

CURRENT PATENTS GAZETTE



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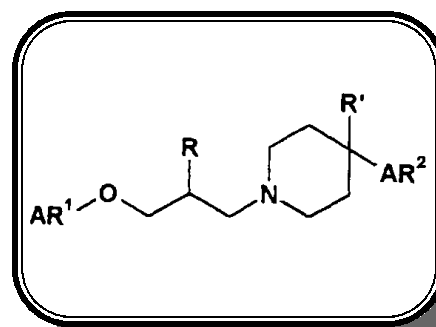
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DRUG PATENTING IN CONTEXT

Current Patents *Gazette* is the most rapid competitive intelligence service covering innovation in the pharmaceutical industry. Patent applications published during the past week have been classified and analysed, in order to place the inventions in context. For the most crucial innovations, those involving new chemical compounds, additional information is given in the form of front page images. These can be enlarged to show details of chemical structures and inventor teams, for example. Applications filed jointly, representing collaborative research, are highlighted, as are sequences of inter-related documents.

Lilly claims possibly the first known selective 5-HT_{1F} antagonists in a new publication disclosing a range of substituted piperidines. The compounds are thought to have applications in the treatment of anxiety disorders (Page 9).



HIGHLIGHTS THIS WEEK

Tap Holdings of Deerfield, Illinois, is rarely named as a patent applicant. However, the **Takeda/Abbott** joint venture this week has a US patent issued on the subject of **COPD (chronic obstructive pulmonary disease)**. The agent claimed for treating this common respiratory disorder is a benzoquinonyl alkanolic acid, preferably **seratrodast**. Takeda launched this **TXA2 antagonist** for bronchial asthma in 1995, and Abbott's interest in the compound is apparent from a series of clinical studies published since 1996, from a team that includes the present inventor. However, **Astra** is also collaborating with Takeda in the internationalization of this product, and early in 1998 issued a press release reporting its potential in COPD. Since the Tap application was not filed until November of that year, Astra's press release predates it. For protection in the US this may not be too important, but elsewhere (where the "first to file" principle applies) the announcement might well be seen as destroying the novelty of the invention. It is all too easy for such confusion to occur in collaborative development, especially when three or more parties are involved. Secondary patenting of this type may become important, since the basic protection for seratrodast (EP171251, etc) begins to expire in 2005.

Omeprazole, originally patented by Astra in the late 1970s, is the subject of an **AstraZeneca** press release dated February 1st. The reason is that a German company, **Ratiopharm GmbH**, has formally challenged the Supplementary Protection Certificate (SPC) for omeprazole, which effectively extends the originator's monopoly. Because the German Supreme Court's initial decision, based on EU legislation, does not favour AstraZeneca, the company welcomes the decision to refer it to the European Court of Justice (ECJ) for review; the final decision in Germany may well form the basis for judgements in the remaining EU states. Basic protection for omeprazole depends on product claims in **EP5129B**, granted in 1981 based on an April 1978 **Swedish priority**. That European patent, valid in the nine states at that time adhering to the Convention, would normally have expired after 20 years, in April 1999. However, three certificates filed between 1993 and 1995 at the German Patent Office resulted in the grant of an SPC in 1995 extending protection there until March 2003. It is this certificate which is now the subject of challenge. According to official records, an action for annulment dated May 1996 was rejected or withdrawn six months later, but another from June 1999 remains to be resolved, and that must be the cause of the present referral. Given that omeprazole is one of the leading pharmaceutical products worldwide, in sales terms, AstraZeneca's fortunes over the next three years are very much dependent on the ECJ's decision in this SPC case.

Research on human embryonic stem cells has come a step closer to being legalized in **Japan** (*Nature* 403, 470; 2000). A subcommittee of the Council for Science and Technology (CST), Japan's principal science policy-making body, is expected to submit its proposal to the CST by the end of the month. The proposal should receive approval by the end of March, then be submitted to the government. The Science and Technology Agency, which manages the CST, will issue guidelines on cloning research and human genetic engineering at the same time. The use of embryo cells for research is expected to be allowed subject to several conditions: First, only cells from fertilized eggs less than 14 days old are used. Second, no money is paid to donors for cells. Third, that research is limited to cells that were not used in fertility treatment.

Finally, following our speculation two weeks ago about the malpractice case reported in the *Cincinnati Enquirer*, there is now a document published, which may reflect an equally unsatisfactory situation in Texas. The application in question, not dissimilar to WO9742939, names **Stanislaw Burzynski** as inventor of a cancer therapy based on **phenylacetylglutamine and related aminoacids**. On 4 December 1995 the Houston US Attorney requested that the **Burzynski Institute** be closed after investigations were launched into fraud, contempt and FDA violation charges against Dr Stanislaw Burzynski, President of the Institute.