

ECJ rules on date of first authorisation

January 13 2016 | Contributed by [Preslmayr Attorneys at Law](#)

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Introduction

Article 13(1) of the EU Supplementary Protection Certificate (SPC) Regulation (469/2009)⁽¹⁾ provides that an SPC will take effect at the end of the lawful term of a basic patent for a period equal to that which elapsed between the date on which the basic patent application was lodged and the date of the first authorisation to place the product on the market, reduced by five years. Article 13 neither clearly indicates whether the rule for calculating the period of exclusivity conferred by an SPC is governed by the procedural law of the member state concerned or solely by the provision nor whether the period counts from the date of adoption or the date of notification of the marketing authorisation. Although there is only a small timespan between these two dates, the economic impact of this difference is substantial.

Facts

Seattle Genetics held European Patent EP1 545 613 (the 'basic patent'), which it applied for on July 31 2003 and received on July 20 2011. On May 31 2011 Takeda Global Research and Development Center (Europe) Ltd applied under the centralised procedure laid down by EU Regulation 726/2004 for a conditional marketing authorisation for a new active substance which it had developed using the basic patent. A conditional marketing authorisation was granted on October 25 2012⁽²⁾ and Takeda was notified of the decision on October 30 2012. Both the date of the decision and the date on which Takeda was notified were published in the *Official Journal of the European Union* on November 30 2012.⁽³⁾

On November 2 2012 Seattle Genetics applied for an SPC based on the basic patent before the Patent Office, which was granted. The Patent Office held that the date of first authorisation to place the product on the EU market was the date on which the decision was made and thus set the SPC's expiry date as October 25 2027.

On April 22 2014 Seattle Genetics appealed before the Vienna Higher Regional Court, claiming that the SPC should be amended to expire on October 30 2027.

Decision

The Vienna Higher Regional Court stayed the proceedings and referred two questions to the European Court of Justice (ECJ) for a preliminary ruling.⁽⁴⁾ The Vienna court wanted to know whether the date of first authorisation is determined according to EU law or the law of the member state in question; and if EU law applies, whether the applicable date is the date of authorisation or the date of notification.

While setting out its reasons for requesting the preliminary ruling, the Vienna court highlighted that Article 13 does not clearly indicate whether the rule for calculating the period of exclusivity conferred by an SPC is governed by the procedural law of the member state concerned or solely by

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the provision. Under Austrian rules of procedure, the decisive criterion would be the date of publication or the date of notification of the decision; thus, in this case the date of notification would be the relevant date. However, in other member states, authorisations take effect once the authorisation instrument has been signed.

In an October 6 2015 judgment, the ECJ⁽⁵⁾ answered the referring court's questions. It held that the date of first authorisation is determined according to Article 13(1) of Regulation 469/2009. The regulation aims to establish a uniform EU-level solution in order to prevent national laws from creating disparities which would likely obstruct the free movement of medicinal products within the European Union. To achieve this purpose, the ECJ held that the provision must be regarded as containing an autonomous concept of EU law.

In concurrence with the advocate general's opinion, the ECJ held that it is impossible – on the basis of both the wording of Article 13(1) in its various languages and the other provisions of the regulation – to give an unequivocal answer to the question of whether the meaning of 'the date of the first authorisation' is the date of the decision granting marketing authorisation or whether the provision should be interpreted as meaning the date on which the addressee was notified of the decision.

The ECJ noted that Regulation 469/2009 seeks to re-establish a sufficient period of effective protection for basic patents by granting holders an additional period of exclusivity on the expiry of their patents. This period is intended as compensation for the delay to the commercial exploitation of an invention caused by the discrepancy between the date on which the patent application is filed and the date on which the first marketing authorisation is granted.⁽⁶⁾ The ECJ also referred to the EU legislature's intention to give SPC holders adequate protection so that the duration of supplementary protection is not calculated without due consideration to the date from which the holder can enjoy the benefits of the marketing authorisation. Thus, the ECJ clarified that SPC holders can market their products only from the date on which they are notified of the decision to grant marketing authorisation, not from the date on which the decision is adopted.

In concurrence with both the advocate general and the commission's submissions to the court, the ECJ held that it would be at odds with Regulation 469/2009 to reduce the period of validity because of the delay caused by the procedural steps between the decision granting marketing authorisation and notification of the decision. Therefore, the court held that Article 13(1) must be interpreted as meaning the date on which the addressee is notified of the decision to grant marketing authorisation.

Comment

Although Regulation 469/2009 has been in effect for over six years and member states have been interpreting the date of first marketing authorisation differently, it took some time for the ECJ to be given a chance to answer this question. It is fortunate that the Vienna court recognised the economic impact of the short interval between the date of a decision and the date of notification and thus gave the ECJ the opportunity to clarify this question.

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Endnotes

(1) OJ 2009 L 152, p.1.

(2) Implementing Decision C (2012) 7764 final.

(3) OJ 2012 C 371, p.8.

(4) OLG Wien, October 2 2014, 34 R 87/14k.

(5) C-471/14.

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