Supplementary protection certificates: The Court of Justice of the EU will have its day after all

The Court of Justice of the EU has been asked to rule on whether it is correct to use the date of notification of a centralised marketing authorisation to set the term of SPC protection. ***Mike Snodin*** argues that the framing of the questions referred to the CJEU leaves something to be desired.

The term of pharmaceutical supplementary protection certificates (SPCs) can sometimes be set as 15 years from the date of the first marketing authorisation (MA) in the European Economic Area for the active ingredient(s) that is (are) the subject of the SPC. This happens when the date of that first MA in the EEA is less than 10 years later than the date of filing of the patent upon which the SPC is based (which patent protects the relevant product).

This author has previously argued[1] that, for setting the term of SPCs, the date that should be used in connection with a centralised MA is the date of notification of that MA to the applicant (as opposed to the earlier date of the European Commission's decision to issue the MA). When the term of the SPC is 15 years from the date of the first MA in the EEA, using the date of notification almost always leads to a longer SPC term. The term is typically two to four days longer, but occasionally it is up to about a week or two longer.

Following a hearing at which the SPC applicant was represented by this author, the UK Intellectual Property Office decided to change its standard practice[2] and, where relevant, to calculate SPC term by reference to the date of notification of a centralised MA.

Subsequent to the UK IPO's decision to change its standard practice, both the Slovenian Patent Office[3] and the Portuguese Intellectual Property Court[4] have also agreed to grant SPCs with a longer term, due to use of the notification date. However, various patent offices (including those of Denmark, Sweden and the Netherlands) have rejected arguments in favour of use of the date of notification. Thus, at the patent office level, there is currently disharmony across the EU in connection with the calculation of SPC term.

This author has previously outlined his view[5] that it should not be necessary for the various national courts to call upon the Court of Justice of the EU to restore harmony – by deciding in favour of the use of the date of notification of centralised MAs. However, it has emerged that a court in Austria (the Oberlandesgericht Wien) decided to refer questions to the CJEU in connection with the date of notification[6]. The case concerned relates to an SPC application filed by Seattle Genetics and which has been allocated the number C-471-14. The case will now be considered by the CJEU, which will then provide a ruling that should harmonise practice across the whole of the EU.

Despite the potential disadvantages associated with the involvement of the CJEU, this development will perhaps be given a cautious welcome by some in the pharmaceutical industry. This is because, as the CJEU could issue its decision as early as next year, the reference should lead to relatively early harmonisation across the EU with regard to the practice on calculation of SPC term.

However, as is always the case, the quality of the ruling by the CJEU could well be influenced by the quality of the questions that are referred to that court. This is because questions that are well drafted and that precisely capture the issues to be decided are more likely to help the CJEU to provide a robust ruling.

It is therefore disappointing that, for various reasons, the questions that have been referred by the Oberlandesgericht Wien in the *Seattle Genetics* case (C471/14) appear to this author to have a number of flaws, at least one of which is significant.

Nevertheless, it is very common for the CJEU to answer slightly different questions than those outlined in the reference. Thus, there is hope yet that the CJEU will instead answer a much more appropriate question which, in the view of this author, has a very clear answer – namely, that the date of notification of a centralised MA is indeed the decisive date for calculating the duration of SPC protection.

Background

Seattle Genetics filed an SPC application in Austria directed towards brentuximab vedotin (which is present in the medicinal product Adcetris). The earliest MA in the EEA for Adcetris is a centralised authorisation issued by the commission less than 10 years after the filing date of the patent upon which the SPC application was based (EP 1 545 613). Seattle Genetics therefore argued that the term of the SPC should be set by reference to the date of notification of the MA (instead of by reference to the date of the commission's decision). At stake is a potential five additional days of SPC term for brentuximab vedotin.

Although the Austrian patent office granted an SPC, it refused to use the date of notification of the MA to set SPC term. Seattle Genetics therefore filed an appeal at the Higher Regional Court of Vienna (the Oberlandesgericht Wien).

Having considered the matter and having concluded that the answer was not obvious (particularly in view of the differing practices across different EU member states), the Oberlandesgericht Wien decided to refer questions to the CJEU in order to settle the issue.

The questions referred

From information on the UK IPO's website[7] this author understands that the questions referred by the Oberlandesgericht Wien can be translated as follows.

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 in 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?

These questions bear a striking similarity to questions that were referred by the Federal Court in Germany (the Bundesgerichtshof) in a case from 2007 that was withdrawn before the CJEU could provide its ruling[8] (case C-452/07, *Health Research Inc.*).

The main point of difference between the questions referred in case C-452/07 and in case C-471/14 is that, in the latter case, question 1 refers to the provision of the SPC legislation that governs SPC term (ie Article 13(1) of Regulation 469/2009) rather than the provision that governs the deadline by which the SPC application must be submitted (which is now Article 7(1) of Regulation 469/2009).

