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OPINION OF ADVOCATE GENERAL
EMILIOU
delivered on 23 April 2026 [1]

Case C-456/24

Halozyme, Inc.
v
Úřad průmyslového vlastnictví

(Request for a preliminary ruling from the Nejvyšší správní soud (Supreme Administrative Court, Czech Republic))

(Reference for a preliminary ruling – Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 1(b) – Definition of 'product' – Active ingredient – Directive 2001/83/EC – Marketing authorisation – Article 1(3a) and (3b) – Active substance – Excipient)

[1] Original language: English.

EN

I. Introduction

1. The present request for a preliminary ruling, submitted by the Nejvyšší správní soud (Supreme Administrative Court, Czech Republic), offers the Court an opportunity to revisit the intricate regime governing the grant of supplementary protection certificates (SPCs), as established by Regulation (EC) No 469/2009 ('the SPC Regulation'). [2]

2. It must be recalled that SPCs constitute *sui generis* intellectual property rights intended to compensate, at least in part, for the effective loss of patent protection resulting from the time required to obtain a marketing authorisation (MA). To that end, they may extend the protection conferred by a patent for a period of up to five years in respect of certain patent-protected substances which function as active ingredients of medicinal products authorised for placing on the market in at least one Member State. [3]

3. In the present case, Halozyme, Inc., a pharmaceutical company established in the United States, applied to the Úřad průmyslového vlastnictví (Industrial Property Office, Czech Republic) for the grant of such an SPC in respect of a combination of substances forming part of the medicinal product known as 'Herceptin SC'. Following the refusal of that authority to grant the SPC sought, the dispute eventually reached the referring court.

4. Against that background, that court now seeks guidance on the interpretation of certain provisions of the SPC Regulation, in particular of Article 1(b) and Article 3(a) thereof. Article 1(b) defines the 'product' eligible for an SPC as the 'active ingredient or combination of active ingredients of a medicinal product', whereas Article 3(a) makes the grant of an SPC subject to the condition that the product in question be 'protected by a basic patent in force'.

5. At the Court's request, the present Opinion will focus on the questions raised by the referring court in so far as they concern Article 1(b) of the SPC Regulation. The central issue is whether the classification in the relevant MA of one of the substances in relation to which Halozyme seeks protection as an 'excipient' – that is to say, a non-active component of the medicinal product – necessarily precludes that substance from being regarded as an 'active ingredient' within the meaning of Article 1(b), and thus from qualifying for SPC protection.

6. Although the Court has already had the opportunity to interpret Article 1(b), it has not, thus far, addressed that specific question in explicit

2 Regulation 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).

3 For the specific nuances of the SPC as a *sui generis* intellectual property right, see my Opinion in Joined Cases *Teva and Others* (C-119/22 and C-149/22, 'my Opinion in *Teva II*', EU:C:2024:472, point 36 et seq.).

terms. [4] In the absence of clear guidance, divergent approaches have emerged at national level. As the present case illustrates, applications lodged by Halozyme in respect of the same substance have led to different outcomes across several Member States. The present preliminary reference therefore provides a timely opportunity for the Court to clarify – and, where necessary, further develop – its case-law in that regard.

II. Legal framework

A. The SPC Regulation

7. Article 1 of the SPC Regulation, entitled 'Definitions', reads as follows:

'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;

...'

8. Article 3 of that regulation provides:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

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

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

9. According to Article 8 of the SPC Regulation:

[4] A similar question was referred but not addressed as such by the Court in the case which gave rise to the judgment of 16 September 1999, *Farmitalia* (C-392/97, EU:C:1999:416).

'1. The application for a certificate shall contain:

(a) a request for the grant of a certificate …

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC;

…'

B. Directive 2001/83/EC

10. Article 1 of Directive 2001/83/EC ('the Medicinal Products Directive') [5] provides:

'For the purposes of this Directive, the following terms shall bear the following meanings:

…

3a. Active substance:

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

3b. Excipient:

Any constituent of a medicinal product other than the active substance and the packaging material.

…'

III. Factual background and the questions referred for a preliminary ruling

11. Halozyme, the appellant in the main proceedings, is the proprietor of European patent EP 2 163 643, entitled 'Soluble hyaluronidase glycoprotein (sHASEGP), process for preparing the same, uses and pharmaceutical

[5] Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), in the version applicable at the material time.

compositions comprising thereof', as validated, inter alia, in the Czech Republic [6] ('the basic patent').

12. That patent concerns an invention relating, in essence, to certain enzymes which, by degrading hyaluronic acid in the body, facilitate the dispersion and absorption of co-administered medicinal products injected subcutaneously. Recombinant human hyaluronidase PH20 (rHuPH20) is one such engineered enzyme. The claims of the basic patent refer, inter alia, to the use of such an enzyme in combination with an anti-cancer agent – more specifically, a monoclonal antibody – for the treatment for breast cancer.

13. Trastuzumab is a monoclonal antibody used as an active substance in the treatment for breast cancer and other malignancies. It has been marketed in the European Union since the early 2000s in a medicinal product known as 'Herceptin', by Roche, a pharmaceutical undertaking not directly involved in the present proceedings. To that end, Roche obtained, in 2000, an MA granted by the European Commission under the centralised procedure, covering the intravenous administration of that product. In August 2013, the Commission granted a line extension [7] of that MA for a new subcutaneous formulation of Herceptin (Herceptin SC), combining trastuzumab with rHuPH20. In the MA documentation, trastuzumab is identified as the active ingredient, whereas rHuPH20 is classified as an excipient and described, moreover, as a 'novel excipient'.

