Court of Justice EU, 5 October 2016, F. Hoffmann-La Roche v Accord Healthcare

PATENT LAW

The Court does not have jurisdiction to rule on the validity of Article 21(2) of SPC Regulation for Medicinal Products

- **The Court of Justice of the European Union does not have jurisdiction to rule on the validity of Article 21(2) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, as amended by the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community.**

Article 21(2) of SPC Regulation for Medicinal Products applies to a supplementary protection certificate granted by a Member State prior to its accession to the European Union

- **Article 21(2) of Regulation No 469/2009, as amended, must be interpreted as meaning that it applies to a supplementary protection certificate, relating to a given medicinal product, granted by a Member State prior to its accession to the European Union.**

If a market authorisation is granted in the EEA before it is granted in a Member State and before its accession to the EU, only the first marketing authorisation must be taken into account for the purposes of determining the duration of validity of the supplementary protection certificate.

- **To the extent that that medicinal product was the subject, within the European Economic Area, of a marketing authorisation before that granted in that Member State, and, as the case may be, before its accession to the European Union, only the first marketing authorisation must be taken into account for the purposes of determining the duration of validity of the supplementary protection certificate.**

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Court of Justice EU, 5 October 2016
(C. Toader (Rapporteur), A. Prechal, E. Jarašiūnas)
JUDGMENT OF THE COURT (Seventh Chamber)

5 October 2016 (*)
(Reference for a preliminary ruling — Industrial and commercial property — Patent — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 21(2) — Transitional provisions — Certificate granted in accordance with the national legislation of a Member State prior to its accession to the European Union — Interpretation of Article 21(2) — Duration of validity of the certificate — Validity of Article 21(2) — Adjustment to secondary legislation resulting directly from the Act of Accession — Lack of jurisdiction of the Court)
In Case C‑572/15,
REQUEST for a preliminary ruling under Article 267 TFEU from the Riigikohus (Supreme Court, Estonia), made by decision of 21 October 2015, received at the Court on 2 November 2015, in the proceedings
F. Hoffmann-La Roche AG
v
Accord Healthcare OÜ,
THE COURT (Seventh Chamber),
composed of C. Toader (Rapporteur), President of the Chamber, A. Prechal and E. Jarašiūnas, Judges,
Advocate General: M. Wathelet,
Registrar: A. Calot Escobar,
having regard to the written procedure,
after considering the observations submitted on behalf of:
– F. Hoffmann-La Roche AG, by C. Ginter and K. Lepasepp, vandeadvokaadid, and by A. Sehver and T. Nelsas, patendivolinikud,
– Accord Healthcare OÜ, by R. Antsmäe, vandeadvokaat,
– the Estonian Government,, by K. Kraavi-Käerdi, acting as Agent,
– the Czech Government, by J. Vláčil, S. Šindelková and M. Smolek, acting as Agents,
– the European Parliament, by J. Rodrigues, I. McDowell and M. Allik, acting as Agents,
– the Council of the European Union, by M. Balta and M. Alver, acting as Agents,
– the European Commission, by T. Scharf, J. Samnadda and E. Randvere, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,
gives the following
Judgment
1. This request for a preliminary ruling concerns the interpretation of Article 21(2) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1), as amended by the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community (OJ 2012 L 112, p. 21) (“Regulation No 469/2009”).
2. The request has been made in proceedings between F. Hoffmann-La Roche AG (“Roche”) and Accord

Healthcare OÜ ("Accord") concerning the enforceability of industrial property rights owned by Roche in relation to the generic medicinal products produced by Accord.

Legal context

3. Annex II to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33) contains a subsection 4, C, II, entitled "Supplementary protection certificates".

4. Paragraph 1(b) of that section specifies that Article 20 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), as amended by the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21) ("Regulation No 1768/92") is supplemented by a second paragraph, worded:

"This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to the date of accession."

5. As recital 1 of Regulation No 469/2009 specifies, Regulation No 1768/92 has been substantially amended several times, which is why the Union legislature decided, in the interests of clarity and rationality, to codify that regulation.