This point of difference reflects the fact that, in case C-452/07, the issue to be decided was whether an SPC application had been filed by the relevant deadline – which, in that case, was six months from the date of the MA concerned (a German national authorisation).

Problems with the questions

In the view of this author, the almost direct copying of the questions from C-452/07 has

caused those questions to be less than ideal in at least three ways. Whilst two of the potential flaws in the questions arguably relate to issues of semantics (and so are perhaps not so serious), the third represents a significant failing on the part of the Oberlandesgericht Wien, as it means that the questions referred are not properly adapted to reflect the facts at issue in the *Seattle Genetics* case.

The biggest problem

Question 1 above implies that there is a choice as to which law (Community or national) applies to determination of the date of effect of a centralised authorisation. However, it appears to this author that, for a centralised MA (ie the type of MA at issue in case C-471/14), there is no choice, and it is only relevant to consider Community law.

The absence of any choice is evident from Regulation 726/2004, which lays down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishes a European Medicines Agency. Article 13(1) of that regulation reads as follows.

> *Without prejudice to Article 4(4) of Directive 2001/83/EC,* ***a marketing authorisation which has been granted in accordance with this Regulation shall be valid throughout the Community****. It shall confer the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 6 of Directive 2001/83/EC* [emphasis added].

This provision makes it clear that a centralised MA is simultaneously valid throughout all member states of the EU. In other words, Regulation 726/2004 overrides all national laws and prevents them from specifying a date of validity for a centralised MA that is different from the date determined under Community law.

In this respect, Question 1 appears to be redundant in the Seattle Genetics case, as it is not an appropriate question to ask in the light of the facts of that particular case.

The lesser problems

The remaining two flaws in the questions referred relate to points where the words chosen by the Oberlandesgericht Wien are potentially confusing or misleading.

Firstly, Question 1 above is potentially confusing in that it discusses the "date of effect" of the MA. However, as previously argued by this author, it is clear that the SPC legislation requires consideration of the **date of validity**.

In this context, it is possible that "validity" may have the same meaning as "effect". However, it is not clear from the question whether the Oberlandesgericht Wien believes this to be the case.

Secondly, Question 2 refers to a "date of authorisation". However, this author is of the view that the reference to such a date is inappropriate and potentially misleading.

This is because, for a centralised MA, there are two potentially relevant dates, namely:

(a) the date that the commission issues its decision upon the MA application; and
(b) the date that the commission's decision is notified to the MA applicant.

Thus, for centralised a MA, there is no such date as the "date of authorisation". This is because the only date that is distinct from the date of notification would be more accurately described as the date of the commission's decision.

Indeed, to label the date of the commission's decision as the "date of authorisation" could be seen as misleading, as it potentially imbues that date with more significance than it deserves.

These two flaws arguably relate to mere issues of semantics, and may well not confuse or mislead the CJEU. Nevertheless, in view of the potential to mislead or cause confusion, it is disappointing to see such imprecise language used in questions referred to the CJEU.

A more appropriate question (and its answer)

In the light of the above, this author is of the view that a more appropriate question for the CJEU might well have been as follows.

If the first authorisation to place the product on the market in the Community is an authorisation issued by the commission in accordance with Regulation 726/2004 and Directive 2001/83, how is the date of validity of that authorisation to be determined in connection with Article 13(1) of Regulation 469/2009 – by reference to the date of the commission's decision or by reference to the date of notification of that decision to the applicant for authorisation?

In the view of this author, the very clear answer to this question is that the date of validity is to be determined by reference to the date of notification.

This is because the Community legislation that governs the date of validity of a centralised MA is Article 297(2) of the Treaty on the Functioning of the European Union. Amongst other things, that article specifies that:

> *Other directives, and* ***decisions which specify to whom they are addressed****, shall be notified to those to whom they are addressed and* ***shall take effect upon such notification*** [emphasis added].

As centralised MAs are issued by way of decisions (of the commission) that specify to whom they are addressed (ie the MA applicant), then Article 297(2) of TFEU clearly applies to those decisions.

Moreover, the fact that the commission's decision does not take effect until the date of notification, and that this date is the date of validity of the MA, is explicitly acknowledged by the commission by way of the following statement (which appears in every centralised MA that is issued):

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

Summary

The questions referred to the CJEU by the Oberlandesgericht Wien in case C-471/14 appear to this author to be less than ideal, most likely due to the questions being "borrowed" from an earlier case that had significantly different underlying facts.

Nevertheless, it is hoped that the CJEU will spot the problems with the questions and will instead answer a different question (eg a question such as that proposed above by this author). It is also hoped that the answer to that question will be in favour of the use of the date of notification of a centralised MA, with the result that SPC proprietors will no longer be denied in some territories the full term of protection to which this author believes they are entitled.

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