

SPCs for formulation patents

According to Regulation 1768/92/EEC supplementary protection certificates (SPCs) can be granted for novel medicines. They are intended to compensate for the reduced effective lifetime of patents covering such medicines.

Article 3 of the Regulation stipulates that an SPC shall be granted if the “product” is protected by a basic patent, has obtained marketing authorization and has not already been the subject of an SPC or of an earlier authorization. The product is defined in Article 1(b) of the Regulation as “the active ingredient” or “combination of active ingredients” of a medicinal product.

In the absence of a legal definition, it has hitherto been assumed that an active ingredient has to be understood as (a) pharmacologically active compound(s), which means that SPCs would only cover novel and first-to-the market drugs.

However, the German Supreme Court (BGH) recently referred to the European Court of Justice (ECJ) a question as to whether a “combination of active ingredients” necessarily means at least two pharmacologically active compounds, or whether this term also covers the situation where one component exerts its pharmacological effect only when combined with another substance providing no pharmacological effect as such.

The case in question concerns the preparation Gliadel which is protected by European Patent 0 260 415. Gliadel comprises the cytotoxic drug carmustine embedded in a matrix made from the polymer polifeprosan.

The Federal Patent Court had rejected the SPC, stating that Gliadel did not comprise a combination of active ingredients but was rather an example of a new formulation for the already known active carmustine. The Court held that even if polifeprosan ensured the constant delivery of therapeutic amounts of carmustine, it would not act as an active ingredient, but as an excipient.

The BGH referred the above questions to the ECJ since the authorities in the UK, France and the Netherlands had interpreted the term differently and granted SPCs on Gliadel.

If the ECJ decides that polifeprosan and carmustine constitute a “combination of active ingredients”, this will pave the way for SPCs on novel formulations providing a therapeutic advantage for a known drug. For the time being, patentees should thus seriously consider requesting SPCs not only for new drugs, but also for novel formulations.