

Current Patents Gazette

Patenting in Context

News & Highlights from week 0804

The UK Patents and Designs Journal (PDJ 6192) does not contain any events relating to Supplementary Protection Certificates (SPCs) this week. However, as reported two weeks ago in this Gazette (Current Patents Gazette 0802), five new SPC applications have been filed with 2008 numbers, including one filed by **Merck & Co** on behalf of the **US Government** protecting **human papillomavirus types 16 and 18 L1 proteins** based on the **Cervarix** approval. A Plant Protection SPC application was also filed by **Syngenta** on **EP0278595**, to protect a mixture of fungicides, **picoxystrobin** and **pyproconazole**.

The **Massachusetts General Hospital Corp (MGH)** has also applied for an SPC for **nitric oxide (NO)** used in the treatment of pulmonary hypertension in newborn infants on **EP1516639**. **INO Therapeutics** under worldwide rights from MGH, has developed and launched inhaled NO as a treatment for pulmonary vasoconstriction and bronchoconstriction under the tradename **INOMax**. If granted the SPC will expire July 31, 2016, fifteen years after its approval for this indication.

Roche has applied for an SPC on **EP1064951** to protect **methoxypolyethylene-glycolated epoetin beta**, which will expire July 2022, if granted. The product is marketed by Roche and its

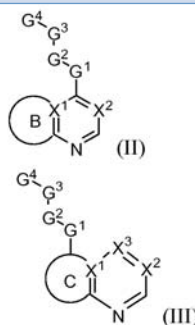
Japanese subsidiary, **Chugai**, as **Mircera** and is indicated for the treatment of anemia associated with chronic kidney disease. **Mircera** was launched in Europe in October 2007, but despite being approved by the FDA in November 2007, it was not launched. This is because in October 2007, the US Federal District Court in Boston, MA, ruled that Roche had infringed 11 **Amgen** patent claims protecting its **epoetin alfa** product (**Epogen**) and Amgen intended to seek an injunction to prevent the US commercialization of **Mircera**. Roche maintained that all its patents were valid and did not infringe any of Amgen's epoetin patents and was considering an appeal. It is possible that Roche will be prohibited by an injunction from marketing **Mircera** in the US until Amgen's patents (the "Lin" patents) expire in 2013. No news appears to have been published yet about an injunction hearing scheduled for November 15, 2007, which would appear to indicate that a permanent injunction has not yet been granted. In Europe and elsewhere the equivalent patents have already expired, so the US ruling does not affect launches elsewhere.

Domantis has a new application (GB0724331) claiming **compositions for pulmonary delivery**. Established in December 2000, the Cambridge-based company is notable for the development of **Domain Antibodies™ (dAbs™)** for

the treatment of immunological, respiratory and oncology diseases. It was later acquired by **GlaxoSmithKline** in December 2006. **Domantis** has been collaborating with **Argenta** on small-molecule, fully human dAb therapeutics for the potential inhalation treatment of COPD and other respiratory diseases. By July 2006, two leads, **DOM-0101** and **DOM-0102** had been identified. More recently, the company has claimed competitive domain antibody formats that bind interleukin receptor and their use in the treatment of asthma, specifically IL-1 in **WO2007063311**, and IL-3/IL-4 in **WO2007085815**. It is also investigating a human domain antibody targeting IL-13, **DOM-1000P**, for potential in asthma with in vivo studies underway by July 2006.

• **Renovo** has filed multiple UK applications covering **methods for inhibiting scarring** (GB0724203, GB0724204 and GB0724237). In fact the last of these has **Renovo (sic)** named as applicant, but this is clearly

an error. Virtually all of the patenting associated with **Renovo** is concerned with fibrotic disorders and epithelial regeneration, beginning in the early 1990s with a handful of cases originally assigned to the Universities of Virginia and then Manchester. Common to all of this patenting is the inventor name of **Mark William James Ferguson**, co-founder and CEO of **Renovo** since October 2000. The professor's earliest application in the name of **Renovo** was in March of the following year, published as **WO02070745** and concerned with genetic diagnosis of Dupuytren's disease, a condition associated with excessive fibrosis or scarring. Such diagnostics have potential for use in conjunction with the various products that the company has in development, including **Juvista**, **Zesteem**, **Prevascar** and **Juvidex**. Confusingly perhaps, **Renovo** is also a trade name used for a **J&J** topical cream formulation of **tretinoin**, as claimed originally by **Dr Albert Kligman** in **EP230498**.



First patenting to emerge from Kalypsys on Rho kinase inhibitors.

