

Current Patents Gazette

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DOLPHIN



The records appearing in this Gazette will be added to DOLPHIN, the database Of all pharmaceutical inventions in the next week. Based on the INPADOC database produced by the European Patent Office, it covers all national and international patents with relevance to pharmaceutical research and development published from 1968 onwards and selected patents from earlier years. DOLPHIN contains information on bibliographic data, contents, associated products, legal status, licensees and context of patents, which is presented in a format to convey all aspects of a patent at a glance.

News & Highlights from Week 0742

The UK Patents and Designs Journal (PDJ No 6178) this week reports details of three lodged Supplementary Protection Certificate (SPC) applications as well as one SPC expiry and the formal notification of one SPC declared invalid. Two of the new applications reported covered **GSK's Daronix** vaccine for the treatment of H5N1 avian influenza and were filed by **MedImmune** and the **Mount Sinai School of Medicine of New York University**. The European patents on which these are based were both originally filed by Mt Sinai. However, the reverse genetics technology used in production of such vaccines was exclusively licensed to **Aviron**, which later became MedImmune. The third SPC application was from **Prosidion** for **sitagliptin**. All of these applications were covered by us in more detail in *Current Patents Gazette 0739*, three weeks ago.

GE Healthcare's SPC for **Omniscan (gadodiamide)** on **GB2181428** was reported by the PDJ to have expired on September 24, 2007. Omniscan was originally developed by **Hafslund Nycomed** and now marketed by GE Healthcare, and is a non-ionic, non-iodinated, water-soluble contrast medium. SPCs were also granted in France and Germany on equivalents to **WO8602841** and expired at around the same time. Hafslund's subsidiary **Salutar** holds another patent, **WO90003804**, which discloses a formulation containing gadodiamide and complexed calcium. The latter is said to reduce the toxicity of gadodiamide.

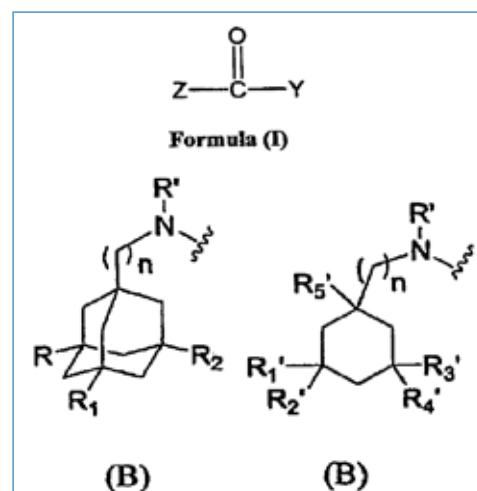
Finally, the PDJ reports that **Roche's** SPC for **mibefradil** on **EP0268148** was declared invalid on November 04, 2002. This appears at first glance to be a rather delayed announcement. However, November 2002 was the date on which the patent lapsed in the UK, due to nonpayment of fees. It also appears

to have lapsed at around the same time in all other EU states. Consequently, the SPCs already granted would not be valid and should not enter into force, so this announcement only confirms the invalidity of the SPC shortly before the date at which it would have entered into force (November 2007). As mibefradil was withdrawn from the market worldwide in June 1998 due to cardiac toxicity, it is not surprising that Roche allowed the patent to lapse.

The UK Intellectual Property Office's (UKIPO) web database of SPCs also contains details of a further two SPC applications filed on September 26 and three more filed in October. In the first of these **Neurim Pharmaceuticals** has filed for an SPC on **EP0518468** to protect its **Circadin**, prolonged release **melatonin** tablets which have been approved as a monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over. On September 24, two days before the SPC application was filed, **Lundbeck** incensed the exclusive rights for Circadin for the majority of markets in Europe including the five major markets. The Lundbeck press-release states that Circadin® is the first and only IP-protected prolonged-release, melatonin containing ethical drug approved in the EU. If granted, the SPC will extend this protection by the 5 year maximum to April 2017.

