

## PATENTWATCH



## EC fines AstraZeneca in Losec antitrust case

AstraZeneca has been found guilty by the European Commission (EC) of giving the wrong market authorization date to European patent offices in an attempt to extend its patent protection for the anti-ulcer blockbuster omeprazole (Losec). The company has also been accused of withdrawing a capsule formulation of the drug to prevent generics companies from copying it. The Commission has fined AstraZeneca €60 million, but the company rejects the validity of the Commission's findings and plans to appeal.

The case revolves around AstraZeneca's applications for Supplementary Protection Certificates (SPCs) for omeprazole made in the 1990s. SPCs came into effect in European legislation in 1993 and, although not official patent extensions, they are designed to allow up to 5 years of extra patent protection when there is a delay in getting market authorization for a drug. However, after several years of legal argument, the Commission recently ruled that AstraZeneca had abused the patent protection system by providing the wrong information in its SPC applications, using the date when the drug was cleared for sale, not the date of the original patent. This enabled the company to prevent generic copies of omeprazole being sold and extended its monopoly of the proton-pump inhibitor (PPI) drug market in several EU countries.

AstraZeneca also attracted further criticism for allegedly removing the capsule formulation of omeprazole, knowing that

cheap generic copies of the drug could only be approved if the original brand was still on the market. However, in a statement on the company's website, AstraZeneca emphasized their right to withdraw or introduce products, and said that the Commission failed to recognize that generics manufacturers could have registered their own versions of omeprazole on the basis of widely available published literature.

AstraZeneca says it will appeal against the ruling because of the potential negative impact it could have on industry competitiveness. Specifically, it criticized the Commission's narrow interpretation of 'market dominance', suggesting that if a company introduces an innovative product then, according to the Commission's interpretation, it could be considered as dominant retrospectively, imposing burdens on the 'dominant' company and hindering market competition.

The ruling represents the first use of antitrust law against abuse of the patent system and comes at a bad time for AstraZeneca, following a troublesome year in which the efficacy and safety of several of its approved and late-stage drugs have been called into question. Sir Tom McKillop, AstraZeneca's CEO, denies that AstraZeneca behaved inappropriately, saying, "We believe that a proper evaluation on appeal of all the facts and legal position will confirm that the Commission's analysis is fundamentally flawed."

*Joanna Owens*