Vastuvõtmise kuupäev : 12/08/2024

Case C-456/24

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

Date lodged:

27 June 2024

Referring court:

Nejvyšší správní soud (Czech Republic)

Date of the decision to refer:

18 June 2024

Appellant:

Halozyme, Inc.

Respondent:

Úřad průmyslového vlastnictví

Subject matter of the main proceedings

The referring court is hearing an appeal in cassation brought by Halozyme, Inc. (‘the appellant’) against the judgment of the Městský soud v Praze (Prague City Court), dismissing the appellant’s action challenging the decision of the President of the Úřad pro průmyslové vlastnictví (Industrial Property Office), which upheld the Office’s decision to reject the appellant’s application for a supplementary protection certificate (‘SPC’) in respect of patent CZ/EP 2163643 for the product Herceptin SC, which was placed on the market as a medicinal product.

Subject matter and legal basis of the request

The referring court entertains doubts as to the interpretation of Regulation No 469/2009 in relation to the question of whether Herceptin SC constitutes a combination of two active ingredients and whether that combination of active ingredients is protected under patent CZ/EP 2163643. In that regard, the referring court submits six questions.

Questions referred

(1) Is Article 1(b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products to be interpreted as meaning that a substance expressly designated as an excipient, in the authorisation for a medicinal product, cannot be regarded as an active ingredient?

(2) If the answer to question 1 is in the negative, is Article 1(b) of Regulation No 469/2009 to be interpreted, in the light of Article 8(1) and Article 10(1) to (3) of that regulation, as meaning that a substance must be deemed to constitute an active ingredient if it has a therapeutic effect of its own which is included in the therapeutic indications of the marketing authorisation and which is also demonstrably identifiable from the basic patent and the documents mandatorily presented with the application for a certificate?

(3) If the answers to questions 1 and 2 are negative, is Article 1(b) of Regulation No 469/2009 to be interpreted as meaning that a substance must be deemed to constitute an active ingredient if it has a therapeutic effect of its own which is included in the therapeutic indications of the marketing authorisation and that a person skilled in the art would identify as documented as of the date of the basic patent application or the date of priority of that patent?

(4) Is Article 1(b) of Regulation No 469/2009 to be interpreted as meaning that, inter alia, an excipient must be deemed to constitute an active ingredient with a therapeutic effect of its own which is included in the therapeutic indications in the authorisation of a medicinal product for treating breast cancer, if it breaks down another substance that occurs naturally in the human body, thereby facilitating the effects of the product's main active ingredient on cancerous cells in breast cancer, if, according to certain studies and scientific articles, that excipient or a substance related thereto has resulted, in and of itself, *in vitro* or in animal models, in arresting the growth of tumours of the same as well as another type, or to the shrinkage thereof, and if other scientific articles confirm its potentially similar effect in humans?

(5) Is Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) thereof, to be interpreted as meaning that a product protected by a basic patent must also be deemed to include a combination of two active ingredients, if the subject of the invention to which the basic patent applies is only one of the two ingredients and the patent claims include its potential combination with other alternatively specified categories of active ingredients, one of which may include the other active ingredient, according to the opinion of a person skilled in the art based on the state of knowledge as at the date of the basic patent application or the priority date of that same patent?

(6) If the answer to question five is negative, is Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) of that regulation, to be interpreted

as meaning that a product protected by the basic patent may be considered as including a combination of two active ingredients, if the subject of the invention to which the basic patent applies is only one of the two substances and the patent claims include its potential combination with other alternatively specified categories of active ingredients, one of which included the only active ingredient that was the subject of the authorisation for the medicinal product, regardless of whether there were, as at that date, other substances falling into that same category?

Applicable provisions of EU and international law

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 (Codified version): Article 1(b) [the referring court cites sub-paragraphs (a) to (d)], Article 3(a) [the referring court quotes sub-paragraphs (a) to (d)], Article 8(1), and Article 10(1) to (3).

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, as amended by Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta: Article 1.