14. Halozyme sought SPC protection across several Member States in respect of that subcutaneous formulation and, more specifically, for the combination of trastuzumab and rHuPH20. In the Czech Republic, it filed an application on 21 July 2015 with the Industrial Property Office, relying on the basic patent and the abovementioned MA. In its application, Halozyme characterised rHuPH20 as an active ingredient and, accordingly, identified the 'product' for which protection was sought as a combination of two active ingredients, namely trastuzumab and rHuPH20.

15. By decision of 11 January 2019, the Industrial Property Office rejected Halozyme's application, a decision that was subsequently upheld by its President on 6 November 2020. That office and its President found, in essence, that the conditions laid down in points (a), (b) and, as the case may be, (d) of Article 3 of the SPC Regulation were not satisfied. In that regard, they considered, first, that trastuzumab is not referred to in the claims or the description of the basic patent and, secondly, that rHuPH20 is classified as an excipient in the MA, without it having been established that it has an anti-cancer effect of its own.

6 CZ/EP 2 163 643, entitled 'Soluble hyaluronidase glycoprotein (sHASEGP), the method of its preparation, use, and the pharmaceutical composition that contains it'.

7 Line extensions are variations to the terms of an MA, required for major changes to an existing authorised medicinal product, including as regards its strength, pharmaceutical form and route of administration.

16. Halozyme challenged the decision of the President of the Industrial Property Office before the Městský soud v Praze (Prague City Court, Czech Republic). By judgment of 13 June 2022, that court dismissed the action on the ground that rHuPH20 cannot be regarded as an 'active ingredient' within the meaning of Article 1(b) of the SPC Regulation. In reaching that conclusion, it observed that it did not clearly appear from the evidence before it that rHuPH20, when used in combination with trastuzumab, exerts its own pharmacological, immunological or metabolic action in the treatment for breast cancer.

17. Halozyme subsequently lodged an appeal on a point of law before the Nejvyšší správní soud (Supreme Administrative Court). Entertaining doubts as to the interpretation of Article 1(b) and Article 3(a) of the SPC Regulation, that court decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 1(b) of [the SPC Regulation] 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 [the SPC Regulation] 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 [MA] 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 [in the] negative, is Article 1(b) of [the SPC Regulation] 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 [MA] and [which] a person skilled in the art would regard as [established] as of the date of the basic patent application or the date of priority of that patent?

(4) Is Article 1(b) of [the SPC Regulation] 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 [the SPC Regulation], 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 [5] is [in the] negative, is Article 3(a) of [the SPC Regulation], 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, as at the date of the basic patent application or the priority date of that same patent, 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?'

18. Written observations were submitted by Halozyme, the Czech Government, Ireland, the French, Netherlands and Finnish Governments (together, 'the governments submitting observations'), as well as the Commission. Those interested parties, with the exception of the Finnish Government, also presented oral argument at the hearing held on 29 October 2025.

IV. Analysis

19. As indicated in the introduction, the Court has requested that the present Opinion focus solely on the first four questions referred. [8] By those questions, the referring court seeks, in essence, clarification as to how to determine whether a substance may be regarded as an 'active ingredient' within the meaning of Article 1(b) of the SPC Regulation, and thus as forming part of a 'product' eligible for the grant of an SPC.

8 I note that Questions 5 and 6 seek, in essence, to ascertain whether the combination of rHuPH20 and trastuzumab is protected, as a product, by the basic patent. They are therefore relevant only if rHuPH20 may be regarded as an active ingredient notwithstanding its classification in the MA. In any event, the issues raised by those questions appear, in my view, to have been resolved by the judgment of 19 December 2024, *Teva and Others* (C-119/22 and C-149/22, 'the judgment in *Teva II*', EU:C:2024:1039), delivered after the present request for a preliminary ruling was made.

20. In order to place those questions in their proper context, it is appropriate to begin by recalling certain fundamental features of both the patent system and MA procedures (A). I shall then outline the salient characteristics of the SPC regime, together with the relevant strands of the Court's case-law (B). Against that background, I will identify the core issue raised by the present preliminary reference and summarise the principal arguments put forward by the interested parties (C). I will subsequently examine in greater depth the concept of 'active ingredient' for the purposes of Article 1(b) of the SPC Regulation (D). As will become apparent, the answer proposed to the first question renders it unnecessary, in my view, to address the second to fourth questions.

A. The intersection of patent law and pharmaceutical regulatory law

21. The SPC regime lies at the intersection of patent law and pharmaceutical regulatory law and is expressly designed by reference to both.

22. As a preliminary point, it should be recalled – as I have already observed in my Opinion in *Teva II* [9] – that, as regards patents in the field of medicinal products, a person, typically a pharmaceutical undertaking, that discovers through research that a given substance (or a family or combination of substances) produces an effect on the human body rendering it suitable for the treatment, prevention or management of a disease or condition may, subject to the applicable requirements, [10] obtain a patent for that invention. Such a patent confers on its holder exclusive rights – amounting, in essence, to a temporary monopoly over the patented invention – for a period of 20 years.

23. However, before the patent holder can place the invention on the market in the European Union as a medicinal product, an MA must be obtained for that medicinal product, following a rigorous scientific assessment of its quality, safety and efficacy. In that regard, the Medicinal Products Directive constitutes the principal legal instrument laying down the rules governing the authorisation, manufacture and marketing of medicinal products within the European Union.

24. An MA may be granted either at EU level, under a centralised procedure, or at national level, through a decentralised, a mutual recognition or a purely national procedure. [11]

25. Under the centralised procedure [12] – which, as noted in point 13 above, was followed in respect of Herceptin SC – the European Medicines Agency (EMA) is

9 See points 34 to 39 of that Opinion.

10 Those requirements are set out in the European Patent Convention and/or national legislation, depending on the type of patent concerned.