6. As set out in recital 9 of Regulation No 469/2009:

"The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community."

7. Article 13 of that regulation, entitled "Duration of the certificate", provides:

"1. 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.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

..."

8. As set out in Article 21(2) of that regulation, whose wording is essentially the same as that of Article 20(2) of Regulation No 1768/92, the latter provision not yet however referring to the Republic of Croatia:

"This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession."

The dispute in the main proceedings and the questions referred for a preliminary ruling

9. Roche, a company established in Switzerland, markets in Estonia a medicinal product called "Xeloda", whose active substance is capecitabine and in respect of which Roche has a basic patent No 03086, granted on 15 April 1998 ("the basic patent"). For the purposes of marketing that medicinal product, Roche registered Xeloda for the first time in Estonia on 8 June 2001 and, after applying for supplementary protection on 1 August 2001, obtained, for that medicinal product, a supplementary protection certificate (SPC) No 00001, issued on 24 October 2001 by the Patendiamet (Estonian Patent Office).

10. Accord Healthcare Limited obtained, through a subsidiary, Accord, established in Estonia, a marketing authorisation (MA) for a generic medicinal product, whose active substance is also capecitabine. On 3 October 2014, that subsidiary applied to the Estonian Ministry of Social Affairs for its generic medicinal product to be included in a list of medicinal products provided for by the national legislature, that inclusion having the effect of reducing the cost of that medicinal product for insured persons, the national sickness insurance fund assuming some of the cost of that medicinal product. On 4 December 2014, the Ministry of Social Affairs approved that application for inclusion. Accord planned to make its own medicinal product available on the Estonian market from 15 December 2014.

11. On 8 December 2014, Roche brought an action before the Harju Maakohus (Harju District Court, Estonia) for the purpose, inter alia, of ordering Accord to refrain from and/or cease conduct infringing the rights held by Roche, as owner of the SPC relating to Xeloda, until the expiry of the validity of that certificate, which, according to Roche, was 8 June 2016, and to prohibit Accord from marketing, offering for sale, selling and advertising in Estonia until the same date medicinal products containing the active substance capecitabine. Moreover, Roche asked that court to order the destruction of all the medicinal products in the ownership or possession of Accord whose active substance is capecitabine.

12. In support of its various claims, Roche maintained that it was owner, until 18 November 2014, of the basic patent and the SPC relating to Xeloda, whose validity, in its submission, expired on 8 June 2016.

13. Submitting that the placing on the market of the generic medicinal product by Accord would cause it substantial damage, resulting in a forecast decline of 50% of its turnover, that is to say approximately EUR 460 000, Roche submitted an application for protective

measures in support of its action consisting, first, in the seizure of all the medicinal products in Accord"s ownership and in prohibiting Accord from passing on to third parties medicinal products in its possession whose active substance is capecitabine and, second, in prohibiting Accord from marketing, offering for sale, selling and advertising in Estonia medicinal products containing that active substance, until the termination of the proceedings by a binding judgment, but not longer than 8 June 2016.

14. Accord asked for the action to be dismissed and also submitted a counterclaim on 6 February 2015, in which it sought the annulment of the SPC or a declaration that the certificate has no validity and could not have any validity.

15. By order of 15 December 2014 the Harju Maakohus (Harju District Court) allowed the applicant"s application for protective measures.

16. Accord challenged that order and applied for it to be set aside by the Harju Maakohus (Harju District Court). According to Accord, such protective measures could not be granted, since Roche"s action has no prospect of succeeding on the substance, Roche having no exclusive right to capecitabine until 8 June 2016. In Accord"s submission, in **the order of 13 February 2014, Merck Canada (C‑555/13, EU:C:2014:92)**, the Court took the view that Article 13 of Regulation No 469/2009, in conjunction with recital 9 thereof, must be interpreted as meaning that it is not permitted for the holder of both a patent and an SPC to rely on the entire period of validity of the certificate, calculated in accordance with Article 13 thereof, in a situation in which, by relying on such a period of validity, it would enjoy an exclusive right in relation to an active substance for more than 15 years from the time when the first MA in the European Union was granted for a medicinal product consisting of that active substance or containing it. The first MA in the European Union of the medicinal product containing capecitabine having been granted on 10 June 1998, the maximum duration of supplementary protection that Roche could claim is 15 years from that first placing on the market, that is to say from 10 June 1998 to 10 June 2013. Since, on 10 June 2013, the validity of the basic patent expired, as did the validity of the SPC relating to Xeloda, Roche has, since then, no longer been the owner of an exclusive right in relation to capecitabine.

