

IN SHORT

The Situation: The French Intellectual Property Office ("IPO") previously refused to adjust the expiration date of a granted supplementary protection certificate ("SPCs") when it had been calculated on the date of grant of the marketing authorization ("MA"), not on the date of notification of the MA, as decided by the CJEU Seattle Genetics decision.

The Result: The French IPO has changed its stance and now extends the expiration date of granted SPCs, in compliance with the CJEU decisions in *Seattle Genetics* and *Incyte Corporation*.

 $\textbf{Looking Ahead} : \textbf{French SPC} \ owners \ are \ able \ to \ file \ requests \ before \ the \ French \ IPO \ to \ alter \ the \ expiration \ date \ of \ granted \ SPCs.$

SPCs take effect at the end of the term of the basic patent for a period equal to the period between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.

Determining the "date of the first authorization to place the product on the market in the Community" was the subject of much debate, until it was settled by the CJEU.

In 2015, the CJEU decided in *Seattle Genetics* that the date of the first authorization is not the date on which the MA was granted but the date of its notification to the patent holder, which usually takes place several days later, thus extending the SPC duration by a few days. In response to this decision, several EU Member States' intellectual property offices indicated that they would correct the calculation methods of the expiration date in cases where the application is still pending. Several offices indicated that they would also adjust the expiration date of granted SPCs.

The French IPO, however, indicated that it would use the MA's notification date to calculate the SPC's duration only going forward and for SPC applications under examination and refused to amend the expiration date of granted SPCs on the ground that, under French law, no provision would enable a change that would also affect third parties' rights. French SPC holders thus were advised to publish the notification date of the MA's grant in the national patent register to inform third parties.

This scenario was far from satisfactory, as it did not change the actual expiration date on the SPC and the Patent Register.



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The French IPO should have applied the *Seattle Genetics* decision to granted SPCs as well because Article 17(2) of Regulation No. 1610/96 provides a specific procedure to rectify the expiration date of SPCs and because of the principle of primacy of EU law over national law, which requires that any legal standard of a Member State that conflicts with a standard of the European Union be set aside.

However, the French IPO refused to amend expiration dates of granted SPCs, even when the holder requested it.

On September 14, 2016, new preliminary questions were referred to the CJEU by a Hungarian court regarding the conditions under which the expiration date of an SPC could be adjusted following *Seattle Genetics*.

In a judgment issued on December 20, 2017 (*Incyte Corporation*), the CJEU stated that Article 18 of Regulation No. 469/2009 must be interpreted as meaning that the date of the first marketing authorization is incorrect if the date led to a method for calculating the SPC's duration that does not comply with the requirements of Article 13(1) of Regulation No. 469/2009, as interpreted by the CJEU in *Seattle Genetics*.

The CJEU also held that Article 18 of Regulation No. 469/2009 must be interpreted as meaning that, in a situation such as the one described above, the holder of an SPC must be able to bring an appeal for adjustment of the duration stated in the certificate, provided that it has not expired.

According to the director of the French IPO on January 18, 2018, the French IPO appears to have accepted the CJEU's holding in the *Incyte Corporation* decision. In a case where the French IPO refused to rectify the incorrect expiration date, and proceedings are pending on appeal of the decision, the French IPO has agreed to withdraw its previous decisions by which it refused to amend the expiration date, so as to comply with the CJEU decisions in *Seattle Genetics* and *Incyte Corporation*.

The French IPO grounds its correction on Article 18 of Regulation No. 469/2009, read in light of recital 17 and of Article 17(2) of Regulation No. 1610/96, and recognizes that these articles enable SPC holders to request a rectification of incorrect expiration dates.

The French IPO issued a <u>public statement</u> on January 15 2018, announcing that French SPC owners can now file requests to adjust the expiration date of granted SPCs. It thus aligns its practice on that of other offices that already accepted such corrections, like those of Germany, the United Kingdom, Ireland, The Netherlands, Portugal, and Denmark.

THREE KEY TAKEAWAYS

- The French IPO previously refused to adjust the expiration date of granted SPCs, in contradiction of the CJEU decision in Seattle Genetics.
- The French IPO now extends the expiration date of granted SPCs to comply with the CJEU decisions in Seattle Genetics and Incyte Corporation.
- French SPC owners can thus file requests before the French IPO to amend the expiration date of granted SPCs.

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