Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

19 December 2024*

(Reference for a preliminary ruling – Medicinal products for human use – Supplementary protection certificate (SPC) – Regulation (EC) No 469/2009 – Conditions for obtaining an SPC for medicinal products – Article 3(a) – Concept of 'product protected by a basic patent in force' – Article 3(c) – Concept of 'product the subject of an SPC' – Criteria for assessment)

In Joined Cases C-119/22 and C-149/22,

REQUESTS for a preliminary ruling under Article 267 TFEU from, respectively, the markkinaoikeus (Market Court, Finland), made by decision of 17 February 2022, received at the Court on 17 February 2022, and by the Supreme Court (Ireland), made by decision of 21 February 2022, received at the Court on 2 March 2022, in the proceedings

Teva BV,

Teva Finland Oy

v

Merck Sharp & Dohme LLC, formerly Merck Sharp & Dohme Corp. (C-119/22),

and

Merck Sharp & Dohme LLC, formerly Merck Sharp & Dohme Corp.,

v

Clonmel Healthcare Limited (C-149/22),

THE COURT (Third Chamber),

composed of K. Jürimäe (Rapporteur), President of the Second Chamber, acting as President of the Third Chamber, N. Jääskinen and N. Piçarra, Judges,

Advocate General: N. Emiliou,

Registrar: C. Strömholm, Administrator,

* Languages of the case: English and Finnish.

having regard to the written procedure and further to the hearing on 8 March 2023,

after considering the observations submitted on behalf of:

– Teva BV and Teva Finland Oy, by O. Jüngst, Rechtsanwalt, W. Kivilä and B. Rapinoja, asianajajat, and J. van Dieck, Patentanwalt,

– Merck Sharp & Dohme LLC, by R. Hilli, asianajaja, E. Liikanen, oikeustieteen maisteri, E. Ledford, Solicitor, J. Newman, Senior Counsel, and K. Smith, Senior Counsel,

– Clonmel Healthcare Limited, by P. Coughlan, Barrister-at-Law, M. Howard, Senior Counsel, and L. Scott, Solicitor,

– Ireland, by M. Browne, A. Joyce and M. Lane, acting as Agents, and by P. Mair, Barrister-at-Law, and D. O'Reilly, Solicitor,

– the French Government, by A. Daniel, A.-L. Desjonquères and B. Fodda, acting as Agents,

– the Latvian Government, by J. Davidoviča and K. Pommere, acting as Agents,

– the Hungarian Government, by M.Z. Fehér and R. Kissné Berta, acting as Agents,

– the Netherlands Government, by M.K. Bulterman, J.M. Hoogveld and J. Langer, acting as Agents,

– the Polish Government, by B. Majczyna, acting as Agent,

– the European Commission, by P. Němečková, J. Samnadda and T. Sevón, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 6 June 2024,

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of Article 3(a) and (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 (OJ 2009 L 152, p. 1).

2 The requests have been made, in Case C-119/22, in proceedings between Teva BV and Teva Finland Oy ('the Teva companies'), of the one part, and Merck Sharp & Dohme LLC, formerly Merck Sharp & Dohme Corp. ('Merck'), of the other part, concerning the validity of a supplementary protection certificate (SPC) granted to Merck for a pharmaceutical product intended for the treatment of diabetes and, in Case C-149/22, in proceedings between Merck and Clonmel Healthcare Limited ('Clonmel') concerning the validity of an SPC obtained by Merck for a medicinal product intended for the treatment of cholesterol.

Legal context

The EPC

3 The Convention on the Grant of European Patents, signed in Munich on 5 October 1973, and which entered into force on 7 October 1977, in the version applicable to the dispute in the main proceedings ('the EPC'), states, in Article 69 thereof, entitled 'Extent of protection':

'(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.'

4 Article 1 of the Protocol on the Interpretation of Article 69, which pursuant to Article 164(1) of the EPC forms an integral part of that convention, is worded as follows:

'Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.'

5 Article 82 of the EPC, entitled 'Unity of invention', provides:

'The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.'

6 Under Article 84 of the EPC, entitled 'Claims':

'The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.'

7 Article 123 of the EPC, entitled 'Amendments', states:

'(1) The European patent application or European patent may be amended in proceedings before the European Patent Office [(EPO)], in accordance with the Implementing Regulations [to the Convention on the Grant of European Patents of 5 October 1973 as adopted by decision of the Administrative Council of the EPO of 7 December 2006 and as last amended by decision of the Administrative Council of the EPO of 14 December 2023]. In any event, the applicant shall be given at least one opportunity to amend the application of his own volition.

