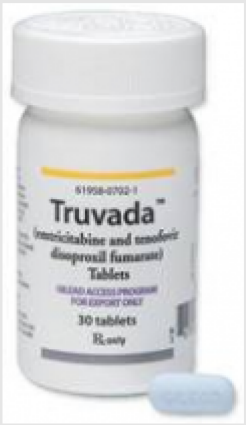
Court of Justice EU, 25 July 2018, Teva v Gilead



PATENT LAW

Product composed of several active ingredients with a combined effect can be protected by a basis patent in force, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, if, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

- **the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and**
- **each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent**

Having regard to all the foregoing considerations, the answer to the question referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product composed of several active ingredients with a combined effect is *'protected by a basic patent in force'* within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

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Court of Justice EU, 25 July 2018

(K. Lenaerts, A. Tizzano, R. Silva de Lapuerta, M. Ilešič, J.L. da Cruz Vilaça, C.G. Fernlund, C. Vajda, J.-C. Bonichot, A. Arabadjiev, C. Toader, M. Safjan, S. Rodin, and K. Jürimäe)

JUDGMENT OF THE COURT (Grand Chamber)

25 July 2018 (*)

(Reference for a preliminary ruling — Medicinal products for human use — Treatment of human immunodeficiency virus (HIV) — Originator medicines and generic medicines — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 3(a) — Conditions for obtaining — Concept of a *'product protected by a basic patent in force'* — Criteria for assessment)

In Case C‑121/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England & Wales), Chancery Division (Patents Court), made by decision of 23 February 2017, received at the Court on 8 March 2017, in the proceedings

Teva UK Ltd,

Accord Healthcare Ltd,

Lupin Ltd,

Lupin (Europe) Ltd,

Generics (UK) Ltd, trading as *'Mylan'*,

v

Gilead Sciences Inc.,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, A. Tizzano, Vice-President, R. Silva de Lapuerta, M. Ilešič, J.L. da Cruz Vilaça, C.G. Fernlund and C. Vajda, Presidents of Chambers, J.-C. Bonichot, A. Arabadjiev, C. Toader, M. Safjan, S. Rodin, and K. Jürimäe (Rapporteur), Judges,

Advocate General: M. Wathelet,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 20 February 2018,

after considering the observations submitted on behalf of:

– Teva UK Ltd, by D. Alexander, QC, and S. Carter and L. Lane, Barristers, instructed by C. Tunstall, Solicitor,

– Accord Healthcare Ltd, by D. Alexander, QC and K. Pickard, Barrister, instructed by S. Ma, Solicitor,

– Lupin (Europe) Ltd and Lupin Ltd, by D. Alexander, QC, and J. Riordan, Barrister, instructed by D. Rose, Solicitor,

– Generics (UK) Ltd, trading as *'Mylan'*, by D. Alexander, QC, and J. Delaney, Barrister, instructed by M. Royle, Solicitor,

– Gilead Sciences Inc., by T. Mitcheson, QC, and J. Whyte, Barrister, instructed by S. Moore, Solicitor,

– the United Kingdom Government, by G. Brown, acting as Agent, and by N. Saunders, Barrister,

– the Greek Government, by M. Tassopoulou, D. Tsagkaraki and S. Papaioannou, actinEu:g as Agents,

– the Latvian Government, by I. Kucina, acting as Agent,

– the Netherlands Government, by M.K. Bulterman and M. Gijzen, acting as Agents,

– the European Commission, by É. Gippini Fournier and J. Samnadda, acting as Agents,

after hearing **the Opinion of the Advocate General** at the sitting on 25 April 2018,
gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

2 The request has been made in proceedings between Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lupin (Europe) Ltd and Generics (UK) Ltd, trading as *'Mylan'*, on the one hand and, on the other, Gilead Science Inc. (*'Gilead'*) concerning the validity of a supplementary protection certificate (*'the SPC'*) granted to the latter for a pharmaceutical product for the treatment of human immunodeficiency virus (*'HIV'*).

