

ASTRA

NEWS RELEASE



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GERMAN SUPREME COURT TO CONSIDER IMPORTANT PATENT CASE FOR ASTRA

The German Supreme Court will consider Astra's appeal concerning the invalidation of a previously granted Supplementary Protection Certificate (SPC) for the period 1999–2003 for the substance in the anti-peptic ulcer medication Losec (omeprazole). The SPC was granted in accordance with the EU's regulation governing Supplementary Protection Certificates, which is intended to compensate pharmaceutical companies for the long time spent on development and gaining regulatory approvals.

A German generics company challenged the validity in Germany of the SPC for the substance omeprazole on formal grounds. In June 1997 the SPC was declared invalid by the German patent court. Astra immediately appealed the ruling to the Supreme Court.

In addition to the substance patent, Losec is also protected by a number of other patents directed to formulation, use, intermediates and processes. In Germany and most other countries these patents expire between 2005 and 2016.

"The Supreme Court's ruling is highly significant for Astra as well as the entire research-intensive pharmaceutical industry," says Martin Nicklasson, head of Therapy Area Gastrointestinal at Astra. "The court can now rule on the interpretation of the rules that the EU adopted in 1993 to grant extended patent protection to the pharmaceutical companies."



Astra's sales of Losec in the German market amounted to approximately SEK 1 bn. for the period January–September 1998. Losec MUPS, the new tablet formulation that offers patients additional benefits, was recently launched in Germany.

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