17. The Harju Maakohus (Harju District Court) referred the case to the Tallinna Ringkonnakohus (Tallinn Court of Appeal, Estonia) for a decision on that dispute.

18. By order of 26 February 2015, the Tallinna Ringkonnakohus (Tallinn Court of Appeal) set aside the order delivered on 15 December 2014 by the Harju Maakohus (Harju District Court) and the associated protective measures.

19. By its appeal before the Riigikohus (Supreme Court, Estonia), Roche claims that the order of the Tallinna Ringkonnakohus (Tallinn Court of Appeal) should be set aside and that the validity of the order of the Harju Maakohus (Harju District Court) should be confirmed.

20. In Roche"s submission, the Tallinna Ringkonnakohus (Tallinn Court of Appeal) misinterpreted Article 21(2) of Regulation No 469/2009. In addition, that court"s interpretation as regards the retroactive effect of Regulation No 469/2009 is contrary to other provisions of European Union law, and in particular the Charter of Fundamental Rights of the European Union.

21. Roche submits that, contrary to what the Tallinna Ringkonnakohus (Tallinn Court of Appeal) held, the SPC relating to Xeloda was valid, since it was issued at a time when Estonia was not a member of the European Union. Accordingly, only Estonian law applies, according to which the duration of validity of the SPC depended not on the grant of the first MA in the European Union, but the grant of that authorisation in Estonia. Article 21(2) of Regulation No 469/2009 does not expressly lay down that the expiry date of SPCs which have been issued before the accession of the Member State concerned to the European Union must be recalculated. Thus, the interpretation of the Tallinna Ringkonnakohus (Tallinn Court of Appeal) of that provision infringes the principle of legal certainty. According to Roche, the SPC relating to Xeloda therefore remains valid until 8 June 2016, that is 15 years from the first Estonian MA of the medicinal product, in accordance with the national legislation applicable at the time. The idea of Article 21(2) of Regulation No 469/2009 is to make it possible for holders of national SPCs predating the accession of the Member State concerned to exercise their rights, and its content or objective is not retroactively to apply in relation to SPCs issued on the basis of national law. According to Roche, the reference to **the order of 13 February 2014, Merck Canada (C‑555/13, EU:C:2014:92)**, is not relevant, since that order does not concern the temporal application of Article 21(2) of Regulation No 469/2009.

22. The referring court emphasises, first, that although, in that order, the Court of Justice interpreted Article 13 of Regulation No 469/2009 in conjunction with recital 9 thereof, that order did not relate either to the interpretation of Article 21(2) of Regulation No 469/2009 or the retroactive application of law deriving therefrom, as the case which gave rise to that decision did not concern a new Member State. Thus, it is not clearly apparent whether the guidance deriving from that order is also applicable to an SPC which was issued in accordance with Estonian legislation before the accession of the Republic of Estonia to the European Union, on 1 May 2004.

23. Second, and in the event that the Court should consider it appropriate to reduce the duration of validity of an SPC, the referring court is uncertain as to the compatibility of that provision with European Union primary law, in particular with the general principles of the European Union relating to the protection of acquired rights and non-retroactivity and with Articles 16 and 17 of the Charter.

