

15 years are enough! ECJ decided on the maximum period of exclusivity of a patent and SPC

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by Miriam Büttner

In a recent decision the European Court of Justice (ECJ) ruled on the maximum period of exclusivity of a patent and a supplementary protection certificate (SPC) (Order of the Court dated 13 February 2014 - case no C-555/13, Merck Canada Inc. vs. Accord Healthcare Ltd and others).

Background:

Merck Canada Inc. (Merck) lodged an application for a patent for the active ingredient "montelukast sodium" in Portugal on 11 October 1991, which was granted on 2 October 1998. The first marketing authorization (MA) for a medicinal product containing that active ingredient within the European Union was obtained in Finland on 25 August 1997. Merck applied for a SPC with the Portuguese National Institute of Intellectual Property on 3 February 1999. The SPC for the active ingredient "montelukast sodium" was granted on 10 January 2000.

In November 2012 Merck sued the defendants in the main proceedings before the Tribunal Arbitral necessário, inter alia, to abstain from producing, importing and/or launching generic drugs containing the active ingredient "montelukast sodium" on the Portuguese market.

In the light of these undisputed facts the parties of the main proceedings calculated different expiry dates of the patent/SPC based on their diverging interpretation of Article 13 of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products. According to Merck's interpretation the SPC should be valid until 17 August 2014 (expiry of the patent on 2 October 2013 + 10 months and 15 days), even if Merck in this case may enjoy a period of exclusivity over the active ingredient "montelukast sodium" for a period which is greater than 15 years.

By contrast, the defendants in the main proceedings were of the opinion that the aim of Regulation No 469/2009 is to guarantee the holder of both a patent and a SPC a maximum period of 15 years of exclusivity from the first MA in the European Union for the medicinal product in question.

In this situation, the Tribunal Arbitral necessário decided to stay the proceedings and referred the case to the ECJ.

Question referred for a preliminary ruling:

The ECJ understood the question of the Tribunal Arbitral necessário in a way that it "essentially asked whether Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it."

The decision:

The ECJ was of the opinion that it could decide on the referral for a preliminary ruling by reasoned order pursuant to Article 99 of its Rules of Procedure as the question referred would leave no room for reasonable doubt and may be clearly deduced from existing case-law, inter alia from the order of the Court dated 14 November 2013 (case no. C-617/12 - AstraZeneca AB vs. Comptroller General of Patents, Designs and Trade Marks).

The ECJ answered the referred question in the affirmative as it would already follow from a literal interpretation of Article 13 of Regulation No 469/2009 in conjunction with recital 9 thereto. Furthermore the ECJ referred to the order cited above (see AstraZeneca AB), although this question has not been relevant in this matter. That decision only dealt with the question which MA should be regarded as a first authorization in the meaning of Article 13 of Regulation No 469/2009.

Anyway, in the case at hand the ECJ concluded as a result that irrespective of the date on which the basic patent in Portugal was granted and the theoretical validity period of the SPC resulting from the application of Article 13 of Regulation No 469/2009, the maximum period of exclusivity conferred by both Patent and SPC cannot exceed a total duration of 15 years, calculated from 25 August 1997.

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All decisions and regulations referred to are available in different languages on the website of the European Court of Justice (<http://curia.europa.eu>).