any that are relevant to the new company's development plans. In addition, the company reports licensing-in IP from **Generics Group** spin-out **3D Molecular Sciences** (3DMS). This seems to be a reference to a deal which SBT entered into in June 2004 relating to coded particle arrays, complementing the company's own IP derived from work carried out at Cambridge University's Cavendish Laboratory.

Sosei R&D, formerly **Arakis**, has filed a new UK initial application claiming **novel cyclic compounds** (GB0725272). Sosei has traditionally focused on the repurposing of established drugs or candidates that have stalled in development, or in licensing Japanese marketing rights from other companies and, as such, genuinely novel NCE patenting from the company is comparatively rare. Compounds claimed here are probably related to Arakis programs under development prior to their acquisition in 2005, notably a series of benzoxazocine-based monoamine reuptake inhibitors and nefopam analogs claimed in **WO2004056788**, **WO2005103019** and **WO2006095187**, targeted at the treatment of pain and emesis.

Syntaxin has filed a new application covering **delivery vehicles** (GB0725321). Syntaxin, incorporated in June 2005 as a spin out from the **UK Health Protection Agency** (HPA), specializes in the exploitation of bacterial toxins, particularly *Clostridium botulinum* neurotoxins, for potential in pain, nerve disorders, and respiratory, endocrine and metabolic diseases. The company has developed a number of novel recombinant proteins which are able to deliver a clostridial neurotoxin protease into a cell of choice. Its most advanced program, developed in partnership with **Allergan**, appears to be focused on chronic pain with claims to a series of non-cytotoxic protein conjugates comprising nociceptin and a non-cytotoxic protease (clostridial neurotoxin or an IgA protease) published recently in **WO2007138336** and **WO2007138339**. Syntaxin is also looking at utilizing the antisecretory activity of proteases of clostridial neurotoxins and the company's novel recombinant proteins to target mucin-secreting cells of the airway as a potential therapy for respiratory disorders such as COPD.