Legal context

European Patent Convention

3 Under the heading *'Extent of protection'*, Article 69 of the Convention on the Grant of European Patents, signed in Munich on 5 October 1973, in the version applicable at the material time in the main proceedings (*'the EPC'*), stipulates as follows:

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

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

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

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

European Union law

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

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

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

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

...

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

...

(9) The duration of the protection granted by the [SPC] should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a[n SPC] should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the [Union].

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the [SPC] cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

6 Article 1 of that regulation provides:

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

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

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

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

...'

7 Article 3 of that regulation, entitled *'Conditions for obtaining a[n SPC]'*, provides as follows:
'A[n SPC] shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
(a) the product is protected by a basic patent in force;
(b) a valid authorisation to place the product on the market as a medicinal product has been granted …;
(c) the product has not already been the subject of a[n SPC];
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.'
8 Article 4 of that regulation, entitled *'Subject-matter of protection'*, provides as follows:
'Within the limits of the protection conferred by the basic patent, the protection conferred by a[n SPC] shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the [SPC].'
9 Article 5 of Regulation No 469/2009, relating to the *'[e]ffects of the [SPC]'*, states:
'Subject to the provisions of Article 4, the [SPC] shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.'
10 Article 13 of that regulation, entitled *'Duration of the [SPC]'*, provides in paragraph 1 thereof as follows:
'The [SPC] shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the [Union], reduced by a period of five years.'

United Kingdom law

11 Section 60 of the UK Patents Act 1977 (*'the Patents Act 1977'*), relating to the *'[m]eaning of infringement'*, is worded as follows:
'(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say:
(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
…
(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.'
12 Under the heading *'Extent of invention'*, section 125 of the Patents Act 1977 provides as follows:
'(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.
…
(3) The Protocol on the Interpretation of Article 69 of the [EPC] (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.
…'
13 Pursuant to section 130(7) of the Patents Act 1977:
'Whereas by a resolution made on the signature of the [EPC] the governments of the member states of the [Union] resolved to adjust their laws relating to patents so as (among other things) to bring those laws into conformity with the corresponding provisions of the [EPC] …, it is hereby declared that the following provisions of this Act, that is to say, sections … 60 … and 125, are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the [EPC] … have in the territories to which [that convention applies].'

The dispute in the main proceedings and the question referred for a preliminary ruling

14 Gilead is a pharmaceutical company which markets an antiretroviral medicinal product indicated for the treatment of persons infected with HIV, under the name TRUVADA. That medicinal product contains two active ingredients, tenofovir disoproxil (*'TD'*) and emtricitabine, which have a combined effect for that treatment. It was granted a marketing authorisation (*'MA'*) on 21 November 2005 by the European Medicines Agency (EMA).
15 Gilead is the holder of the European patent (UK) EP 0 915 894 (*'the basic patent at issue'*). The patent application, filed on 25 July 1997, had a priority date, for the purposes of Article 88 of the EPC, of 26 July 1996. That patent was granted by the European Patent Office (EPO) on 14 May 2003 and expired on 24 July 2017. The description of the invention contained in that patent indicates that the patent covers, in general terms, a series of molecules which are helpful in the therapeutic treatment of a number of viral infections in humans and animals, in particular HIV.
16 That description gives a series of pharmaceutical formulae which may be envisaged for the compounds claimed, without referring specifically to individual compounds or to any particular use for those compounds. Claim 25 of the basic patent at issue

expressly mentions TD as one of the claimed compounds.

17 That description also mentions the fact that those compounds may, if necessary, be associated with *'other therapeutic ingredients'*. The words *'other therapeutic ingredients'*, however, are neither defined nor explained in the basic patent at issue.

18 In that regard, claim 27 of the basic patent at issue states:

'A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.'

19 In 2008, Gilead obtained an SPC on the basis of claim 27 of the basic patent at issue and the MA (*'the SPC at issue'*). That SPC relates to a *'composition containing [TD], optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine'*.

20 The order for reference states that there is no evidence that at the priority date of the basic patent at issue, emtricitabine was an effective agent known to the person skilled in the art for the treatment of HIV in humans. The EMA did not approve emtricitabine until 2003.

