Case C-354/19

Request for a preliminary ruling

Date lodged:

3 May 2019

Referring court:

Svea Hovrätt, Patent- och marknadsöverdomstolen (Sweden)

Date of the decision to refer:

3 May 2019

Appellant:

Novartis AG

Other party to the proceedings:

Patent-och registreringsverket

[...]

PARTIES

Appellant

Novartis AG

[…] Basel

Switzerland

[…]

Other party to the proceedings

Patent-och registreringsverket

[…] Stockholm

MATTER

Supplementary protection certificates for medicinal products; now, inter alia, a need to obtain a preliminary ruling from the Court of Justice of the European Union.

[…]

The question has arisen as to whether there are grounds for requesting a preliminary ruling from the Court of Justice.

The parties have submitted their observations on the question. **[OR.2]**

After presentation of the arguments, the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal, Sweden) made the following

ORDER (to be served on 3 May 2019)

1. The Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal) decides to request a preliminary ruling from the Court of Justice of the European Union under Article 267 of the Treaty on the Functioning of the European Union and to submit a request for a preliminary ruling in accordance with Annex A to these minutes.

2. The Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal) declares that the proceedings shall be stayed pending the ruling from the Court of Justice.

[…] **[OR.3]**

[…]

Request for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union

Facts of the case

1. On 17 December 2013, Novartis AG (Novartis) applied to the Patent- och registreringsverket (Swedish Patent and Registration Office; 'PRV'), for a supplementary protection certificate ('SPC') for medicinal products for the product canakinumab, as an extension of the period of validity of the basic patent EP 1 940 465 B1 for 'New use of anti il-1-beta antibodies'.

2. The autonomous patent claims 1 and 10 of this basic patent refer to the use of a human IL-1 beta binding antibody for the manufacture of medicinal products for the treatment of juvenile rheumatoid arthritis in a patient (1) and a pharmaceutical composition, including human IL-1 beta binding antibody for use in the treatment of idiopathic juvenile arthritis (10).

3. [The original, English-language], patent claims 1 and 10 have the following respective wording.

1. Use of a human IL-1 beta binding antibody for the manufacture of a medicament for the treatment of juvenile rheumatoid arthritis in a patient, comprising:

at least one antigen binding site comprising a first domain having an amino acid sequence as shown in SEQ ID NO:1, and a second domain having an amino acid sequence as shown in SEQ ID NO:2. [**OR.4**]

10. A pharmaceutical composition comprising human IL-1 beta binding antibody comprising at least one antigen binding site comprising a first domain having an amino acid sequence as shown in SEQ ID NO:1, and a second domain having an amino acid sequence as shown in SEQ ID NO:2 or ACZ885 for use in the treatment of systemic onset idiopathic juvenile arthritis in a combination with a pharmaceutically acceptable excipient, diluent or carrier, wherein said antibody is parenterally administered.

[1. Användning av en human IL-1-betabindande antikropp för framställning av ett läkemedel för behandling av juvenil reumatoid artrit hos en patient, innefattande: åtminstone ett antigenbindande säte innefattande en första domän med en aminosyrasekvens såsom visas i SEKV ID NR:1, och en andra domän med en aminosyrasekvens såsom visas i SEKV ID NR:2.

10. Farmaceutisk komposition innefattande human IL-1-betabindande antikropp innefattande åtminstone ett antigenbindande säte innefattande en första domän med en aminosyrasekvens såsom visas i SEKV ID NR:1 och en andra domän med en aminosyrasekvens såsom visas i SEKV ID NR:2 eller ACZ885 för användning vid behandling av idiopatisk juvenil artrit med systemisk början i en kombination med ett farmaceutiskt godtagbart konstituens, utspädningsmedel eller en farmaceutisk godtagbar bärare, varvid antikroppen administreras parenteralt.]

