

DE BERTI ■ JACCHIA

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studio legale

CJEU clarifies that the Seattle judgement on SPC duration is retroactive

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Pursuant to Sect. 13, para. 1, of Reg. (EC) No. 469/2009 (on Supplementary Protection Certificate for medicinal products) concerning **SPC duration**, *“The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.”*.

In **Seattle decision** (CJEU, 06.10.2015, C-471/14) the Court clarified that “the date of the first authorization” (Marketing Authorization, MA) is not the date of the adoption of the decision of the competent regulatory body granting the MA, but the (later) date when that decision is notified to its addressee. The reason for this is to be found in the EU legislator’s intention to assure the SPC holder effective protection for the stipulated length of time, considering that the benefits of the MA can be enjoyed by the MA holder only as from when it is notified thereof.

This is good news for SPC holders and results in a longer SPC duration compared to the different option of considering, as SPC duration, that from the filing of the patent and the grant of the MA.

In the recent **Incyte decision** (CJEU, 20.12.2017, C-492/16) the Court held that the Seattle judgement has retroactive effect and also in case of SPCs issued before the Seattle decision, the date to be considered by the national Patent Office in calculating the certificate duration is that of notification.

The reason is that *“in accordance with settled case-law, the interpretation which the Court, in the exercise of the jurisdiction conferred upon it by Article 267 TFEU, gives to a rule of EU law clarifies and, where necessary, defines the meaning and scope of that rule as it must be, or ought to have been, understood and applied from the date of its entry into force. It follows that the rule as thus interpreted may, and must, be applied by the courts even to legal relationships arising and established before the delivery of the judgment ruling on the request for interpretation”* (para. 41, Incyte judgement).

In a situation where the date considered by the Patent Office in calculating the SPC duration is not compliant with Seattle criterium, the SPC holder may bring an appeal for rectification of SPC duration before the same body having granted such SPC, provided that the certificate has not expired. On the other hand, the Incyte judgement does not clarify whether national Patent Offices must rectify ex officio SPC terms not in line with the Seattle decision. It remains to be seen how national Offices, including the Italian Patent and Trademark Office (UIBM), will implement both judgements in the future.