(2) The European patent application or European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.

(3) The European patent may not be amended in such a way as to extend the protection it confers.'

European Union law

8 Recitals 3 to 5, 7, 9 and 10 of Regulation No 469/2009 state:

'(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the [European] Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

…

(7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.

…

(9) The duration of the protection granted by the [SPC] should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and [an SPC] 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 [SPC] 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.'

9 Article 1 of Regulation No 469/2009 provides:

‘For the purposes of this Regulation, the following definitions shall apply:

(a) “medicinal product” means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) “product” means the active ingredient or combination of active ingredients of a medicinal product;

(c) “basic patent” means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of [an SPC];

…’

10 Article 3 of that regulation, entitled ‘Conditions for obtaining [an SPC]’, provides:

‘[An SPC] 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 …;

(c) the product has not already been the subject of [an SPC];

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

11 Article 4 of Regulation No 469/2009, entitled ‘Subject matter of protection’, provides:

‘Within the limits of the protection conferred by the basic patent, the protection conferred by [an SPC] shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the [SPC].’

12 Article 5 of Regulation No 469/2009, entitled ‘Effects of the [SPC]’, provides:

‘Subject to the provisions of Article 4, the [SPC] shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.’

13 Article 13 of that regulation, entitled ‘Duration of the [SPC]’ provides in paragraph 1:

‘The [SPC] 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.'

Finnish law

14 Under Article 39 of the patenttilaki (Law on patents), the claims of the patent are to determine the extent of protection under the patent. The description can be used to help understand those claims.

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

Case C-119/22

15 Merck, a pharmaceutical company, is the holder of European patent EP 1 412 357, designating, inter alia, Finland, with a priority date of 5 July 2002 ('the basic patent at issue in Case C-119/22'). That patent covers, in general, dipeptidyl peptidase IV ('DP-IV') inhibitors, which are useful in the treatment or prevention of diseases in which DP-IV is involved, such as diabetes and, more particularly, type 2 diabetes. One of those inhibitors later became known as sitagliptin. The patent expired on 5 July 2022.

16 The basic patent at issue in Case C-119/22 provides that those DP-IV inhibitors may, where appropriate, be combined with other active ingredients for the prevention or treatment of diseases in which DP-IV is involved. In particular, claim 30 of that patent relates to a pharmaceutical composition consisting of one of those inhibitors, or an acceptable salt thereof, combined with metformin. It is apparent from the order for reference that metformin was, at the priority date of that patent, an active ingredient known and used for decades in the treatment of diabetes.

17 Merck was granted a first SPC in Finland, namely SPC No 343, on the basis of marketing authorisation ('MA') EU/1/07/383/001-018 granted to the medicinal product Januvia and of the basic patent at issue in Case C-119/22. That SPC related solely to sitagliptin as an active ingredient and expired on 23 September 2022.

18 Merck also obtained a second SPC in Finland, namely SPC No 342, on the basis of MA EU/1/08/455/001-014 granted to the medicinal product Janumet and of the basic patent at issue in Case C-119/22. The product which is the subject of that SPC is a combination of sitagliptin and metformin. That SPC was valid until 8 April 2023.

19 The Teva companies then brought an action for a declaration of invalidity of SPC No 342 before the markkinaoikeus (Market Court, Finland), which is the referring court, on the basis of Article 3(a), (c) and (d) of Regulation No 469/2009. Those companies submit that that SPC does not comply with the conditions laid down in that article. First, the product, within the meaning of Article 1(b) of that regulation, which is the subject of that SPC is a combination of two active ingredients which is not protected as such by the basic patent at issue in Case C-119/22. Second, that product was already the subject of SPC No 343, with the result that SPC No 342 was granted in breach of Article 3(c) of that regulation. Third, the MA on which the application which gave rise to SPC No 342 was based did not constitute the first MA for that product as a medicinal product, which infringes Article 3(d) of that regulation.

20 Merck contended that the action for a declaration of invalidity brought by the Teva companies should be dismissed. As regards, more specifically, the condition laid down in Article 3(c) of Regulation No 469/2009, it submits that that provision does not preclude the grant of an SPC for the combination of the active ingredients covered by SPC No 342. SPC No 343, granted before SPC No 342, covers a different product, namely sitagliptin alone.

