

Current Patents Gazette

Patenting in Context

News & Highlights from week 0816

We would like to welcome all our readers to the first edition of the **Current Patents Gazette** produced by the **Scientific Division of Thomson Reuters**, following the combination this week of **The Thomson Corporation** and **Reuters Group PLC** into one company. Although the look of the Gazette may change slightly over the next few issues, to reflect our new name and branding, the content will remain the same.

In this issue we highlight several notices relating to Supplementary Protection Certificates (SPCs), published by the **UK Intellectual Property Office (UKIPO)**, the **Società Italiana Brevetti (SiB)** and the **Icelandic Patent Office**. In its Patents Journal (No 6204), the **UKIPO** reports the expiry of two Plant Protection SPCs granted to **Novartis** and **Rhone-Poulenc Agriculture** on March 23 and 24 respectively. Also expiring on March 23 is the SPC granted to **BTG International** on **EP0093498** for **deferiprone**. Launched as **Ferriprox** in Europe by licensee **Apotex** in March 2000, deferiprone is an orally active chelating agent used in the treatment of iron overload. It does not appear to have been launched in the USA, and was first launched in India in March 1995 by **Cipla**, which launched it independently in the absence of intellectual property rights to the drug. Apotex also has a use patent granted in the US, based on

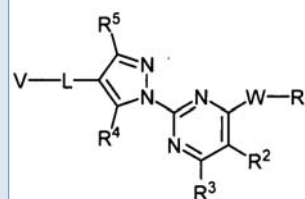
WO0202114 which claims the use of deferiprone for preventing heart disease in patients having iron overload, and methods of preventing, reversing and treating iron-induced cardiac disease in patients having iron overload, such as in thalassemia. The European equivalent is currently undergoing examination. If granted this will extend protection in Europe until June 2021 for the approved use.

The **SiB** April 2008 newsletter, *sibprima*, reports on a new provision in Italian Law introduced March 1, 2008 which seeks to clarify the situation regarding the duration of SPCs granted according to Law 349/1991 prior to the introduction of the European legislation. Under that law, some exceptionally long SPC durations were granted and in 2002, Law 112 provided for a gradual reduction of these terms by 6 months per remaining calendar year. This led to confusion where the final "year" of the SPC was less than one calendar year and in particular less than 6 months. According to the new provision, the reduction always applies to the last year, even if this is less than 1 calendar year. If the remaining term is less than 6 months, the SPC will expire December 31 of the previous year. If the remaining term is greater than 6 months, it is reduced by 6 months. Hopefully this should settle any remaining uncertainties about the expiry of Italian Certificates.

In the UK an SPC filing by the **General Hospital Corporation of Massachusetts (MGH)** is the cause of some uncertainty and confusion. The Hospital has filed for an SPC for **nitric oxide** on **EP0786264**, based on the August 2001 approval for **INOmax** developed by licensee **INO Therapeutics** (now part of **Ikaria**). This patent is divided out of **EP0560928** on which SPCs were granted in several EU states including the UK. However, following Opposition by a number of companies, including **Air Products and Chemicals** and **Air Liquide Sante**, EP0560928 was revoked on appeal, making the granted SPCs invalid. Since then MGH has also filed for an SPC for the same product on **EP1516639** which is a division of EP0786264. Since only one SPC can be granted to an organization for a given product, it remains to be seen whether the invalidation of the previously granted SPCs on the revoked parent will allow the grant of a second SPC for that product. However, unless MGH is anticipating further opposition against one or both

divisionals it is unclear why it has applied for an SPC on both patents, as any SPC will expire at the same time as that granted on the original parent, July 31, 2016. **INOmax**, a treatment for pulmonary vasoconstriction and bronchoconstriction, has been launched in several major markets including the US and Europe for the treatment of respiratory distress in newborns.

The Icelandic Patent Office has also been busy with SPCs, publishing details of four grants, two human and two veterinary, and a correction to a previously granted SPC in the April gazette. The duration of **Pfizer's** SPC for **eletriptan hydrobromide** on **IS1850** has been recalculated using the earlier Swiss Approval date and now expires December 13, 2015. SPCs were granted to **sanofi-aventis** for **rimonabant** on **IS1960**, expiring June 2021 and to **Bayer Schering** on **IS2100** for **drospirenone**, based on the authorization for Yasminelle (drospirenone + ethinylestradiol), expiring August 2020.



