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The CJEU Calls Extra Time For SPCs – But There May Be Further Battles Ahead For Companies

Mike Snodin analyses a new ruling from the Court of Justice of the European Union that will lead to a significant percentage of supplementary protection certificates becoming eligible for additional days of protection.

On Oct. 6, the Court of Justice of the EU issued its judgement in *Seattle Genetics* (C-471/14), the most recent case relating to supplementary protection certificates (SPCs)[1,2].

The innovative pharmaceutical industry will be delighted by the outcome, as it should mean that a significant proportion (perhaps up to 30% or even 40%) of SPCs for medicinal products will become eligible for additional days of protection in all EU member states.

Whilst only a few additional days (typically two to four, but occasionally up to seven or more) will be up for grabs for each affected SPC, the cumulative financial gain from additional days across the whole EU could be significant, especially for "blockbuster" medicinal products.

This author has a particular reason to welcome the judgement, as it represents complete validation of arguments that he originally devised and published four years ago in *Scrip Regulatory Affairs*[3]. As discussed in more detail below, he also notes that the CJEU's decision may well have broader implications, and that it may be some time yet before that decision is put into full effect for SPCs already granted.

Background

In an article published in SRA in October 2011, this author argued that SPC proprietors were not always being awarded the full term of protection to which they should be entitled. At that time, the standard practice of almost all national patent offices was to calculate the duration of SPCs based upon centralised marketing authorisations (MAs) by reference to the date of the European Commission's decision to issue the authorisation – whereas the view of this author was that the offices should instead use the (later) date of notification of that decision to the MA applicant.

Since the publication of that first article, this author personally succeeded in persuading the Intellectual Property Office in the UK to change its standard practice[4] and, where relevant, to calculate SPC term by reference to the date of notification of a centralised MA. Subsequently, the Slovenian Patent Office[5] and the Portuguese Intellectual Property Court[6] also agreed to grant SPCs with a longer term, due to reliance upon the notification date. However, other patent offices, including those in Austria, Denmark, Sweden and the Netherlands, resisted any change in practice, and therefore rejected requests to calculate SPC term based upon the notification date.

Following the refusal of one such request, in connection with Seattle Genetics' Austrian SPC application relating to brentuximab vedotin (the active ingredient in Adcetris), the Appellate Court in Vienna (Oberlandesgericht Wien) referred the following questions to the CJEU[7]:

1. Is the date for the first authorisation to place the product on the market pursuant to Article 13(1) of Regulation 469/2009 concerning the supplementary protection certificate for medicinal products determined according to Community law, or does that provision refer to the date on which the authorisation takes effect under the law of the member state in question?
2. If the Court determines that the answer is that the date is determined by Community law, is this the date of authorisation or the date of notification?

The Judgement

The Oct. 6, 2015 judgement of the CJEU is relatively unusual for a case relating to SPCs, in that both of the questions posed were answered in a clear and straightforward manner, and without being rephrased. The answers provided are discussed briefly below.

Question 1

The CJEU ruled that the date of first authorisation in Article 13(1) is determined under EU law. The CJEU's reasons for reaching this conclusion focussed upon the need for a uniform interpretation of the relevant date in order to prevent "disparities" that would "be likely to create obstacles to the free movement of medicinal products within the European Union".

Question 2

On the crucial question of which of the two dates associated with a "centralised" MA should be used for the purposes of calculating SPC term, the CJEU ruled that it should be the date of notification of grant to the MA applicant (and not the date of the commission's decision to issue the MA).

In justifying this conclusion, the CJEU pointed to the fact (as previously observed by this author[8]) that the provisions of the third subparagraph of Article 297(2) of the Treaty on the Functioning of the European Union mean that the commission's decision to issue a MA only takes effect upon notification to the applicant.

Longer duration for some SPCs

The duration awarded to an SPC is effectively set as the earlier of:

(a) 15 years from the date of the earliest MA for the product in "the Community" (i.e., the EU and the European Economic area); and

(b) five years from expiry of the patent upon which the SPC is based.