21 According to the referring court, although the Court of Justice has recently clarified its case-law relating to Article 3(a) and (d) of that regulation, that is not the case in relation to the condition laid down in Article 3(c) of that regulation. The referring court notes that, in the judgment of 12 March 2015, *Actavis Group PTC and Actavis UK* (C-577/13, 'the judgment in *Actavis II*', EU:C:2015:165), the Court interpreted paragraphs (a) and (c) of Article 3 of that regulation together. In those circumstances, it questions the relevance of recent judgments relating to the interpretation of Article 3(a) of Regulation No 469/2009 for the interpretation of Article 3(c) of that regulation.

22 In that regard, the referring court observes that, in the judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833), the Court used the terms 'core inventive advance' of the basic patent. In the judgment in *Actavis II*, the Court referred to the 'subject matter of the invention' of the basic patent. However, the Court expressly rejected the relevance of 'core inventive advance' for the interpretation of Article 3(a) of Regulation No 469/2009 in the judgment of 30 April 2020, *Royalty Pharma Collection Trust* (C-650/17, 'the judgment in *Royalty Pharma*', EU:C:2020:327).

23 The referring court is, therefore, uncertain as to the relevance of those concepts for the interpretation of Article 3(c) of that regulation, the interpretation of which, in its view, the Court has linked to that of Article 3(a) of that regulation. The referring court is also uncertain whether those concepts must, if necessary, be understood differently depending on whether a product consisting of only one or more than one active ingredient is at issue.

24 In those circumstances the markkinaoikeus (Market Court) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) What criteria must be applied to determine when a product has not already been granted [an SPC] within the meaning of Article 3(c) of Regulation [No 469/2009]?

(2) Must the assessment of the condition set out in Article 3(c) of [Regulation No 469/2009] 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 [Regulation No 469/2009] in the judgments of [25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585)] and [in *Royalty Pharma*] be regarded as relevant to the assessment of the condition in Article 3(c) of [that] 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 [that] 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 [Regulation No 469/2009] and, if any or all of those concepts are relevant, how are they to be understood for purposes of interpreting Article 3(c) of [that] 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?'

Case C-149/22

25 The dispute in the main proceedings in Case C-149/22 is between Merck and Clonmel concerning the validity of an SPC ('the SPC at issue in Case C-149/22') obtained by Merck in Ireland for the medicinal product marketed under the name Inegy, intended to reduce the blood level of LDL (low-density lipoprotein) cholesterol with a view to limiting the risk of atherosclerosis, a condition affecting arteries.

26 The SPC at issue in Case C-149/22 was obtained on the basis of European patent EP 0 720 599 designating, inter alia, Ireland and having as its priority date 21 September 1993 ('the basic patent at issue in Case C-149/22'). The teaching on that patent reveals that ezetimibe inhibits the absorption of cholesterol into the bloodstream at the borders of the intestinal villus in the small intestine. Claims 1 to 8 of that patent related to ezetimibe alone, whereas claims 9, 12, 15 and 16 of that patent related to uses of ezetimibe in combination with other active ingredients and, in particular, statins. The combination of ezetimibe and simvastatin is expressly mentioned in the claims of the basic patent at issue in Case C-149/22, in particular in claim 17 thereof.

27 It is not in dispute that simvastatin was in the public domain at the priority date of the basic patent at issue in Case C-149/22. Furthermore, in view of the evidence provided by the referring court, that patent does not appear to disclose a combined effect of that active ingredient with ezetimibe that would differ from the sum of the effects of each of those active ingredients taken separately.

28 In 2003, Merck had obtained an MA and a first SPC with respect to the medicinal product Ezetrol, containing ezetimibe as its sole active ingredient. In 2004 and 2005, Merck obtained another MA, on the basis of which it was granted the SPC at issue in Case C-149/22, for a product consisting of ezetimibe and simvastatin.

29 Since Clonmel had launched a competing product during the lifetime of that SPC, Merck brought infringement proceedings before the High Court (Ireland). That court declared that SPC invalid, taking the view that it did not satisfy the conditions laid down in Article 3(a) and (c) of Regulation No 469/2009, which require, respectively, that the product be protected by a basic patent in force and that it has not already been the subject of an SPC.