Convention on the Grant of European Patents of 5 October 1973, as amended by subsequent Revision Acts (‘European Patent Convention’: Article 69(1).

Protocol on the Interpretation of Article 69 of the Convention.

Summary of the facts of the case and original proceedings

1 On 21 July 2015, the appellant lodged an application with the Industrial Property Office for an SPC in respect of patent CZ/EP 2163643 titled Soluble hyaluronidase glycoprotein (sHASEGP), the method of its preparation, use, and the pharmaceutical composition that contains it, for a product that was placed on the market as the medicinal product HERCEPTIN PRO SUBKUTÁNNÍ POUŽITÍ (HERCEPTIN FOR SUBCUTANEOUS USE; ‘Herceptin SC’). The appellant claims that Herceptin SC is a combination of two active ingredients – trastuzumab and recombinant human hyaluronidase (‘rHuPH20’). Trastuzumab falls into the category of monoclonal antibodies for use in the treatment of breast cancer. The substance rHuPH20, its preparation, and its medicinal usage in combination with various categories of active ingredients, identified by type and function, was the subject of the invention to which patent CZ/EP 2163643 applies.

2 The Industrial Property Office ('the respondent') rejected the applicant's application for the SPC concerned, on 11 January 2019, and the President of the Office upheld that decision on 6 November 2020. Both found that the application did not meet the requirements of Article 3(a), (b), and [as the case may be, (d)] of Regulation 469/2009, as trastuzumab is not listed in the patent claims of patent CZ/EP 2163643 (nor does it appear from its description), while in the marketing authorisation for Herceptin SC, the substance rHuPH20 is listed as an excipient and the possibility of rHuPH20 having an anti-cancer effect of its own has not been documented. The appellant challenged the decision of the respondent's president with an action lodged with the City Court in Prague, which dismissed it by judgment of 13 June 2022, primarily on the grounds that rHuPH20 is not an active ingredient as it did not clearly appear from the evidence that rHuPH20 in combination with trastuzumab had its own particular pharmacological, immunological or metabolic action in the treatment of breast cancer. The appellant has filed an appeal in cassation with the referring court against that judgment.

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

3 According to the referring court, there is no dispute in the present case that trastuzumab is an active ingredient. It was not, however, the subject of the invention to which patent CZ/EP 2163643 applies does not in itself fall under its protection. In order for an SPC to be issued in respect of the patent, rHuPH20 would also have to constitute an active ingredient and the product would, therefore, have to constitute a combination of two active ingredients. In such a case, an SPC could be issued for the product only if the combination in question fell under the protection of the patent concerned.

4 The first three questions seek in essence to ascertain whether the inclusion of a substance in the category of excipients in the marketing authorisation for a medicinal product excludes the possibility of that substance constituting an active ingredient under Article 1(b) of Regulation No 469/2009, or is it necessary to examine, even in such a case, whether that substance has a pharmacological, immunological, or metabolic action of its own, and if so, on the basis of what background documents and as at what point in time.

5 According to the referring court, the Court of Justice has repeatedly held that an 'active ingredient' within the meaning of Article 1(b) of Regulation No 469/2009 must have a 'therapeutic effect' of its own, [1] whereas in the context of Article 1(3a) of Directive 2001/83, it has applied the criterion of 'pharmacological, immunological, or metabolic actions'. [2] In the questions

[1] Judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 27; of 4 May 2006, *Massachusetts Institute of Technology*, C-431/04, EU:C:2006:291, paragraph 25 et seq.; '*MIT*'; order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma*, C-210/13, EU:C:2013:762, paragraph 29; '*Glaxosmithkline Biologicals*').

