The CJEU – for supplementary protection certificates, who needs it?

Mike Snodin explains why patent offices do not need to seek guidance from the Court of Justice of the EU in order to decide to award longer terms to some pharmaceutical supplementary protection certificates.

The UK Intellectual Property Office issued a decision in October 2013[1] in which it accepted arguments advanced by this author and thereby changed its standard practice with regard to the calculation of the term of certain supplementary protection certificates (SPCs) that are based upon a centralised marketing authorisation (MA) issued by the European Commission.

That is, the UK IPO decided that for centralised MAs, the calculation of SPC term should be based upon the notification date of the MA, and not the (earlier) date of the commission's decision to issue the MA.

As a consequence, additional term (typically of 2-4 days, but occasionally up to one week or more) is available in the UK for those SPCs where:

(a)the earliest MA in the European Economic Area for the relevant active ingredient(s) is a centralised MA issued by the EC; and

(b) less than 10 years have elapsed between the date of filing of the patent upon which the SPC is based and the date of the commission's decision to grant an MA.

Since the IPO made its decision, both the Slovenian Patent Office[2] and the Portuguese Intellectual Property Court[3] have also agreed to grant SPCs with a longer term, due to use of the notification date. Prior to the UK IPO's decision, however, at least three patent offices (those of Denmark, Sweden and the Netherlands) issued decisions in which arguments in favour of use of the notification date were rejected.

More worryingly, the Danish Board of Appeal for Patents and Trademarks has recently confirmed[4] the original decision of the Danish Patent Office, despite being made aware of contrary decisions reached by the UK and Slovenian patent offices.

The current situation is therefore one of disharmony, which raises the possibility of the Court of Justice of the EU being asked to provide a ruling that will settle the matter. However, the view of this author is that the correct interpretation of the legislation is obvious, and so it will not be necessary to involve the CJEU.

The reason for this is that the decisions of the Danish, Swedish and Dutch patent offices, which are all based upon similar reasoning, are fatally flawed. This article discusses the arguments for and against the use of the notification date and explains why the arguments against, as typified by the reasoning of the Danish Patent Office, do not stand up to any serious scrutiny.

Arguments in favour

There are many reasons why the notification date of a centralised MA should be used to calculate the term of SPCs for which that MA is the first in the EEA. However, the most important reasons are as follows.

Article 3(b) of the SPC Regulation (Regulation 469/2009) requires that the applicant for an SPC has "a valid authorisation to place the product on the market as a medicinal product" (emphasis added).

According to the principles established in C-127/00 (Hassle AB), the same interpretation must be applied to the same wording unless there is a compelling reason to apply a different interpretation. Thus, for example, the phrase "authorisation to ... place ... on the market" must be given the same interpretation in both Article 3(b) and Article 13(1) of Regulation 469/2009.

With this in mind, given that Article 3(b) requires a **valid** authorisation, then so must Article 13(1).

A centralised MA only becomes valid if and when it is notified to the applicant. This is evident, for example, from Article 4 of a centralised MA, which contains the following statement:

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

That statement is based in part upon the provisions of Article 297(2) of the Treaty on the Functioning of the European Union, which specifies that certain decisions of the commission, such as the decision to issue a "centralised" MA:

> *shall be notified to those to whom they addressed and* ***shall take effect upon such notification*** (emphasis added).

Thus, the following conclusions can be reached, based solely upon a combination of EU legislation (Regulation 469/2009 and Article 297(2) TFEU) and the case law of the CJEU (C-127/00):

1.The MA referred to in Article 13(1) must be a valid MA; and

2.A centralised MA only becomes valid on the date that it is notified to the applicant.

The further conclusion that inevitably follows is that, when the earliest MA in the EEA is a centralised MA, then the date that should be used in connection with that MA is the date that the MA first became valid – ie the date of notification of the MA.

This of course leads to difference between centralised and national MAs with respect to how patent offices should determine the relevant date under Article 13(1) of Regulation 469/2009. This is because, in contrast to centralised MAs, national MAs from countries such as the UK have only one relevant date associated with them, namely the date of grant.

However, such differences are mere formalities and should not provide any excuse to resist use of the notification date. This is because, for the purposes of calculating the duration of an SPC, there is only one date that matters, and that is the date of validity of the MA.

The precise manner in which the date of validity of a MA is determined should not matter, so long as independent verification of that date is possible. In this respect, it is important to point out that notification dates are easily determined (or verified) by reference to their publication in the Official Journal of the EU (links to which publications are provided on the publicly available Community Register for Medicinal Products[5]).

The arguments against (and their failings)

The patent office decisions rejecting the use of the notification date to calculate SPC term are typified by the decision of the Danish Patent Office (and the subsequent, confirmatory decision of the Danish Board of Appeal for Patents and Trademarks).

As discussed below, the reasoning of the Danish Patent Office not only fails to consider all relevant aspects of the SPC legislation but also relies heavily upon an assumption that is demonstrably false.

The reasoning of the Danish Patent Office

The main reasons for the Danish Patent Office rejecting use of the notification date can be summarised as follows.

- The documents supporting an SPC application are specified in Article 8, and those documents should provide sufficient information to enable a determination of SPC term and validity.
- Article 8(1)(b) requires the submission of *a copy of the authorisation to place the product on the market, as referred to in*

Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC.

- The documents specified in Article 8(1)(b) do not provide the notification date of a centralised MA, whereas they do indicate the (earlier) date of the commission's decision, as that appears on the MA.
- To keep the SPC system "simple and transparent", the date of the commission's decision must be therefore be used in preference to the notification date.

However, as discussed below, a detailed consideration of the relevant legislation reveals that the reasoning of the Danish Patent Office is fatally flawed.