30 That judgment was upheld on appeal by the Court of Appeal (Ireland), which relied on the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, 'the judgment in *Teva*', EU:C:2018:585), according to which a product consisting of several active ingredients would be protected by a basic patent in force only if the combination of those active ingredients necessarily fell under the invention covered by that patent. According to the Court of Appeal, in

order to ascertain whether a product actually falls under the 'invention covered by the basic patent', within the meaning of that case-law, it is necessary to assess the scope of the invention covered by that patent. It concluded, in that regard, that the combination of ezetimibe and simvastatin did not fall under that invention.

31 Merck brought an appeal against the judgment on appeal, before the Supreme Court (Ireland), which is the referring court. It submits that it is apparent from the judgments in *Teva* and in *Royalty Pharma* that only the wording of the claims of the basic patent at issue in Case C-149/22 is relevant for determining whether a product is protected by a 'basic patent in force', within the meaning of Article 3(a) of Regulation No 469/2009, where that product is expressly mentioned in the claims of that patent. That case-law should, therefore, be understood as meaning that it is only in the absence of such an express mention that that those claims must relate to that product necessarily and specifically. In the latter case alone, it would be necessary, first, to establish that the combination of active ingredients at issue necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent and, second, that each of those active ingredients is specifically identifiable in the light of all the information disclosed by that patent.

32 On the contrary, Clonmel concurs, in essence, with the interpretation adopted by the Court of Appeal (Ireland) and contends that the test identified in the judgment in *Teva* is of general application. It contends, in that regard, that where an SPC has already been granted on the basis of a patent, the national court must identify, in the context of the examination of the validity of a subsequent SPC obtained on the basis of that patent, the 'subject matter of the invention' and that it may conclude that that subsequent SPC is valid only if it finds that the product for which supplementary protection is sought comes within that invention.

33 The referring court has doubts as to the interpretation of the concept of 'product protected by a basic patent in force', within the meaning of Article 3(a) of Regulation No 469/2009, as interpreted in particular in the judgment in *Teva*, where the product at issue comprises a composition of active ingredients specifically mentioned in the claims of the basic patent.

34 According to the referring court, if the Court interprets the requirement laid down in the judgment in *Teva*, according to which the combination of active ingredients at issue must necessarily fall under the invention covered by the basic patent, as meaning that it necessitates an assessment of the invention or inventive step of the patent, the combination of ezetimibe and simvastatin would not fall under that invention and the SPC obtained for the medicinal product Inegy would have to be declared invalid.

35 Furthermore, the referring court is uncertain, on reading the judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833) and the judgment in *Actavis II*, whether the interpretation to be given to Article 3(c) of Regulation No 469/2009 depends on that of Article 3(a) of that regulation. In particular, it wishes to ascertain, in that regard, whether, for the purposes of applying Article 3(c) of that regulation, which precludes obtaining an SPC where the product for which it is sought has already been the subject of an SPC, it is sufficient to establish that the combination of active ingredients at issue has not been the subject of an earlier SPC or whether the fact of having obtained an SPC for one of the active ingredients of which that combination consists precludes obtaining a second SPC covering that combination.

36 Lastly, the referring court justifies the request for a preliminary ruling in the light of the divergent decisions of several national courts relating to cases similar to that in the main proceedings involving, inter alia, Merck.

37 In those circumstances the Supreme Court (Ireland) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) (a) For the purpose of the grant of [an SPC], and for the validity of that SPC in law, under Article 3(a) of Regulation [No 469/2009] does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted [an MA], also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

(b) If the latter, the invention covered by the patent, what must be established by the patent holder and [MA] holder to obtain a valid SPC?

(2) Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of [Regulation No 469/2009] only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

(3) Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

(4) If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of [Regulation No 469/2009] limit the grant of an SPC;

(a) only to the single molecule if marketed as a product,

(b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or

(c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?

And if any of the above, why?’

Consideration of the questions referred

The first to fourth questions in Case C-119/22 and the third and fourth questions in Case C-149/22

38 The first to fourth questions in Case C-119/22 and the third and fourth questions in Case C-149/22 relate to the interpretation of Article 3(c) of Regulation No 469/2009 and all concern, in essence, an identical issue.

39 By those questions, which it is, therefore, appropriate to examine together, the referring courts ask, in essence, whether Article 3(c) of that regulation precludes the grant of an SPC for a product consisting of two active ingredients where one of those two active ingredients has already, alone, been the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was already known at the filing date or priority date of that patent.

40 Article 3(c) of Regulation No 469/2009 provides that, for an SPC to be granted, the product must not have already been, at the date of the application, the subject of an SPC in the Member State in which that application is submitted.