[2] Judgment of 15 January 2015, *Forsgren* (C-631/13, EU:C:2015:13).

referred, the referring court uses the term therapeutic effects, but it maintains that the two categories overlap and, for the purposes of Article 1(b) of Regulation No 469/2009, it is appropriate to rely on the definition in Article 1(3a) of Directive 2001/83. At the same time, the Court of Justice has stated that the therapeutic effect of its own of an active ingredient must be included among the therapeutic indications of the authorisation for the medicinal product. [3]

6 The referring court maintains that if a particular substance has been explicitly classified as an 'excipient' in the authorisation for a medicinal product, there is no room in the SPC application proceedings to revisit the nature of that substance. The accuracy of that conclusion is the subject of the first question. If a substance is designated in the authorisation decision as an 'adjuvant', which, according to Annex I to Directive 2001/83 is classified in the category of excipients, it cannot at the same time be an active ingredient as the two terms are clearly distinct in the context of that directive and that must also be the case in the context of Regulation No 469/2009. [4] According to the referring court, that conclusion may be applied generally to all of the excipients listed in a decision on the authorisation of a medicinal product.

7 The referring court maintains that that conclusion is not altered by the judgments in *Bayer CropScience* [5] and *Forsgren*, contrary to the views of the applicant, as well as those of the Spanish court and the Polish patent office, which evaluated identical applications by the applicant for an SPC in Spain and Poland. The judgment in *Bayer CropScience* concerns the term active substance under Article 1(3) of 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. Even though, in interpreting the term 'active substance', the Court of Justice was repeatedly inspired by its own case-law concerning Article 1(b) of Regulation No 469/2009 and vice-versa, [6] the referring court maintains that the conclusions in *Bayer CropScience* concerned the very specific case of safeners in plant protection products, which cannot be directly compared to active ingredients or excipients in medicinal products. Hence, only the basic argument (subsequently confirmed by the judgment in *Forsgren*) can be transferred to medicinal products, that is, that the failure to list a substance among the active ingredients does not preclude the possibility that it is indeed an active ingredient. It is precisely to that limited extent that, according to the referring court, it is also necessary to view the judgment in *Forsgren*, which concerned the assessment of a substance that is generally considered to be an adjuvant but which was not explicitly designated as such in the marketing

3 Judgments in *MIT*, paragraph 31; and *Forsgren*, paragraph 55; or order in *Glaxosmithkline Biologicals*, paragraph 34.

4 Order in *Glaxosmithkline Biologicals*, paragraphs 36 to 38.

5 Judgment of 19 June 2014, C-11/13, EU:C:2014:2010.

6 Judgments in *MIT*, paragraph 22; *Bayer CropScience*, paragraph 34; or *Forsgren*, paragraph 50.

authorisation (or, more precisely, classified as an excipient). In that situation, it seemed logical to leave it for the national court to ascertain whether the substance concerned has a pharmacological, immunological or metabolic action of its own, which is covered by the therapeutic indications listed in the marketing authorisation, whereas in a case when that possibility had already been effectively examined within the framework of registration and the substance had been explicitly classified as an excipient, the referring court maintains that the conclusions reached in *Glaxosmithkline Biologicals* [7] should be applied.

8 According to the referring court, the proceedings concerning an SPC application should be, in the light of Article 8(1) and Article 10(1) to (3) of Regulation No 469/2009, a rather formal procedure resulting de facto solely in the extension of the basic patent, in view of the specific nature of the invention. The only thing required in those proceedings should be a confirmation of that specific nature – namely, of the fact that it applies to a product that was the subject of an authorisation as a medicinal product. Whereas, pursuant to the provisions referred to above, any shortcomings in the SPC can be remedied, shortcomings concerning the product cannot. [8] According to the referring court, the abovementioned proceedings should not result de facto in revisiting the registration process of a medicinal product on the basis of an extensive examination of evidence.

9 The referring court holds that, for those reasons, the answer to the first question should be in the affirmative. Even though it derives that conclusion primarily from the order in *Glaxosmithkline Biologicals*, it does not consider the matter to be an *acte éclairé,* in view of the fact that different patent offices and courts in the European Union have made different assessments of compliance with the conditions for issuing an SPC in respect of this same European patent on the basis of the same regulation. [9]

10 The referring court maintains that, in the event of a negative answer to the first question, the second question should be answered in the affirmative. Any substantive assessment of the therapeutic effects of a substance should be limited to the contents of the documents mandatorily submitted with the application and the basic patent, which is the necessary basis for the decision. According to the referring court, there is no room in the proceedings concerning an SPC for a complex examination of the nature of the substances contained in the medical product that would be comparable to the patent or authorisation proceedings.