11 The choice amongst those four possible procedural routes depends notably on the type of medicinal product concerned and the scope of marketing intended.

responsible for carrying out the scientific evaluation of an MA application. On the basis of the EMA's opinion, the Commission then decides to grant or refuse the MA, valid throughout the European Union.

26. By contrast, under the other procedures, the scientific assessment of the MA application is conducted by the competent authorities of the Member States, which may then grant the corresponding national authorisations.

27. In all cases, both the EMA and the competent national authorities (together, 'the competent medicines authorities') assess, as part of their scientific evaluation, the composition of the medicinal product, distinguishing between its active substances and its excipients. The composition thus approved, together with a list of excipients, is set out in the 'summary of product characteristics', which forms part of the MA. [13] It is to that classification of a substance in the MA that reference will be made throughout the present Opinion.

28. The process leading to the grant of an MA is often lengthy, owing to the extensive pre-clinical tests and clinical studies required. As a consequence, the effective period during which a patent holder may commercially exploit a pharmaceutical invention under patent protection is significantly curtailed.

B. The SPC regime and the case-law on 'active ingredients'

29. It is in the context outlined above that the EU legislature deemed it necessary to compensate, to a certain extent, for the delays inherent in the regulatory process by providing for a mechanism capable of extending, in certain circumstances, the protection conferred by a patent for a further period of up to five years after the expiry of its normal term. That objective is pursued through the grant of SPCs which, under the SPC Regulation, confer, in principle, the same rights as the underlying patent, subject to the same obligations and limitations.

12 The centralised MA procedure is governed by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1). That regulation is not expressly referenced in the SPC Regulation, which makes the grant of an SPC contingent upon the existence of a valid MA in accordance with the Medicinal Products Directive. It is nevertheless firmly accepted, both in administrative practice and in the case-law of the Court, that SPCs may be granted in relation to medicinal products authorised under the centralised procedure provided for in Regulation No 726/2004, not least since all the substantive provisions of the Medicinal Products Directive are also applicable in the centralised procedure. See also Opinion of Advocate General Jääskinen in *Seattle Genetics* (C-471/14, EU:C:2015:590, footnote 5).

13 See also, in that regard, albeit with a specific focus on the decentralised procedure, my Opinion in *Laboratoires Eurogenerics and Theramex France* (C-118/24, EU:C:2025:815, point 30 et seq.).

30. At present, SPCs are granted exclusively at national level. Consequently, even where a pharmaceutical undertaking holds a European patent [14] and has obtained an MA under the centralised procedure which is valid throughout the European Union, it must nevertheless submit separate SPC applications in each Member State in which it seeks supplementary protection.

31. The competent national authorities ('national patent offices' [15]) are responsible for examining whether those applications satisfy the conditions laid down in the SPC Regulation. A preliminary and indispensable requirement in that regard is that the SPC application must concern a 'product'.

32. Pursuant to Article 4 of the SPC Regulation, the protection conferred by an SPC extends only to the 'product' covered by the relevant MA. As already noted, Article 1(b) thereof defines that term as 'the active ingredient or combination of active ingredients of a medicinal product'. It follows that an SPC is not granted for the medicinal product as such, but only for the 'product' in the strict sense, that is to say, the active ingredient or combination of active ingredients contained therein.

33. However, the SPC Regulation does not define the term 'active ingredient'. The Court has therefore held that its meaning and scope must be determined having regard to the general context in which it is used and its usual meaning in everyday language. [16] On that basis, the Court has held that, in pharmacological terms, the notion of 'active ingredient' does not encompass substances forming part of a medicinal product which do not exert a therapeutic effect of their own on the human or animal body. [17]

34. Furthermore, the Court has clarified that the terms 'active substance' and 'active ingredient', as used in the Medicinal Products Directive and the SPC Regulation respectively, are to be understood as synonymous. [18] It has accepted that the definition of 'active substance' in Article 1(3a) of the directive – referring, in essence, to substances exerting a pharmacological, immunological or metabolic

14 To be precise, however, such a European patent corresponds to a bundle of national patents.

15 I will use the term 'patent office' for ease of reference to denote the national authorities competent for granting SPCs, but the terms in the various Member States vary and may also be referred to as 'industrial property offices', 'intellectual property offices' or other.

16 See the judgment in *Teva II*, paragraph 42 and the case-law cited.

17 See judgments of 4 May 2006, *Massachusetts Institute of Technology* (C-431/04, 'the judgment in *MIT*', EU:C:2006:291, paragraphs 18 and 25); of 21 March 2019, *Abraxis Bioscience* (C-443/17, EU:C:2019:238, paragraph 27); and in *Teva II*, paragraph 44; order of the President of the Court of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C-210/13, 'the order in *GSK*', EU:C:2013:762, paragraph 29).

18 See the judgment in *MIT*, paragraph 21. I accordingly also refer to those terms interchangeably in the present Opinion.

action with a therapeutic purpose – is equally relevant for the interpretation of the SPC Regulation.

35. It follows from the Court's case-law as it currently stands that a substance which does not exert, in its own right, a therapeutic effect through such pharmacological, immunological or metabolic action cannot be regarded as an active ingredient and, accordingly, a 'product' within the meaning of Article 1(b) of the SPC Regulation. [19] That conclusion holds true even where that substance enhances, or is necessary for, the therapeutic efficacy of another substance contained in the medicinal product. [20]

36. In that context, the Court has, on several occasions, been called upon to examine the position of excipients, which are defined in Article 1(3b) of the Medicinal Products Directive as 'any constituent of a medicinal product other than the active substance and the packaging material'. Excipients may perform a variety of functions, such as improving the stability of a medicinal product, facilitating its absorption or even enhancing the therapeutic efficacy of the active ingredient. [21] Nevertheless, the Court has consistently drawn a clear distinction between excipients and active ingredients, under both the Medicinal Products Directive and the SPC Regulation. [22] It follows that an excipient cannot be covered by the concept of 'product' for the purposes of the SPC Regulation and is therefore not eligible for the protection conferred by an SPC.

