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Supplementary Protection Certificates

What is the relevant date of marketing authorization to determine the term of an SPC?

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1 Background

For medicinal products and plant protection products, the economically useful protection term conferred by a patent in the European Economic Area (EEA) is usually restricted significantly by the fact that the respective product may not be placed on the market without a marketing authorization by the European Medicines Agency (EMA, formerly EMEA). Accordingly, the date on which the product may be placed on the market is usually delayed for several years due to the time-consuming authorization procedure. In order to compensate for this, supplementary protection certificates (SPCs) may extend the duration of protection of the basic patent for up to five years, and optionally a further six months extension may be awarded in the case of a paediatric application of medicinal products.

In most cases, each day of protection, conferred by the patent and SPC, is precious. Therefore, it is highly relevant which date shall determine the duration of the SPC protection period. According to Article 13 of the EC Regulation (ECR) 469/2009,

"[t]he 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 authorization to place the product on the market in the Community****, reduced by a period of five years"* (emphasis added).

Article 7, point 1 of the same regulation specifies that

"[t]he application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product ***was granted****"* (emphasis added).

Depending on how this language is interpreted, a different duration of protection may result, as has been clarified in case C-471/14 (*Seattle Genetics*) by the European Court of Justice (ECJ).

2 The case of issue

The patent proprietor of EP 1 545 613 (Auristatin conjugates and their use for treating cancer, an autoimmune disease or an infectious disease), Seattle Genetics, applied for an SPC at the Austrian Patent Office using the corresponding marketing authorization (Community register of medicinal products No. EU/1/12/794/001, decision C(2012)7764) which was granted on October 25, 2012. The product concerned is *"Adcetris - Brentuximab vedotin"*, an orphan medicinal product for human use. The SPC was granted based on this date, with a maximum duration until October 25, 2027. In this case, the *"grant date"* of the marketing authorization refers to the date on which the European Commission decides to grant the marketing authorization (the date of issue). The same date is also the only date which is found on the published marketing authorization document as referred to above.

Seattle Genetics lodged an appeal against this decision at the Higher Regional Court (Oberlandesgericht, OLG) of Vienna, requesting that the duration of the SPC should instead be calculated based on the date of notification of the marketing authorization, October 30, 2012. This would result in a maximum duration of protection until October 30, 2027.

This request is based on the Treaty on the Functioning of the European Union, Article 297, para. 2, last sentence, which states that

"[...] decisions which specify to whom they are addressed, shall be notified to those

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*to whom they are addressed and shall **take effect upon such notification**"* (emphasis added).

Furthermore, Seattle Genetics argued that the relevant date for the permission to place the product on the market is the notification date of the marketing authorization. In the case of a European authorization, the centralized marketing authorization document itself specifies under Article 4 that

*"[t]he period of validity of the authorization shall be one year from the date of **notification** of this Decision"* (emphasis added).

Furthermore, the notification date is also published in the Official Journal of the EU (for the present case, cf. OJEU 55, 10; C 371/8). The OLG Vienna observed that the relevant date is determined differently in the EEA member states. For example, at least at the time of the OLG Vienna's decision, the German Patent Office (DPMA) determined the protection period based on the date of issue (cf. the DPMA's Guidelines for Examination of SPCs, Sec. 3.2.1.3.).

In Germany, a referral of the Federal Court of Justice (BGH, *Porfimer*, X ZB 30/05 of June 27, 2007) to the ECJ, concerned the question which date is relevant for the SPC duration in the case of a decentralized (national) authorization procedure, and whether EU or national law is applicable. In contrast, the present case, *Seattle Genetics*, concerns a centralized authorization. The national procedure is coordinated by a national office, such as the German Federal Institute for Drugs and Medical Devices (BfArM), whereas the centralized procedure takes place before the European Commission, who is supported by the EMA and the competent authorities of the Member States. The corresponding *"centralized"* marketing authorization is valid for the whole European Economic Area. However, the referred questions of *Porfimer* remain to be addressed, since the referral was withdrawn before a decision could be reached by the ECJ (C-452/07, *Health Research*).

Moreover, the OLG Vienna noted that in the German legal commentary literature, there is no unanimous opinion as to which date should be relevant. One of the reasons for this is that SPCs are considered a *sui generis* right at the interface between patent law and pharmaceutical provisions. Referring to the ECJ decisions C-130/11 and C-617/12, among others, the OLG Vienna opined that for the purpose of a harmonized interpretation with Guideline 2001/83 and ECR 726/2004, it might be concluded that the date of grant be the relevant date.

The Court concluded that the answer to this question depends on whether European or national law is applicable in this context, which cannot be determined directly and unambiguously from the relevant European provisions (C-281/81, C-62/90). Therefore, the Court decided to stay the proceedings, and referred the following questions to the ECJ:

"Is the date of the first authorization to place the product on the market in the Community pursuant to Article 13(1) of Regulation (EC) No 469/2009 (1) of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products determined according to Community law or does that provision refer to the date on which the authorization takes effect under the law of the Member State in question?

If the Court's answer is that the date referred to in Question 1 is determined by Community law, which date must be taken into account — the date of authorization or the date of notification?"