21 The applicants in the main proceedings, who intend to market generic versions of TRUVADA on the UK market, brought an action before the referring court, the High Court of Justice (England & Wales), Chancery Division (Patents Court), seeking to challenge the validity of the SPC at issue.

22 In support of their action, the applicants in the main proceedings submit that the SPC does not meet the condition laid down in Article 3(a) of Regulation No 469/2009. They point out that to meet the requirement in that provision, the product in question must, in accordance with **the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773)**, be *'specified in the wording of the claims'*. Where there is a functional definition in the relevant claim relating to the product, that claim must *'relate, implicitly but necessarily and specifically'* to that product, in accordance with the terms used by the Court in **the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835)**. The applicants in the main proceedings submit that emtricitabine is not specified in the wording of claim 27 of the basic patent at issue and that the expression *'other therapeutic ingredients'* used in that claim does not specify any active ingredient, whether structurally or functionally. The TD/emtricitabine combination cannot therefore be considered to be protected by a basic patent in force, within the meaning of Article 3(a) of Regulation No 469/2009.

23 By contrast, Gilead contends in essence that, in order to check whether Article 3(a) of Regulation No 469/2009 is satisfied, it is necessary and sufficient that the product in question falls within the extent of the protection conferred under at least one claim of the basic patent. It submits that the expression *'other therapeutic ingredients'* used in claim 27 of the basic patent at issue relates implicitly but necessarily to emtricitabine, in accordance with **the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835)**. The TD/emtricitabine combination therefore, it argues, satisfies the condition laid down in that article.

24 The referring court takes the view that, notwithstanding the judgments delivered by the Court on interpretation of Article 3(a) of Regulation No 469/2009, the meaning to be given to that provision remains unclear.

25 That court states that, admittedly, it is clear from the Court's case-law that the concept of a *'product protected by a basic patent'* within the meaning of Article 3(a) of Regulation No 469/2009 refers to the rules governing the extent of protection, not the rules governing infringement. Furthermore, it follows from paragraph 28 of **the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773)**, that to be considered *'protected by a basic patent'* within the meaning of that provision, the active ingredients should be specified in the wording of the claims of the patent in question.

26 Nevertheless, the judgments of **12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833)**, of **12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835)**, and of **12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165)** imply that the principles described in the preceding paragraph are not sufficient for the purposes of determining whether a *'product is protected by a basic patent in force'* and that it is also necessary to take into account the *'subject-matter of the invention covered by the patent'* or the *'core inventive advance'* of the patent. The referring court takes the view that it is not clear from that case-law whether those requirements are relevant for the purposes of the interpretation of Article 3(a) of Regulation No 469/2009.

27 According to the referring court, there are also divergent decisions in a number of Member States concerning the issue, before the court in the present case, of the availability of an SPC for the TD/emtricitabine combination and, more generally, concerning the interpretation of Article 3(a) of Regulation No 469/2009.

28 In those circumstances, the High Court of Justice (England & Wales), Chancery Division (Patents Court) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No 469/2009?'

Consideration of the question referred

29 It must be observed at the outset that it is apparent from the information provided by the referring court that, in the case in the main proceedings, the product which is the subject of the SPC at issue is composed of two active ingredients, identified as TD on one hand

and emtricitabine on the other. The claims in the basic patent at issue mention expressly only the first of those two active ingredients, and the second can only be covered by the phrase *'other therapeutic ingredients'* in claim 27 of that patent.

30 In that regard, that court raises the issue of the interpretative criteria applicable to the claims in a basic patent for the purposes of ascertaining whether a product is *'protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009. In particular, it wonders, first, what the applicable rules of patent law are for that purpose and, secondly, having regard to the Court's case-law, whether, in order for the condition laid down in Article 3(a) of Regulation No 469/2009 to be satisfied, it is sufficient that the active ingredients of the product which is the subject of the SPC are mentioned in the claims in the basic patent in force or that those claims relate to the active ingredients implicitly but necessarily, or whether an additional criterion must be applied.