C. The core issue raised and the positions advanced

37. Bearing the foregoing in mind, what nevertheless remains to be clarified in the Court's case-law is how to determine whether a given substance possesses an autonomous therapeutic effect and thus qualifies as an active ingredient for the purposes of the SPC Regulation. That is, in essence, the issue raised by the first four questions referred in the present case. Those questions crystallise into a single dilemma: must the competent authorities – national patent offices and, where appropriate, national courts – confine themselves to the classification adopted in the MA for the medicinal product (first question), or are they instead required to undertake an autonomous and substantive assessment, independently of that classification; and, if so, on the basis of which criteria (second to fourth questions)?

19 See also judgment of 9 July 2020, *Santen* (C-673/18, 'the judgment in *Santen*', EU:C:2020:531, paragraph 42).

20 See the order in *GSK*, paragraphs 30, 31 and 45.

21 See, inter alia, section 3.2.2.1 of Part I of Annex I to the Medicinal Products Directive, which provides a non-exhaustive list of certain types of excipients, including adjuvants. See also the EMA's *Guideline on excipients in the dossier for application for marketing authorisation of a medicinal product*.

22 See the order in *GSK*, paragraphs 36 and 37.

38. The resolution of that dilemma is decisive for the dispute in the main proceedings. I recall that Halozyme sought an SPC for the 'product' consisting of the combination of rHuPH20 and trastuzumab as a 'combination of active ingredients' within the meaning of Article 1(b) of the SPC Regulation. However, rHuPH20 is classified as an 'excipient' in the relevant MA. If that classification by itself were to preclude rHuPH20 from being an active ingredient for the purposes of the SPC Regulation, trastuzumab would remain the sole active ingredient in Herceptin SC. In that event, the combination relied upon by Halozyme could not be regarded as a combination of 'active ingredients' and would therefore not qualify as a 'product' eligible for the protection conferred by the SPC. [23] Conversely, if that classification were not decisive, and the national patent offices were required to carry out an autonomous substantive assessment of the role of rHuPH20, the outcome might be different. [24]

39. The interested parties that have submitted observations before the Court are divided on the issue. In particular, the governments submitting observations and the Commission [25] take the view that the classification adopted in the MA is determinative and the authorities examining an SPC application may not depart from it. If that reasoning is to be followed, rHuPH20 cannot qualify as an active ingredient for the purposes of the SPC application at issue. I note that this position corresponds, in essence, to the referring court's provisional assessment.

40. Halozyme, by contrast, contends that the classification of a substance in the MA is not decisive for the purposes of the SPC Regulation. It argues in favour of a separate assessment within the SPC procedure, based on actual therapeutic effects of the substance rather than on its regulatory classification. In that regard, it submits that, although identified as an excipient in the MA, rHuPH20 has been shown, in studies and clinical trials, to have a therapeutic effect of its own in the treatment for breast cancer, beyond merely facilitating the subcutaneous administration and absorption of trastuzumab.

41. Both positions claim to have support in the Court's case-law. At the same time, as already noted, national authorities across the European Union have reached divergent conclusions in respect of equivalent SPC applications submitted by Halozyme. Decisions favourable to that company have been adopted in Belgium, Bulgaria, Spain, Italy, Cyprus, Luxembourg, Poland and Slovenia,

23 Whether trastuzumab alone could be granted an SPC is not at issue in the present case, and it appears, in any event, to be common ground that that substance, which has been authorised and marketed since 2000, would not by itself satisfy the other conditions laid down in the SPC Regulation.

24 Indeed, several national patent offices took the view that rHuPH20 does qualify as an 'active ingredient' and accordingly granted the SPC requested by Halozyme (see point 41 below).

25 Reference is made, in that regard, to the Commission's statements during the hearing.

whereas the French, Dutch and Swedish competent authorities have rejected the application. [26] That divergence is in itself indicative of the need for clarification.

42. In those circumstances, a clarification of the Court's case-law on Article 1(b) of the SPC Regulation appears to me to be necessary and timely. I shall therefore examine the concept of 'active ingredient' within the meaning of that provision, with a view to determining the manner in which a substance is to be so classified.

D. How to determine whether a substance is an 'active ingredient' for the purposes of the SPC Regulation

43. Article 1(b) of the SPC Regulation does not specify how to determine whether a substance qualifies as an 'active ingredient'. Nevertheless, having regard to the context of that provision (1) and the objectives of the SPC Regulation (2), and notwithstanding the arguments put forward by Halozyme (3), I am of the view that such a determination must be made exclusively on the basis of the classification of the substance in the relevant MA.

1. The concept of 'active ingredient' seen in context

44. As regards the context surrounding Article 1(b) of the SPC Regulation, it is immediately apparent that, as explained in Section A above, the SPC regime is inextricably linked to the regulatory framework governing medicinal products and, in particular, to the Medicinal Products Directive.

45. The grant of an SPC for a 'product' is contingent upon the prior grant of an MA concerning that same 'product', under the provisions of the Medicinal Products Directive. In that regard, it is sufficient to recall that, under Article 4 of the SPC Regulation, the protection conferred by an SPC 'shall extend only to *the product covered by the* [*MA*] to place the corresponding medicinal product on the market' (emphasis added). Recital 10 of that regulation likewise emphasises that such protection should 'be strictly confined to *the product which obtained authorisation* to be placed on the market as a medicinal product' (emphasis added).

