

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 0713

This week due to difficulties we are unfortunately unable to publish comments on US and EP documents. These comments will be published next week in Gazette 0714.

The UK Patents and Designs Journal (PDJ No 6149) reports that **Genentech** has lodged an SPC for **ranibizumab**, published March 28, 2007. Based on **EP973804**, if granted, this SPC should provide further patent-like protection until at least January 2022. This is the first SPC to be lodged for this product; however, SPCs for Genentech's other Hu anti-VEGF fragment, **bevacizumab (Avastin)**, have already been granted on family member **EP1325932** for a number of countries including the UK, most of which are due to expire in December 2019.

The humanized anti-VEGF antibody fragment, ranibizumab (**Lucentis**), manufactured by **XOMAs** bacterial cell expression technology, was approved in the US in June 2006, as a treatment for age-related macular degeneration (AMD). The drug is marketed outside the US by **Novartis Ophthalmics**, which filed for EU approval in February 2006. The drug was approved in Switzerland on August 25, 2006. Data from a phase III study reported in The New England Journal of Medicine in October 2006, demonstrated that the drug improved vision in AMD patients. US sales of ranibizumab (Lucentis) reported by Genentech for 2006 totaled \$380.0 million, representing sales since approval in June 2006. In January 2007, Atlantic Equities analysts expected Lucentis to achieve "healthy sales" in 2007 on the back of increased market penetration and share gains from Macugen (pegaptanib) and Visudyne (verteporfin), although growth was predicted to slow in the second half of the year due to the initial cohort of patients converting from a monthly dose to a once-per-quarter maintenance dose. CIBC World Markets analysts believed any decline should be offset by "growth in new patients,

continued switches from other therapies, as well as physician attempts to maximise the drug's therapeutic benefits".

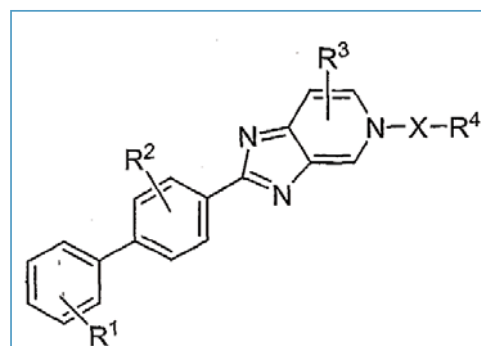
The PDJ also reports that **Novartis'** SPC for **letrozole** entered into force on March 05, 2007. Based on **EP236940**, the effective date of expiry is given as July 23, 2011. Novartis launched the non-steroidal aromatase inhibitor as **Femara** in the UK for the second-line treatment of breast cancer in December 1996, then in France for the same indication in May 1997 and the US launch took place in September 1997. Japanese licensee **Chugai** received approval in January 2006 and in May launched letrozole for the treatment of breast cancer. Worldwide sales of letrozole (Femara) reported by Novartis for 2006 totalled \$719.0 million, representing a year-on-year US dollar growth of 34%. US sales were up 40% and sales outside of the US grew by 27%. Chugai reported 2006 letrozole sales totaling YEN 0.3 billion (\$2.58 million). Analysts for our *Strategic Drugs Database* (SDdb) and *Thomson-Pharma* forecast letrozole's market share to rise from approximately 15% (in 2005) to 27% by 2010.

Also reported in the PDJ was the news that **Shionogi's** SPC covering **ceftibuten** and based on **GB2154580**, expired on March 02, 2007. Cefitbuten was developed and launched by **Schering-Plough**, under license from Shionogi and received FDA approval in December 1995. **Handok Pharma** and **Il Dong Pharm Co** have acquired ceftibuten rights in South Korea and **Recordati** markets ceftibuten in Italy under the brand name **Isocef**.

Ahead of publication in the PDJ, **Schering AG** has lodged a UK SPC for a combination of **17 α -ethinylestradiol betadex clathrate** and **drosiprenone** based on **EP771217**. If granted the SPC will provide protection until August 2020. Alongside the UK SPC application,

Schering AG lodged two French SPCs for the ethinylestradiol betadex clathrate (07C0002) and the drosiprenone combination (07C0001), which were published in the BOPI (07/10). The earliest market authorization date appears to be missing from 07C0001, but presumably matches that provided for 07C0002 and the present UK SPC application (SPC/GB07/020) of August 4, 2005, which is the Yasminelle authorisation.

