

Making the Most of Paediatric SPC Extensions

Mike Snodin and John Miles report that the UK has recognised the validity of zero or negative term supplementary protection certificates.

In a previous article for *RAJ Pharma*¹, we argued that the six-month supplementary protection certificate extension under Regulation (EC) No 1901/2006², on medicinal products for paediatric use, should make it possible to apply for and obtain unextended SPCs having either zero or negative term in order to obtain an SPC to serve as the basis for the paediatric extension.

The UK Intellectual Property Office has now agreed with the logic of the arguments put forward in our article, and has granted the first ever SPC having a negative term³. The SPC term awarded by the UKIPO was not as generous as it could have been. Nevertheless, the UKIPO decision confirms our view that it may always be worth applying for an SPC, even if fewer than five years have elapsed between patent filing and the grant of the marketing authorisation.

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Background

The term afforded to an SPC is defined in Article 13 of Regulation (EEC) No 1768/92⁴, and can be summarised as follows:

- the SPC shall take effect at the end of the lawful term of the basic patent;
- the term of the SPC is equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the European Economic Area, reduced by a period of five years; and
- the term may not exceed five years from the date on which the SPC takes effect.

...showing that it may be worth applying for an SPC if fewer than five years have elapsed

Thus, the normal term of an SPC can be more succinctly expressed by equations (I) and (II) below:

$$\text{Normal term} = \{(\text{date of first EEA MA}) - (\text{patent filing date})\} - 5 \text{ years} \quad (\text{I})$$

$$\text{Normal term} - 5 \text{ years} \quad (\text{II})$$

If the first marketing authorisation for a product in the EEA is issued less than five years after the date of filing of the basic patent protecting that product, then equation (I) yields a normal SPC term that is negative. In other words, the rather unusual situation arises where the SPC nominally expires before it comes into force.

There is, of course, no benefit in obtaining an SPC that is incapable of extending the term of protection for a product. For this reason, before Regulation (EC) No 1901/2006 came into force, there was no reason to contemplate the concept of "negative term SPCs". Interestingly, however, the legislation does not appear to prevent SPCs with zero or negative terms from being applied for (or granted).

The paediatric extension

The six-month extension of an SPC's term can be awarded as compensation for obtaining and submitting data from paediatric clinical trials (conducted in accordance with an agreed Paediatric Investigation Plan) on the product protected by the SPC.

If the six-month extension is taken into account, the value of obtaining SPCs with a normal term that is zero or negative can be appreciated. For example, obtaining an SPC with a normal term of -1 month provides, after extension, an SPC with a term of +5 months.

In our previous article, we argued that, if the validity of zero or negative term SPCs is acknowledged, there are two possible ways of calculating the extended SPC term, namely Model A and Model C.

The six-month extension can be awarded for submitting paediatric clinical trial data

Model A

In Model A, the SPC term is calculated in a straightforward manner from equations (I) and (II) above. That is, a numerical value (which can be positive, zero or even negative) for the normal

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SPC term is determined. The extended term is then calculated by adding six months to the normal term.

If Model A is used, then there is benefit in applying for an SPC if:

- (a) results from an agreed PIP on the patented product will be submitted; and
- (b) more than four and a half years have elapsed between the filing of the basic patent protecting the product and the issuance of the first marketing authorisation for the product in the EEA.

Model C

In Model C, the SPC term is calculated in a slightly different manner. First, the normal SPC term is calculated by using equations (I) and (II) above, but all terms that are less than zero are "rounded up" to zero term. Thus, when the six-month extension is added to the normal term, the minimum extended term is six months.

If Model C is used, then there is *always* benefit in applying for an SPC if results from an agreed PIP on the patented product will be submitted.

There is always benefit in applying for an SPC under Model C if PIP results will be submitted

The UKIPO decision

The UK decision in question related to SPC application No SPC/GB07/046. That application was filed by Merck & Co, and related to the product sitagliptin phosphate monohydrate (Januvia).

In the SPC application, the basic patent protecting Januvia was stated to be EP 1 412 357 B1, which was filed on 5 July 2002. The centralised marketing authorisations for Januvia (EU/1/07/383/001-018) were granted on 21 March 2007. Thus, the time that elapsed between patent filing and first marketing authorisation in the EEA was four years and 259 days (four years, eight months and 16 days).

The UKIPO was initially not inclined to grant an SPC for Januvia, as its calculations indicated that the SPC would not have a positive term. However, after carefully considering the argumentation put before it, the UKIPO agreed that there was no basis in law to refuse the application.

The SPC term awarded by the UKIPO was based upon a calculation in accordance with Model A, as described above. Thus, the normal term of the SPC is set to expire on 20 March 2022, some 106 days (three months and 15 days) *before* the expiry of the basic patent (EP 1 412 357 B1).

The normal term of Januvia's SPC will expire before the basic patent does

Discussion

SPCs having a zero or negative term represent a concept that will be alien to many involved in product lifecycle management. Nevertheless, such SPCs have now been confirmed by the UKIPO as having a rightful place in the armoury of those seeking to obtain the maximum possible benefit from the six-month extension to SPC term.

By awarding a negative term under Model A (rather than a zero term under Model C), the UKIPO has not been as generous as it could have been. We continue to believe that there are reasonable arguments in favour of using Model C to calculate the extended SPC term, although the UKIPO has expressed the view in its decision that rounding up to zero should not take place.

Model C provides six months of SPC term regardless of how short the period of time was between the filing of the basic patent and the issuance of the first marketing authorisation in the EEA. This is consistent with the reasons given in Regulation (EC) No 1901/2006 for providing various rewards (including a six-month extension to SPC term). That is, the rewards are compensation for conducting clinical studies in the paediatric population. The reasons for providing those rewards are entirely separate from (and independent of) the original reasons for creating the SPC system.

It remains to be seen whether it will be possible to persuade a patent office (or a national court or the European Court of Justice) to accept a calculation of extended SPC term under Model C. However, given the potential benefits involved, this seems to us to be a point worth arguing.

References

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