46. That logic is also reflected in the procedural provisions of the SPC Regulation. Article 8(1)(b) thereof requires an SPC application to include 'a copy of the [MA], ... *in which the product is identified*' (emphasis added). Article 9(2)(d) thereof, for its part, provides that the publication of an SPC application must indicate, inter alia, 'the number and date of the [MA], ... and *the product identified in that authorisation*' (emphasis added).

26 As noted, inter alia, by the referring court and the Commission.

47. It follows, in my view, that the SPC Regulation is based on the premiss that the 'product' is the substance – or combination of substances – identified as an active ingredient in the MA. The terms 'active substance' and 'active ingredient', used in the Medicinal Products Directive and the SPC Regulation respectively, are therefore not only conceptually synonymous (as Halozyme seems to accept), but must also be understood and applied in an aligned, uniform and consistent manner across those two closely connected legal frameworks.

48. That conclusion necessarily extends to the distinction between active substances and excipients. The Medicinal Products Directive treats those categories as distinct and mutually exclusive; a distinction which, as noted in point 36 above, the Court has likewise recognised as relevant in the context of the SPC Regulation. It follows that a substance classified as an excipient in the MA procedure cannot subsequently be reclassified as an active ingredient in the context of the SPC procedure.

49. That interpretation is further borne out by Article 3(b) of the SPC Regulation, which makes the grant of an SPC conditional upon the existence of 'a valid authorisation to place the product on the market as a medicinal product'. That condition cannot, in my view, be regarded as satisfied when a substance is merely present in the medicinal product. Rather, the authorisation must relate to that substance in its capacity as an active ingredient. Accordingly, as contended by a number of the governments submitting observations, a substance not authorised as active in the MA cannot fulfil that requirement.

50. It follows, in my opinion, that the SPC procedure is not intended to revisit – much less disregard – the regulatory classification adopted in the MA procedure, but must instead rely upon it. That conclusion is also consistent with the overall architecture of the system. The assessment of the properties and effects of a substance in a medicinal product entails complex and thorough scientific evaluations, which the legislature has entrusted to the competent medicines authorities, in order for the medicinal product to be marketed to the public. Those authorities possess the requisite technical expertise and resources, and the MA they issue constitutes the authoritative determination of the therapeutic role of the substances concerned.

51. That reading is, in my view, further corroborated by the objectives pursued by the SPC Regulation.

2. The objectives of the SPC Regulation

52. As is apparent from its recitals and its legislative history, the SPC Regulation pursues three interrelated objectives: first, to compensate patent holders for regulatory delays; secondly, to establish a simple and transparent system for the grant of SPCs; and thirdly, to ensure a uniform approach across the Member States.

(a) Compensation for regulatory delays

53. In the first place, the primary objective of the SPC Regulation [27] is to encourage pharmaceutical research and innovation in the European Union by compensating patent holders for the delays inherent in obtaining an MA, which postpone the commercial exploitation of their patented inventions. [28]

54. However, as the Court has clarified, that objective is not unlimited. The intention of the EU legislature is to protect 'research leading to the first placing on the market of an active ingredient or a combination of active ingredients', namely 'new active ingredients'. It is those substances which are subject to extensive testing as regards their quality, safety and efficacy, [29] and which therefore give rise to the regulatory delays that the SPC seeks to offset.

55. By contrast, excipients, although subject to certain safety assessments, are not, as a rule, subject to the same level of scrutiny, in particular as regards efficacy, or the same regulatory burden. [30] Consequently, where a substance has been assessed in the MA procedure solely as an excipient, the type of regulatory delay for which the SPC seeks to compensate does not arise in respect of that substance.

56. Moreover, to allow what would, in essence, amount to a reclassification of a substance in the context of the SPC procedure would risk opening the door to strategic behaviour aimed at circumventing the MA framework. [31] More specifically, in practical terms, a request to reclassify a substance from excipient to active ingredient in the context of the SPC procedure is liable to arise in two types of situations.

57. First, a substance may have been declared and hence assessed as an excipient in the MA procedure. If an applicant were subsequently to assert, in the context of an SPC application, that the same substance is in fact an active ingredient, that would amount to circumventing the requirements applicable to active substances under the MA procedure – requirements which, precisely because of their rigour and duration, justify the compensatory mechanism of the SPC Regulation.

27 See recitals 2 to 6 and 9 of the SPC Regulation.

28 See also point 29 above and the judgment in *Teva II*, paragraph 61.

29 See the judgment in *Santen*, paragraphs 55 and 57.

30 See Annex I to the Medicinal Products Directive setting out the requirements regarding active substances and excipients; see also Max Planck Institute for Innovation and Competition, *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, Publications Office of the European Union, 2018 ('the MPI Study'), pp. 138 and 143.

