

ATTENTION SPC OWNERS! THE CJEU OPENS DOOR TO RECTIFICATION OF SPC EXPIRY DATES.

The Court of Justice of the European Union (CJEU) has ruled in the *Incyte* case that holders of a Supplementary Protection Certificate (SPC) are entitled to lodge an appeal for rectification of an incorrect expiry date, provided that the certificate has not yet expired. This is welcome news for Spain, where the Spanish Patent and Trademark Office has staunchly refused to rectify Spanish SPCs already granted.

BACKGROUND

Pursuant to Regulation (EC) No. 469/2009 concerning the supplementary certificate for medicinal products (SPC Regulation), an SPC shall take effect, upon patent expiry, for a period equal to the one which elapsed between the date on which the basic patent was applied for and the date of the first authorisation to place the product on the market in the European Community, reduced by a period of five years. However, as is well known, the uncertainty surrounding the interpretation of the "date of the first authorisation to place the product on the market in the European Community" has led to the grant of numerous SPCs across Europe whose registered expiry dates are incorrect in being too early or too late. In particular, two types of anomalous situations have surfaced:

- The *Novartis* line of cases. In its 2005 *Novartis* judgment, the CJEU held that, in the context of the European Economic Area, Swiss marketing authorisations issued for medicinal products, which are automatically recognised in neighbouring Liechtenstein, must be regarded as the first authorisation to place the product on the market. This meant that the term of many SPCs was calculated by European patent offices on the basis of later authorisations from medicine agencies in Member States of the European Union. Consequently, the registered duration of those SPCs was *longer* than legitimately established in the SPC Regulation.
- The *Seattle Genetics* line of cases. In the 2015 *Seattle Genetics* judgment, the CJEU ruled that the date of the "first marketing authorisation" must be interpreted as meaning the date on which notification of the decision to grant the authorisation was served on the

Key issues

- The CJEU has ruled in *Incyte* that national patent offices must allow the rectification of granted SPCs whose expiry date has been incorrectly calculated.
- Following the criterion set out in the *Seattle Genetics* judgment, this is highly relevant in situations where the registered duration of the SPC is too short, because it was wrongly calculated on the basis of the grant date of the marketing authorisation and not, as it should be, on the basis of the notification date of the grant decision.
- *Incyte* is good news for SPC holders in Spain, since the Spanish Patent and Trademark Office has always refused to rectify the expiry dates of granted SPCs. This practice will now presumably cease to exist.

addressee of the decision (as opposed to the date of grant as such). Conversely, this led to many SPCs having a *shorter* duration than they ought.

In view of these judgments, SPC holders have requested European patent offices to rectify the expiry dates of their SPCs. In the case of *Seattle Genetics*, they have understandably done so in order to enjoy the entire legitimate duration of their exclusive rights. In cases falling under the *Novartis* case law, some holders have chosen to correct the expiry date for reasons of legal certainty in respect of third parties. However, in some countries such as Spain, they have met a surprisingly staunch resistance from the patent offices: in spite of the clear case law of the CJEU, certain patent offices refused to rectify the expiry dates of SPCs after they had been granted. According to them, once the SPC grant decision becomes final, there is no legal mechanism for its holder to apply for rectification.

However, the CJEU has now removed this obstacle in its recent judgment delivered on 20 December 2017 in the *Incyte* case.

THE *INCYTE* CASE

US pharmaceutical company Incyte is the holder of a Hungarian SPC for the pharmaceutical product Jakavi. The Hungarian Intellectual Property Office (HIPO) calculated the expiry date of the SPC based on the date on which the marketing authorisation for Jakavi was granted by the European Commission (23 August 2012), and not on the date when the decision had been notified to Incyte. The expiry date thus calculated was 24 August 2027. Following the *Seattle Genetics* judgment, Incyte applied to HIPO for a rectification of the expiry date, which ought to be 28 August 2027 (based on the notification date). However, the Hungarian authorities refused to comply: under Hungarian law, the SPC grant decision had become final and not appealable. Thus, no rectification was possible at that point, even in view of the *Seattle Genetics* judgment. In subsequent judicial review proceedings, the High Court of Budapest then referred a request for a preliminary ruling to the CJEU in relation to wrongly calculated expiry dates of SPCs.

In *Incyte*, the CJEU ruled that, pursuant to Article 18 of the SPC Regulation and regardless of national law, the holder of an SPC granted with an incorrect expiry date may lodge an appeal for rectification of the duration stated in the SPC.

To reach this conclusion, the CJEU interpreted the SPC Regulation in light of the provisions of the closely related Regulation (EC) No. 1610/96, which governs SPCs for phytosanitary products. Its Article 17(2) states that a decision to grant an SPC "shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market, contained in the application [...], is incorrect". The CJEU found this provision to be applicable *mutatis mutandis* to medicinal SPCs, and clarified that the meaning of "incorrect" does not refer solely to mere clerical errors, but rather to any date leading to a method for calculating the duration of the SPC term which fails to comply with the SPC Regulation. Therefore, one may infer that this *rationale* should apply not only to *Seattle Genetics*-type situations, but also to

other possible calculation errors (e.g. *Novartis*-type situations where the SPC's term is too long and the SPC holder might nevertheless wish to rectify it).

Consequently, the CJEU found that the holder of an incorrect SPC has the right to apply for the rectification of the SPC's expiry date, as long as the SPC has not expired – otherwise, if left to the discretion of national authorities and their domestic administrative rules and practices, the overriding objective of providing uniform SPC protection across the single market would be thwarted.

WILL SPAIN FOLLOW SUIT?

The *Incyte* decision is welcome news for SPC holders in countries such as Spain, where companies have also faced the surprising refusal of local authorities to do something as apparently simple as amending the expiry date. In the wake of *Incyte*, it is very likely that the Spanish Patent and Trademark Office will change its position and allow the rectification of incorrect expiry dates of SPCs already granted in Spain. Where applicable, holders of these certificates in Spain are therefore advised to consider applying for such rectification – or otherwise miss out on a presumably valuable additional term of exclusivity.

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