24. In those circumstances, the Riigikohus (Supreme Court) decided to stay the proceedings and to refer the

following questions to the Court for a preliminary ruling:

"(1) Must Article 21(2) of Regulation No 469/2009 ... be interpreted as shortening the duration of [an SPC] issued in a Member State which was issued under national law before the accession of the State in question to the European Union and whose duration in relation to an active substance, as stated in the [SPC], would be longer than 15 years from the time when the first [MA] in the Union was granted for a medicinal product consisting of the active substance or containing it?

(2) If the answer to the first question is in the affirmative, is Article 21(2) of Regulation No 469/2009 ... compatible with European Union law, in particular the general principles of European Union law on the protection of acquired rights, the principle of the prohibition of retroactive effect of law, and the Charter ...?"

The questions referred

The second question

25. By its second question, which it is appropriate to examine first, the referring court seeks a ruling from the Court of Justice on the validity of Article 21(2) of Regulation No 469/2009 in the light of European Union law.

26. It should be noted at the outset that point (b) of the first paragraph of Article 267 TFEU confers jurisdiction on the Court to give preliminary rulings concerning both the interpretation of the acts of the institutions, bodies, offices or agencies of the European Union and the validity of those acts.

27. In the present case, as is apparent from paragraph 4 above, Article 20(2) of Regulation No 1768/92 was inserted into that regulation by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded.

28. As provided in Article 20(2), Regulation No 1768/92 is to apply to SPCs "granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to the date of accession".

29. Regulation No 469/2009 consolidated Regulation No 1768/92, so that Article 20(2) of Regulation No 1768/92 became Article 21(2) of Regulation No 469/2009.

30. As regards a provision such as that at issue in the main proceedings, the Court has already held that adjustments set out in an annex to an Act of Accession are to be the subject of an agreement between the Member States and the applicant State and that they do not constitute an act of an institution, but are provisions of primary law which may not be suspended, amended or repealed otherwise than by means of the procedures laid down for the revision of the original Treaties (see, to that effect, judgment of 28 April 1988, LAISA and CPC España v Council, 31/86 and 35/86, EU:C:1988:211, paragraph 12).

31. It should be specified in that respect that the difference in treatment resulting from the foregoing is not arbitrary, but is merely the consequence of the respective procedures chosen for the purpose of adoption of those provisions. Whereas some of those provisions are adopted pursuant to acts of the institutions, which are subject as such to the general rules on the review of legality provided for in the FEU Treaty, the provisions resulting directly from an Act of Accession do not constitute acts of institutions and are not therefore open to such review (see, to that effect, judgment of 28 April 1988, LAISA and CPC España v Council, 31/86 and 35/86, EU:C:1988:211, paragraph 17).

32. Moreover, as the European Parliament argues, the fact that Regulation No 1768/92 was repealed and replaced by Regulation No 469/2009 in no way alters the foregoing considerations, since Regulation No 469/2009 merely consolidates amendments made previously in the original text, in the interests of clarity and rationality, whilst maintaining their substance.

33. It follows that the Court does not have jurisdiction to rule on the validity of Article 21(2) of Regulation No 469/2009.

The first question

34. By its first question the referring court asks, in essence, whether Article 21(2) of Regulation No 469/2009 must be interpreted as meaning that it applies to an SPC, relating to a given medicinal product, issued by a Member State prior to its accession to the European Union.

35. The Court would first of all point out that Article 21(2) of Regulation No 469/2009 states that that regulation applies to SPCs granted in accordance with the national legislation of the Republic of Estonia prior to the date of its accession to the European Union.

36. Next, Article 13 of that regulation, in conjunction with recital 9 thereof, provides that the holder of both a patent and an SPC should not be able to enjoy more than 15 years of exclusivity from the time of the first MA, granted in the European Union, of the medicinal product concerned (see, to that effect, **order of 13 February 2014, Merck Canada, C-555/13, EU:C:2014:92**, paragraph 30 and the case-law cited).

37. Thus, as the Estonian Government states, since 1 May 2004, the duration of validity of the SPC has depended not on when the first MA was granted in the Republic of Estonia, but in the European Union.

