

# CURRENT PATENTS GAZETTE



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ISSN 1464-3499

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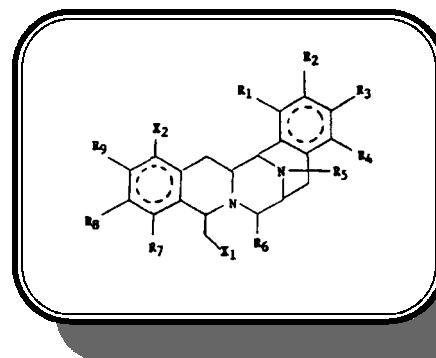
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## DRUG PATENTING IN CONTEXT

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.

**Synthetic analogs of Pharma Mar's tetrahydroisoquinoline alkaloid Ectinascidin-743, currently in phase II trials for cancer, are the target of a team of inventors based at Harvard (Page 7)**



## HIGHLIGHTS THIS WEEK

**The serotonin uptake inhibitor sibutramine**, originated by **Boots** in the early 1980s, is turning out to be a very versatile product. Originally seen as an **antidepressant** and **obesity treatment**, it is now the subject of claims by **BASF** to use in **urinary incontinence**. As the basic patent protection for sibutramine begins to expire, however, **Sepracor** is also seeking protection for this specific new indication in WO0010551, which is directed primarily to active metabolites. Sepracor's interest in the product can be traced back to 1992, when an application was filed claiming synthesis of the (-)-enantiomer of sibutramine (WO9400114).

**Thalidomide** is another product displaying great adaptability following its disastrous launch as a sedative in 1958. These Highlights have often included comments on the claiming of new indications for a compound once regarded as impossibly teratogenic. The rehabilitation of thalidomide is confirmed by the issue of a US patent in which **Celgene** claims a computer-based method for ensuring that thalidomide is prescribed only to patients who cannot possibly be pregnant. Despite its severe teratogenicity, thalidomide is a very effective treatment for a wide range of conditions, including leprosy, wasting and aphthous ulcers occurring in AIDS patients, cancers, inflammatory bowel diseases, Behcet's Disease, rheumatoid arthritis, and macular degeneration. This patent, apparently without foreign equivalents, is oddly classified (A61n), and its claims are very unusual, making reference to such concepts as registering information concerning the ability of female patients to become pregnant and the ability of male patients to impregnate females. Like all the best ideas, this computerized registration system is known by a trademarked acronym, STEPS - System for Thalidomide Education and Prescribing Safety.

**The recent UK budget** included an intellectual property provision which may well have gone unnoticed, were it not for a note in the Official Journal (Patents) highlighting the **abolition of stamp duty on IP transactions**. As a result, "...declarations relating to stamp duty on patents Form 21/77, registered designs Form 12A and trade marks Form TM16 will not serve any legal purpose for transactions effected on or after 28 March 2000, and, accordingly they no longer need to be completed for such transactions."

**An issue raised in the courts** last week was, 'Does a patent on a recombinantly produced protein give the owner rights to versions of that protein produced in other ways?'. The biotechnology company **Amgen**, based in California, is suing **Transkaryotic Therapies**, based in Massachusetts, alleging infringement of several patents on its blockbuster drug **Epogen** (*Nature* **404**, 532; 2000). Used to treat anemia, Epogen is the trade name for erythropoietin (EPO). Amgen developed the drug by cloning the human EPO gene and inserting it in Chinese hamster ovary cells, which then produce the hormone. Worldwide, the Epogen market is estimated to be worth \$5 billion a year. TKT researchers have developed an alternative way to produce EPO, taking advantage of the fact that all human cells carry the EPO gene, even though it is active only in kidney cells. In TKT's process, a promoter for the gene is inserted in human cells along with other regulatory and structural elements that guide the promoter to the EPO gene. The gene becomes activated and the cells begin producing the hormone. TKT plans to market EPO produced in this way in collaboration with Aventis.