41 In the first place, in order to determine the meaning and scope of the condition laid down in that provision, regard must be had, in the light of the wording of that provision, to the concept of 'product'. That concept is defined in Article 1(b) of Regulation No 469/2009 as 'the active ingredient or combination of active ingredients of a medicinal product'.

42 In that regard, in the absence of any definition of the concept of 'active ingredient' in Regulation No 469/2009, the meaning and scope of those terms must be determined by considering the general context in which they are used and their usual meaning in everyday language (see, to that effect, judgments of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 25, and of 9 July 2020, *Santen*, C-673/18, EU:C:2020:531, paragraph 41).

43 The Court has held that the strict view of the concept of 'product', as it emerged from the analysis of the origins of Regulation No 469/2009, was given concrete form in Article 1(b) of that regulation, which defines that concept by reference to an active ingredient or combination of active ingredients and not by reference to the therapeutic application of an active ingredient protected by the basic patent or of a combination of active ingredients protected by that patent (see, to that effect, judgment of 9 July 2020, *Santen*, C-673/18, EU:C:2020:531, paragraphs 45 and 46).

44 From that perspective, the Court has stated that it is generally accepted in pharmacology that the term 'active ingredient' does not include substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (see, to that effect, judgments of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 25, and of 9 July 2020, *Santen*, C-673/18, EU:C:2020:531, paragraph 45). Similarly, it has been established that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that the fact that an active ingredient, or a combination of active ingredients (A+B), is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where that active ingredient, or that combination of active ingredients, has been used for the purposes of a different, already known, therapeutic application (see, to that effect, judgment of 9 July 2020, *Santen*, C-673/18, EU:C:2020:531, paragraph 47).

45 It follows from that strict definition, first, that whether two products are identical or different, in the framework of Regulation No 469/2009, depends only on the comparison of the active ingredient or ingredients which they contain, irrespective of their therapeutic applications. In particular, where, as in the cases in the main proceedings, one of the products to be compared is a combination of active ingredients (A+B), it must be regarded as being a different product from the product consisting of only one of the active ingredients comprising the aforementioned product (A or B).

46 Second, it also follows that the concept of 'product', within the meaning of Article 1(b) of Regulation No 469/2009, cannot depend on the context in which it is relied on. On the contrary, the definition of 'product', set out like the other definitions in Article 1 of that regulation 'for the purposes' of the regulation taken as a whole, is identical for all the provisions of Regulation No 469/2009 in which that concept is used. In particular, that concept cannot have a different meaning and scope depending on whether it is interpreted in the context of Article 3(a) or Article 3(c) of that regulation.

47 In the context of Article 3(c) of Regulation No 469/2009, that definition, as clarified in paragraphs 42 to 46 above, necessarily leads to the conclusion that an SPC application relating to a product consisting of two active ingredients (A+B) cannot be refused, under that provision, on the ground that a product, consisting of only active ingredient A or only active ingredient B, has already been the subject of an SPC at the date of application in the Member State in which that application is submitted.

48 In the second place, as regards the relevance of the basic patent in assessing the condition laid down in Article 3(c) of Regulation No 469/2009, it is necessary to have regard to the context of that provision.

49 In that regard, it should be noted that it is apparent from the very wording of Article 3 of Regulation No 469/2009 that the four conditions which it lays down are cumulative (see, to that effect, judgment of 15 January 2015, *Forsgren*, C-631/13, EU:C:2015:13, paragraph 32). As the Advocate General observed, in essence, in point 61 of his Opinion, the cumulative nature of those conditions means that they must be interpreted and applied independently, in order to guarantee the integrity of the system.

50 Each of those conditions pursues its own logic and objective, which would be compromised if those conditions were to be confused or merged. In particular, the conditions set out in Article 3(a) and (c) cannot be confused or merged without compromising the legal certainty and the balance of interests sought by the EU legislature.

51 Thus, while the condition laid down in Article 3(a) seeks to delimit the material scope of the SPC by reference to the basic patent, Article 3(c) lays down a separate condition which seeks to limit the temporal scope of the supplementary protection conferred on a given product.

52 It follows that the notions and concepts identified by the Court in its case-law relating to the condition laid down in Article 3(a) of Regulation No 469/2009, in particular that arising from the judgments in *Royalty Pharma* and in *Teva*, cannot be regarded as being relevant for the purpose of interpreting the condition laid down in Article 3(c) of that regulation.