11 Should the Court of Justice answer the first two questions in the negative, the referring court suggests that it answer the third question in the affirmative. In that

7 In support of this conclusion, see also judgment in *Forsgren*, paragraphs 42 and 43.

8 In this context, see judgment of 7 December 2017, *Merck Sharp*, C-567/16, EU:C:2017:948, paragraphs 50 to 53.

9 For example, High Court in Madrid (judgment of 28 December 2020, No 696/2020) and Polish Patent Office (Order of 16 December 2022, No DB.SPC.0357.315.2017.41.mkoz).

context, it addresses the question of whether a therapeutic effect of its own covered by the therapeutic indications listed in the authorisation is an objective fact, for the establishment of which it is irrelevant when such an effect was demonstrably proven. In particular, in relation to rHuPH20, certain scientific documents examined its effects before the priority date arising from the patent, some in the period between that date and the date on which the medicinal product received marketing authorisation, and others afterwards.

12 The referring court maintains that if the therapeutic effects of an active ingredient are to be deemed to constitute an objective fact, the time when they were demonstrably established should not play a role. That argument, however, ultimately results in the SPC not fulfilling the purpose intended by Regulation No 469/2009 (covering the investment put into the research of the medicinal product) [10] and will not take into account all the interests at stake, including those of public health, which was also one of the objectives of that regulation. [11] In a situation when the subject of the research was the use of a certain substance as an excipient, but subsequent research revealed that it had a therapeutic effect of its own, it cannot be said that the SPC compensates for the research into those therapeutic effects. Pointing to paragraph 37 of the judgment in *Abraxis Bioscience*, the referring court holds that it would be contrary to the purpose and meaning of Regulation No 469/2009 if research were to be taken into account, in the assessment of an active ingredient's therapeutic effects of its own, that only took place after the basic patent application or after the priority date thereof. One exception could perhaps be the case of a specific finding of an active ingredient having its own therapeutic effects made within the framework of the authorisation proceedings concerning that medicinal product (in particular during clinical studies) as in that instance it would also be possible to speak of pharmaceutical research into a new active ingredient by the applicant.

13 The fourth question referred concerns the interpretation of the concept 'therapeutic effect of its own' (or, as the case may be, 'a pharmacological, immunological or metabolic action of its own') that is covered by the therapeutic indications of the marketing authorisation, as used by the Court of Justice for the purpose of defining the term 'active ingredient' within the meaning of Article 1(b) of Regulation No 469/2009. The answer to question 4 is essential, particularly if the Court of Justice answers the first three questions in the negative.

14 The referring court questions whether that definition specifies the legal concept of 'active ingredient' so precisely that relating specific findings of facts to that definition is a question of fact for a person skilled in the art or whether it is a question of a legal classification that is reserved to the administrative authorities and the courts. According to the referring court, the case-law of the Court of Justice does not set out sufficiently clear criteria in this situation for determining

[10] Recitals 3 and 4 of Regulation No 469/2009.

[11] Recital 10 of the regulation.

the therapeutic effects of its own that are covered by the therapeutic indication of the authorisation, which results in different assessments of the same situation by different industrial property authorities, [12] despite the Court of Justice considering that it has provided answers in its case-law to the questions at issue that admit of no reasonable doubt. [13] The referring court maintains that the inconsistent interpretation of Regulation No 469/2009 and the case-law of the Court of Justice is also shown by the fact that the patent offices in Albania, Belgium, Bulgaria, Cyprus, Italy, Luxembourg, Poland, Northern Macedonia, Slovenia, Spain, and Switzerland in particular decided in favour of the appellant, whereas the patent offices in France, [14] the Netherlands, and Sweden, in particular, decided against it. [15]