Evidence of a new collaboration between Amgen and Daiichi as insulin secretagogues are claimed

UK Initial Applications

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A0 applications filed March 10th – March 16th 2008 – expected to see publication in mid September 2009

• **BTG International** claims the use of **cyclopenta[g]quinazoline derivatives** in GB0805035. Surprisingly, this seems to read on to thymidylate synthase inhibitor work carried out in the early 1990s in conjunction with **Zeneca**, whose **WO9530673** describes compounds active in the L1210 mouse leukemia cell test. There was then a gap of more than seven years before the filing of **WO03020300**, with claims to the use of this same class of compound in cancer, with one of the original inventors named again. Several candidate research codes are identified there, including for example **CB-300945**. Further conformation of ongoing development work in this field came in the form of **WO2005012260**, with claims to a synthesis suitable not only for **raltitrexed** (claimed in **EP239362**) but also **plevitrexed** (**EP562734**), both structurally related to the fused quinazolines now being patented. The inference may be that BTG has identified a third candidate with this action deserving development; launched in 1996, raltitrexed begins to lose SPC protection in August 2010.

• **Consort Medical** has filed GB0804436 to protect **dispensing apparatus**. Although this appears to be the first time the name has appeared on a patent application, the company itself is by no means new, having traded until October 2007 as **Bespak**, a leading supplier of delivery devices to the pharmaceutical industry, especially metered dose inhalers (MDIs).

• **Myotec Therapeutics** has filed its first patent application, GB0804454, with claims to a **new therapeutic use**. Spun off from **Imperial College**, the young company plans to exploit the expertise of Professors Stefan Anker and Andrew Coats in identifying and developing so-called "nichebusters". As an example of this drug repurposing activity, the **Imperial Innovations** interim report from January 2007 quotes an initial focus on cachexia treatment, and the present invention could be in that field. The work seems to have begun in the mid-1990s with work carried out at the **National Heart and Lung Institute (NHLI)** on aldosterone antagonists – see **WO9848812** and **WO0021509**. More recently, however, in **WO2007083119**, there are indications that statins such as **simvastatin** and **atorvastatin** are under consideration. **Myotec** may also have access to work carried out by its founders at the Max Delbruck Center, as claimed in **WO0053165**.

• **New Era Biotech** has filed an application (GB0804213) for a **method of preventing pain**. New Era Biotech is registered in the Virgin Islands but its inventors are based in Israel, particularly Eliahu Kaplan. It appears to have links to **Ben Gurion University** through Shmuel Bittner. The company's primary interests appear to be antiviral agents and autoimmune diseases, in particular the treatment of treatment of HIV, AIDS and immuno-allergic diseases with claims in

WO9903350, **WO2004031129** and **WO2005092305**. A particular focus appears to be Syk tyrosine kinase modulators, such as lead compounds **AV-61S** and **AV-74S**, with recent claims to the use of these compounds in the treatment of cell proliferative diseases, particularly breast and ovarian cancer in **WO2007129226**. The treatment of pain appears to be a new target for this applicant.

• **Pastel BioScience** has filed three applications (GB0804680, GB0804681 and GB0804696) to **protect binding polypeptides, polypeptide detection** and for **detecting polypeptides**, respectively. This company was established in 2002 by Dr Stephen Osborne, formerly of the diagnostics company **Diasorin**, in Italy, and operates from laboratories within **Centre for Biomolecular Design and Drug Development** at the **University of Sussex**, Brighton. These are the first filings by this company which has developed **InVenio**, a biomarker discovery & validation platform, which it is offering for licensing and which the company stated is patent protected. The current applications appear to relate to **Pastel BioScience's epimer technology** which it is developing for its proteomics research program and capture molecule technology.

• **Peter Lachmann** is named as inventor on GB0804663, which is concerned with **treatment of diseases related to hyperactivity of the complement system**. Assuming that this is Professor

Sir Peter Julius Lachmann, the new invention may follow on from work which he carried out on **streptococcal inhibitor of complement (SIC)** eight years previously while at **Cambridge University's Centre for Veterinary Science**, as described in **Cambridge University Technical Service's WO02072624**. Prof Lachmann came to public prominence in 1999 when he intervened in the GM food debate sparked by Dr Arpad Pusztai's publication of results obtained by feeding modified potatoes to rats.

• **Rosemont Pharmaceuticals** has filed applications claiming a **clopidogrel solution** (GB0804242) and a **losartan composition** (GB0804536). The only published application in this name, **WO2007125339**, relates to a **simvastatin** formulation, though earlier patenting in the name of **Akzo** on **tamoxifen**, for example, may effectively be from the same source. **Savient Pharmaceuticals** acquired Rosemont from Akzo in September 2002. Tamoxifen now appears on the company's website product list under the trade name **Soltamox**, but none of the three cardiovascular drugs now being patented is yet listed. Savient, whose own patenting is focused on biologicals and imaging agents, disposed of Rosemont to a private equity buyer in August 2006.