The combination, marketed as Yasmin, has been developed and extensively launched by Schering (now **Bayer Schering**) as an oral contraceptive since the launch in Germany (November 2000) and the US (June 2001) and the EU launch in May 2006 of Yasminelle (which has a lower ethinylestradiol dosage). In March 2006, a low dose version (**Yaz**) with a 24 day active / 4 inactive regimen, was approved by the FDA. The product was additionally approved by the FDA for acne vulgaris in January 2007.



First patenting to emerge from Pfizer on NCEs targeting the complement component C3a.

UK initial ("A0") applications filed between February 12th - 18th 2007

a2sp has filed UK initial application (GB0703074.5) for a **viral attachment**. This appears to be the second application from the **University of Warwick**-based chemical genomics company, formed in May 2006. The first application, filed with **Biophage Pharma Inc** in February 2007, relates to methods for immobilizing **viruses (phages)** using **photo-reactive linkers**. The company is developing a portfolio of therapeutic programs based on the use of **Magic Tag® technology** to identify drug re-profiling opportunities.

Asterion has filed a UK initial application (GB0702818) for a **growth factor**. Previous applications from Asterion relating to growth disorders include **WO2006010891** and **WO2005003165**. The company's proprietary technology creates novel proteins comprising whole or partial cytokines linked to a second molecule, providing lower dose requirements, reduced side effects and delayed clearance.

Avidex has filed a UK initial application (GB0702799) for **T cells** presenting modified **CD8**. This may continue from **WO02077030** (claiming inhibition of MHC-presenting T cells which inhibit binding of CD8 or CD4) or **WO0144296** (claiming a method for inhibiting binding of a CD8+ T-cell to a class I MHC). At present, Avidex do not appear to have any CD8 projects in clinical trials.

Britannia Pharmaceuticals has filed two UK initial applications for an improved **phospholipid** and method for its production (GB0703277 and GB0703278). Britannia has a number of filings relating to phospholipids and their uses, for example for **wound healing (WO2006056800)**, for **allergic inflammatory** conditions (**WO2006125970**).

Health Protection Agency and **Serum Institute of India** have teamed up to file a UK initial application (GB0703369) titled "Compositions comprising capsular polysaccharides and their use as **vaccines**". This move will benefit the agency as Serum has a wealth of experience, having been founded in 1966, and is claimed to be the worlds largest producer of measles and DTP (**Diphtheria**, **Tetanus** and **Pertussis**) group of vaccines. This filing may relate to pneumococcal polysaccharide & conjugate vaccines which are one of four types of vaccines Serum has been planning to manufacture. See **WO2005035733**.

Inion has this week filed two initial UK patent applications (GB0703061 and GB0703062) both titled "**Osteogenic compounds**". This Finland-based company specialises in the development of biodegradable medical implants such as plates, screws, pins and membranes used to enhance the healing of skeletal injuries (bone and soft tissue), such as those caused by trauma or by reconstructive surgery. They appear to be new to patenting.

Pharmacure Health care AB is a Swedish based pharmaceutical company that mainly focuses on developing and marketing medical devices and traditionally herbal medicines within the area of **nasal disorder**. They have this week filed a UK initial application (GB0703377) entitled "Composition for combating **epistaxis**". As the few products that they have in the market are used for rinsing the nose or combating nasal dryness and snoring, see **WO2004022141**, which is their first and only filing on our records, disclosing a nasal spray containing **sesame oil**.

PLIVA dd has filed two UK initial applications. One is for preparations and compositions of solid dosage form containing **bicalutamide** (GB0702826). Bicalutamide (**Casodex**) is an oral, non-steroidal anti-androgen developed and extensively launched by **AstraZeneca** for the treatment of **prostate cancer**. The product case for bicalutamide, **EP00100172**, has SPCs running out in July 2008. The second is for a gel forming compound (GB0703328).

Posidion files two UK initial applications for compounds (GB0702960 and GB0702961). Posidion is the **diabetes** and **obesity** R&D group within **OSI Pharm**.

Renovo has filed two UK initial applications for medicaments and methods for acceleration of **wound healing** (GB0702929) and **inhibition of scarring** (GB0702930). Renovo, founded October 2000, is a spin off from **Manchester University** and claims to be a world leader in scar prevention and reduction research. Its lead product is **Juvista**.

TCP Innovations is seeking protection for two applications relating to improved compositions and combinations. This may follow on from their most recent publication **WO2007020386**, which discloses **apoE mimetics** used to prevent and treat **inflammatory** or **neurodegenerative** diseases. This consultancy and research service company also seems to have an interest in **TGF-beta** elevating agents for preventing heart disease and immunological fingerprinting as a diagnostic tool.

Applications due for publication in August 2008.