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ECJ decision C-125/10 on SPCs

SPCs with 'negative' duration allowed by the ECJ: Success for Merck Sharp & Dohme with Abitz & Partner and Hogan Lovells

In the request for preliminary ruling C-125/10 the ECJ has decided on December 8, 2011 that supplementary protection certificates can also be granted with a 'negative' duration.

The ECJ held that if the SPC application had to be refused because the calculation provided for in Article 13(1) of the SPC Regulation results in a negative or zero duration, the holder of the basic patent could not obtain an extension of protection conferred by such a patent, even if it conducted all the studies according to the approved paediatric investigation plan. Such a refusal would be liable to adversely impact on the useful effect of the Pediatric Regulation and might jeopardise the objectives of that regulation, namely the compensation of effort made to evaluate the paediatric effects of the medicinal product at issue.

This decision opens the possibility for the grant of SPCs with 'negative' duration which after 6 months pediatric extension can lead to an effective extension of the protection conferred by the basic patent.

Merck was represented by Abitz & Partner, Dr. Monica Heinemann