

# CJEU: SPC term can be rectified to be in line with Seattle Genetics judgment

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Just before Christmas, on 20 December 2017, the Court of Justice of the European Union (CJEU) announced its judgment in *C-492/16, Incyte*, in a preliminary ruling proceeding initiated by the Budapest High Court. The decision can be considered a sequel to the CJEU's earlier judgment *C-471/15, Seattle Genetics*, both dealing with the term of Supplementary Protection Certificates (SPCs). While *Seattle Genetics* brought unity among the Member States regarding the relevant dates for the calculation of the SPC term, *Incyte* clarifies on what basis the term of SPCs that were granted before and are not in line with *Seattle Genetics* can be recalculated. Some more insight and reflections on this decision after this [earlier post in this blog](#).

As a brief background for those less familiar with the sweet details of SPC rules (or for all of us who just slept too much during the Christmas holidays) the calculation of the term of medicinal SPCs are determined in Articles 13 and 14 of SPC Regulation EC/469/2009 (SPC Regulation). In Article 13 the duration is determined by two key dates one being the application date of the basic patent and the other being the date of the first marketing authorization to place the concerned medicinal product on market in the Community. Out of the difference of the two the duration of the SPC is calculated. Article 14 defines that the SPC expires at the end of the term calculated on the basis of Article 13.

Regulation EC/1610/96 on Plant Protection Product SPCs (PPP Regulation) contains identical rules regarding the duration. However, the two regulations differ regarding appeal provisions. Both regulations contain [Art 18(1) SPC Regulation and Article 17(1) PPP Regulation] that against the decisions of the national patent offices regarding SPCs the same appeal options shall be available as those provided in national law against similar decisions concerning national patents. The PPP Regulation contains an additional provision, Art. 17(2), that the granting decision shall be open to an appeal to rectify the duration if the date of the first marketing authorization in the Community was given incorrectly in the application. While there is no similar provision in Article 18 of the SPC Regulation, recital 17 of the PPP regulation states that Article 17 PPP Regulation shall be applicable *mutatis mutandis* for the interpretation of the corresponding Article of the SPC Regulation.

In *Seattle Genetics* the CJEU interpreted Art 13 (1) SPC Regulation, specifically the wording „date of first authorization to place the product on the market in the Community“. The CJEU first established that the „date to place the product on the market“ is defined by EU law and is not to be determined state by state based on national laws. As a second point the CJEU decided that the date of the first marketing authorization shall be interpreted as the date on which the addressee is given notification of the approval rather than the issue date that appears on the decision. Agreeing with the opinion of the Advocate General that neither the wording nor the various language versions of the term to be interpreted provide unequivocal answer to the question which date – issue or notification date – is meant in the SPC Regulation, the CJEU derived its interpretation mostly from the purpose of the SPC Regulation and the legislature's intention to provide the SPC holder adequate effective protection with a uniform nature throughout the EU. This led the CJEU to refuse accepting an interpretation that would allow the period of validity of the SPC be reduced by procedural steps carried out between the decision granting marketing authorization and the notification of that decision, and eventually to accept that the date means the later date, that is the notification date.

The decision made many national patent offices change their earlier practice, and was welcomed by SPC holders who from then on could enjoy a few days longer duration.

The judgment in *Seattle Genetics*, however, gave rise to the question that became the subject of *Incyte*. Namely, many SPCs were granted before the *Seattle Genetics* interpretation, resulting in shorter terms than under *Seattle Genetics*, and many of them already ran out of the national appeal terms. Member States began to follow divergent practices regarding the recalculation of the SPC term after *Seattle Genetics*. Some refused recalculation with reference to finality of administrative decisions and the requirement of legal certainty, others found legal basis to rectify the durations in their national laws or directly in EU law. *Incyte* – having an SPC granted well before *Seattle Genetics*, and no longer having the right to appeal it under national law – filed a request with the Hungarian Intellectual Property Office (HIPO) for the correction of the SPC term with respect to the new interpretation given in *Seattle Genetics*. *Incyte's* request was rejected because, according to the HIPO, the SPC granting decision did not contain any miscalculation or error, which is the only ground for correcting an administrative decision – after the appeal term – under Hungarian law. *Incyte* appealed to the Metropolitan Court also referring to Art 17 (2) PPP Regulation as a basis for rectification, as it is applicable to the interpretation of Art. 18 SPC regulation via its recital 17.

