Making the Most of Paediatric SPC Extensions

Companies planning to conduct paediatric trials in Europe may be entitled to more extended supplementary protection certificate protection than they think, say *Mike Snodin* and *John Miles*.

On 26 January 2007, Regulation (EC) No 1901/2006, on medicinal products for paediatric use, came into force[1]. Among other things this regulation provides for a six-month extension to the term of a supplementary protection certificate (SPC).

Extension of the supplementary protection certificate (SPC) term is far from straightforward

Although the SPC term extension appears to be a fairly straightforward provision, we have concluded that this is far from the case. In this paper, we discuss three possible models for calculating the term of "extended" SPCs. Two of the three models involve the new concept of applying for SPCs that, without the six-month extension, would have no term (or even a negative term).

The conclusions that we reach could have a significant impact upon strategies for product lifecycle management. This is because we believe that, if paediatric trials are to be conducted on a product, then 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.

Background

SPCs are intended to compensate for the loss of effective patent term caused by regulatory delays in bringing new products to market

In the European Union (EU), SPCs are a form of intellectual property associated with certain marketed medicinal products. They are intended to compensate for the loss of effective patent term caused by regulatory delays in bringing new medicinal products to market. The principal EU legislation relating to SPCs is Regulation (EEC) No 1768/92[2]. This permits the grant of an SPC for a "product", provided that certain preconditions are met.

The most important preconditions are those set out by Article 3, which requires that, in the country where the SPC application is made, and at the date of that application:

- the product is protected by a basic patent in force;
- a valid marketing authorisation (MA) has been granted in respect of the country in question;
- the product has not already been the subject of an SPC; and
- the MA referred to above is the first MA to place the product on the market as a medicinal product.

Thus, provided that the "product" is new to the market (and has not been previously protected by an SPC), all that is required to provide eligibility for an SPC in a particular country is the existence in that country of both a relevant patent that is in force and a valid MA. The term afforded to an SPC is defined in Article 13 of Regulation (EEC) No 1768/92, and can be summarised as follows:

The term afforded to an SPC may not exceed five years from the date on which it takes effect

i) the SPC shall take effect at the end of the lawful term of the basic patent;
ii) 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 (EEA), reduced by a period of five years; and
iii) the term may not exceed five years from the date on which the SPC takes effect.

Provisions (ii) and (iii) above can be more succinctly expressed by equations (I) and (II) below.

Normal term = {(date of first EEA MA) - (patent filing date)} - 5 years (I)
Normal term = 5 years (II)

If an SPC is granted, it has the effect of providing extended exclusivity for a marketed product. Figure 1 is a graphical representation of the period of exclusivity (provided by patent alone or by a combination of patent and SPC protection) that is available to such a product following the grant

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of the first MA in the EEA. This exclusivity is plotted against the time elapsed between the date of patent filing (the patent being one protecting the product in question) and the date of MA issuance for the product in question.

Figure 1. Postmarketing exclusivity provided by patent and (unextended) SPC protection