53 It follows from the foregoing that where an SPC application relates to a product consisting of two active ingredients (A+B), it is irrelevant, with regard to the condition laid down in Article 3(c) of Regulation No 469/2009, that only one of the active ingredients comprising a product the subject of an SPC application has been disclosed by the basic patent. First, the considerations relating to the basic patent are assessed solely in the light of Article 3(a) of that regulation, and not in the light of Article 3(c) of that regulation, which refers to a separate condition. Second, the fact that only one of the active ingredients comprising the product at issue (A or B) has been disclosed in the basic patent cannot be taken into account in the definition of the product.

54 Accordingly, the content of the basic patent is irrelevant in the context of Article 3(c) of Regulation No 469/2009. In order to assess whether the condition laid down in that provision is complied with, it is sufficient, first of all, to identify the product for which the SPC application examined is submitted, or for which the SPC at issue has been granted and, next, to ascertain whether that product has already been the subject, at the date of the application, of an SPC in the Member State in which that application is submitted.

55 That interpretation is consistent with the intention of the EU legislature. As is apparent from point 16 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) – which led to 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), itself repealed and replaced by Regulation No 469/2009 – the EU legislature intended to establish a simple system based on conditions which are, in principle, easy to verify.

56 In the light of all the foregoing considerations, the answer to the first to fourth questions in Case C-119/22 and the third and fourth questions in Case C-149/22 is that Article 3(c) of Regulation No 469/2009 must be interpreted as not precluding the grant of an SPC for a product consisting of two active ingredients even if one of those two active ingredients has already been, alone, the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was known at the filing date or priority date of that patent.

The first question in Case C-149/22

57 By its first question in Case C-149/22, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that it suffices that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision.

58 By that question, the referring court raises the issue of the scope of the two-stage test identified by the Court in the judgment in *Teva* and asks whether that test is specific only to situations in which the product at issue is not expressly mentioned in the claims of the basic patent.

59 Admittedly, in the case giving rise to the judgment in *Teva*, the Court was seised of a question relating to a particular situation in which the product in question was not expressly mentioned in the claims of the basic patent. That said, as the Advocate General observed in point 93 et seq. of his Opinion, it follows from that judgment that, in order for a product to be regarded as 'protected by a basic patent', within the meaning of Article 3(a) of Regulation No 469/2009, it does not suffice that the claims of the patent relate to that product expressly and specifically. It is

also necessary, in order to satisfy the condition laid down in that provision, that the product fall under the invention protected by that patent (see, to that effect, the judgment in *Teva*, paragraph 46).

60 In the judgment in *Teva*, the Court held that, in order to determine whether a product is protected by a basic patent, within the meaning of Article 3(a) of Regulation No 469/2009, that product, at the end of a first stage of examination, must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by that patent. In a second stage, that product must also be either expressly mentioned in the claims of that patent or be specifically identifiable. In the latter case, the person skilled in the art must be able to identify that same product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the basic patent (see, to that effect, judgment in *Teva*, paragraph 52).

61 The general scope of that test and, in particular, of the first stage thereof, is justified by the fact that the purpose of the SPC is not to extend the protection conferred by the basic patent beyond the invention which that patent covers. It would indeed be contrary to the objective referred to in recital 4 of Regulation No 469/2009, namely to encourage research by allowing the investment put into that research to be covered, to grant an SPC for a product which does not fall under the invention covered by the basic patent, because such an SPC would not relate to the results of the research claimed under that patent (see, to that effect, judgment in *Teva*, paragraph 40).

62 More specifically, if that first stage were applicable only where the product is not expressly mentioned in the claims, the mere mention of a product in the claims, without any explanation as to how the product is required for the solution of the technical problem disclosed by the basic patent, would be sufficient for that product to be regarded as being protected by that basic patent, which would be contrary to the limits which the EU legislature intended to set, namely that the product falls under the invention protected by that patent.

63 It is for that reason that the Court has held that, for the purposes of the application of Article 3(a) of Regulation No 469/2009, the claims of the basic patent must be construed in the light of the limits of the protected invention, as it appears from the description and the drawings of the basic patent (see, to that effect, judgment in *Teva*, paragraph 43).

64 If the mere mention, even if an express mention, of a product in those claims were to suffice, without the patent specification disclosing how that product constitutes a technical feature required for the solution of the technical problem disclosed by that patent, this would make it possible to obtain an SPC for a product which is not the result of the research which led to the invention protected by the same patent.

