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## **ASTRAZENECA WELCOMES GERMAN SUPREME COURT DECISION TO REFER OMEPRAZOLE SPC CASE TO EUROPEAN COURT OF JUSTICE**

AstraZeneca today welcomed a decision by the German Supreme Court to refer a number of questions about the company's Supplementary Protection Certificate (SPC) for omeprazole to the European Court of Justice (ECJ).

The Court agreed with AstraZeneca's submission that issues involved in the case were of such a nature that the ECJ should decide if Germany can interpret and apply European Union (EU) legislation on SPCs to the detriment of the company.

The dispute is a result of the German generics company ratiopharm GmbH challenging the SPC for omeprazole on formal grounds.

Omeprazole is the active ingredient in Losec®, a treatment for such acid-related disorders as peptic ulcers. In 1998, Losec had sales of USD 185m in Germany, representing 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).

"The referral means that the German interpretation of the applicability of SPCs will be judged against the overall context of what happens elsewhere in member states of the EU," said Dr. Martin Nicklasson, Executive Vice-President of AstraZeneca's Gastrointestinal (GI) Franchise. "The German interpretation has not been as supportive of the research based pharmaceutical industry as other countries and, in our view, does not reflect the original intention of SPCs."

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AstraZeneca has filed requests in Germany for preliminary injunctions against ten companies, has filed six main actions and is currently defending its patent rights in eight other patent cases related to omeprazole. In August 1999, AstraZeneca was granted an interlocutory injunction to prevent ratiopharm GmbH and Merckle GmbH selling a generic version of omeprazole. This ruling is not affected by the Supreme Court decision and is still in force.

#### **NOTE TO NEWS EDITORS:**

In 1992, the EU introduced legislation to restore patent term to support the innovative European research-based pharmaceuticals industry and compensate it for the long, regulatory medical approval procedures. All EU member states were in favour of the legislation.

However, Germany, together with Denmark, decided to limit the scope of the legislation and opted for the least industry-supportive transitional rule.

In addition, the German patent court in 1997 interpreted the legislation in a more restrictive fashion in making its decision regarding AstraZeneca's SPC for omeprazole. This decision negated the intention of the legislation to support an innovative pharmaceuticals industry.

The substance patent for omeprazole began expiring in the first countries in 1999. In most countries, AstraZeneca has been granted Patent Term Extensions or Supplementary Protection Certificates (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 formulations, uses, intermediates and processes.

Further enquires to:

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