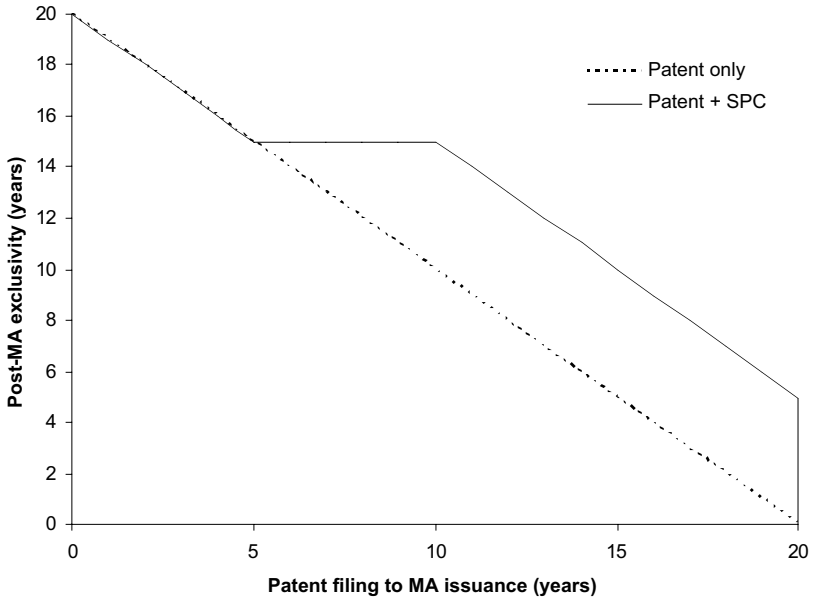


Figure 1 is a graphical representation of the exclusivity period available…

As can be seen in Figure 1, equation (I) above allows for a "plateau" at 15 years of postmarketing exclusivity. This plateau lasts for five years, after which equation (II) takes effect and causes a linear decline to a value of five years (which is the period of exclusivity obtained if the MA is granted on the last day of the term of the basic patent, and an SPC is applied for on that date).

The dramatic drop to zero term after 20 years from patent filing reflects the lapse of the basic patent at this point, and the loss of a critical condition for the grant of an SPC (the existence of a basic patent in force).

…plotted on the assumption that no SPC application would be made if five years or less had elapsed between filing and the grant of the marketing authorisation

The graph of Figure 1 has been plotted on the assumption that no SPC application would be made if five years or less had elapsed between patent filing and the grant of the MA. This is because, before five years and one day had elapsed, the term calculated according to equation (I) above would be either zero or negative (and thus of no use in extending postmarketing exclusivity).

As far as we can tell, there is nothing in Regulation (EEC) No 1768/92 that actually prevents an SPC being awarded for either zero or negative term, provided that the preconditions for the award of an SPC (including those specified by Article 3) are met.

Of course, given that an SPC does not take effect until after the basic patent has expired, the concept of negative term for an SPC seems slightly absurd. However, it may have some sense (and reality) when one considers the six-month extension to the SPC term provided by Regulation (EC) No 1901/2006.

The paediatric extension

Article 36 of Regulation (EC) No 1901/2006 details the extension to the SPC term that is available under certain conditions (including, most importantly, the submission of a new MA application containing data from all trials conducted in accordance with a paediatric investigation plan).

The extension to the SPC term defined in Article 36(1) is *a six-month extension to the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92*. Thus, the extended term available can be described by the following equations:

Extended term = {(date of 1st EEA MA) - (patent filing date)} - 5 + 0.5 years (I′)
Extended term = 5.5 years (II′)

There are three possible interpretations of the extended term

In applying equation (I′) above, there are three possible interpretations, which we shall discuss below as Models A, B and C.

Model A

In Model A, the phrase *reduced by a period of 5 years* from Article 13(1) of Regulation (EEC) No 1768/92 is considered to be modified by Article 36(1) of Regulation (EC) No 1901/2006 such that it

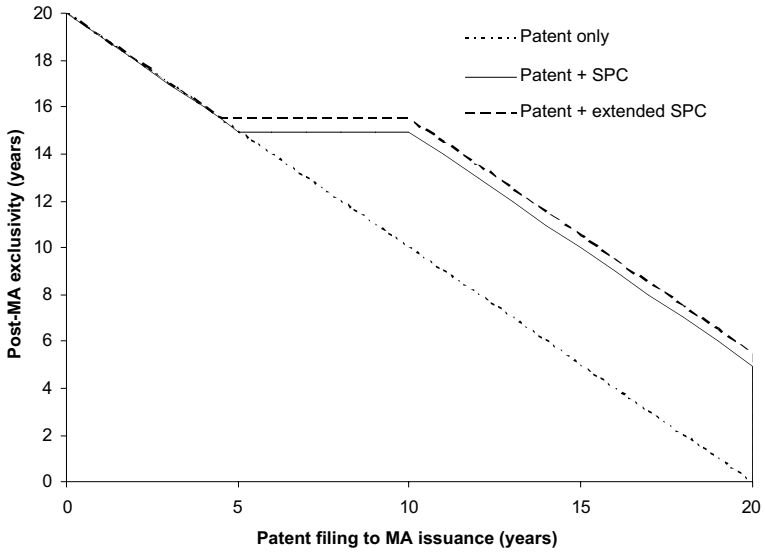
reads *reduced by a period of 4.5 years*. The plot of postmarketing exclusivity produced under this model is set out in Figure 2.