4. In support of its request, Novartis relied on Decision C (2013) 5600 of the European Commission of 26 August 2013 as the first marketing authorisation for the product in the EEA. The decision, which amends Commission Decision C (2009) 8375 of 23 October 2009, concerns the medicinal product ILARIS — canakinumab, the therapeutic indications of which, in accordance with point 4.1 of the relevant Summary of Product Characteristics, are ‘cryopyrinassociated periodic syndromes, gouty arthritis and systemic juvenile idiopathic arthritis’.

5. Novartis previously held SPCs for the product of canakinumab, which relate to the extension of the period of validity of another basic patent, EP 1 313 769 B2, concerning ‘Antibodies against human il-1b’. The basis for that previous SPC was the Commission’s marketing authorisation of 23 October 2009 in Decision C (2009) 8375, which concerns the therapeutic indication ‘cryopyrinassociated periodic syndromes’.

6. The PRV, by decision of 24 September 2015, rejected Novartis's application for an SPC. In summary, the PRV stated that Novartis had previously been granted SPCs for the product of canakinumab and that a new SPC for the product could therefore not be granted pursuant to Article 3(c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the [SPC] for medicinal products.

7. Novartis appealed against the decision to Stockholms tingsrätt, Patent- och marknadsdomstolen (District Court, Stockholm, Patent and Market Court, Sweden), maintaining its application for an SPC to be granted. The PRV then contested any amendment to its decision. By decision of 27 September 2017, the Patent- och marknadsdomstolen dismissed Novartis's appeal. In summary, [**OR.5**] the Patent- och marknadsdomstolen, found, as had the PRV, that the SPC could not be granted on the ground that SPCs had previously been granted for the product canakinumab.

Details of the case in the Patent- och marknadsdomstolen (Patent and Market Court)

8. Novartis applied to the Patent- och marknadsdomstolen (Patent and Market Court) for an order that the PRV's decision to reject the company's application for an SPC be annulled/withdrawn and that the case be remitted to the PRV for further handling [and the granting of an SPC].

9. The PRV opposed the annulment/withdrawal of its decision.

10. Before the Patent- och marknadsdomstolen (Patent and Market Court), the parties relied on the evidence which they put forward in support of their claim before the PRV and extended their legal arguments on the matter.

Assessment by the Patent- och marknadsdomstolen (Patent and Market Court)

11. With reference to the Swedish language version of Article 3(c) 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, the Patent- och marknadsdomstolen (Patents and Market Court) initially stated that, in order for an SPC to be granted, it is required that 'ett tilläggsskydd inte redan har meddelats för läkemedlet' ('the medicinal product has not already been the subject of a certificate'). The Patent- och marknadsdomstolen stated that 'medicinal product' should be understood as 'product'.

12. The Patent- och marknadsdomstolen (Patents and Market Court) subsequently stated, referring, inter alia, to the judgment of the Court of Justice of the European Union of 14 November 2013, C-210/13, *GlaxoSmithKline Biologicals*, EU:C:2013:762, that the term 'product' is to be understood in the strict sense of 'active ingredient' and that small changes to a medicinal product, such as a new dosage, the use of another salt or other ester, or a different pharmaceutical form, cannot be granted a new SPC. [**OR.6**]

13. In addition, the Patent- och marknadsdomstolen (Patents and Market Court) stated that the Court of Justice has ruled in, inter alia, the abovementioned judgment, *GlaxoSmithKline Biologicals*, cited above, that the definition of the terms 'product' and 'active ingredient' has not been amended by its judgment of 19 July 2012, *Neurim Pharmaceuticals*, C-130/11, EU:C:2012:489, in relation to the Court's earlier ruling in its judgment of 4 May 2006, *Massachusetts Institute of Technology*, C-431/04, EU:C:2006:291. The Patent- och marknadsdomstolen noted in that regard, that, in *Neurim Pharmaceuticals*, the Court of Justice did not take a position as to how Article 3(c) of [Regulation No 469/2009] should be interpreted.

