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Court rules on SPCs with negative duration

Recently, the Court of Justice of the EU (CJEU) decided on yet another referral on the interpretation of Regulation 1768/92 EEC, which established supplementary protection certificates (SPCs). In the specific case (C-125/10, *Merck Sharp & Dohme v DPMA*), the Court had to comment on SPCs with negative duration.

Article 3 of the Regulation stipulates that an SPC shall be granted if the product is protected by a basic patent in force, has obtained a marketing authorisation and has not already been the subject of an SPC or of an earlier marketing authorisation. Articles 7 and 8 set further requirements on deadlines for timely filing an SPC request and information to be submitted with an SPC request, which according to Article 10 must be fulfilled for an SPC to be granted.

Article 10 does *not* refer to Article 13(1), which stipulates that the duration of an SPC starting after expiry of the basic patent is calculated as the difference between the filing date of the basic patent and the date of the first marketing authorisation within the European Union minus five years. Where the difference between the filing date of the basic patent and the date of the first marketing authorisation is less than five years, the SPC duration would thus be zero. In such a case, it would usually make no sense to apply for an SPC.

This situation is, however, complicated by Regulation 1901/2006 EC, which was implemented to improve development of pharmaceutical products for paediatric populations. Article 36 of Regulation 1901/2006 EC established that an SPC term can be extended by six months if the request for marketing authorisation comprises results of a paediatric investigation plan (PIP) as imposed by this Regulation. Even though Regulation 1901/2006 EC foresees that any request for a marketing authorisation should comprise results of a PIP, under certain circumstances such data may be provided after the initial marketing authorisation. A paediatric extension may be applied for, for example when a marketing authorisation for the product had already issued before implementation of Regulation 1901/2006 EC or if the requirement of the PIP was initially waived by the regulatory authorities.

Thus, pharmaceutical companies may be confronted with a situation where the six-month bonus provided by Regulation 1901/2006 EC would theoretically result in a factual SPC term, but where the SPC term calculated on the basis of the first marketing authorisation without the six-month bonus would be (less than) zero. The question therefore arose whether an SPC with a negative term may be granted, which after completion of the PIP and a correspondingly broadened MA could be extended by six months.

In C-125/10, the CJEU decided that an SPC with a negative term may be granted and may then serve as the basis for a paediatric six-month extension. The Court further decided that the overall term of such an extended SPC shall be calculated as the difference between the negative SPC term plus the six months bonus, from which a term of five years is then to be deducted.

Pharmaceutical companies obtaining a marketing authorisation and having the option of later pursuing a paediatric extension should thus make sure that they initially apply for an SPC with a negative term within six months of the first marketing authorisation or grant of the basic patent in accordance with Article 7 of Regulation 1768/92 EEC. This SPC can then serve for the six-month paediatric extension leading to an SPC term ranging from one day to six months.