

# Current Patents Gazette

## Patenting in Context

### News & Highlights from week 0821

**Arriva Pharmaceuticals Inc** issued a press release on 21 May 2008 reporting the grant of a US patent in the context of its investigational asthma therapy known as **SLAPI**. This fusion protein consists of **Secretory Leukocyte Protease Inhibitor (SLPI)** and **recombinant alpha 1-antitrypsin (rAAT)**. Helpfully, the Alameda-based biotech company gives the patent number as **US7247704**, but this turns out to be a patent issued in July 2007. Arriva also mentions grant of the corresponding European patent, and it is that January 2008 event that seems to hold the key to the company's wish to publicize the project. This patent filing programme, already becoming quite complex, was initiated on 18 December 2000 by the filing of a US application, resulting in the publication of **WO250287** and ultimately the grant of **EP1366175**. As is often the case with complex inventions, that grant required the filing of a divisional application at the EPO, **EP1903113**, to cover related subject matter that could not properly be claimed in the same case as the original fusion protein. The divisional seems to cover **TAPI**, an rAAT combination with a **tissue metalloproteinase inhibitor (TIMP)**, which the Arriva website shows as being at an earlier investigatory stage. The corresponding US divisional is US20080085854, and it was the 10 April publication of this latest document in the family that seems to have triggered the press release,

more than seven years after the initial filing.

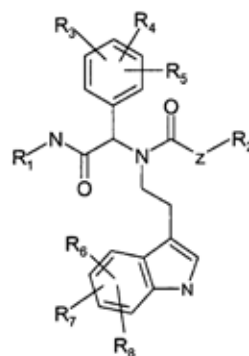
UK Daily news coverage this week (21 May 2008) gave prominence to work being carried out at **INSERM** and **Université Pierre et Marie Curie** in Paris, by Dr Jean-Antoine Girault. A protein known as **DARPP-32**, known to accumulate in parts of the brain linked to cocaine addiction, has now been shown to have a possible role in food and alcohol addictions. Girault seems to have no published patent applications as yet - though he will almost certainly have taken the precaution of filing one before speaking to the press! The IP history of DARPP-32 is however interesting, being centered on a cluster of patent applications filed by **Rockefeller University's** Professor Paul Greengard over the past 12 years. Professor Greengard describes this neostriatum-enriched phosphoprotein in terms of an integrating mechanism for neurotransmitter signals, giving it a key role in a complex signal transduction cascade. Like many fundamental discoveries, DARPP-32 was first flagged up through the patenting of a transgenic model, in this case the knockout mutant mouse of **US5777195**. That May 1996 filing was quickly followed up by **WO9920273**, featuring the use of **tacrolimus** as an inhibitor or DARPP-32 dephosphorylation, hence useful in treatment of schizophrenics. The Greengard/Rockefeller filing program continued until mid-2001,

before the subject was taken up by others, including **Merck & Co** (see **WO2005113572**) and various non-industrial patentees. At the very end of 2007 however Rockefeller re-emerged onto the scene with **WO2007146372**, which our analysts linked with a Swedish co-inventor, associated with the **Karolinska Institute** and **Denator AB**. This seminal work on neurotransmitter mechanisms won a Nobel Prize for Greengard in 2000, and it seems likely that anyone seeking to commercialize a product based on DARPP-32 would need to take into account the IP that Rockefeller University has built up.

**Acacia Pharma** has filed a UK initial application to protect a **new therapeutic use** (GB0807931). There seems to be no published patent property assigned directly to the Cambridgeshire-based repurposing company, although the **University of Barcelona's formoterol** use case **WO2006003222** is now formally assigned to it. The

formoterol case probably corresponds to the cancer cachexia product reportedly in development as **APD-209**, and the present invention may relate to the postoperative nausea and vomiting (PONV) product designated **APD-405**. However, Thomson Reuters patent analysts noted the filing of two intermediate new use cases early in 2007, due to be published towards the end of 2008, and these too could offer protection to the PONV candidate.

**Rosemont Pharmaceuticals** has filed a UK initial application (GB0807068) relating to **rosiglitazone solutions**. Acquired from **Akzo** in September 2002 by **Savient Pharmaceuticals**, the Leeds-based company was sold to a private equity company in August 2006. It has a single published PCT application to its name, relating to a **simvastatin** suspension (**WO2007125339**). Rosemont specializes in liquid formulations for dysphagic patients, listing a **metformin** hydrochloride oral solution currently for diabetics.



**(Indol-3-yl) ethylamide derivatives as adenosine A2A antagonists, a new area of research for AcurePharma.**

# UK Initial Applications

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A0 applications filed April 14th – April 20th 2008 – expected to see publication in early mid-November 2009

• **Breath** has filed (GB0806873) to protect a **steroid nebulizer formulation**. The company, an **Arrow Group** subsidiary based at Biggin Hill, began filing international patent applications in 2000, and the small portfolio accumulated so far includes **WO0241925** relating to **budesonide**; more recently a combination of the latter with **formoterol** (**AZ's Symbicort**) was the focus of **WO2007099329**. Breath also filed a Paragraph IV challenge on **Sepracor's Xopenex** levalbuterol product, but a May 01, 2008 announcement indicated that this dispute had been settled, in a licensing deal which also involved ciclesonide.

