Every day counts: why pharmaceutical companies in the EU need to make sure they get the right SPC term

Pharmaceutical companies using the centralised authorisation procedure in the EU may be entitled to a slightly longer supplementary certificate procedure term than they might think, says ***Mike Snodin***.

Because of the way in which the period of validity of a centralised marketing authorisation in the EU is calculated, the duration of certain supplementary protection certificates may be a few days longer than the information provided by certain national patent offices might suggest. At the very least, the proprietors of certain SPCs based upon centralised authorisations will be able to file appeals aimed at obtaining a corrected (and longer) term. Having even a few extra days on the market without any generic competition can make a substantial difference in terms of additional sales.

In addition, SPC applicants who rely on a centralised authorisation may have at least one day longer to apply for their SPC than they might have thought.

Background

In the centralised authorisation procedure, the European Medicines Agency acts as the evaluating authority and the European Commission issues the marketing authorisation. In recent years, there has been an increase in the number of products for which a centralised marketing authorisation is the first marketing authorisation obtained in the European Economic Area.

For SPCs, both the term of the certificate and the deadline by which an application must be filed are determined by reference to the date a marketing authorisation is obtained.

Article 13 of the updated SPC Regulation (Regulation (EC) 469/2009[1]) defines the term of an SPC. In essence, this is the difference between the fifth anniversary of patent filing and the date of the first marketing authorisation in the EEA for the relevant medicinal product (plus six months if a paediatric extension is obtained). The term of an SPC, however, is capped at a maximum of five years (or five years and six months if a paediatric extension is obtained).

Article 7 of Regulation (EC) 469/2009 defines the deadline by which an SPC application must be filed, which is six months from the date on which a marketing authorisation is granted in the country where the SPC application in question is filed.

For marketing authorisations obtained via the centralised procedure, there are two dates associated with the grant of a marketing authorisation, namely:

(1) the date that the commission reaches a decision to issue a marketing authorisation; and

(2) the date that the applicant is notified of the commission's decision.

Date (2) is always at least one day later (typically from 1-4 days later) than date (1).

In many national patent offices, including the offices of Germany, France, the UK, Italy, Ireland, Sweden, the Czech Republic and the Netherlands, the standard practice appears to be to use, where relevant, the decision date (ie date (1) above) to determine the term of an SPC and/or the period for applying for an SPC.

However, as will be discussed below, this standard practice appears to be at odds with the period of validity of marketing authorisations obtained via the centralised procedure.

Legal basis

Each marketing authorisation issued via the centralised procedure (as a commission decision) contains an indication, in Article 4 of the decision, that:

> *The period of validity of the authorisation shall be five years from the* ***date of notification*** *of this Decision (emphasis added).*

Thus, it can be seen that a marketing authorisation issued via the centralised procedure does not actually take legal effect until the authorisation is notified to the applicant. In other words, the marketing authorisation holder is unable to lawfully sell the product that is the subject of the authorisation until the notification date (date (2) above). This is consistent with the fact that the marketing authorisation holder will not be aware of the commission's decision until the notification date.

The date of legal effect of the commission decision is confirmed in the commission's Notice to Applicants[2], which (at point 2.3 of Volume 2A, Chapter 6) indicates that the commission decision mentioned "only takes effect upon the date of notification".

Moreover, the notification date is also used (in preference to the decision date) in connection with another form of intellectual property (ie regulatory data protection, otherwise known as data exclusivity) that has a term set by the date of a centralised marketing authorisation. That is, procedural advice from the EMA[3] for users of the centralised procedure for generic/hybrid applications makes it clear (in the answer to question 12 in the January 2011 version of the advice) that it is the notification date that determines the period of regulatory data protection.

Relevance to SPCs

With respect to determining the term of an SPC, Article 13 of Regulation (EC) 469/2009 refers to:

> *the date of the first authorisation to place the product on the market in the Community.*

For determining the deadline for applying for an SPC, Article 7 of Regulation (EC) 469/2009 refers to:

> *six months of the date on which the authorisation referred to ... to place the product on the market as a medicinal product was granted.*

These phrases derive from provisions[4] that predate the creation of centralised authorisations. Thus, there is nothing in the articles (or indeed the relevant official preparatory documents) of the SPC legislation that can be used to help clarify whether the decision date or the notification date should be used in connection with SPCs. Further, no ruling of the Court of Justice of the European Union has ever addressed the date of validity of a centralised authorisation in connection with SPCs.

