Case C-119/22

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

17 February 2022

Referring court:

Markkinaoikeus (Finland)

Date of the decision to refer:

17 February 2022

Applicants:

Teva B.V.

Teva Finland Oy

Defendant:

Merck Sharp & Dohme Corp.

Subject matter of the main proceedings

Request for a preliminary ruling – Article 267 TFEU – Convention on the Grant of European Patents – Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products – Declaration of invalidity of a supplementary protection certificate

Subject matter and legal basis of the request

The dispute concerns an action for a declaration of invalidity of a supplementary protection certificate granted in Finland on the basis of Article 3(a), (c) and (d) 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 (hereinafter also referred to as ‘the SPC Regulation’).

The case concerns, in particular, the interpretation of Article 3(c) of the SPC Regulation.

Questions referred for a preliminary ruling

1. What criteria must be applied to determine when a product has not already been granted a supplementary protection certificate within the meaning 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 ('SPC Regulation')?

2. Must the assessment of the condition set out in Article 3(c) of the SPC Regulation be regarded as being different from the assessment of the condition set out in Article 3(a) of that regulation, and if so, in what way?

3. Must the statements on the interpretation of Article 3(a) of the SPC Regulation in the judgments of the Court in Case C-121/17 and Case C-650/17 be regarded as relevant to the assessment of the condition in Article 3(c) of the SPC Regulation and, if so, in what way? In that connection, particular attention should be paid to the statements made in those judgments regarding Article 3(a) of the SPC Regulation, specifically:

   – the essential meaning of patent claims; and

   – the assessment of the case from the point of view of a person skilled in the art and in the light of the prior art at the filing date or priority date of the basic patent.

4. Are the concepts 'core inventive advance', 'central inventive step' and/or 'subject matter of the invention' of the basic patent relevant to the interpretation of Article 3(c) of the SPC Regulation and, if any or all of those concepts are relevant, how are they to be understood for purposes of interpreting Article 3(c) of the SPC Regulation? For the purposes of applying those concepts, does it make any difference whether the product in question consists of a single active ingredient ('mono-product') or a combination of active ingredients ('combination product') and, if so, in what way? How is the latter question to be assessed in a case in which the basic patent contains, on the one hand, a patent claim for a mono-product and, on the other hand, a patent claim for a combination product, the latter patent claim relating to a combination of active ingredients consisting of the active ingredient of the mono-product plus one or more active ingredients from the known prior art?

Provisions of European Union law relied on

Convention on the Grant of European Patents of 5 October 1973, signed in Munich, Article 69, and the Protocol on the Interpretation of Article 69 of the Convention

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, Articles 1, 3 and 7

Case-law of the Court relied on

Judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833).

Judgment of 12 December 2013, *Georgetown University* (C-484/12, EU:C:2013:828).

Judgment of 12 March 2015, *Actavis Group PTC and Actavis UK* (C-577/13, EU:C:2015:165, paragraphs 33, 37 to 38).

Judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585).

Judgment of 30 April 2020, *Royalty Pharma Collection Trust* (C-650/17, EU:C:2020:327, paragraphs 31 to 32).

Provisions of national law relied on

Patenttilaki (550/1967, Law on patents No 550/1967), Paragraph 39

Succinct presentation of the facts and procedure in the main proceedings

1 The company Merck Sharp & Dohme Corp. (hereinafter also referred to as 'MSD') was granted supplementary protection certificate No 342 in Finland. The application which led to the grant of the supplementary protection certificate in question was based on European patent No FI/EP 1 412 357, granted to MSD and later validated in Finland, and on the following marketing authorisations granted to MSD: EU/1/08/455/001-014 in respect of the product Janumet, EU/1/08/456/001-014 in respect of the product Velmetia and EU/1/08/457/001-014 in respect of the product Efficib.