31 See also, in that regard, the MPI Study, p. 143.

58. Secondly, a substance may have been declared as an active ingredient in the MA application, but ultimately assessed by the competent medicines authorities as having the role of an excipient. In such a case, the Medicinal Products Directive provides specific mechanisms for seeking a re-examination of that assessment. [32] The SPC procedure cannot serve as an alternative for challenging the conclusions reached in the MA procedure nor, as all of the intervening governments have observed, can national patent offices be called upon to substitute their assessment for that of the competent medicines authorities. [33]

59. The present case falls, in essence, within the first of those scenarios, albeit with a particular feature: Roche – which, as I understand it, has concluded an agreement with Halozyme concerning the use of rHuPH20 in Herceptin SC – did not declare rHuPH20 as an active ingredient in the relevant MA application. However, it is not Roche that has applied for the SPC, but Halozyme, in its capacity as holder of the basic patent. Halozyme submitted at the hearing that Roche ought, in its view, to have presented rHuPH20 as an active substance in the MA procedure. Be that as it may, the considerations set out above remain fully applicable. The SPC procedure cannot serve to rectify what Halozyme perceives as an error in the MA procedure, nor can it confer an advantage where the regulatory delay – which the SPC is intended to compensate – did not arise from the assessment of rHuPH20 as an active ingredient. [34]

(b) A simple and transparent system

60. In the second place, the Court has already recognised that, as is apparent from the legislative history of the SPC Regulation, the EU legislature intended to establish a system that is simple in its operation and based on conditions that are, in principle, straightforward to verify. [35] In that regard, paragraph 16 of the

32 As emphasised by the French Government and the Commission during the hearing; see Article 32(4) of the Medicinal Products Directive.

33 This is all the more so considering that, as the French Government correctly noted at the hearing, the EU Courts exercise only limited review in that field and cannot substitute their own scientific assessment for that of the competent medicines authorities; see, in that regard, judgment of 24 September 2025, *Sanofi* v *Commission* (T-483/22, EU:T:2025:912, paragraphs 73 to 81 and the case-law cited).

34 It should be added that the pathway followed for the approval of Herceptin SC (see point 13 above) also made it possible to avoid the additional constraints inherent in the assessment of a combination product – assuming, for the sake of argument, that rHuPH20 could have been regarded as an active substance. As observed by the Commission at the hearing, the modification of a medicinal product consisting in the introduction of an additional active ingredient cannot, in principle, be authorised as a line extension, but would require a new MA for a combination product. Such a procedure entails compliance with additional requirements, including, in particular, the need to demonstrate that the clinical advantages of the combination outweigh its potential disadvantages when compared with monotherapy (see, inter alia, in that regard, the EMA's *Guideline on clinical development of fixed combination medicinal products*).

35 See the judgment in *Teva II*, paragraph 55.

Explanatory Memorandum to the Commission's proposal for what eventually became the first regulation on SPCs ('the Explanatory Memorandum') [36] expressly refers to the establishment of 'a simple, transparent system which can easily be applied by the parties concerned', without imposing an excessive administrative burden on national patent offices. That same passage emphasises that the documentation required for an SPC application is 'limited to what is strictly necessary to enable the offices to take a decision' whether to grant the SPC and that examination of the relevant conditions 'involves the use of objective data that are easy to verify'.

61. Consistently with that objective, national patent offices are called upon to determine whether an SPC should be granted for a given substance, or combination of substances, on the basis of three documents only: (i) the applicant's request, (ii) the basic patent relied upon, and (iii) the MA relating to the medicinal product concerned.

62. It should be recalled, in that connection, that, under Article 8 of the SPC Regulation, the only essential supporting document required, in principle, in addition to the request itself, is a copy of the MA. [37] Significantly, as stated in paragraph 48 of the Explanatory Memorandum, that document is required precisely because it 'enables the product to be identified'.

63. Those elements taken together confirm, in my view, with particular clarity that the task of the national patent offices, when determining whether a substance qualifies as an 'active ingredient' for the purposes of the SPC Regulation, is confined to a formal verification of the classification attributed to that substance in the MA. In that regard, I concur with the majority of the governments submitting observations that the SPC Regulation neither requires nor permits national patent offices to go beyond the MA and undertake a fresh substantive assessment of the function of a substance within a medicinal product.

64. Such a reassessment in the context of the SPC procedure would be at odds with the objective of simplicity and efficiency pursued by that regulation, whilst at the same time undermine legal certainty. As stated in point 50 above, the evaluation of the properties and effects of a substance within a medicinal product entails complex and highly technical scientific evaluations. To replicate that

36 Explanatory Memorandum of 11 April 1990 to the Proposal for a Council Regulation (EEC) 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 the SPC Regulation. That explanatory memorandum must be considered relevant in so far as it concerns recitals and provisions (such as the ones at issue in the present case) that have remained essentially identical in the current SPC Regulation.

37 I note that the applicant is not even required to submit a copy of the basic patent claimed to cover the 'product' within the meaning of Article 3(a) of the SPC Regulation, as the national patent offices are expected to identify it themselves.

exercise in the context of the SPC procedure would inevitably render the examination more burdensome and protracted and would impose additional demands, in terms of both expertise and resources, on national patent offices. Indeed, it is far from evident how those offices, which do not possess the specialised scientific expertise of the competent medicines authorities, could reasonably carry out such an assessment in a consistent and reliable manner. Nor would recourse to external material, such as scientific publications or studies, as suggested by Halozyme, resolve those difficulties; on the contrary, it would introduce further uncertainty, in particular as regards the selection, probative value and consistent interpretation of such material across the Member States. [38]

(c) A uniform approach across Member States

65. In the third place, recitals 7 and 8 of the SPC Regulation make it clear that the EU legislature intended to establish a uniform system under which SPCs are granted, subject to identical conditions in all Member States, thereby safeguarding the proper functioning of the internal market.

66. That objective would be jeopardised if national patent offices were each to undertake an autonomous substantive assessment as to whether a given substance qualifies as an 'active ingredient' within the meaning of Article 1(b) of the SPC Regulation. Given the technical complexity inherent in such an assessment, that approach would inevitably give rise to divergences in the application of the SPC Regulation across the European Union, thus undermining the very objective pursued by the legislature.

