

# News Release from AstraZeneca

Södertälje, Sweden, May 12, 1999

## **ASTRAZENECA INTENDS TO APPEAL FOLLOWING REVIEW OF PATENT RULING IN AUSTRALIA**

AstraZeneca intends to appeal a patent ruling pertaining to omeprazole (Losec<sup>®</sup>) handed down today by The Federal Court of Australia in Sydney in a dispute with the generic company Alphapharm Pty Ltd. The court clearly established, that under Australian patent law, the formulation used by Alphapharm in its generic omeprazole version infringed AstraZeneca's patented formulation technology. However, the court declared, that under Australian patent law, AstraZeneca's formulation patent was invalid.

"We will be examining the details of the judgement and will continue to strongly assert all patent rights pertaining to omeprazole," comments Dr Martin Nicklasson, head of AstraZeneca's Gastrointestinal Franchise.

"The design and application of patent legislation often varies from country to country. The research and development work behind Losec is very extensive and covers – in addition to the substance – formulations, manufacturing methods and intermediates. As a result, Losec today is protected by a wide range of different patents", continues Dr Nicklasson.

In most countries, AstraZeneca has been granted Patent Term Extensions or Supplementary Protection Certificates (SPCs) for the substance omeprazole. This extended coverage is valid in the USA until 2001, in most European countries until 2002-2004, and in Japan until 2004. The product is also protected by patents directed to formulation, uses, intermediates and processes, which expire in most markets between 2005 and 2016. In Australia, the substance patent expired on 11 April 1999.

Sales of Losec in Australia in 1998 amounted to approximately USD 105 M, corresponding to roughly 2 per cent of total sales of the product.

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