Basic patent

2 It is common ground that the application leading to the grant of supplementary protection certificate No 342 was based on European patent No FI/EP 1 412 357 ('basic patent'), granted to MSD and later validated in Finland.

3 The English title of that basic patent is ‘Beta-amino-tetrahydroimidazo(1,2-a)pyrazines and -tetrahydrotriazolo(4,3-a)pyrazines as dipeptidyl peptidase inhibitors for the treatment or prevention of diabetes’. The basic patent contains a total of 30 patent claims, of which the following are the most relevant to the present case:

– independent Claim 1, which is a product claim relating to a compound, drafted in the form of a Markush formula;

– independent Claim 15, which is a product claim relating to a compound, wherein the compound is selected from a group consisting of 33 different compounds, represented in the form of chemical structural formulae, or a pharmaceutically acceptable salt thereof;

– Claim 20 of the patent, which is a product claim relating to a combination, wherein the combination consists of

  1) a compound according to any one of Claims 1 to 15, or a pharmaceutically acceptable salt thereof, and

  2) one or more other compounds selected from a group of compounds listed in that claim;

– Claim 25, which is a product claim relating to a pharmaceutical composition, wherein the pharmaceutical composition comprises

  1) a compound according to any one of Claims 1 to 15, or a pharmaceutically acceptable salt thereof,

  2) one or more compounds selected from a group of compounds listed in that claim, and

  3) a pharmaceutically acceptable carrier.

– Claim 26, which is a product claim relating to a compound, wherein the compound is selected from a group consisting of five different compounds according to Claim 15 of the patent, represented in the form of chemical structural formulae, or a pharmaceutically acceptable salt thereof;

– Claim 28, which is a product claim relating to a compound, and comprising only one compound, represented in the form of a chemical structural formula, or a pharmaceutically acceptable salt thereof;

– Claim 30, which is a product claim relating to a pharmaceutical composition as claimed in Claim 25, wherein the pharmaceutical composition comprises a compound according to any one of Claims 1 to 15 or a pharmaceutically acceptable salt thereof, metformin, and a pharmaceutically acceptable carrier.

4 It is common ground in the present case

– that the Markush formula within the meaning of independent Claim 1 of the basic patent comprises a large number of different compounds;

– that that formula comprises, inter alia, a compound that later became known as sitagliptin;

– that the seventh chemical structural formula in independent Claim 15 represents a compound that later became known as sitagliptin;

– that the fourth chemical structural formula in Claim 26 represents a compound that later became known as sitagliptin;

– that the sole structural formula according to Claim 28 is a compound that later became known as sitagliptin;

– that, as one of the DP-IV inhibitors referred to above, the basic patent refers to a compound that later became known as sitagliptin.

5 In the ‘Summary of the invention’ section of the description of the basic patent, it is stated that the invention according to the basic patent is directed to compounds which are inhibitors of the dipeptidyl peptidase-IV enzyme (‘DP-IV inhibitors’) and which are useful in the treatment or prevention of diseases in which the dipeptidyl peptidase-IV enzyme is involved, such as diabetes and particularly type 2 diabetes. Furthermore, it is also stated in that section that the invention is also directed to pharmaceutical compositions comprising those compounds and the use of those compounds and compositions in the prevention or treatment of such diseases in which the dipeptidyl peptidase-IV enzyme is involved.

6 The basic patent states that DP-IV inhibitors can be used, alone or in combination with other compounds, to treat diabetes, for example. In the light of expert evidence adduced in the case, Claims 20 and 25 of the basic patent list as such other compounds, inter alia, all compounds used in the treatment of diabetes at that time. One of the groups of other compounds referred to in Claims 20 and 25 of the basic patent are biguanides, which, in the light of the expert evidence adduced in the case, comprised, in essence, two compounds as at the priority date of the basic patent, one of which was metformin, a compound which at that time had already been used for decades in the treatment of diabetes, and the other of which was phenformin, the use of which as a medicinal product for human use was associated with known safety risks, according to the expert evidence adduced in the case.