67. This is, in essence, precisely what appears to have occurred in the present case. Halozyme's SPC applications, relating to the same medicinal product and based on the same basic patent and the same MA, [39] have led to conflicting

38 I would add that the approach advocated by Halozyme would, in practical terms, considerably complicate the task entrusted to national patent offices. It would affect not only the verification of whether a substance qualifies as a 'product', but also the assessment of whether the conditions for the grant of an SPC are satisfied. In that regard, reference may be made, in particular, to the condition, laid down in Article 3(d) of the SPC Regulation, according to which the MA relied upon must be 'the first authorisation to place the product on the market as a medicinal product'. As pointed out by Ireland, MAs are indexed in the Union Register of Medicinal Products by reference to their active substances. Accordingly, when determining whether an active ingredient – or a combination of active ingredients – has already been authorised, national patent offices are expected to carry out their verification by reference to the name of the substance concerned. If, however, a substance authorised solely as an excipient could nevertheless be treated as an active ingredient for the purposes of the SPC Regulation, that verification would become significantly more complex. In such a scenario, it would no longer be readily ascertainable whether that substance had already formed part of a medicinal product covered by an earlier authorisation, thereby undermining the clarity and reliability of the system.

39 The risk of divergent approaches is particularly pronounced in a situation such as that at issue in the present case, where a single centralised MA defines the composition of a medicinal product. That said, I would observe that, even where MAs are granted under decentralised or mutual recognition procedures, the coordination mechanisms established at EU level are designed to

outcomes across Member States – a result which, in my view, should not have arisen.

3. Halozyme's arguments

68. That conclusion is not, however, called into question by the arguments put forward by Halozyme, which I shall now examine.

(a) Actual efficacy over regulatory classification

69. Halozyme submits that, for the purposes of the SPC Regulation, the decisive criterion in determining whether a substance constitutes an 'active ingredient' lies in its actual efficacy, rather than its regulatory classification in the MA. Halozyme seeks to draw that proposition from the Court's case-law.

70. It should be clarified at the outset that, by 'actual efficacy', Halozyme does not refer to an intrinsic and immutable property of a given substance; all interested parties, including Halozyme itself, acknowledged at the hearing that the 'active' nature of a substance cannot be determined in the abstract, but depends on the function it performs within a specific medicinal product. The same substance may thus constitute an active ingredient in one medicinal product but an excipient in another. By way of illustration, as mentioned during the hearing, vitamin C is an active substance when used for the treatment for scurvy, but serves merely as an excipient – typically as an antioxidant – in many other medicinal products. That understanding is reflected in Article 1(3a) of the Medicinal Products Directive, which defines an active substance as one that, 'when used in [the] production [of a medicinal product], *becomes an active ingredient* of that product' (emphasis added).

71. Whilst that premiss is not in dispute, the parties diverge as to its implications. The governments submitting observations take the view that the function of a substance in an authorised medicinal product can only be that which has been assessed, approved and expressly identified in the MA. Halozyme, by contrast, contends that that function must be reassessed autonomously in the context of the SPC procedure. In support of that argument, it relies principally on the Court's judgment in *Forsgren*. [40]

72. In that judgment, the Court held that a substance may be classified as an active ingredient within the meaning of Article 1(b) of the SPC Regulation 'only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the [MA], a

ensure, in principle, a consistent classification of substances across Member States. That consistency ought, in turn, to be reflected in a uniform approach to the grant of SPCs.

40 Judgment of 15 January 2015, *Forsgren* (C-631/13, 'the judgment in *Forsgren*', EU:C:2015:13).

matter which it is for the referring court to determine, in the light of all the facts of the dispute in the main proceedings'. [41] Halozyme infers from that passage that Article 1(b) requires a substantive assessment of therapeutic efficacy based on all relevant facts, rather than a strict reliance on the classification set out in the MA. It further submits that rHuPH20 satisfies the criteria laid down in the judgment in *Forsgren*, in so far as it produces an action of its own which is covered by the therapeutic indications of Herceptin SC, namely the treatment for breast cancer (see also point 40 above).

73. Admittedly, if read in isolation, that passage of the judgment in *Forsgren* might be seen as lending support to Halozyme's position. It also appears to have contributed, to some extent, to the divergent outcomes observed in the present case across the Member States.

74. However, in my view, that judgment cannot be interpreted in such broad terms. It must instead be read in the light of its specific factual context. [42] In that case, the substance at issue had not been clearly classified in the MA: it did not appear on the list of excipients but was mentioned alongside the active substances, as a carrier protein, without being designated explicitly as an active substance. It was precisely because of that ambiguity that the Court left it to the referring court to determine the function of the substance at issue on the basis of all the relevant facts. Accordingly, and in line with the position taken by the governments submitting observations, the Commission and the referring court, the judgment in *Forsgren* should, at most, be understood as applying to such exceptional circumstances. [43]

75. In any event, as emphasised at the hearing by the French Government, the judgment in *Forsgren* does not call into question the authority of the MA. On the contrary, in that judgment the Court repeatedly referred to the wording of the MA, holding in particular that an SPC cannot be granted for 'an active ingredient whose effect does not fall within the therapeutic indications covered by *the wording of the* [*MA*]' (emphasis added). [44]

76. Against that background, I find it difficult to qualify Halozyme's position as consistent. It accepts that the therapeutic indications set out in the MA must be taken into account, yet seeks, at the same time, to disregard the MA as regards the classification of the substances which are considered to fulfil – or not – those indications. In essence, that approach would treat the MA as authoritative with

41 Ibid., paragraph 54 and the operative part.

42 This seems also to have been the case in the facts giving rise to the order in *GSK*, on which Halozyme also relies. The same considerations are, therefore, equally relevant.

43 If the Court were to consider that the judgment in *Forsgren* can only be read in the broad terms proposed by Halozyme, then I would respectfully propose, as the Netherlands Government has also submitted, that the Court revisit that judgment.

