

Court of Justice rejects supplementary protection certificates for products marketed before regulatory approval

Background

In two cases, [*Synthon v Merz \(C-195/09\)*](#) and [*Generics v Synaptech \(C-427/09\)*](#) the patentee applied for a supplementary protection certificate (SPC) to extend patent life for a product. In each case, the patentee had marketed the product in various countries within the Community under national regulatory rules. The Europe-wide regulatory rules referred to in the law concerning SPCs did not come into force until later. Those rules required certain safety and efficacy testing to be carried out before marketing the product in the Community. The patentees later obtained Europe-wide authorisation under the recently-introduced rules, and based their SPC applications on that authorisation.

The cases were referred to the Court of Justice of the European Union (CJEU), the highest court in Europe, which we reported in our Life Sciences Winter 2009 update. If you would like a copy, please let us know.

Decision

The CJEU decided that the products could not be the subject of an SPC, even where the patentee subsequently obtained Europe-wide regulatory authorisation.

The CJEU reasoned that the SPC Regulation compensates the patentee for the time required to acquire authorisation before marketing, during which the patent protection is ineffective. Granting an SPC, which is an extension of exclusivity, for a product which has already been sold in the Community would be contrary to the objective of the Regulation.

Conclusions

An SPC for a product will be valid only if the first marketing authorisation in the European Community is under the Europe-wide regulatory rules. If the product that was on the market in the Community before the Europe-wide regulatory rules came into force, you cannot have an SPC for such a product.

This ruling could further stifle innovation. In particular it is likely to affect research into new medical uses for older pharmaceuticals, for which it is becoming increasingly difficult to obtain SPC protection.