7 Metformin is expressly referred to in Claim 30 of the basic patent as the second compound of the pharmaceutical composition referred to in that claim.

8 None of the claims of the basic patent, taken alone, discloses a pharmaceutical composition consisting of a compound which later became known as sitagliptin and metformin.

Marketing authorisations

9 In the first place, MSD was granted marketing authorisation, under No EU/1/07/383/001-018, for a product called Januvia, which contains sitagliptin as the only active ingredient.

10 MSD subsequently received marketing authorisations for a product called Janumet under No EU/1/08/455/001-014, for a product called Velmetia under No EU/1/08/456/001-014 and for a product called Efficib under No EU/1/08/457/001-014, all containing, as a combination of active ingredients, sitagliptin and metformin hydrochloride, which is a pharmaceutically acceptable salt of metformin.

11 It is common ground in the present case that sitagliptin was the first active ingredient in the DP-IV class of inhibitors to receive marketing authorisation.

Supplementary protection certificates

12 MSD was first granted supplementary protection certificate No 343 on 13 March 2012 on the basis of the basic patent and the marketing authorisation for the product Januvia. The title of that supplementary protection certificate is 'Sitagliptin, optionally in the form of a pharmaceutical salt'.

13 In addition, on 20 March 2012, MSD was granted supplementary protection certificate No 342 on the basis of the basic patent and the marketing authorisation for the product Janumet, which is the subject of the action for a declaration of invalidity at issue in the present case. The title of that supplementary protection certificate is 'Sitagliptin, optionally in the form of a pharmaceutically acceptable salt, in particular monophosphate, plus metformin, optionally in the form of a pharmaceutically acceptable salt, in particular the hydrochloride'. Supplementary protection certificate No 342 is valid until 8 April 2023.

The essential arguments of the parties in the main proceedings

Forms of order sought by the parties

Teva B.V. and Teva Finland Oy

14 Teva B.V. and Teva Finland Oy (hereinafter also referred to collectively as 'Teva') brought an action before the Markkinaoikeus (Market Court) against MSD for a declaration of invalidity of supplementary protection certificate No 342 granted in Finland. Teva bases its action on the allegation that supplementary

protection certificate No 342 was granted in breach of Article 3(a), (c) and (d) of the SPC Regulation.

15 Teva submits that:

– first, supplementary protection certificate No 342 was granted in breach of Article 3(a) of the SPC Regulation, since European patent FI/EP 1 412 357, granted to MSD and subsequently validated in Finland, does not protect the combination of active ingredients under supplementary protection certificate No 342 in the manner referred to in Article 3(a) of the SPC Regulation;

– supplementary protection certificate No 342 was granted in breach of Article 3(c) of the SPC Regulation. The fact that supplementary protection certificate No 343 had already been granted in Finland on the basis of European patent No FI/EP 1 412 357 must be regarded as precluding the grant of a certificate for the combination of active ingredients covered by supplementary protection certificate No 342;

– supplementary protection certificate No 342 was granted in breach of Article 3(d) of the SPC Regulation, since the marketing authorisation on which the application leading to the grant of supplementary protection certificate No 342 was based was not the first authorisation to place the combination of active ingredients covered by supplementary protection certificate No 342 on the market as a medicinal product.

Merck Sharp & Dohme Corp.

16 MSD opposes the form of order sought by Teva and requests that the action be dismissed. MSD disputes that supplementary protection certificate No 342 was granted in breach of Article 3(a), (c) or (d) of the SPC Regulation.

