Hopes rise for a bright future for paediatric SPC extensions in the EU

It will be good news for the innovative pharmaceutical industry if the Court of Justice of the EU accepts the opinion of one of its advocates general that negative term supplementary protection certificates should be accepted in order to meet the objectives of the regulations governing SPCs and their extension. ***Mike Snodin*** reports.

In an article in 2007 for *RAJ Pharma*[1], a predecessor of this publication, John Miles and I argued that the six-month supplementary protection certificate extension under the EU Paediatric Regulation (No 1901/2006) 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.

In a non-binding opinion issued on 9 June 2011[2,3], Advocate General Yves Bot of the Court of Justice of the EU concluded that negative term SPCs should indeed be granted, in order to meet the combined objectives of the regulations[4] governing SPCs and their extension.

The CJEU will now consider the opinion of Mr Bot in the preparation of its final, binding ruling, which is likely to be issued within the next six months. Rulings of the CJEU often follow opinions of advocates general, although this is not always the case.

It will be good news for the innovative pharmaceutical industry if the CJEU follows Mr Bot's opinion. Acceptance of negative term SPCs would increase the number of patents upon which (extended) SPCs can be based. It would also eliminate a perverse incentive to delay the issuance of marketing authorisations for some new products that would exist if negative term SPCs were rejected.

Mr Bot's opinion, however, is a disappointment to patent holders who obtain marketing authorisations four years and six months or less after patent filing. This is because those patent holders could, if the CJEU follows Mr Bot's opinion, be in the unenviable position of having a new burden imposed upon them (the obligation to conduct trials in the paediatric population), but no extended monopoly period to help them to recoup the additional costs involved.

Background

SPCs provide protection for the use in authorised indications of (combinations of) active agents present in marketed medicinal products. SPCs are awarded to the holders of patents that provide compound, composition, process or use protection for the relevant (combination of) active agent(s).

The term of an SPC is set by the difference between the fifth anniversary of patent filing and the date of the first marketing authorisation in the European Economic Area for a medicinal product containing the (combination of) active agent(s) concerned. The term of an (unextended) SPC, however, is capped at a maximum of five years.

The effect of (unextended) SPCs is to ensure that, for medicinal products that qualify for SPC protection, the SPC monopoly period expires at the very least five years after the date of first marketing in the EEA, and at the very most 15 years from that date.

Before the possibility of a six-month extension of SPC term was introduced by the Paediatric Regulation, there was no point in applying for an SPC if less than five years and one day had elapsed between the date of patent filing and the date of first marketing authorisation issuance in the EEA. This is because any SPC obtained would not have had a positive term, and would not, therefore, have served to provide any further monopoly period beyond patent expiry.

The possibility of a six-month extension to SPC term, however, means that it might now be possible to obtain a period of monopoly beyond patent expiry even in the circumstances where the calculation of unextended SPC term reaches a zero or negative figure.

Sitagliptin

Whether it is possible to obtain unextended SPCs of zero or negative term was put to the test by Merck & Co, in connection with SPC applications for sitagliptin phosphate monohydrate (the active agent present in Januvia).

The SPC applications filed by Merck & Co identified a patent filing date (for EP 1 412 357 B1) of 5 July 2002 and an earliest marketing authorisation date (for EU/1/07/383/001-018) of 21 March 2007. The time elapsed between patent filing and earliest marketing authorisation issuance was, therefore, less than five years and one day (ie only four years, eight months and 16 days).

Merck & Co's SPC applications resulted in different decisions at different national patent offices, wherein, for example:

- the offices in the UK[5], the Netherlands and Ireland granted SPCs with a negative term of three months and 15 days ("Model A" of the above-mentioned 2007 *RAJ Pharma* article);
- the offices in Germany, Portugal and Slovenia rejected the SPC applications ("Model B" of the 2007 article); and
- the office in Greece granted an SPC with zero term ("Model C" of the 2007 article).

Upon appeal of the rejection of the SPC application in Germany, and in view of the inharmonious situation across different territories of the EU, the German Federal Court of Justice (Bundesgerichtshof) asked the CJEU to clarify whether SPCs can be granted in the situation where the unextended SPC would not have a positive term. This question is now pending before the CJEU, as case C-125/10.

AG opinion in C-125/10

Advocate General Bot is of the opinion that SPCs can be granted with a non-positive term. His reasoning for reaching this view is based on his belief that the legislation governing SPCs and their extension[6] can be viewed as having the combined objective of ensuring a maximum total of 15 years and six months of post-marketing exclusivity for products benefiting from both patent and SPC protection.

In essence, Mr Bot agrees with the patent offices of the UK, the Netherlands and Ireland that "Model A" of the above-mentioned 2007 *RAJ Pharma* article should be applied. This would enable patent holders to obtain an additional (extended SPC) monopoly period beyond patent expiry in the circumstances where more than four years and six months have elapsed between patent filing and earliest marketing authorisation issuance.

Commentary

The innovative pharmaceutical industry will welcome Mr Bot's opinion as representing a pragmatic interpretation of the objectives of the legislation governing SPCs and their extension. A particularly important practical aspect of the opinion is that, if followed in the CJEU's final ruling, there will no longer be a perverse incentive in some cases to delay marketing authorisation issuance in order to obtain a longer patent/SPC monopoly period.

However, the opinion will not allay the concerns of those who obtain marketing authorisation issuance four years and six months or less after patent filing. This is because this category of patent holder could still be obliged to conduct additional clinical trials in the paediatric population, but would not have the option of using an extended monopoly period to recoup the costs associated with the additional trials.

There may, therefore, be some in the innovative industry who will be hoping that the CJEU does not follow Mr Bot's opinion, but instead agrees with the patent office of Greece. If this were to happen, patent holders

might be able to obtain a full six-month period of (extended) SPC monopoly beyond patent expiry, regardless of how short the time between patent filing and marketing authorisation issuance.

As discussed in the 2007 *RAJ Pharma* article, a uniform reward of a full (additional) six months of SPC exclusivity after expiry of a patent meeting the qualifying criteria of the SPC legislation[7] could well be viewed as being consistent with the objectives of the Paediatric Regulation.

In particular, Recital (26) of the Paediatric Regulation indicates that, for those products where the marketing authorisation holder has satisfied the obligations of the regulation:

> "***a reward should be granted*** *in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92*" (emphasis added).

It will be interesting to see what the CJEU makes of this point, especially with regard to what "reward" will be granted to those who are able to obtain an SPC having a term of negative six months or less.

References

1. *Snodin M and Miles J, Making the Most of Paediatric SPC Extensions, Regulatory Affairs Journal – Pharma, 2007, 18(7), 459-463*
2. *CJEU opinion, Merck, Sharpe & Dohme v German Patent and Trademark Office, C-125/10 (in German), 9 June 2011, http://bit.ly/rkOTuM*
3. *EU court's decision on negative-term SPCs could extend drugs' patent protection, Regulatory Affairs Pharma, 13 June 2011*
4. *Regulation (EEC) No 1768/92 of 18 June 1992 and Regulation (EC) No 1901/2006 of 12 December 2006 (the relevant provisions of which are now codified in Regulation (EC) No 469/2009 of 6 May 2009)*
5. *Snodin M and Miles J, Making the Most of Paediatric SPC Extensions, Regulatory Affairs Journal – Pharma, 2008, 19(6), 387-388*
6. *See Reference 4*
7. *Article 3 of Regulation (EC) 469/2009 of 6 May 2009*

For author details, see following article.