15 If the assessment of the therapeutic effects of its own that are included in the therapeutic indication specified in the authorisation decision is a legal question that depends on specific criteria, the fourth question is intended in essence to ascertain those criteria and to determine a standard of evidence for establishing the effects of the substance on humans. At the present time, it appears likely on a preliminary basis that the substance rHuPH20 has proven to have certain metabolic effects (it is an enzyme that degrades hyaluronan, which is naturally found in the human body and which reduces the effect of trastuzumab when administered subcutaneously); nevertheless, it is not clear whether those effects can be deemed to be therapeutic effects that are covered by the therapeutic indication specified in the marketing authorisation for Herceptin SC. One reason is that existing studies and scientific articles have researched the effect of the substance on its own (or substances related to it) *in vitro* or in animal models and have found that the substance under investigation has resulted in arresting the growth of a tumour of the same or other type, or to its shrinkage. Other scientific documents confirm its potentially similar effect in humans.

16 The fifth and sixth questions concern the interpretation of Article 3(a) of Regulation No 469/2009, which sets out the condition that the product must be protected by a basic patent. If in the present case the substance rHuPH20 were to be assessed as an active ingredient, the question arises, according to the referring court, whether its combination with trastuzumab falls under the protection of patent CZ/EP 2163643. That combination may be classified under patent claim 21 (in conjunction with patent claims 12, 18, 19, and 20), where one of the pharmaceutical compositions listed is a composition containing, in addition to rHuPH20, a monoclonal antibody for use in the treatment of breast cancer.

[12] Order in *Glaxosmithkline Biologicals*, paragraph 21.

[13] Order in *Glaxosmithkline Biologicals*, paragraph 23.

[14] The decision was confirmed by the judgment of the Court of Cassation of 1 February 2023, No 101 FP-B, ECLI:FR:CCASS:2023:C00101.

[15] The decision was confirmed by a decision of the Supreme Court in Stockholm of 29 March 2023, No Ö 6725-22.

17 Specifically, the patent claims are worded as follows:

> ‘12. A pharmaceutical composition, comprising the substantially purified hyaluronidase polypeptide of any of claims 1-4.
>
> …
>
> 18. The pharmaceutical composition of claim 12 for use in treating a tumour, wherein the composition further comprises an anti-cancer agent selected from among a chemotherapeutic, an antibody, a peptide, a gene therapy vector, a virus or a DNA molecule.
>
> 19. The pharmaceutical composition of claim 18 for use in treating a tumour wherein the anti-cancer agent is an antibody.
>
> 20. The pharmaceutical composition of claim 19 for use in treating a tumour, wherein the antibody is a monoclonal antibody.
>
> 21. The pharmaceutical composition of any of claims 19 or 20 for use in treating a tumour, wherein the tumour is a cancer of the breast.’

18 In regard to the question as to when an active ingredient or a combination of active ingredients is protected by the basic patent, the referring court points to the case-law of the Court of Justice. [16] As the regulation of patent protection has not been harmonised at EU level, the extent of the protection granted by a basic patent may be determined only on the basis of the rules regulating such a patent. [17] As regards the European patent, the referring court adds, with reference to Article 69 of the European Patent Convention and Article 1 of the Protocol on the Interpretation of that article of the Convention, that patent claims cannot be used exclusively as a guide nor be interpreted to the effect that the extent of the protection conferred by a patent should be understood as being defined by a strict and literal interpretation of the wording used in patent claims.

19 Hence, according to the referring court, the Court of Justice has stated that it is not necessary for an active ingredient to be identified in the claims of the patent by a structural formula, and it suffices if it is possible to reach the conclusion, on the basis of the patent claims interpreted, inter alia, in the light of the description of the invention, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question. [18] As for a combination of active ingredients, then it must (1) necessarily fall, in the light of the description and drawings of the patent, under the invention covered by the patent, and (2) it must be possible to

[16] Judgments of 12 December 2013, *Eli Lilly and Company*, C-493/12, EU:C:2013:835; of 25 July 2018, *Teva UK and Others*, C-121/17, ECLI:EU:C:2018:585; and of 30 April 2020, *Royalty Pharma Collection Trust*, C-650/17, EU:C:2020:327.

