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# *Seattle Genetics (C-471/14)*: CJEU confirms that SPC terms are to be calculated from the date of notification of the marketing authorisation

It's good news from the CJEU for those SPC owners who have been hoping for additional SPC term in Europe. The CJEU's decision in case C-471/14 means that for those SPCs where the term is not already the maximum five years, SPC owners will in most cases get some additional term for their SPCs across Europe, in line with the term previously available in only a few countries.

In confirming that the date of notification of the marketing authorisation should be used as the date for calculating SPC term, the CJEU has not deviated from the Advocate General's (AG) opinion, issued less than one month ago, perhaps explaining why it has produced this decision so quickly. What is disappointing, however, is the lack of practical guidance for stakeholders. The position seems clear on how to calculate the SPC term for new applications. On the other hand, local patent offices will now need to determine how this important change is handled for existing applications and granted SPCs, where a different calculation may have been used. Can the term be corrected retrospectively? And if so, what is the procedure for this?

The Seattle Genetics referral to the CJEU concerns Article 13 of the SPC Regulation, which states that 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 already 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. The notification date in many cases is after the date of the marketing authorisation decision because the marketing authorisation generally takes a few days to reach its intended recipient. This means that unless the SPC term is already the maximum five years that is 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 referral relates to 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 first asked whether Community law applies, or whether instead the relevant date should be determined under national law. It also asked whether under Community law the authorisation's notification or decision date should be used to calculate the SPC term.

In his opinion, AG Jääskinen had emphasised the purpose of the SPC Regulation, including the desirability of uniform protection in the internal market. He proposed that Community law should apply and that the authorisation's notification date should be used to calculate the SPC term. The CJEU decision confirms all of these points, noting in particular that the marketing authorisation holder cannot enjoy the benefit of the marketing authorisation until the date on which he is given notification of the decision, and therefore this should be the date that forms the basis of the SPC term calculation.

If you have a granted SPC or an SPC application that is affected by this decision and would like advice as to possible next steps then please contact Anna Leathley.

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## Need advice?

For more information, please contact email@carpmaels.com.

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