To the knowledge of the author, there is no specific reason why so many national patent offices have, as their standard practice, used the decision date of a centralised authorisation to determine SPC term. Indeed, in the light of the commission and EMA documents discussed above, this standard practice appears to be incorrect.

Moreover, a further rationale for the notification date in preference to the decision date can be found in Recital (9) of Regulation (EC) 469/2009, which states that:

> *the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.*

The clear inference from this recital is, therefore, that the legislators intended to ensure that the holder of an SPC should be able to obtain 15 years of exclusivity on the market. For those SPCs where the first marketing authorisation in the EEA is a centralised authorisation, such a period of exclusivity is only possible if the notification date is used to set the term of the SPC. This is because there is not even a hypothetical possibility of the marketing authorisation holder lawfully placing his product on the market until the notification date.

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At this point, it is important to note that determining the date of validity of an authorisation (as in the present situation) is a completely different issue to determining when, as a matter of practicality due to other regulatory hurdles, an authorisation can be used. The latter question has already been considered by the CJEU in case C-127/00[5], wherein it was held that the relevant authorisation date for the purposes of the SPC legislation is not the date of an authorisation required under legislation on pricing of or reimbursement for medicinal products.

Practical significance

This article argues that the notification date of a centralised authorisation should be used for the purposes of Articles 7 and 13 of Regulation (EC) 469/2009. If this were to happen, it would have the following effects:

(a) Where the relevant medicinal product is authorised by way of a centralised authorisation, the deadline for applying for an SPC will be six months from the notification date (in all EU territories), ie at least one day later than under current practice in the national patent offices of some territories.

(b) Where the centralised authorisation is the first authorisation of the relevant medicinal product in the EEA and the decision date is less than 10 years after the date of patent filing, the use of the notification date will lead to longer SPC terms.

Although the difference between the decision and notification dates is typically only in the region of 1-4 days, the additional application time and/or SPC term that could be obtained could nevertheless be of considerable significance to both the marketing authorisation holder and those seeking to launch generic products upon SPC expiry. In particular, given the trend for generic product licence holders to be primed for launch on the day of SPC expiry, an additional SPC term of even a few days will have an impact on the timing (or legal consequences) of the launch of generic products. Indeed, preliminary research (by the author) has identified granted SPCs (or SPC applications) for at least four marketed products that could have a longer term than is currently indicated on the official registers in territories such as the UK. For those products, the additional term would be 2-4 days.

With respect to the additional period for applying for an SPC, this article is not advocating that applicants should routinely rely on the proposed, later deadline. Rather, unless and until all national offices bring their standard practice into line with the proposals outlined herein, a more cautious approach could perhaps be adopted, in which the later deadline (based on the notification date) is only asserted in instances when a deadline based on the decision date is inadvertently missed (by a small enough margin).

Correction of SPC term

An interesting question arises in connection with those SPCs that have been granted (incorrectly) with a term that is too short (ie falling under category (b) above, and granted with a term based upon the decision date). That is, could a generic product licence holder defend any allegation of SPC infringement (for acts committed during the additional term discussed in this article) by pointing to good faith reliance on SPC expiry information provided by the national patent offices?

The publication of this article could well have an impact on the chances of success with such defences to allegations of infringement. Moreover, it is noteworthy that at least the national patent office in Belgium appears to rely on the notification date for setting the SPC term. This means that, in some instances, the SPC expiry date in Belgium is different from the expiry date in territories that instead rely on the decision date. As a rule, SPCs in different territories of the EU that set identical national patent terms should expire on the same date, and so a generic product licence holder who was aware of a later expiry date in one territory (such as Belgium) might also have difficulty alleging in good faith that they had relied on an apparently earlier expiry date in another territory.

In any event, Article 17(2) and Recital (17) of Regulation (EEC) No 1610/96 together make it possible for an SPC holder to file an appeal aimed at correcting the term of a granted SPC. Thus, practical steps taken by the SPC holder can eliminate any room for doubt as to the expiry date of an SPC. Whether it is cost-effective to file such appeals in every territory in which the SPC term is too short will depend on the value to the SPC holder of the few additional days of SPC term that could be confirmed as being valid if the appeals were successful.

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5. *Hässle AB v Ratiopharm GmbH, ECJ Case C-127/00, http://bit.ly/rcRo3r*

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