Incorrect interpretation of the legislation

The reasoning of the Danish Patent Office relies upon the absence, from the list of documents in Article 8(1)(b), of an official publication of the authorisation.

If such an official publication were listed in Article 8(1)(b), then the Danish Patent Office's reasoning would fall down. This is because the grant of each and every centralised MA is accompanied by a publication of that grant in the Official Journal of the EU, which publication provides the notification date for the MA.

However, although absent from Article 8(1)(b), precisely such a publication is listed in Article 8(1)(c), which reads as follows.

if the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, ***together with a copy of the notice publishing the authorisation in the appropriate official publication*** (emphasis added).

For those SPCs where a centralised MA is the first in "the Community" (ie the EEA), that MA will invariably also be the relevant MA under Article 8(1)(b) (and Article 3(b)) in all EU member states. This is because such MAs are effective in all EU member states.

Thus, for EU member states (but not for the EEA member states Norway, Iceland and Liechtenstein), there is perhaps a question over whether the wording "if the authorisation referred to in point (b) is not the first authorisation ... in the Community" means that it is not appropriate to consider the provisions of Article 8(1)(c) in connection with a centralised MA. However, bearing in mind the timing of the original SPC legislation relative to the introduction of centralised MAs (as discussed below), it hardly seems appropriate to adopt such a narrow interpretation of the legislation.

In any event, it is clear that publications of notification dates in the Official Journal are relevant under a proper (ie teleological) interpretation of the legislation. This is because those dates represent "objective data that are easy to verify" and which therefore fully satisfy the objective (as set out in point 16 of the explanatory memorandum to the original SPC legislation[6]) of providing "a simple, transparent system which can easily be applied by the parties concerned".

Thus, the reasoning of the Danish Patent Office is flawed because it relies upon an interpretation of the legislation that is both incomplete (in that it omits consideration of Article 8(1)(c)) and overly literal.

False assumption

A key assumption made by the Danish Patent Office is that if the notification date were to be used in favour of the date of the commission's decision, then the legislators would have mentioned further documents in Article 8 (eg the official publication listing the notification date).

However, it is straightforward to demonstrate why this assumption is false. That is, the system for granting centralised MAs (as introduced by Regulation 2309/93) did not come into force until 1995, ie some two years after the original SPC legislation (Regulation 1768/92) and almost five years after the drafting of the explanatory memorandum to that legislation.

In 1993, the only MAs that were granted in EU member states were those issued by the regulatory bodies of individual states. In contrast to centralised MAs, national MAs from countries such as the UK have only one relevant date associated with them, namely the date of grant.

Thus, the legislators for the original SPC system would have had no reason to put in place a system that explicitly addresses (eg in Article 8(1)(b)) the date-related consequences of MAs being issued by way of a decision from the commission.

Recent codification of the SPC legislation makes no difference

Although the SPC legislation has been updated since 1993, this is only by way of a codification procedure. That is, as outlined in points 3 and 4 of the explanatory memorandum to Regulation 469/2009[7], the current legislation is the result of a procedure that:

- specifically rules out any changes of substance to the law;
- allows only such formal amendments as are required by the codification exercise itself; and
- merely amends Regulation 1768/92 in view of the provisions of the Acts of Accession from 1994, 2003 and 2005 (ie the Acts expanding the membership of the EU) and Regulation 1901/2006 (on medicinal products for paediatric use).

Thus, it is clear that the legislation has not been adapted in any way to account for the peculiarities of centralised MAs.

Patent offices rely upon other provisions also omitted from Regulation 469/2009

From the above it can be concluded that the SPC legislation itself does not explicitly address how Article 297(2) TFEU dictates the date for a centralised MA that is relevant to the calculation of SPC term.

However, just because the effects of Article 297(2) TFEU are not explicitly addressed does not mean that patent offices are free to ignore those effects.

The reasons for this are perhaps best illustrated by the fact that there are long-standing provisions of another piece of EU legislation (Regulation 1610/96, relating to SPCs for plant protection products), which provisions are regularly relied upon by patent offices when assessing SPC applications for medicinal products but which do not appear in the codified legislation.

For example, Article 3(2) of Regulation 1610/96 represents the sole legislative provision that explicitly enables multiple patent holders to each obtain their own SPC for the same product. This is because that provision states:

where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

That provision is notably absent from both the original legislation (Regulation 1768/92) and the codified legislation (Regulation 469/2009) governing SPCs for medicinal products.

However, quite rightly, the absence of that provision from Regulation 469/2009 does not prevent patent offices from routinely relying upon it when granting more than one SPC directed to the same active ingredient(s) in circumstances where there are multiple patent holders. This is because it is clear from Recital (17) of Regulation 1610/96 that Article 3(2) of that regulation is intended to aid the interpretation of Article 3 of the legislation governing SPCs for medicinal products.

In the light of the above, it is clear that all patent offices accept the principle that other pieces of EU legislation can affect the interpretation of Regulation 469/2009. Given

that the TFEU is such a fundamental piece of EU legislation, it would therefore be completely inconsistent for any patent office to ignore that legislation when interpreting Regulation 469/2009.

Conclusions

With compelling reasons in favour of the use of the notification date for calculating the term of certain SPCs, it is disappointing to see continued resistance in some countries to acceptance of the use of that date. However, it is clear that this resistance is based upon arguments that do not stand up to any serious scrutiny. Thus, there would appear to be no legal barrier to acceptance by all patent offices within the EU of the use of the notification date.

For this reason, it is the view of this author that this is a situation where harmonisation of SPC practice across the EU can be achieved without the involvement of the CJEU. Such a situation is so rare, and comes with the huge benefit of avoiding the risk of obtaining yet more Delphic utterances from the CJEU, that it is hoped that it will be seized upon by all concerned.

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