

Seattle Genetics: Advocate General's opinion points towards longer SPC terms

Good news could be on the horizon for SPC owners hoping for additional SPC term in Europe, following the Advocate General's (AG) opinion in the Seattle Genetics SPC referral currently being considered by the CJEU (C-471/14).

The AG has recommended that the date of notification of the marketing authorisation should be used as the date for calculating SPC term. If the CJEU follows this recommendation, it would mean that for those SPCs where the term is not already the maximum 5 years, SPC owners will in most cases get some additional term across Europe, in line with the term previously available in only a few countries.

According to Article 13 of the SPC Regulation, the "date of the first authorisation to place the product on the market in the Community" is used to calculate the term of an SPC. Some countries (e.g. the UK, Belgium, Slovenia and Portugal) have been using the date of notification of the decision to calculate the SPC term, while others have been using the date of the decision itself. So, unless the SPC term is already the maximum available, SPCs for the same product can have different terms in different countries. Although this difference is generally only a few days, the extra term can be valuable, given that SPCs protect commercial products on the edge of the patent cliff.

The Seattle Genetics referral is based on an SPC application where the authorisation for the product Adcetris

(brentuximab vedotin) is dated 25th October 2012, but was notified 5 days later, on 30th October 2012, and where the Austrian patent office had used the decision date of the authorisation to calculate the SPC term. Given the different approaches to calculating SPC term in different European countries, the Oberlandesgericht Österreich referred questions to the CJEU in October 2014. The referral not only asked whether under Community law the authorisation's notification or the decision date should be used to calculate the SPC term, but first asked whether Community law even applies, or whether instead the relevant date should be determined under national law.

The AG has emphasised the purpose of the SPC Regulation, including the desirability of uniform protection in the internal market, and has proposed that Community law should apply and that the authorisation's notification date should be used to calculate the SPC term. This means that SPC owners may be entitled to additional SPC term. **The AG does not, however, seem to consider the practical implications for the term of pending or already granted SPCs that may be affected by this approach.** For example, would it be possible to correct the term of granted SPCs retroactively?

The referred questions were framed in connection with Article 13, and the AG has addressed them in this context. The issue of what is the "date" of an authorisation is relevant to other articles of the SPC Regulation, e.g. Articles 3(d) and 7, and so it will be interesting to see whether the CJEU's decision confirms that the same approach should apply to these other articles.

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