[17] Judgments in *Eli Lilly and Company*, paragraph 32; and *Teva UK and Others*, paragraph 32.

[18] Judgment in *Eli Lilly and Company*, paragraphs 39 and 44.

specifically identify each active ingredient in the light of all of the information disclosed by the patent. [19]

20 The above phrases ‘necessarily and specifically’ and ‘specifically identify’ could indicate that each active ingredient included in the product should be listed in the patent in a manner that is not interchangeable with another substance, even if it be, for example, by means of a functional definition. According to the referring court, that interpretation is apparently advanced by the parties to the proceedings in this case, as they are de facto arguing as to whether a person skilled in the art would consider trastuzumab, at the priority date of patent CZ/EP 2163643, to be a synonym for *monoclonal antibody for use in the treatment of cancer*.

21 With regard to the judgments in *Eli Lilly and Company* and *Royalty Pharma Collection Trust*, the referring court notes that they concerned products comprised of a single active ingredient. The aim of the requirement for patent claims to concern ‘necessarily and specifically’ that active ingredient is to prevent the patent holder from claiming more rights than would arise from the basic patent and for the SPC to indeed constitute compensation for the costs of the patent holder’s own research. In another words, an SPC may be issued only for an active ingredient that was the subject of the invention to which the patent applies.

22 The judgment in *Teva UK and Others* is more instructive for the present case, according to the referring court. The difference from the present case is that in *Teva UK and Others*, the combination of active ingredients was included under a more generally worded patent claim. [20] Accordingly, the case concerned a combination of a substance that was the subject of the invention with *another therapeutic ingredient*. The present case concerns a combination of a substance that is the subject of the invention with a *monoclonal antibody for use in the treatment of cancer of the breast*.

23 The referring court does not view the judgment in *Teva UK and Others* as an extension of the rule set out in *Eli Lilly and Company* – according to which patent claims must necessarily and specifically concern active ingredients – to each of the active ingredients which in combination constitute the product in question. The Court of Justice specified therein the rule expressed in the *Eli Lilly and Company* judgment in relation to a combination of active ingredients and embodied it in the first condition. It thus created an amended rule according to which a combination of active ingredients must necessarily, in the light of the description and drawings of the basic patent, fall under the invention covered by that patent. It applies to the product as a whole, that is, for the combination of

[19] Judgment in *Teva UK and Others*. See also judgment in *Royalty Pharma Collection Trust* applicable to cases when a product consists of a single active ingredient.

[20] ‘A pharmaceutical composition comprising a compound according to any one of claims 1 to 25 together with a pharmaceutically acceptable carrier, and optionally other therapeutic substances.’

active ingredients itself.[21] The purpose was to confirm that the product must be the result of the patent holder's own research (which is why the condition says that the combination of substances should be based on the invention rather than the patent claims).

24 The second condition set out in the judgment in *Teva UK and Others* likewise cannot be deemed to constitute an extension of the requirement of the judgment in *Eli Lilly and Company* to each active ingredient, in the case of a product that consists of a combination thereof. The purpose of that condition is not to ensure that a product is the outcome of the patent holder's own development. The condition requires 'only' the identification of each of the active ingredients from the information disclosed by a patent. According to the referring court, it is therefore necessary for a person skilled in the art to clearly identify, on the basis of the prior art as at the filing date (or the priority date), which substances fall under which patent claim (and whether the combination in question therefore falls under them), but it is not necessary for individual patent claims to pertain only to a single substance (or to a combination of entirely specific substances).

25 With reference to point 77 of the Opinion in Joined Cases *Royalty Pharma Collection Trust* and *Sandoz and Hexal*,[22] the referring court notes that, in the case of the combination of the active ingredients currently under consideration, it is sufficient for the ingredient that is not the subject of the invention to be classified, by a person skilled in the art, as of the filing or priority date for that patent, under a relatively specific category included in the patent claims, even though it includes several active ingredients.