17 MSD submits that:

– European patent FI/EP 1 412 357, granted to it and subsequently validated in Finland, does protect the combination of active ingredients under supplementary protection certificate No 342 in the manner referred to in Article 3(a) of the SPC Regulation;

– Article 3(c) of the SPC Regulation must also be regarded as being complied with in relation to the grant of supplementary protection certificate No 342. Article 3(c) of the SPC Regulation does not preclude the grant of a certificate for the combination of active ingredients covered by supplementary protection certificate No 342, even if a supplementary protection certificate had previously been granted on the basis of the same patent for an active ingredient which constitutes one of the two compounds of the combination of active substances under supplementary protection certificate No 342;

– the granting of supplementary protection certificate No 342 cannot be considered to have infringed Article 3(d) of the SPC Regulation either. The marketing authorisation on which the application leading to the grant of supplementary protection certificate No 342 was based was the first authorisation to place the combination of active ingredients covered by supplementary protection certificate No 342 on the market as a medicinal product.

Succinct presentation of the reasoning in the request for a preliminary ruling

18 The Court has given several preliminary rulings on the interpretation of Article 3(a) of the SPC Regulation over the last two decades. The interpretation of that provision will have been significantly clarified by the judgments of the Court in Case C-121/17 in July 2018 and in Case C-650/17 in April 2020.

19 In addition, the Court has given two preliminary rulings on the interpretation of Article 3(d) of the SPC Regulation in the last two years (judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, and judgment of 9 July 2020, *Santen*, C-673/18, EU:C:2020:531).

20 As regards Article 3(c) of the SPC Regulation, on the other hand, the Court gave its most recent preliminary rulings in its judgments in Case C-443/12 and Case C-484/12 of December 2013 and in Case C-577/13 of March 2015.

21 As regards the latter judgment in particular, it should be emphasised that, as explained above, the Court's decision concerned the interpretation of both Article 3(a) and Article 3(c) of the SPC Regulation.

22 In the light of the foregoing, the question already arises, in a general manner, as to whether the Court's case-law on Article 3(a) of the ESC Regulation in its judgments in Cases C-121/17 and C-650/17 must be regarded as being relevant to the interpretation of Article 3(c) of the SPC Regulation, and, if so, in what way.

23 With regard to the abovementioned preliminary rulings, it should be noted that, in the judgment of the Court in Case C-443/12, which concerned the interpretation of Article 3(c) of the SPC Regulation, reference was made, on the one hand, to [in the German language version] 'die zentrale erfinderische Tätigkeit' [literally: 'the central inventive advance'] of the basic patent (paragraph 30; 'l'activité inventive centrale' in French and 'the core inventive advance' in English) and, on the other hand, to the 'Kern der erfinderischen Tätigkeit' [literally: 'core inventive advance'] of the basic patent (paragraph 41; 'le cœur de l'activité inventive' in French, but once again 'the core inventive advance' in English). In the Court's judgment in Case C-577/13, concerning the interpretation of Article 3(a) and (c) of the SPC Regulation, reference was made, in turn, to the 'subject matter of the invention' of the basic patent. In the Court's judgment in Case C-650/17, concerning the interpretation of Article 3(a) of the SPC Regulation, it was stated,

in turn, that the concept of ‘core inventive advance’ of the basic patent is not relevant in the context of Article 3(a) of the SPC Regulation.

24 Furthermore, the question arises as to whether the concepts of ‘central inventive step’, ‘core inventive step’ and ‘subject matter of the invention’ are still relevant to the interpretation of Article 3(c) of the SPC Regulation and, if so, how those concepts are to be understood in the context of the interpretation of Article 3(c) of the SPC Regulation. In particular, the question arises as to how those terms are to be regarded as being different – if they are considered to be different – and how they are to be understood in the case of a product consisting of a single active ingredient (‘mono-product’), on the one hand, and in the case of a product consisting of a combination of active ingredients (‘combination product’), on the other hand.

25 The need for uniform application of EU law and the need to obtain a preliminary ruling in the present case is underlined by the fact that proceedings relating to a declaration of invalidity of supplementary protection certificates similar to that at issue in the present case which were granted in other Member States of the European Union are pending in several other Member States of the European Union.