

European court ruling on SPCs brings relief to industry

The acceptance by the European court of justice of supplementary protection certificates having non-positive terms is welcome news for the innovative pharmaceutical industry, says *Mike Snodin*.

In July 2007, in a predecessor publication to *Scrip Regulatory Affairs*, my colleague John Miles and I introduced the revolutionary concept of zero or negative term supplementary protection certificates (SPCs)¹. Our view was that the granting of such SPCs was necessary in order to provide full effect to the reward of a six-month SPC extension governed by Article 36(1) of the EU Paediatric Regulation².

In a decision issued on 8 December 2011^{3,4}, the Court of Justice of the EU has now agreed with our proposition and has effectively ruled that Model A of our 2007 article represents the correct approach for calculating the term of an extended SPC. The decision of the Court of Justice follows the opinion previously provided by advocate general Yves Bot⁵.

This ruling represents good news for the innovative pharmaceutical industry, as it means that useful (extended) protection for a marketed medicinal product can be provided by SPCs when the date of the first marketing authorisation for the product in the European Economic Area is at least four years, six months and one day later than the date of filing of a patent protecting the product. Prior to the ruling, some national patent offices were of the view that no SPC protection could be granted unless at least five years and one day had elapsed between patent filing and marketing authorisation issuance.

The ruling of the court has increased the number of patents upon which (extended) SPCs can be based. It has also eliminated a perverse incentive to delay the issuance of marketing authorisations for some new products that would have existed if negative term SPCs had been rejected.

However, the ruling will not benefit those patent holders who obtain very rapid approval of their new products (ie four years and six months or less after patent filing). Those patent holders will therefore need to look to options other than an extended post-marketing monopoly period for recouping the additional costs involved in conducting (often mandatory) clinical trials in the paediatric population.

Background

The decision of the CJEU is connected to an appeal against the refusal of a German SPC application that was filed by Merck & Co on 14 September 2007. The product for that SPC application was sitagliptin (optionally in salt form, particularly sitagliptin phosphate monohydrate).

Sitagliptin and its salts are protected by European patent no: 1 412 357 B1, which was filed on 5 July 2002. An EU authorisation for Januvia (sitagliptin phosphate monohydrate) was issued on 21 March 2007.

For the product identified on Merck's German SPC application, the time elapsed between patent filing and earliest marketing authorisation issuance was therefore four years, eight months and 16 days. Calculating SPC term according to the normal rules⁶ (X – five years, where X is the time elapsed from patent filing to marketing authorisation issuance) would result in an SPC for sitagliptin with a term of minus three months and 15 days. The German Patent and Trademark Office refused to grant such an SPC, because it believed that it was not correct to grant an intellectual property right with a non-positive duration.

The refusal of the German SPC application was appealed to the Federal Court of Justice (Bundesgerichtshof). In the light of diverging decisions in respect of corresponding SPC applications in other European territories – SPCs for sitagliptin, based upon EP 1 412 357 B1, had been granted in the UK, the Netherlands and Greece⁷ – the Bundesgerichtshof sought clarification from the CJEU with regard to whether it was permissible to grant an SPC with a non-positive term (and, if so, how the term of such an SPC should be calculated, especially once extended by six months).

The decision

In relation to the first question referred to it, the CJEU has ruled that non-positive term SPCs are acceptable. The court's reasoning on this point is based upon its belief that, taken together with the six-month extension provided by the Paediatric Regulation, the SPC legislation provides patent holders with a maximum of 15 years and six months of post-marketing exclusivity for products that are the subject of extended SPC protection. Such maximum post-marketing exclusivity could not be guaranteed without allowing the grant of zero or negative term SPCs.

The court has also ruled that extended SPC term is to be determined by simply adding six months to the term (whether negative, zero or positive) calculated by using the normal rules. This second aspect of the decision rules out "rounding up to zero" of any negative term calculated according to the normal rules. As discussed in connection with Model C of

the above-mentioned 2007 article, such "rounding up" could have been adopted so as to ensure that the reward for conducting paediatric trials is always an additional six months of SPC term.