14. Furthermore, the Patent- och marknadsdomstolen (Patents and Market Court) stated that the Court of Justice, in its judgment of 12 March 2015, *Actavis Group PTC and Actavis UK [Boehringer]* (C-577/13, EU:C:2015:165), held that the objective of SPCs is not to compensate the holder fully for the delay to the marketing of an invention or to compensate for such delay in connection with the marketing of that invention in all its possible commercial forms, including in the form of combinations based on the same active ingredient. The Patent- och marknadsdomstolen noted in that regard that, pursuant to Article 3(2) of Council Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, the holder of a number of patents for the same product cannot be granted several SPCs for that product.

15. Against the background of the above, the Patent- och marknadsdomstolen (Patents and Market Court) found that the provision set out in Article 3(c) of [Regulation No 469/2009] means that the previous SPC based on a medicinal product (with the active ingredient canakinumab) for the treatment of cryopyrinassociated periodic syndromes, precludes [the grant of the requested] SPC for a medicinal product [with the active ingredient canakinumab] for the treatment of systemic juvenile idiopathic arthritis.

16. Further, the Patent- och marknadsdomstolen (Patents and Market Court) stated that nor does the fact that a prior SPC for a product, in accordance with Article 14 of [Regulation No 1610/96], does not preclude the grant of a subsequent SPC for [**OR.**7] derivatives (salts and esters) of the product, provided that the derivative is protected by a patent *per se*, alter the court's assessment. The Patent- och marknadsdomstolen noted in that regard that the product at issue, canakinumab, does not constitute a derivative.

The case before the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal)

17. Novartis has appealed against the decision of the Patent- och marknadsdomstolen (Patent and Market Court) and maintained its application for an SPC.

18. The PRV contested any amendment to the judgment.

19. Before the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal), the parties relied on the same facts as those which formed the basis of their claims before the Patent- och marknadsdomstolen (Patent and Market Court). The parties have further developed their legal arguments.

Applicable legislation

[Regulation No 469/2009]

20. Recitals 2, 3, 9, 10 and 11 of the regulation are worded as follows:

> (2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.
>
> (3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.
>
> (9) 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.
>
> (10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product. [**OR.8**]
>
> (11) Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law.

21. Under Article 3 of the regulation, entitled ‘Conditions for obtaining a certificate’:

> ‘A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
>
> (a) the product is protected by a basic patent in force;
>
> (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive [2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the

Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)] ...;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

22. Article 6 of the regulation, entitled 'Entitlement to the certificate', is worded as follows:

'The certificate shall be granted to the holder of the basic patent or his successor in title.'

[Regulation No 1610/96]

23. Recital (17) of the regulation is worded as follows:

Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17(2) of this regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92,

24. Article 3(2) of the regulation provides as follows:

The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders. [**OR.9**]

The need for a preliminary ruling

[Regulation No 469/2009]

25. In accordance with the wording of Article 3(c) of Regulation No 469/2009 in the Swedish-language version, a fundamental condition for the granting of a certificate is that a certificate has not previously been granted for 'the medicinal product'. A comparison with other language versions of the regulation indicates that the term 'medicinal product' must be understood as 'the product' (see, to this effect, the judgment of the Patentbesvärsrätten (Court of Patent Appeals, Sweden) of 28 February 2011 in Case 07-278).

26. Point 11 of the Explanatory Memorandum to the Proposal of 11 April 1990 for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM (90) 101 final) states that the proposed regulation concerns only new medicinal products and that it does not involve granting a certificate for all medicinal products that are authorised

to be placed on the market. It also states that only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense, and that minor changes to the medicinal product, such as a new dose, the use of a different salt or ester or a different pharmaceutical form, will not lead to the issue of a new certificate.

