

News and Views

Europe is now poised to award longer terms to some SPCs

Summary

On 10 September 2015, Advocate-General (A-G) Jääskinen of The Court of Justice of the European Union (CJEU) issued his opinion in a case ([C-471/14](#), *Seattle Genetics*) concerning the calculation of the term of certain Supplementary Protection Certificates (SPCs).

Although not binding upon the CJEU, A-G Jääskinen's opinion represents good news for those in the innovative pharmaceutical industry. This is because the opinion essentially concludes that:

- the SPC legislation must be interpreted in a manner that allows for longer SPC term to be awarded to certain "centrally" authorised medicinal products; and
- any different interpretation would be contrary to the fundamental objectives of the SPC legislation.

In this respect, A-G Jääskinen's opinion is in full agreement with arguments originating in [an article from October 2011 authored by Mike Snodin](#) (and first published in SCRIP Regulatory Affairs).

Background: the dispute

An SPC is a stand-alone form of intellectual property in Europe that provides an additional period of exclusivity for certain products that suffer significant regulatory delays prior to marketing - i.e. certain human or veterinary medicinal products, or so-called Plant Protection Products (agrochemicals and the like).

In some instances, the term of an SPC runs for 15 years from the date of the 1st Marketing Authorisation (MA) in the European Union (or the European Economic Area). Thus, if a later date is ascribed to the MA for a particular product, that can sometimes lead to longer SPC term being awarded in respect of that product.

There are two dates associated with a MA obtained *via* the "centralised" procedure in Europe, namely:

- (A) the date that the European Commission issues its decision to grant the MA; and
- (B) the (later) date that the Commission's decision is notified to the MA applicant.

In the above-mentioned article from October 2011, Mike Snodin argued that, contrary to the standard practice of almost all national patent offices at that time, SPC term should be calculated upon the basis of date (B) above. As reported in [an article from December 2013](#) (and first published in SCRIP Regulatory Affairs), Mike then succeeded in personally persuading the Intellectual Property Office in the UK to change their standard practice and, where relevant, to calculate SPC term by reference to date (B) above.

Cases in Portugal and Slovenia also concluded that the date (B) should be used. However, various national offices (including those of Austria, Denmark, the Netherlands and Sweden) have resisted changes to their standard practice – see, for example, [an article from October 2014 authored by Mike Snodin](#) (and first published in SCRIP Regulatory Affairs).

The refusal of the Austrian patent office to award longer term to an SPC filed by Seattle Genetics (for the product brentuximab vedotin) led to the Higher Regional Court of Vienna seeking clarification from the CJEU regarding the correct interpretation of the law. The questions referred by the Austrian court are discussed in detail in [an article from December 2014 authored by Mike Snodin](#) (and first published in SCRIP Regulatory Affairs).

In essence, the questions posed to the CJEU by the Austrian court relate to the following points.

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1. Is the date of the 1st MA in the Community determined under national law or Community law?
2. If the answer to question 1 is under Community law, which of dates (A) and (B) above should be used to determine SPC term?

The Advocate-General's opinion

Although not available in English at the time of writing, it appears that the opinion of A-G Jääskinen is essentially as follows.

- The term “*date of first marketing authorization in the Community*” in Article 13(1) of Regulation 469/2009, is an autonomous concept of European Union (i.e. Community) law.
- Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the “*date of the first authorization to place the product on the market in the Community*” is that of the notification of the decision upon the MA to the recipient.

Commentary

Whilst the CJEU can (and sometimes does) reach a decision that contradicts an A-G's opinion, it would appear difficult for the Court to do so in this case. This is not least because, at point 39 of his opinion, A-G Jääskinen points out that a contrary conclusion (i.e. determining SPC term by reference to date (A) instead) would be inconsistent with the fundamental objectives of the SPC legislation.

Thus, it appears more likely than not that the CJEU is now poised to confirm the A-G's opinion (possibly even before the end of 2015). If this happens, longer SPC terms will be awarded in all EU Member States to products for which:

- (i) the earliest MA in the Community is a “centralised” MA issued by the European Commission (EC); 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 EC's decision to grant a MA.

If the CJEU confirms that the later (notification) date of a “centralised” MA should be used, then this could also lead to later filing deadlines for certain SPC applications (as such deadlines are set by reference to the MA date in the country of application).

Broader Applicability?

Whilst some national MAs (e.g. those in the UK) take effect upon their date of issuance, Park Grove IP understands that others (e.g. those in Germany) are more similar to “centralised” MAs, in that they only take effect upon the date of their notification to the MA applicant.

Thus, if the CJEU confirms A-G Jääskinen's opinion, then it may become arguable that longer SPC terms (and/or later SPC application deadlines) should be granted to products where:

- (a) the 1st MA in the Community is a *national* (as opposed to a “centralised”) authorisation; and
- (b) the date that the national MA takes effect is that upon which the decision upon the MA is notified to the applicant.

It remains to be seen, however, whether the arguments for such national MAs are as persuasive as those for “centralised” MAs.

Further Battles Ahead?

Confirmation of the A-G's opinion would pave the way for **pending SPC applications** to be granted with a longer term.

However, it is not yet clear whether such confirmation would also lead to all national patent offices and/or courts allowing appeals aimed at correcting the (too short) terms of **previously granted SPCs**. Indeed, the indications are that at least some national patent offices may reject such appeals if they are filed after the expiry of a time limit set under national law for challenging the grant of an SPC.

Thus, there may be further battles ahead before SPC proprietors are awarded, across all EU Member States, the full SPC term to which they are entitled.

Please contact Mike Snodin (at mike.snodin@parkgrove-ip.com) if you would like our advice on these or any other matters.