The case was handled at the ECJ under No. C-471/14, *Seattle Genetics*.

3 The ECJ's decision

The ECJ firstly stated that Article 13 of ECR 469/2009 does not define "the date of the first authorization to place the product on the market in the [European Union]", and does not refer to the national law in this respect. Accordingly, the ECJ concluded that, according to its established case law, this provision "must be regarded [...] an autonomous concept of EU law which must be interpreted in a uniform manner throughout the territory of the European Union. The ECJ further held that, according to recitals 7 and 8 of the preamble of ECR 469/2009, this regulation establishes a uniform solution at the EU level, and aims to prevent the heterogeneous development of national laws, which *"would be likely to create obstacles to the free movement of medicinal products within the European Union and thus directly affect the establishment and functioning of the internal market"*. The ECJ concluded that if the date of MA was to be determined according to national law, the objective of establishing a uniform solution at European Union level would be undermined.

Responsive to the first referred question, the ECJ therefore decided that the relevant date of MA in Article 13(1) of ECR 469/2009 is **determined by EU law**.

Regarding the second question, the Advocate General stated in his Opinion that it is not possible on the basis of either the wording of ECR 469/2009 in its various language versions or the other provisions of that regulation to give an unequivocal answer. The ECJ thus concluded the answer has to be given on the basis of the objective of the regulation. In this respect, the ECJ referred to the preamble of the regulation, as well as to the explanatory memorandum (COM(90) 101 final), and concluded that the legislator's objective was to give the holder of an SPC adequate effective protection. In light of this objective, the ECJ concluded that the date from which the SPC holder is *"able to enjoy the benefit"* of the MA should not be disregarded in the calculation the SPC duration (as discussed above, the product may only be put on the market starting from the notification date).

The ECJ also followed the Advocate General's argument that it would contravene the regulation's objective *"that procedural steps carried out between the decision granting marketing authorization and the notification of that decision — the duration of which is not within the control of the SPC holder — reduce the period of validity of an SPC"*.

Furthermore, the ECJ held that the requirement to give notification of a Commission decision to the person to whom it is addressed according to the third subparagraph of Article 297(2) of the Treaty of the Functioning of the European Union (TFEU), should not be disregarded in the calculation the SPC duration.

Based on these considerations, the ECJ answered the second referred question by stating that the **notification date of the MA** should be relevant for calculation of the SPC duration according to Article 13(1) of ECR 469/2009.

4 Citing national decision in Germany

The ECJ's decision has already been taken up by a recent decision of the German Federal Patent Court (Bundespatentgericht), 7 W (pat) 27/15 of December 11, 2015. This case concerned an SPC that was granted based on the German part of EP 1 999 109 as a basic patent and a centralized MA (EU/1/12/805). The medicinal product concerned is Florbetapir (18F), a diagnostic agent for Alzheimer's disease. In this case, the German Patent Office had calculated the term of the SPC based on the date of grant of the MA. The holder of the SPC (The Trustees Of The University Of Pennsylvania) appealed the decision of the German patent office, and requested that the calculation should instead be based

on the notification date according to the *Seattle Genetics* decision of the ECJ. The court concluded that the German Patent Office had calculated the SPC term based on the wrong date, and remitted the case to the previous instance for further substantial examination.

5 Conclusion and comments

Based on convincing arguments, the ECJ has ruled that the term of an SPC should be calculated based on the notification date of the MA, thus providing SPC holders with the opportunity to obtain a few, but precious, additional days of protection. A possible extension of the SPC is, in principle, pertinent in those cases where a centralized authorization has been issued by the European Commission and where the time between the filing date of the basic patent and the date of grant of the MA is less than 10 years.

At least in the case of SPCs that have already been granted based on the date of grant of the MA, applicants should consider to request a correction of their SPC duration, since the national patent offices will not necessarily grant the extension *ex officio*. According to our current understanding, the German Patent Office will take into account the new ruling for any pending SPC application based on a centralized authorization. An appeal to the Federal Patent Court, as in the "*Florbetapir*" decision, will most likely not be necessary, unless the DPMA refuses to grant the extension.

It is clear that the ECJ's ruling in *Seattle Genetics* applies for any centralized (EMA) authorization. However, the ECJ has not explicitly clarified if the answer to the second question applies for any (national or centralized) MA. At least, the answer to the second question (as well as the question itself) does not differentiate between these two different types of MAs. Since the provisions relating to SPCs are mainly based on European law, the ruling of the ECJ might, in principle, apply for both national and centralized MAs. The ECJ has concluded in the answer to the first question that the date of MA according to Article 13 of the Regulation (EC) 469/2009 is determined according to EU law. Article 13 itself does not distinguish between national or centralized authorizations. This would generally support the view that the decision also applies for national MAs. However, the ECJ's ruling is based, in part, on Article 297, para. 2, last sentence of the Treaty on the Functioning of the European Union, which might not necessarily apply for a national MA.

Thus, it is not entirely clear at the moment if the national patent offices will actually calculate the SPC term based on the notification date in the case of a national MA. Applicants could therefore consider requesting a recalculation of the SPC term also in case of national authorizations.

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