65 It follows from the foregoing that the answer to the first question in Case C-149/22 is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that it does not suffice that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision. It is also necessary, in order to satisfy the condition laid down in that provision, that that product necessarily fall, from the point of view of a person skilled in the art, and in the light of the description and drawings of that patent, under the invention covered by that patent at the filing date or priority date.

The second question in Case C-149/22

66 By its second question in Case C-149/22, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B which is an active ingredient in the public domain at the filing date or priority date of that patent.

67 In accordance with what is apparent, in essence, from the answer to the first question in Case C-149/22, it must be pointed out that the two-stage test resulting from paragraph 52 of the judgment in *Teva* is of general application because it applies indistinctly, whether or not the product at issue is expressly mentioned in the claims of the basic patent.

68 As regards, in particular, a product consisting of two active ingredients (A+B), both of which are expressly mentioned in the claims of the basic patent, that product must, for the purposes of Article 3(a) of Regulation No 469/2009, from the point of view of a person skilled in the art, at the filing date or priority date, necessarily fall under the invention covered by that patent, in the light of the latter's description and drawings. The express mention of the two active ingredients comprising the product at issue, in the claims of the basic patent, is sufficient only in the light of the second stage of the test resulting from the judgment in *Teva*, as is apparent from paragraph 56 of that judgment. It is also necessary, in order for the condition laid down in Article 3(a) to be satisfied, that the first stage also be complied with.

69 To that end, as the Advocate General observed, in essence, in points 115 and 116 of his Opinion, the mere mention, even if an express mention, in a claim of the basic patent, of the possibility of combining an active ingredient disclosed by that patent with another known active ingredient, in the public domain, cannot be sufficient to satisfy that first stage. Indeed, the specification of that patent must still disclose how the combination of those two active ingredients is a feature required for the solution of the technical problem disclosed by the same patent (see, to that effect, judgment in *Teva*, paragraph 48).

70 That said, it should be made clear that the fact that one of the active ingredients comprising the product at issue is known at the filing date or priority date of that patent and is, at that date, in the public domain does not necessarily disqualify that product with regard to the first stage of the test arising from the judgment in *Teva*. If the basic patent discloses that the combination of the two active ingredients has a combined effect going beyond the mere addition of the effects of those two active ingredients and which contributes to the solution of the technical problem, it may be concluded that the combination of those two active ingredients necessarily falls under the invention covered by that patent.

71 Such an interpretation of Article 3(a) of Regulation No 469/2009 makes it possible to meet the objective pursued by that regulation of encouraging research by allowing the investment put into that research to be covered, while taking into consideration all the interests at stake, by permitting the grant of SPCs only for products falling under the invention covered by the basic patent.

72 In the present case, it is apparent from the file before the Court in Case C-149/22 that the combination of ezetimibe and simvastatin is expressly mentioned in the claims of the basic patent at issue in that case, in particular in claim 17 thereof. Similarly, it is not in dispute that simvastatin was in the public domain at the priority date of that patent and it is apparent from

the request for a preliminary ruling that that patent does not disclose a combined effect of that active ingredient with ezetimibe that would differ from the sum of the effects of each of those active ingredients taken separately.

73 In the light of the foregoing, the answer to the second question in Case C-149/22 is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B, which is an active ingredient in the public domain at the filing date or priority date of that patent, provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent.

Costs

74 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring 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 (Third Chamber) hereby rules:

1. **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**

   must be interpreted as not precluding the grant of a supplementary protection certificate (SPC) for a product consisting of two active ingredients even if one of those two active ingredients has already been, alone, the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was known at the filing date or priority date of that patent.

2. **Article 3(a) of Regulation No 469/2009**

   must be interpreted as meaning that it does not suffice that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision. It is also necessary, in order to satisfy the condition laid down in that provision, that that product necessarily fall, from the point of view of a person skilled in the art, and in the light of the description and drawings of that patent, under the invention covered by that patent at the filing date or priority date.

3. **Article 3(a) of Regulation No 469/2009**

   must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B, which is an active ingredient in the public domain at the filing

date or priority date of that patent, provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent.

Jürimäe Jääskinen Piçarra

Delivered in open court in Luxembourg on 19 December 2024.

A. Calot Escobar
Registrar

K. Lenaerts
President