

News Release from AstraZeneca

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ASTRA FILES SUIT AGAINST GERMAN GENERIC COMPANY

Astra has filed suit in Germany against the German generic company Azupharma. The company recently launched a generic capsule version of omeprazole in Germany. Omeprazole is the substance used in Losec[®].

Astra maintains that Azupharma's action infringes Astra's formulation patent, which expires in 2007. In addition, Azupharma's action infringes Astra's Supplementary Protection Certificate (SPC)¹ for the substance patent.

"We will strongly assert our patent rights pertaining to omeprazole. The research and development work behind the product is very extensive and concerns – in addition to the substance – formulations, manufacturing methods and intermediates. As a result of this advanced work, Losec today is protected by a number of different patents," says Martin Nicklasson, head of AstraZeneca's Gastrointestinal Franchise.

Sales of Losec in Germany amounted to approximately USD 185 M. in 1998, corresponding to approximately 4 per cent of total sales of the product. In Germany, omeprazole is marketed under the brand name Antra MUPS[®] (MUPS – Multiple Unit Pellet System). Antra MUPS was launched during the fourth quarter of 1998 and has successfully replaced the old capsule formulation. MUPS is a new tablet formulation that offers additional patient benefits.

The substance patent for omeprazole begins expiring in the first countries in 1999. In most countries, Astra has been granted Patent Term Extensions or SPCs. This extended coverage for the substance expires in the USA in 2001, in most European countries in 2002-2004, and in Japan in 2004. The product is also protected by patents directed to formulation, uses, intermediates and processes, which expire in most markets between 2005 and 2016.

Further Enquiries:

Media:

Mikael Widell, tel +46 8 553 264 28
+46 70 311 99 60

Steve Brown, tel +44 171 304 5033
Rachel Bloom, tel +1 302 886 7858

Investor Relations:

Michael Olsson, tel +46 8 553 259 52
Jörgen Winroth, tel +1 609 896 4148

Angus Russell, tel +44 171 304 5100
Ed Seage, tel +1 302 886 4065

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The validity in Germany of the SPC for omeprazole for the period 1999-2003 has been challenged, on formal grounds. In June 1997 the SPC was declared invalid by the court of the first instance. This decision was appealed and a decision by the German Supreme Court is pending. In Astra's opinion the decision of the court of the first instance does not have legal force.