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ECJ to rule on SPC dates

Supplementary protection certificates (SPCs) as provided by Regulation 1768/92/EEC can extend the lifetime of a patent protecting medicines for 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.

In a recent decision (BGH X ZB 30/05 “Porfimer”) the German Federal Supreme Court (BGH) referred to the Court of Justice of the European Communities for a preliminary ruling two questions on the interpretation of Article 7 of the Council Regulation (EEC) 1767/92.

In particular Article 7 of the regulation requires that the application for a certificate shall be lodged within six months of the date on which the authorization to place the product on the market as a medicinal product was granted. However, the Article does not specify whether the term of six months has to be interpreted according to Community law, or whether the term has to be interpreted as the date when the marketing authorization becomes effective according to the national law of the respective member state. If the answer to the first question is that the term is to be interpreted according to Community law, the second question is from what date the calculation of the six-month application term of the SPC applies.

In the present case, the marketing authorization, issued on July 9 1997, was served to the applicant on July 15 1997. An application for an SPC was lodged on January 13 1998. In the previous instances, the German Patent and Trade Mark Office and the German Federal Patent Court refused the application as being belated, thus following the interpretation that the term has to be calculated from the issuance date of the authorization.

If, however, the relevant date is the date on which the German marketing authorization becomes effective, the application would have been filed in

due time since according to §25 of the German medicine law (Arzneimittelgesetz), the marketing authorization becomes effective only upon notification of the applicant.

Summarizing, it is clearly advisable to apply for an SPC within the six-month period starting with the (earlier) date of issuance of the marketing authorization to ensure that the application is not refused as being belated.