UK Initial Applications

Current Patents Gazette

A0 applications filed December 10th - December 16th 2007 – expected to see publication in mid-June 2009

• **Asterion** is seeking patent protection for **granulocyte colony stimulating factor** (GB0724013). Among the handful of existing international applications from this **University of Sheffield** spin-out are cases originating several years ago (**WO0196565** and **WO2005003165**) which mention G-CSF in the context of fusion protein construction and cytokine ligand polypeptide modification, but in each instance the peptide is only one of many to which the technique could be applied. The current application however appears to have a clear focus on G-CSF. As yet there seem to be no products in active development based on this cytokine work, which is based on long-term work at Sheffield by **Professor Richard Ross**, but in 2006 a joint development project with **Ipsen** was announced, focusing on growth hormone antagonists. Confirming this in a July 2007 press release, Asterion's **BioFusion** parent announced that research was being extended to encompass G-CSF, as well as EPO and leptin.

• **ImuThes Therapeutics UK** has filed a new UK initial application entitled '**lipid**' (GB0724193). ImuThes, a privately owned London-based biotech company, was founded in November 2005 to develop immune therapies for potential in immunological and inflammatory disorders,

including infection. This appears to be the first patenting that ImuThes has filed in its own right, the bulk of its existing IP portfolio being acquired from **Imperial College London** spin-out company **IC-Vec**, including **WO0248170**, **WO 2 0 0 4 0 0 0 8 5 4**, **WO2006016097** and **WO2006082397**. This work primarily relates to adjuvants, dinucleoside polyphosphates, and tetradecylthioacetic acid (TTA) containing formulations. ImuThes eventually acquired IC-Vec outright in November 2006. Subsequently this has shifted their focus from anti-inflammatory therapies towards siRNA delivery, entering into alliances with Japan-based **RNAi Co** and Norwegian **Thia Medica** in July 2007. The company's main product appear to be Chimera RNAi technology targeted at Hepatitis B (HBV) and Oncology, and TTA and TTA-derived compounds for cardiovascular/metabolic disease, pain and tissue protection.

• **Newmarket Laboratories (New Labs)** has filed a new application claiming a **syphilis detection reagent** (GB0724163). Newmarket Laboratories was originally founded in 1994, specialising in the development of immunodiagnosics for infectious diseases, notably syphilis and malaria. The company was acquired by

Lab21 Group in 2006. New Labs main syphilis diagnostics appear to focus on RPR (a non-treponemal antibody test detecting rapid plasma reagin antibodies), TPHA (a treponemal antibody test using preserved avian erythrocytes coated with antigens of *Treponema pallidum*) and EIA (a treponemal antibody test using three recombinant antigens in a sandwich format to detect *T. pallidum* specific IgG, IgM and IgA antibodies). The company is also developing a range of Syphilis IgM assays used to diagnose primary syphilis infections and to aid in the differentiation diagnosis of genital ulceration.

• **Sentinel Oncology** has filed (GB0724379) with claims to **pharmaceutical compounds**. This may be only the third application from the **Cambridge Science Park** company, which was founded in 2005. Initiated in February of that year, its earliest application was **WO2006120573**, followed by **WO2007144579**. The latter claims Chk-1 inhibitors, and probably relates to the preclinical cancer candidate **S144**, for which Sentinel has very recently issued a fact sheet supporting an offer to license for development. S144 is the company's most advanced candidate, followed by a PARP1 modulator, Aurora/KDR hypoxia-activated inhibitors, and a targeted synergy project; it is likely that the most recent

patent application relates to one of these earlier stage projects. The lead compound in the PARP1 program is apparently designated **S111**.

• **UUTech** has filed (GB0724131) in order to protect the **use of KIR genes for predicting response to therapy**. This **University of Ulster** technology transfer company already has a dozen applications published in the biotech field, several of them with third party involvement in evidence. This takes the form of inventorship contributions traceable to the **University of Fuzhou**, and licenses granted to the University's Coleraine spin-off **Diabetica**. As this latter relationship indicates, diabetes and obesity therapies are recurring themes in the patenting, so it is possible that the present application is in this same therapeutic area. However, there are recent indications of a move into a remote field of research, in the form of **WO2007141533**, concerned with FKBP-L peptides acting as angiogenesis modulators, showing potential in cancer and proliferative disorders. This invention names **Almac Sciences** as applicant, rather than UUTech, but **Thomson Scientific** analysts noted that two of the inventors have previously been associated with applications filed by UUTech.