44 The judgment in *Forsgren*, paragraph 39 and the operative part.

respect to the 'ends' of the medicinal product, but not as to the 'means' by which those ends are achieved. I do not find that distinction convincing.

77. For the sake of completeness, I shall briefly address the remaining arguments put forward by Halozyme. First, it relies on the judgment in *MIT*, one of the earliest judgments on the topic, arguing that therein the Court examined the efficacy of the substance at issue from a purely factual perspective, without regard to its classification in the MA. That argument, however, overlooks the legislative context of that case. At the material time, the predecessor of the Medicinal Products Directive in respect of MAs [45] did not define the concepts of 'active substance' and 'excipient', or clearly distinguish between them, or require a list of excipients to be included in the summary of product characteristics. In that less-developed regulatory framework, it was only natural for the Court to clarify the meaning of those concepts first, before concluding that excipients do not fall within the concept of 'product'.

78. Secondly, Halozyme refers to the judgment in *Bayer CropScience*, [46] arguing that it likewise shows that the classification in the MA is not decisive. That case, however, concerned plant protection products which are governed by a distinct legal framework. The question was whether a substance classified as a 'safener' [47] in the MA could nevertheless constitute a 'product' and thus justify the grant of an SPC. The Court held that a substance classified as a 'safener' in the relevant MA could constitute a 'product', provided that it exerts a toxic, phytotoxic or plant protection action of its own, in particular through its effect on plant metabolism.

79. Whilst I harbour certain reservations as to the reasoning adopted in that judgment, suffice it to observe, for present purposes, that, as noted by most of the governments submitting observations and by the Commission, even though there are similarities between the two SPC regimes, the regulatory framework applicable to plant protection products differs in significant respects from that governing medicinal products. Accordingly, the reasoning in *Bayer CropScience* cannot be transposed to the present case.

(b) Regulatory delays actually incurred

80. Halozyme has put forward a further argument based on the objective of the SPC Regulation, namely to compensate for regulatory delays so as to encourage

45 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition: Series I Chapter 1965-1966, p. 24), in the version applicable at the material time.

46 Judgment of 19 June 2014, *Bayer CropScience* (C-11/13, EU:C:2014:2010).

47 Safeners are substances or preparations which are added to a plant protection product to eliminate or reduce the latter's phytotoxic effects on certain plants.

costly and lengthy pharmaceutical research. In that regard, it submits that rHuPH20 ought to be eligible for an SPC, since its combination with trastuzumab required extensive clinical testing, including full Phase III trials, in order to obtain the line extension of the MA for Herceptin SC (see point 13 above). A strict reliance on the classification contained in the MA would, in its view, deprive the holder of the basic patent of the possibility of obtaining an SPC, notwithstanding the delays thus incurred.

81. However, as has been explained in point 54 et seq. above, the SPC regime is not intended to compensate for every regulatory delay encountered by a patent holder, but only for those associated with the authorisation of 'new active ingredients'. While it is not disputed that Halozyme may have faced significant delays, the decisive consideration is that those delays did not arise from the assessment and approval of rHuPH20 as a new active ingredient; rather, they stemmed from the fact that Herceptin SC involves a new route of administration, which necessitated additional studies to assess its impact on the performance of trastuzumab. Moreover, rHuPH20 as a novel excipient – that is to say, an excipient used for the first time in a medicinal product – required a specific safety assessment and the submission of additional supporting data. [48]

82. Whether other forms of pharmaceutical and medical innovation, such as the development of novel excipients or medical devices, [49] should also benefit from supplementary protection is ultimately a matter for the legislature. Under the current legal framework, however, such innovations, in so far as they do not relate to new active substances, may be protected by patents but do not qualify for the supplementary protection afforded by SPCs.

83. As a final point, I would add that even if research carried out after the granting of the MA, such as that reflected in scientific articles or external studies, were to demonstrate that rHuPH20 performs a function comparable to that of an active ingredient, that would not justify disregarding its classification in the MA. As already noted, SPCs are intended to protect 'the investment put [by the patent holder] into research' leading to the first placing on the market of an active ingredient or a combination of active ingredients. [50] Scientific findings that emerge after the grant of an MA, and which did not form part of its assessment, cannot, in my view, be taken into account for the purposes of granting an SPC. [51]

84. In the light of all the foregoing considerations, I am of the opinion that the first question referred should be answered in the affirmative, to the effect that a

48 See, inter alia, sections 2.4 and 3.2.2.4(d) of Annex I to the Medicinal Products Directive.

49 See, in that regard, the MPI study, pp. 465 to 469.

50 See point 54 above and the judgment in *Santen*, paragraphs 55 and 57.

51 See, by analogy, judgments of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraphs 41 to 43), and of 30 April 2020, *Royalty Pharma Collection Trust* (C-650/17, EU:C:2020:327, paragraphs 45 and 46).

substance expressly designated as an excipient in the relevant MA cannot be regarded as an active ingredient within the meaning of Article 1(b) of the SPC Regulation.

85. In those circumstances, there is no need to answer the second to fourth questions, which have been raised only in the event that the first question was answered in the negative, since they concern the material on the basis of which an autonomous assessment would have to be carried out if the MA classification were not decisive.

V. Conclusion

86. In the light of the foregoing, I propose that the Court of Justice answer the first question referred as follows:

Article 1(b) 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 meaning that the qualification of a substance as an 'active ingredient' within the meaning of that provision is to be determined by reference to the classification of substances set out in the marketing authorisation relied upon in support of the application for a supplementary protection certificate. Consequently, a substance which is expressly designated as an 'excipient' in that marketing authorisation cannot be regarded as an 'active ingredient' for the purposes of that regulation.