26 In the present case, that would mean that it is not important whether, as at the application for patent CZ/EP 2163643, there were several *monoclonal antibodies for use in treating cancer of the breast*, but rather, whether a person skilled in the art could specifically identify, as at the given date, that trastuzumab is a monoclonal antibody for use in treating cancer of the breast. That would meet the second condition of the judgment in *Teva UK and Others*. What would be vital for meeting the first condition is whether it follows from the patent, according to a person skilled in the art, that the invention did not consist merely in the discovery of rHuPH20 or the process for obtaining it, but also in the discovery of a method for its use together with *monoclonal antibodies for use in treating cancer of the breast.*

27 For the sake of completeness, the referring court states that the conclusions described above cannot result in multiple SPCs being issued for the combination of rHuPH20 with a number of other monoclonal antibodies for use in the treatment of breast cancer or any other active ingredients that can be classified

21 Judgement in *Teva UK and Others*, paragraphs 52 to 55.

22 Opinion of Advocate General Hogan delivered on 11 September 2019, C-650/17 and C-114/18, EU:C:2019:704.

under other patent claims according to patent CZ/EP 2163643. Inasmuch as those would be different products, the conclusions set out in the judgment in *Actavis Group PTC and Actavis UK* [23] would apply to them. Multiple SPCs for various combinations of active ingredients or independent active ingredients may be issued only if each of the active ingredients as such is protected by a basic patent. [24] That should mean that the condition for the issuance of multiple SPCs is for each active ingredient to be the subject of an invention. It follows from the judgment in *Actavis Group PTC and Actavis UK* [25] that only one SPC can be obtained for medicinal products containing various combinations of an active ingredient that is protected as such by a basic patent and which constitutes the subject of an invention, with other substances that are not the subject of the invention.

28 In view of that consequence, it is not necessary, according to the referring court, in the case of a product consisting of several active ingredients, to place high standards on those substances that do not constitute the subject of the invention, in terms of their being fully individualised in patent claims (whether by name, formula, or functional definition that rules out placing other ingredients under such a definition). If the subject of an invention is a single active ingredient and its combination with other types of previously invented substances, the patent holder will be unable to obtain several SPCs for products consisting in a combination of that 'new' substance with other substances. At the same time, it will never be able to derive from an SPC more rights (broader protection) than it derived from the basic patent. [26]

29 For the reasons given above, the referring court proposes that the Court of Justice answer the fifth question in the affirmative.

30 Should the Court of Justice conclude that, for the purpose of Article 3(a) of Regulation No 469/2009, it is necessary, in the case of a product comprised of a combination of two active ingredients, for each active ingredient to be specified in the patent claims in an individual and non-interchangeable manner, question six seeks to ascertain what aspects must be taken into account when considering compliance with that requirement. Does it suffice for an active ingredient to be specified in patent claims as a substance of a certain type, if, as of the date of the basic patent application or the priority date thereof, the only active ingredient that was the subject of the authorisation for the medicinal product fell into that same

[23] Judgment of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165C-577/13, EU:C:2015:165.

[24] Judgment of 12 December 2013, *Georgetown University*, C-484/12, EU:C:2013:828, paragraph 30; and judgment in *Actavis Group PTC a Actavis UK*, paragraph 33.

[25] In particular, paragraphs 36 to 38.

[26] Judgment in *Georgetown University*, paragraph 39; judgments of 19 July 2012, *Neurim Pharmaceuticals (1991)*, C-130/11, EU:C:2012:489, paragraphs 24 and 25; and of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraph 39.

category? That circumstance could lead a person skilled in the art, as of a particular date, to automatically link the given category of substances with that active ingredient. Similarly, however, a person skilled in the art should be familiar with the existence of other substances of the same type that have been developed but cannot be yet used in treatment. Question six therefore seeks in essence to ascertain whether or not such substances should be taken into account in the application of Article 3(a) of Regulation No 469/2009.