Two SPC applications were filed on October 3 to extend protection for **Pfizer's fesoterodine (Toviaz)** product. The SPC applications were filed in the name of **Schwarz Pharma** on **EP1077912** and by **Pfizer** on **EP1019358** with Pfizer named as the Patent Agent on both. The reason for this is that Pfizer holds the rights to the fesoterodine program in most major markets worldwide, under an agreement signed in April 2006 transferring rights from Schwarz Pharma. Pfizer had originally initiated

infringement proceedings against Schwarz Pharma claiming that its fesoterodine product infringed a number of Pfizer's tolterodine patents. Schwarz countered by submitting a counterclaim for revocation against **EP1019358** and **EP667852**. As part of the settlement which resulted in Pfizer licensing fesoterodine from Schwarz, all litigation was formally discontinued by a Consent Order in the UK High Court on July 25, 2006. Toviaz was approved in April 2007 for the treatment of overactive bladder (OAB) in Europe and has also received an approvable letter from the FDA in the USA. If the SPCs are granted, protection on both patents will be extended to April 2022, fifteen years after the earliest EU Marketing authorisation.



First patenting to emerge from SSV Therapeutics on N-methyl-D-aspartate (NMDA) modulators for the treatment of Alzheimer's disease, AIDS, and rheumatoid arthritis.

UK initial ("A0") applications filed September 3rd – September 9th 2007

UUTech has filed two UK initial patent applications (GB0717388 and GB0717399) in order to protect the use of **GIP and GLP-1** respectively to treat **disorders associated with dysfunctional synaptic transmission**. The company, established to handle the University of Ulster's technology and knowledge transfer, already has patent property on these peptides, beginning with a case filed in 1999, WO0058360, concerned with Tyr1-glycitol gastric inhibiting peptide. Like three later cases, and probably also the present applications, this original invention names Professors Peter Flatt and Finbarr O'Harte as inventors, and it is licensed to Diabetica, established in 2004 to exploit the research of the university's Diabetes Research Group. The insulinotropic GIP analogs Incretide and Metalog are under investigation as a product of this venture. In May 2006 Diabetica announced the sublicensing of its GIP technology to Amylin.

Norwegian life science company, **Mole Genetics** of Lysaker, has filed a cluster of five UK initial applications on September 07 2007, three entitled "**Liquid delivery apparatus**" (GB0717451, GB0717462, GB0717459) and a further two claiming **Separation apparatus** (GB0717452, GB0717461). Mole Genetics was established in 2005 with the stated aim of developing products and methods for biomedical research and nucleic acid based diagnostics. The founders, Ole J Dahlberg (CEO), Arne Deggerdal, Tone Yrvum and Frank Larsen (Chairman), have been previously associated with Dynal (Invitrogen) and were founders of GenoVision (acquired by Qiagen in 2002). Dr Larsen has also been CEO of Birkeland Innovation, the University of Oslo Technology Transfer Office since November 2004. Mole Genetics recently unveiled its **GeneMole™**, a compact benchtop nucleic acid extraction system utilizing magnetic particle separation technology developed specifically for individual researchers.

Novartis has filed a UK initial application covering **yersinia pestis antigen compositions** on September 4, 2007 (GB0717187). *Yersinia pestis*, the causative agent of plague, was the focus of a recent PCT publication assigned to Novartis Vaccines & Diagnostics, WO2007049155, which discloses similar compositions of *Yersinia pestis* antigens, including **YPO4003, YPO1604, YPO3489** and **YPO0499**. Appears to be a relatively new target for the company.

Proximagen of London has filed a recent UK initial application claiming **dopaminergic compounds** on September 5, 2007 (GB0717263). The company was spun out from University of London's King's College in 2005 with a focus in neurodegenerative disorders, notably Parkinson's and Alzheimer's diseases. The company recently claimed a series of amino acid derivatives acting as dopamine modulators in **WO2007091017, WO2007091018** and **WO2007104959** in late August/September (corresponding to UK initial applications we had previously recorded in February 2006). A much clearer picture is now developing of the company's drug pipeline, with reports of several dopaminergic agents currently under preclinical investigation (**PRX-1, PRX-2004** and **PRX-5**) for a range of indications including Parkinson's disease, tardive dyskinesia and cognitive disorder.

Aimsco of Eastbourne, UK has claims to a **treatment of hepatitis C** in a new UK initial application (GB0717139) filed on September 4, 2007. The company, founded in July 2003, appears to specialise in therapeutic agent derived from goats, with previous claims to a series of goat-derived peptides and antibodies, including corticotropin releasing factor (CRF), proopiomelanocortin (POMC) peptides and anti-HLA antibodies. See **WO03064472, WO2005097183, WO2006021814, WO2006082451, WO2006111776, WO2006117573** and **WO2007077465**. Hepatitis C may be a new target.

Applications can be expected to see publication in early March 2009.