27. In addition, point 36 of the explanatory memorandum to the proposal for a regulation states that the purpose of Article 3(c) of Regulation No 1768/92 is to prevent the same product from being the subject of several successive SPCs so that the total term of protection for a single medicinal product could be exceeded. Moreover, as is apparent in particular from paragraphs 4 and 5 of point 28 of the explanatory memorandum, the protection conferred by an SPC is largely intended to cover the cost of research leading to the discovery of new 'products', that term being used as a common denominator covering the three different types of patent which can confer entitlement to an SPC. [**OR.10**]

28. The Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal) finds that the statement of reasons in the proposal for Regulation No 469/2009 confirms the requirement set out in Article 3(c) for the grant of an SPC that no previous SPC have been granted for the product. Accordingly, the statement of reasons in the proposal may also, in the view of the court, be regarded as confirming that Regulation No 469/2009 seeks in particular to stimulate research leading to the discovery of new products.

29. In its case-law, the Court of Justice has ruled that only one SPC may be granted for any one product, a 'product' being understood to mean an 'active substance' in the strict sense and that minor changes to the medicinal product, such as a new dose, the use of a different salt or ester or a different pharmaceutical form, will not lead to the issue of a new SPC (see judgment of the Court in *Massachusetts Institute of Technology*, [C-431/04, EU:C:2006:291], paragraph 19).

30. The Court of Justice has also held that the purpose of Article 3(c) of Regulation No 1768/92 is to avoid the same product being the subject of several successive SPCs so that the overall duration of protection for one and the same medicinal product could be exceeded (see, to that effect, judgment of the Court of 3 September 2009, *AHP Manufacturing*, C-482/07, EU:C:2009:501, paragraph 42).

31. As regards the purpose of the SPC, the Court of Justice, referring to recital 11 of Regulation No 469/2009, has stated that the fundamental aim is to ensure sufficient protection to encourage pharmaceutical research and that that plays a decisive role in the continuing improvement in public health (see, inter alia, judgments of the Court of 16 September 1999, *Farmitalia*, C-392/97, EU:C:1999:416, paragraph 19, and of 15 January 2015, *Forsgren*, C-631/13, EU:C:2015:13, paragraph 51).

32. In addition, the Court of Justice has confirmed that the SPC is largely intended to cover the cost of research leading to the discovery of new 'products' (see judgment of the **[OR.11]** Court of 24 November 2011, *Georgetown University*, C-422/10, EU:C:2011:776, paragraph 26, and *Forsgren*, cited above, paragraph 52).

33. However, referring to recital 10 of Regulation No 469/2009, the Court of Justice has held that account should be taken of all the interests at stake. In that regard, the Court has held that a balance must be struck between promoting research in the European Union by means of SPCs, the interests of the pharmaceutical industry and those of public health (see, inter alia, the judgment of the Court of 12 December 2013, *Actavis Group PTC and Actavis UK (Sanofi)*, C-443/12, EU:C:2013:833, paragraph 41).

34. The Court has subsequently stated, with regard to its judgment in *Neurim Pharmaceuticals*, that it had not rejected the restrictive interpretation of Article 1(b) set out in the abovementioned case *Massachusetts Institute of Technology*, and that, according to that interpretation, the term 'product' does not include a substance which does not meet the definition of 'active ingredient' or 'combination of active ingredients' (see the judgment in *GlaxoSmithKlein Biologicals*, cited above, paragraph 44).

35. In the case of *Neurim Pharmaceuticals*, the Court of Justice has stated, however, that an SPC may be granted when a patent protects a new use of a product already known, regardless of whether or not the product is protected by an earlier patent, including in cases where a new basic patent protects a new therapeutic use of a known active ingredient, provided that a valid authorisation to place the product on the market as a medicinal product has been granted (see *Neurim Pharmaceuticals*, paragraphs 24 and 25).

