

## GERMANY



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## ECJ denies SPCs for novel indications

Supplementary protection certificates (SPCs) as provided by Regulation 1768/92/EEC can extend the lifetime of a patent protecting medicines up to five years. SPCs were devised to compensate for the reduced duration of these patents caused by the lengthy procedures involved in obtaining marketing authorization before the launch of a new medicinal product.

With this rationale in mind, it would be reasonable to assume that an SPC could be obtained for a new indication of a known pharmaceutically active agent, since a party seeking to market a known pharmaceutically active agent for a new indication has to conduct clinical studies in order to gain marketing approval, which may result in similar delays as encountered when requesting marketing authorization for a new pharmaceutically active agent. Moreover, novel indications of active agents can also be subject to patent protection, which is one of the requirements for obtaining an SPC.

Nevertheless, the European Court of Justice (ECJ) recently decided that an SPC should not be granted for a novel indication (C-202/05). In this case, the product for which an SPC was requested was an ointment of calcitriol for treating psoriasis. However, calcitriol had previously received marketing approval for treatment of osteoporosis and hypocalcemia.

As in a case dealing with SPCs for novel formulations (C-431/04), the ECJ gave as its reason the fact that Article 3 d) of Regulation 1768/92/EEC would require that the marketing authorization, on which the request for an SPC was based, has to be the first authorization for the product in question. According to Article 1 b), a product would be defined as an active ingredient. This definition would leave no room for the term product to relate also to an active ingredient with a (novel) therapeutic use. Therefore, if the same product, that is the same active agent, had received marketing approval in the past, a request for an

SPC on a novel use for this product must be denied.

In essence, the ECJ has thus taken the position that SPCs may only be granted to extend the lifetime of patents for new pharmaceutically active agents.