

## GERMANY



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## ECJ limits SPCs to active ingredients

In a recent judgment (C-431/04), the European Court of Justice (ECJ) has gone against the Opinion of the Advocate General and ruled that the German courts were correct in rejecting an application for a supplementary protection certificate (SPC) for the chemotherapeutic Gliadel.

SPCs are provided under Regulation 1768/92/EEC and extend the lifetime of patents covering medicines up to five years. Article 1(b) of the Regulation defines the product to be protected by an SPC as “the active ingredient or combination of active ingredients of a medicinal product”.

The product in question, Gliadel, comprises the cytotoxic drug carmustine embedded in a matrix made of the polymer polifeprosan. The Federal Patent Court had rejected the SPC, arguing that Gliadel was no true combination of active ingredients but rather a new formulation of the long known carmustine.

On appeal, the German Supreme Court (BGH) had addressed a referral to the ECJ, asking whether the concept of a “combination of active ingredients” within the meaning of Article 1(b) of the Regulation must be interpreted as including a combination of two substances, the first of which has pharmacological properties of its own for a specific therapeutic indication while the second substance is necessary for the therapeutic efficacy of the first.

In his opinion on the case, the Advocate General concluded that the ECJ should respond in the affirmative.

The decision issued by the ECJ reaches entirely the opposite conclusion to that of the Advocate General, holding that “a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of active ingredient”.

In coming to its decision, the ECJ sought to define the term “active ingredient”. Therefore, the Court referred to the Explanatory Memorandum to the Regulation specifying: “The proposal

for a Regulation therefore concerns only new medicinal products. It does not involve granting a SPC for all medicinal products that are authorized to be placed on the market. Only one SPC may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new SPC.”

The ECJ found that the same reasoning also applied to the interpretation of Article 3 of Regulation 1768/92/EEC. Accordingly, the combination of a substance not having a therapeutic effect with an active ingredient could not give rise to a “combination of active ingredients” within the meaning of Article 1(b) of Regulation No 1768/92.

Thus, this judgment of the ECJ does not enable patent owners to obtain SPCs for novel formulations of known drugs which will be a disappointment to the research-based drugs industry.