38. In that regard, it should be borne in mind that the words "first [AM] in [the European Union]", for the purposes of Article 13(1) of Regulation No 469/2009, make reference to the first MA granted not in the Member State of the application, but in any Member State. Only that interpretation ensures that the extension of protection of the product covered by the certificate will expire at the same time in all of the Member States in which the certificate was granted (**order of 13 February 2014, Merck Canada,**

C-555/13, EU:C:2014:92, paragraph 31 and the case-law cited).

39. In the present case, it is however apparent from the documents before the Court that the first MA for Xeloda was granted not by a Member State of the European Union, but by a Member State of the European Economic Area (EEA), namely the Swiss Confederation, on 10 June 1998. The Court has nonetheless already held that, to the extent that the MA for a medicinal product granted by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under the legislation of that State is the first MA for that medicinal product in one of the States of the EEA, it constitutes the first MA, for the purposes of Article 13 of Regulation No 1768/92, as it is to be read for the purposes of the application of the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3) (see, to that effect, **order of 14 November 2013, Astrazeneca, C-617/12, EU:C:2013:761**, paragraphs 41 and 42 and the case-law cited).

40. Furthermore, the fact that MAs granted in Switzerland do not permit the free movement of the medicinal products to which they relate within the territory of the EEA, with the exception of Liechtenstein, is not relevant to the interpretation of Article 13 of Regulation No 469/2009, as it is to be read for the purposes of the application of the EEA Agreement (**order of 14 November 2013, Astrazeneca, C-617/12, EU:C:2013:761**, paragraph 43 and the case-law cited).

41. It follows from the foregoing considerations that the effects of a first MA granted in a Member State of the EEA are equivalent to those of a "first [MA] in [the European Union]", for the purposes of Article 13 of Regulation No 469/2009.

42. Accordingly, in circumstances such as those in the main proceedings, and for the purposes of calculating the duration of validity of the SPC, it is necessary, as is apparent from the findings of the referring court, to rely on the date on which the first MA was granted for Xeloda not in Estonia, that is on 8 June 2001, but in Switzerland, namely on 10 June 1998.

43. Lastly, it should be pointed out, on the one hand, that, according to the settled case-law of the Court, new rules falling within the substantive rules of European Union law apply immediately to the future effects of a situation which arose under the old rules. Furthermore, from the date of accession of a new Member State, the provisions of European Union law are to apply under the conditions laid down in the original Treaties and in the relevant Act of Accession (see, to that effect, judgment of 12 September 2013, Kuso, C-614/11, EU:C:2013:544, paragraph 25 and the case-law cited).

44. On the other hand, as the Estonian Government and the Commission observe, and in accordance with the wording of Article 13 of Regulation No 469/2009, an SPC takes effect only at the end of the lawful term of the basic patent.

45. However, it is not disputed in the present case that that patent expired after the accession of that Member State.

46. Since, on expiry of that patent and at the time that the SPC could have taken effect, that regulation was already in force, there can be no question of retroactive application of that regulation arising.

47. It follows from all the foregoing that the answer to the first question is that Article 21(2) of Regulation No 469/2009 must be interpreted as meaning that it applies to an SPC, relating to a given medicinal product, granted by a Member State prior to its accession to the European Union. To the extent that that medicinal product was the subject, within the EEA, of an MA before that granted in that Member State, and, as the case may be, before its accession to the European Union, only the first MA must be taken into account for the purposes of determining the duration of validity of that SPC.

Costs

48. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Seventh Chamber) hereby rules:

1. The Court of Justice of the European Union does not have jurisdiction to rule on the validity of Article 21(2) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, as amended by the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community.

2. Article 21(2) of Regulation No 469/2009, as amended, must be interpreted as meaning that it applies to a supplementary protection certificate, relating to a given medicinal product, granted by a Member State prior to its accession to the European Union. To the extent that that medicinal product was the subject, within the European Economic Area, of a marketing authorisation before that granted in that Member State, and, as the case may be, before its accession to the European Union, only the first marketing authorisation must be taken into account for the purposes of determining the duration of validity of the supplementary protection certificate.

[Signatures]

* Language of the case: Estonian.