As can be seen from Figure 2, the extended SPC provides an exclusivity "plateau" at 15.5 years, a plateau that begins at 4.5 years from patent filing. As with normal (unextended) SPC protection, the exclusivity declines linearly after 10 years from patent filing, but to a final level of 5.5 years (instead of five years).

The most interesting fact about Model A is that, if correct, it allows for the granting of SPCs that, without the extension provided by Regulation (EC) No 1901/2006, would have either zero or negative term. That is, in contrast to the situation before the regulation came into force, there would now appear to be the possibility of obtaining additional exclusivity in situations where an MA for a product is granted between 4.5 and five years from filing of the basic patent protecting that product.

Model A allows for the granting of SPCs that, without the extension, would have either zero or negative term

Figure 2. Postmarketing exclusivity provided by Model A extended SPC protection



Model B

In Model B, it is assumed that the granting of an SPC is a two-step process, wherein:

Model B assumes that the granting of the SPC is a two-step process

(1) an SPC under Regulation (EEC) No 1768/92 is obtained; and
(2) a six-month extension is added to the term of that SPC.

Model B also assumes that, in step (1) above, SPCs with negative terms will *not* be granted.

A plot of postmarketing exclusivity produced under this model is set out in Figure 3, which focuses upon the part of the plot that differs from Figure 2. Between 4.5 and five years from patent filing, Model B produces the curious result of a decline, and then a sudden increase in postmarketing exclusivity.

Model C

Model C is the same as Model B, except that it is assumed that, in step (1) above, SPCs will be granted with zero term if the time from patent filing to MA issuance is five years or less. The plot in Figure 4 shows that Model C simply produces a 0.5 year upwards shift of the normal (unextended) exclusivity provided by a combination of patent and SPC protection.

Under Model C, SPCs will be granted with zero term if the time from patent filing to marketing authorisation issuance is five years or less

Worked example

We shall take a "hypothetical" (but still perfectly possible) worked example of a situation where Models A, B and C will produce different results. In this example, we shall assume the following:

Patent filed:	1 January 2000
Patent granted:	1 January 2008
First EEA (adult) MA granted:	1 October 2004
Paediatric MAs granted in all EU states:	1 January 2010

Thus, the time elapsed between filing of the (basic) patent and issuance of the first MA for the product in the EEA is four years and nine months. An application for an SPC can be made any time from patent grant to six months thereafter (1 July 2008). If an SPC is applied for in this period, Models A, B and C would produce the following results.

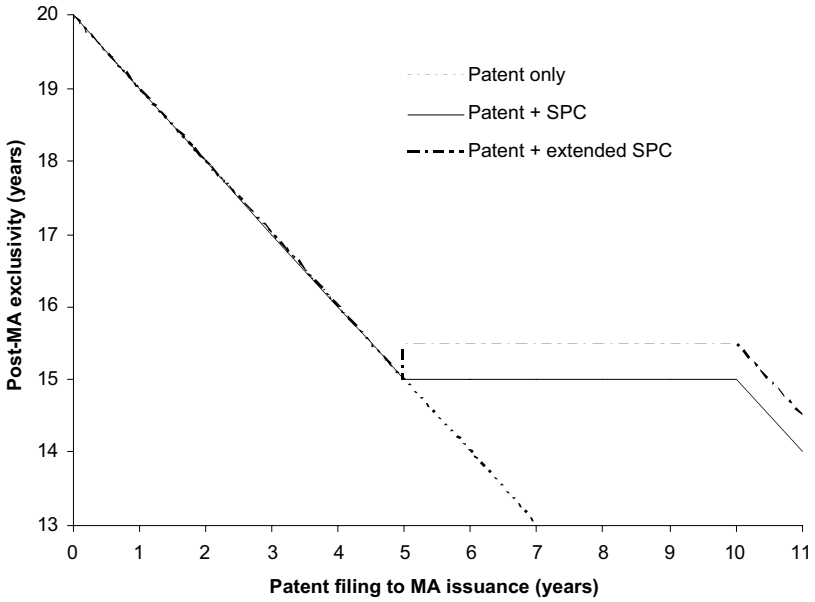
Model "Normal" SPC Term	
A	– 3 months
B	0 (No SPC available)
C	0 months

Following the grant (on 1 January 2010) of paediatric MAs in all EU member states, an application for extension of the SPC could be made. The terms then afforded by Models A, B and C would be as follows.