The Budapest High Court stayed the proceeding and referred two questions to the CJEU:

(1) Must Article 17(2) of Regulation ... No 1610/96 ... be interpreted as meaning that “the date of the first marketing authorisation [MA] in the [European Union]” is incorrect in an application for a[n] [SPC], within the meaning of that regulation and of Regulation ... No 469/2009, where that date was determined without taking account of the Court of Justice's interpretation of the law in the judgment of 6 October 2015, *Seattle Genetics (C-471/14, EU:C:2015:659)*, with the result that it is appropriate to rectify the date of expiry of the [SPC] even if the decision to grant that certificate was made prior to that judgment and the time limit for appealing against that decision has already expired?

(2) Is the industrial property authority of a Member State which is entitled to grant a[n] [SPC] required to rectify, of its own motion, the date of expiry of that [SPC] in order to ensure that that certificate complies with the interpretation of the law set out in the judgment of 6 October 2015, *Seattle Genetics (C-471/14, EU:C:2015:659)*?

The CJEU – proceeding in a senate of 5 judges and without obtaining the opinion of the Advocate General – answered both questions. As to the first question, the CJEU firmly pointed out that using the date of the first MA (and not the notification date) to calculate the SPC term in a situation such as the one in the basic proceedings is incorrect under Art 18 of the SPC Regulation, read in the light of Art 17 (2) PPP Regulation, which is relevant via its recital 17. It follows from the CJEU's decision that this is even the case if the applicant provided the incorrect date – that is the issue date of the MA – in the SPC application. The Court reasoned this with reference to its interpretation of the date of first MA in *Seattle Genetics* and the *ex tunc* effect of that judgment. Since the date given in the application should have always been – in light of *Seattle Genetics* – the date of notification, any other date must be regarded as incorrect. With this statement the Court made it clear that Art 17(2) PPP Regulation is not restricted to rectification with respect to clerical errors and the like but has a broader scope.

In the context of answering the second question the judgment makes clear that the right to bring an appeal for the longer SPC term to be calculated based on the notification date in accordance with *Seattle Genetics* shall be enjoyed not only by those whose application is still pending but also by those whose SPC term has not yet expired. The CJEU pointed out that the right to such motion is not limited by the finality of the SPC granting decision and that in the absence of any indication to the contrary in Art 17 (2) of the PPP Regulation, Art 18 of the SPC Regulation – read in light of Art 17 (2) – shall be interpreted as allowing an appeal for rectification to be brought before the authority, as long as the certificate in question has not expired. The CJEU derived its conclusions referring particularly to the goals of the SPC Regulation. That is, the purpose of the whole SPC system, as given in recitals 7 and 8, referring to the desired uniform solution regarding SPCs throughout the EU and the avoidance of disparities between Member States. Furthermore the CJEU laid down that the authority granting the SPC enjoys no discretion regarding the duration of the SPC as it is wholly determined by the criteria of the SPC Regulation itself. The decision is also important in the aspect that it highlighted the role of recital 17 of the PPP Regulation. This recital has already been mentioned in a few CJEU cases (e.g. *C-392/97, Farmitalia, C-127/00, Hässle*) but – in the authors' opinion – never so far with such clarity to its direct relevance to the provisions of the other SPC regulation as in this case.

The decision has a few takeaways also beyond the world of IP. Even though the Hungarian court sought expressly the interpretation of Art 17(2) of the PPP Regulation, the CJEU responded with regard to the interpretation of Art 18 of the SPC Regulation and noted that the fact that the referring national court has worded the question with reference to certain provisions of EU law does not preclude the CJEU from providing to the national court all the elements of interpretation which may be of assistance in adjudication the case before it whether or not the court has referred to them in its questions.

Also the judgment fine-tunes the principles regarding the balance of requirement of legality and legal certainty when it comes to reviewing final administrative decisions (*C-453/00 Kühne & Heitz, C-2-06 Kempter, C-249/11 Byankov*), which was the major argument against the rectification. The court pointed out that contrary to its earlier case law the present case does not require the review of the HIPO's final administrative decision, but only the rectification of the SPC duration. The CJEU emphasized that changing the SPC's expiry – from 24 to 28 August in *Incyte's* case – is by its nature less capable of affecting legal certainty than the more substantive changes which require a review.

The decision will make many national offices adapt their practice, likely under pressure of SPC holders with soon expiring SPCs as it follows from the judgment that the rectification is only possible as long as the SPC is in effect. It seems therefore wise for SPC holders to obtain information on the available options in Member States to have the SPC term rectified if appropriate.

*Disclaimer:* the authors represented *Incyte* before the CJEU; the present article contains the authors' personal views.