The court's decision on this point means that those patent holders who obtain approval of their new products four years and six months or less after patent filing cannot use the SPC system to obtain an extended post-marketing monopoly period. This is so even if those patent holders elect to, or are obliged to, conduct clinical trials in the paediatric population in accordance with a plan agreed with the European Medicines Agency.

Commentary

The innovative pharmaceutical industry will welcome the acceptance of SPCs having non-positive terms, as this increases the number of patents upon which useful (extended) SPC protection can be based. It also irons out a potential peculiarity (a perverse incentive to delay authorisation of new products in order to obtain longer post-marketing exclusivity) that would have existed if the court had reached a contrary decision.

An unusual aspect of the decision is that the court adopted different approaches for ruling upon the two questions that it addressed. That is, for approving the validity of SPCs with non-positive term, the decision looks to the combined objectives of the SPC Regulation and the Paediatric Regulation⁸. On the other hand, for ruling out the use of SPCs to obtain post-marketing exclusivity greater than 15 years and six months (ie for deciding to adopt Model A in preference to Model C from the above-mentioned July 2007 article), the decision looks only to a provision of the SPC Regulation⁹.

The ruling of the court has increased the number of patents upon which (extended) SPCs can be based

The adoption of Model A in preference to Model C may have disappointed some in the innovative industry, as it means that conducting (often mandatory) clinical trials in the paediatric population will not always lead to a "reward" of an extended post-marketing monopoly period. This is because those patent holders obtaining authorisation of products four years six months or less after patent filing

will not be able to obtain grant of extended SPCs with a positive term (though it appears that they may not be prevented from obtaining extended SPCs with zero or negative term).

Nevertheless, it is possible to view the decision to limit combined patent and SPC protection to a maximum of 15 years and six months as being consistent with the intention of the Paediatric Regulation, even if the manner in which that intention is put into effect (by way of unextended SPCs with non-positive term) was never contemplated by the legislators.

Following the decision of the CJEU, we can now expect a number active ingredients (or combinations of actives) to be protected by SPCs that, at least until extensions are awarded, will have a negative term. This could lead to some interesting situations if six-month extensions of term are not granted before the expiry of original SPC term. That is, it remains to be seen what the legal significance (if any) of a negative term SPC will be in the period between its expiry date and the (later) date of expiry of the patent upon which it is based.

Regardless of how this issue is ultimately decided, two factors mean that it is not likely to be of great relevance in the long term.

Firstly, more and more newly authorised medicinal products will have been subject to the provisions of Article 7 of the Paediatric Regulation. Those provisions are such that, in the absence of a relevant waiver, data from paediatric trials must be submitted at the same time as data from clinical trials involving adults. For such new products, it is therefore likely that applications for extension of SPC term will be submitted at the same time as applications for unextended SPCs.

Secondly, from 26 January 2012, the deadline for applying for an extension of SPC term will be brought forward 18 months (to two years before SPC expiry). This should provide national patent offices ample time to grant extensions of term before expiry of even a negative term SPC.

Taken together, these two factors should ultimately eliminate any chances of (unextended) SPCs reaching expiry before the patents upon which they are based.

References

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2. *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)

3. CJEU case C-125/10, *Merck, Sharpe & Dohme v Deutsches Patent- und Markenamt*, <http://bit.ly/lrkOTuM>
4. *Top European court confirms validity of negative term SPCs; welcome news for pharma industry*, *Scrip Regulatory Affairs*, 14 December 2011
5. Snodin M, *Hopes rise for a bright future for paediatric SPC extensions in the EU*, *Scrip Regulatory Affairs*, 19 July 2011
6. *Article 13 of Regulation (EEC) No 1768/92 (which Regulation is now codified as Regulation (EC) No 469/2009)*
7. Snodin M and Miles J, *Making the Most of Paediatric SPC Extensions*, *The Regulatory Affairs Journal – Pharma*, 2008, 19(6), 387-388 (*Scrip Regulatory Affairs*, 13 June 2008)
8. See paragraph 38 of the decision in case C-125/10
9. The calculation of term rules set out in Article 13(1) of Regulation 1768/92: see paragraph 41 of the decision in case C-125/10

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