Model Extended SPC Term	
A	+ 3 months
B	0 (No SPC available)
C	+ 6 months

The terms followed by the three models can be shown in a worked example

Figure 3. Postmarketing exclusivity provided by Model B extended SPC protection



Discussion

Two of the models discussed above (ie Models A and C) introduce a new concept for SPC applications, namely applying for an SPC that, without the six-month extension, would have either zero or negative term.

The concept of a zero or negative term must surely be correct

Although this concept will be alien to those dealing with SPCs, we believe that it must surely be correct. This is because the only alternative model (Model B above) produces a perverse situation where the period of postmarketing exclusivity obtained can be *longer* if an MA is obtained *later*. That is, under Model B, the granting of an MA in the period between 4.5 and five years from patent filing leads to shorter postmarketing exclusivity than does obtaining an MA grant at any time from five to 10 years after patent filing.

In deciding between the two models that do not produce this perverse result, we are of the view that, based upon a literal reading of the texts of the various regulations, Model A is the more likely to be correct. However, if Regulation (EC) No 1901/2006 is interpreted teleologically (which is the usual approach for EU legislation), then we believe that there are reasonable arguments for asserting that Model C is correct. This is based primarily upon the grounds that Model C does not result in a relative disadvantage for those that obtain rapid grant of an MA (less than 4.5 years from patent filing).

Finally, we note that the reasons given in Regulation (EC) No 1901/2006 for providing various rewards (including a six-month extension to SPC term) are based upon the conduct of clinical studies in the paediatric population. Because these reasons are entirely separate from (and independent of) the reasons for creating the original SPC system, it is our view that this provides an additional argument for asserting that either Model A or Model C is the correct interpretation of the six-month extension.

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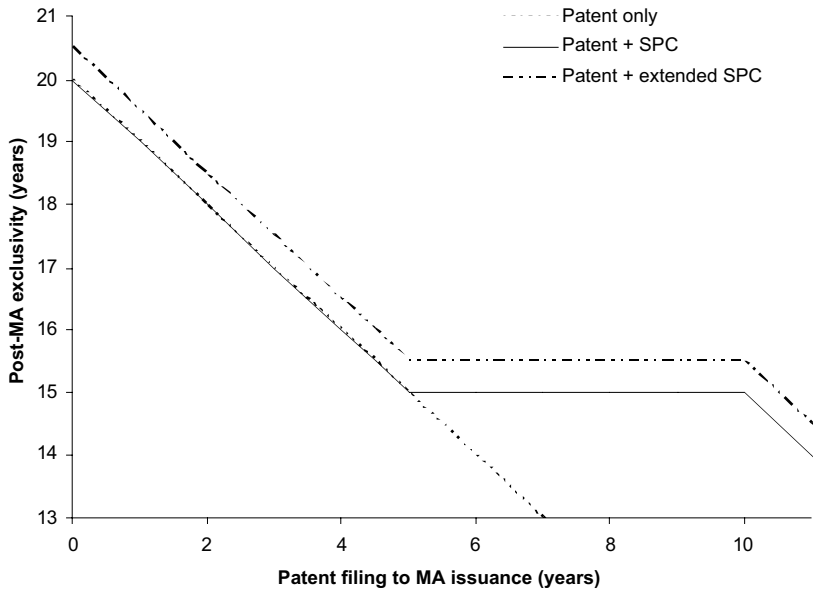
If either Model A or Model C is correct, then this will have an impact on the development of strategies for product lifecycle management, on the grounds that it will now be possible to apply for and obtain useful SPC protection even for those products that benefit from rapid granting of an MA.

Figure 4. Postmarketing exclusivity provided by Model C extended SPC protection



Model C simply produces a 0.5 year upwards shift of the normal (unextended) exclusivity provided by a patent plus SPC protection