

The CJEU allows negative term SPCs

The Court of Justice of the European Union (CJEU) has ruled that a Supplementary Protection Certificate (SPC) may have a “negative term”. This is important to applicants looking to obtain paediatric extensions to their SPC protection.

Overview

SPCs are intended to compensate pharmaceutical companies for the loss of effective patent term caused by the delay in getting regulatory approval. If the first marketing authorisation (MA) for a product takes more than 5 years to obtain after filing for a patent, the SPC will extend patent protection for that product for the time over that 5 years.

The formula for calculating the term of an SPC for a product is:

Term = ([date of 1st MA in the EEA] - [date of filing of corresponding patent]) - 5 years

The maximum term of an SPC is 5 years.

If the time taken to obtain the first MA is less than 5 years, the formula gives a negative term. Until recently, a negative term was meaningless and was thought to be the equivalent of no term at all.

The Paediatric Regulation introduced a 6 month paediatric extension to a granted SPC, to promote research in the paediatric population. A MA for paediatric use can often take longer to obtain than one for the equivalent product for use in adults.

When this regulation came into force, pharmaceutical companies started applying for SPCs, even though the basic term would be zero or even negative, because a subsequent paediatric extension could take the effective term up to 6 months. A paediatric extension can only be obtained if an SPC has been granted.

Background to the case

Merck obtained SPCs for sitagliptin throughout Europe, with differing outcomes. In the UK and the Netherlands the SPCs had negative terms. In Greece, the SPC had a zero term, because the authorities believed a negative term was not available, while the German, Lithuanian, French and Portuguese authorities refused the applications, because the SPCs would have a negative term.

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Merck appealed the German decision. The German court referred to the CJEU the question of whether an SPC must have a positive term. It did not refer the question of whether, if so, it should have a negative term or a zero term.

The Decision

The CJEU concluded that an SPC need not have a positive term.

It found that the Regulations do not to preclude a negative or zero term, and not allowing such a term would be against the objectives of the Regulations, to compensate for the time taken to obtain the MA. The Court noted that the paediatric extension serves a useful purpose.

The CJEU found that the basic SPC can have a negative or a zero term, and that a negative term should not be rounded to zero. The 6 month paediatric extension should start at the “end” of the negative term of the SPC, not the patent expiry date.

In the *Merck* case, the basic SPC had a term of minus 3 months and 14 days. The 6 month paediatric extension gave a final term that ended 2 months and 16 days after the patent expired.

Conclusion

Helpfully, the CJEU did not restrict itself to the referred question, but also decided that the SPC term could be negative. This decision will harmonise Europe on this point.

Innovative pharmaceutical companies will welcome the CJEU’s opinion. They can now benefit from paediatric extensions of their SPCs even when the SPC itself does not extend patent protection.