When option (a) applies, a longer SPC duration can arise if a later date is ascribed to the MA for the product (active ingredient or combination of active ingredients) in question. The CJEU's decision may therefore lengthen the duration of some SPCs, on the grounds that the date of notification of a "centralised" MA is almost always later (typically two to four days later) than the date of the commission's decision to issue the authorisation.

However, for option (a) to apply, the MA in question must have been issued less than 10 years after the date of filing of the patent upon which the SPC is based. Thus, the CJEU's decision will only lengthen the duration of those SPCs for which:

(i) the earliest MA in the Community is a "centralised" authorisation issued by the commission; and
(ii) 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 the MA.

Both (i) and (ii) above will not be true for all SPCs. Nevertheless, based upon research that this author has conducted, it appears that the CJEU's decision will lead to approximately 30% of SPCs for medicinal products filed in the UK within the last 15 years being confirmed as qualifying for additional term (with the percentage being higher for SPCs filed in recent years, e.g., in excess of 40% of SPC applications for medicinal products filed in the UK from January 2010 to September 2015).

Other consequences?

There are other provisions of the SPC legislation (articles 3(b), 3(d) and 7(1) of Regulation 469/2009) for which it is important to establish the precise date of a marketing authorisation.

Disappointingly, the CJEU did not clarify whether the same (notification) date of a "centralised" MA should also be used in connection with those provisions. However the wording used in those provisions ("(first) authorisation... to place the product on the market") is very similar to that used in Article 13(1). Moreover, the CJEU has previously observed (in C-127/00, *Hässle* AB) that there is no justification for interpreting such similar wording differently.

Thus, there are good reasons to believe that the notification date of a "centralised" MA should also be used for assessments under all of articles 3(b), 3(d) and 7(1) of Regulation 469/2009.

If this is indeed correct, then a notable consequence would be that the deadline for applying for an SPC based upon a "centralised" MA will (in some circumstances) be six months from the date of notification of the MA.

However, unless and until this point is confirmed by all national patent offices, a sensible (i.e., cautious) approach would be to continue, where relevant, to aim to file SPC applications within six months from the (earlier) date of the commission's decision to issue the MA.

Still broader applicability?

This author is of the view that the CJEU's reasoning for selecting the notification date of a "centralised" MA could well be applied to the determination of the date of certain national MAs.

This is because it is arguable that, if it determines the legal effect of the national MA, then the notification date of the national MA should, where relevant, be used for calculation of SPC term and/or for assessments under articles 3(b), 3(d) and 7(1) of Regulation 469/2009.

Whilst some national MAs (e.g., those in the UK) take immediate effect upon their issuance, this author understands that others (e.g., those in Germany) only take effect when the applicant is notified of the decision to grant the MA. In the light of the CJEU's decision in *Seattle Genetics*, some applicants may therefore be emboldened to attempt reliance upon the notification date of such national MAs.

Corrective appeals

All national patent offices and courts throughout the EU should now grant SPCs with a duration determined in accordance with the CJEU's decision in *Seattle Genetics*.

However, matters may not be so straightforward for SPCs that were granted prior to the CJEU's decision and that were awarded a term that was too short. This is because it will almost certainly be necessary for SPC proprietors to take action (i.e., file an appeal) in order to correct the erroneously calculated duration.

In this respect, there may be further battles ahead for SPC proprietors. This is not least because few countries currently have formal procedures in place for handling the relevant appeals. Moreover, different countries are likely to place different limitations upon such appeals, particularly in connection with the time limit within which such appeals can be filed.

Nevertheless, this author believes that no appeals aimed at correcting SPC term should be rejected for being out of time. This is because Article 17(2) of Regulation 1610/96 provides an appeal that is applicable to all SPCs and that is not time-limited, which is a point that was confirmed by the Dutch Council of State[9] in a decision from February 2015.

Of course, it is open to other national patent offices and courts to reach a decision contrary to that of the Dutch Council of State. If this happens, it may be some time yet before the full effect of the *Seattle Genetics* decision is felt for SPCs already granted.

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