• **Fusion Antibodies** has filed an application (GB0807018) for **antibodies and treatment**. The applicant was established in 2001 as a spin-out company from **Queen's University Belfast** and specializes in developing therapeutic antibodies and recombinant proteins to disease specific markers. It currently has several antibodies in preclinical trials for the treatment of tumors and several more candidates (for example, **Fsn-1107** and **Fsn-1007**) also for the potential treatment of cancers and the inhibition of angiogenesis. Fusion Antibodies, headed by Professor Jim Johnston, who is currently Chair of Immunology and Head of the Infection and Immunity division at Queen's University Belfast, has a sound patent portfolio mainly covering anticancer treatments utilizing anticancer antibodies and, for example, a cathepsin C inhibitor (an example of which is its **Fsn-0503**).

• **Inspirato** has filed a new UK initial application claiming an **inhaler** (GB0807057). The

company appears to be new and our researchers can find no further references in the public domain. The UK Companies House lists an **Inspirato LLP** incorporated in June 2005 based in Barry, Vale of Glamorgan, but no detail is given as to the business conducted, and the connection (if any) with Inspirato is unclear.

• **Medivir** lodged a cluster of eight applications at the UK Intellectual Property Office on April 16, 2008 claiming **polymerase inhibitors** (GB0806911, GB0806912, GB0806913, GB0806914, GB0806915, GB0806917, GB0806919 and GB0806920). These applications probably relate to hepatitis C (HCV) polymerase inhibitors, particularly NS5B polymerase inhibitors, that Medivir has been reported to be developing, most recently in **WO2008043704**. On May 15, 2008, Medivir announced that it had entered into a new Research, Development and License agreement with **Tibotec** targeted at the identification and development of orally active inhibitors of HCV polymerase NS5B, screening new and existing libraries of nucleoside analogues developed by Medivir, for in vitro anti-HCV activity. The two companies will collaborate on preclinical investigations, flagging up potential candidates that Tibotec then progresses into clinical development and will eventually market. Medivir retains marketing rights in the Nordic countries while Tibotec has been granted an exclusive license in all other territories. Tibotec and Medivir have previously collaborated on a series of NS3/4A protease inhibitors of HCV for the same indication; the lead

candidate, **TMC-435350**, entered phase IIa trials in November 2007.

• **Pharmasol** is seeking protection for **novel formulations** in a new UK initial application (GB0806978) lodged on April 17, 2008. The company is a contract manufacturer providing services in the area of product development, delivery and packaging concepts, specializing in aerosol formulations and ultrafine suspensions, providing solutions to overcome solubility and bioavailability problems. Recently, the company has claimed buprenorphine-containing nonpressurized spray composition for transmucosal administration in **WO2008047163**, which also names an inventor previously associated with spray formulation applications assigned from **Sosei**.

• **RespiVert** is seeking patent protection for a **novel compound** (GB0807021). The **Imperial College** (ICL) December 2006 spin-out aims to discover and develop therapies for respiratory diseases such as asthma and COPD, based on the work of Professor Peter Barnes at the **National Heart and Lung Institute**. Although the present application seems to be the first filed in the name of RespiVert, the company may have access to some of Barnes' earlier IP. This includes ICL's resveratrol case **WO0232410**, but also several cases filed by companies with which the Professor has become associated, such as **Medical Science Systems, Boditech Diagnostics** (subsequently acquired by **Kiotech International** from ICL), and **Duska Therapeutics**.

• **Sinclair Pharmaceuticals** has lodged a new UK initial application entitled simply **composition** (GB0806948). The company was founded in 1971 but has been trading since 2000 as Sinclair Pharma plc, following its acquisition from Andrew Sinclair and merger with **Pharmarights**. It specializes in identifying and acquiring niche, patented, late-stage or fully-developed products in the oral health, oncology support and dermatology fields. Recent patenting has focused on delmopinol (SPHD-420) with claims to methods of its synthesis and its use in the treatment of microbial infections, acne, gingivitis and periodontitis (**WO 2 0 0 6 0 8 2 3 9 3**, **WO 2 0 0 7 0 8 0 3 7 8**, **WO 2 0 0 7 0 9 1 0 0 9**, **WO 2 0 0 7 0 9 9 3 0 2**, **WO2007135390** and **WO2008017814**). More recently, Sinclair has announced the EU registration of its pipeline product **SPHR-900** for *Herpes simplex* in January 2008.

• **The University of York** has applied (GB0806965) to protect a **P450 reductase**. Although the university does not appear to have filed similar applications in the past, the university's website reveals that its Bruce Laboratory, which specializes in microbial metabolism and environmental biotechnology with a particular focus on a novel cytochrome P450 system termed **XplA/B** from *Rhodococcus rhodochromus* that degrades the high explosive RDX, has been conducting research into soil decontamination which is useful for the removal of toxic high explosives from soil. It is possible that they have purified a novel P450 reductase from similar sources.