36. It should be noted here that the questions referred in *Neurim Pharmaceuticals* were essentially aimed at establishing whether there is a link between, on the one hand, the marketing authorisation referred to in Article 3(b) and (d) of Regulation No 469/2009, and on the other, the basic patent referred to in Article 3(a) of that regulation (see paragraph 19 of that judgment). Furthermore, it should be noted that, as stated in that judgment, no SPC had previously been granted in respect of the product covered by the new basic patent. [**OR.12**]

37. In addition, with regard to Article 6 of Regulation No 469/2009, the Court of Justice has stated that several different holders of basic patents may obtain the benefit of an SPC without instituting any preferential ranking amongst them (see judgment of the Court of 23 January 1997, *Biogen*, C-181/95, EU:C:1997:32, paragraph 27). Consequently, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate (see that judgment, paragraph 28).

38. The Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal) states that neither an SPC granted in a case where a new basic patent protects a new therapeutic use of a known active ingredient, nor in a case where an SPC granted to several different basic patent holders corresponds directly to the aim of stimulating pharmaceutical research such as leads to the discovery of new products. The granting of SPCs in such cases does meet, however, a wider objective which means that pharmaceutical research is stimulated in its sense of continuing to improve public health.

[Regulation No 1610/96]

39. Another matter of relevance for the assessment of the purpose and application of the provisions on SPCs is the provision in Article 3(2) of Regulation No 1610/96. That article provides that one holder of several patents for the same product cannot be granted more SPCs for that product, while, however, a number of different holders of patents for the same product may be granted SPCs for that product if the applications for SPCs are still pending.

40. However, the Court of Justice has held that the special condition for the grant of two or more SPCs for the same product, in accordance with the second sentence of Article 3(2) of Regulation No 1610/96, is limited to **[OR.13]** the making of applications for them by different holders of basic patents (see the judgment of the Court in *AHP Manufacturing*, paragraph 25).

41. In that connection, in the view of the Court of Justice, the aforementioned second sentence does not require the applications to be examined at the same time, stating that the Italian language version of Regulation No 1610/96 does not contain the term ‘pending’, and that it is also not a substantive condition that the applications be lodged at the same time (see paragraphs 25 and 26 of that judgment).

42. The Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal) finds that an application of the provision of Article 3(2) of Regulation No 1610/96 whereby an SPC may be granted to several different holders of basic patents without requiring that applications are still ‘pending’ does not directly meet the aim of stimulating pharmaceutical research such as leads to the discovery of new products. However, such an application does indeed meet a wider objective, that of stimulating research into new therapeutic uses of products already known, with the importance that has for public health.

Summary

43. It follows from the foregoing that, in the understanding of the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal), the manner in which Article 3 of Regulation No 469/2009 and of Article 3(2) of Regulation No 1610/96 has been applied was not limited to the purpose of stimulating research such as leads to the discovery of new products. In the view of the Court of Justice, that application has, in practice, been given a wider purpose of stimulating research into new therapeutic uses of products already known,

although one and the same holder of several basic patents could not be granted more SPCs for the same product. [**OR.14**]

Request for a preliminary ruling

44. In order to determine whether an SPC may be granted, it is necessary to apply Article 3(c) of Regulation No 469/2009 and Article 3(2) of Regulation No 1610/96. However, the interpretation of those provisions in a case such as the present appears unclear, particularly in view of the fact that the application of the provisions, in the understanding of the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal), has, in practice, been intended to stimulate research into new therapeutic uses of products already known. The Patent- och marknadsöverdomstolen therefore requests a reply to the following question.

[…] In view of the fundamental purpose which the supplementary protection certificate for medicinal products is intended to fulfil, namely that of stimulating pharmaceutical research in the European Union, does Article 3(c) of Regulation No 469/2009, having regard to Article 3(2) of Regulation No 1610/96, preclude an applicant who has previously been granted a supplementary protection certificate in respect of a product protected by a basic patent in force in respect of the product per se, from being granted a supplementary protection certificate for a new use of the product in a case such as that at issue in the main proceedings in which the new use constitutes a new therapeutic indication which is specifically protected by a new basic patent?

For the Patent- och marknadsöverdomstolen (Patent and Market Court of Appeal),

[...]