31 According to the Court's settled case-law, since no harmonised European Union patent rules are applicable in the main proceedings, the extent of the protection conferred by a basic patent can be determined only in the light of the non-European Union rules governing patents (see, to that effect, **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraph 31 and the case-law cited).

32 The Court has stated that the rules for determining what is *'protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, just as is provided, in the case before the Court, in Article 69 of the EPC and the Protocol on the interpretation of that provision, to which section 125 of the UK Patents Act 1977 gives effect in the United Kingdom (see, to that effect, **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraph 32).

33 First, for the purpose of applying Article 3(a) of Regulation No 469/2009, recourse may not be had to the rules governing infringement proceedings, such as, in the main proceedings, those laid down in section 60 of the UK Patents Act 1977 (see, to that effect, **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraph 33).

34 Secondly, the Court has repeatedly emphasised the key role played by the claims for the purpose of determining whether a product is protected by a basic patent within the meaning of that provision (see, to that effect, **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraph 34 and the case-law cited).

35 So far as, specifically, the European patent is concerned, pursuant to Article 69 of the EPC, the extent of the protection conferred by such a patent is determined by the claims. The information in Article 1 of the Protocol on the Interpretation of Article 69 of the EPC states that those claims must ensure both a fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties. Thus, they are not to serve only as a guideline, nor can they be interpreted as meaning that the extent of the protection conferred by a patent is that defined by the narrow, literal meaning of the wording used in the claims.

36 In this respect, the Court has held that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a basic patent issued by the EPO being regarded as protected by the patent, on condition that it is possible, on the basis of those claims as interpreted inter alia in the light of the description of the invention, as required under Article 69 of the EPC and Protocol on the Interpretation of that provision, to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question (see **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraph 39).

37 Therefore, a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a) of Regulation No 469/2009 unless the product which is the subject of the SPC is either expressly mentioned in the claims of that patent or those claims relate to that product necessarily and specifically.

38 For that purpose, in accordance with the case-law cited in paragraph 36 above, the description and drawings of the basic patent must be taken into account, as stipulated in Article 69 of the EPC read in the light of the Protocol on the Interpretation of that provision, where that material shows whether the claims of the basic patent relate to the product which is the subject of the SPC and whether that product in fact falls under the invention covered by that patent.

39 That requirement is in line with the objective of the SPC, which is to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted. As indicated in recital 4 of Regulation No 469/2009, the purpose of that additional period of exclusivity is to encourage research and, to that end, it is designed to ensure that the investments put into such research are covered (see, to that effect, **judgment of 12 December 2013, Eli Lilly and Company, C‑493/12, EU:C:2013:835**, paragraphs 41 and 42 and the case-law cited).

40 However, it is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers. It would be contrary to the objective of Regulation No 469/2009, reiterated in the preceding paragraph, to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent.

41 In the light of the need, referred to inter alia in recital 10 of the preamble to Regulation No 469/2009, to take into account all the interests at stake, including those of public health, to accept that an SPC could grant to the holder of the basic patent protection which goes beyond the protection guaranteed by that patent in connection with the invention it covers would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs (see, by analogy, **judgment of 12 March 2015, Actavis Group PTC and Actavis UK, C‑577/13, EU:C:2015:165**, paragraph 36 and the case-law cited).
42 It must be added that, in view of the interests referred to in recitals 4, 5, 9 and 10 of Directive 469/2009, it cannot be accepted that the holder of a basic patent in force may obtain an SPC each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject matter of the invention covered by the basic patent (see, to that effect, **judgment of 12 March 2015, Actavis Group PTC and Actavis UK, C‑577/13, EU:C:2015:165**, paragraph 37 and the case-law cited).
43 Accordingly, having regard to the objectives pursued by Regulation No 469/2009, the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent. Thus for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that invention, as it appears from the description and the drawings of that patent.
44 That interpretation is borne out by Article 4 of Regulation No 469/2009, which provides that the protection granted by the SPC extends only to the product covered by the MA granted for the corresponding medicinal product and for any use of the product as a medicinal product that has been authorised before the expiry of the SPC, exclusively *'[w]ithin the limits of the protection conferred by the basic patent'*.
45 The same is true regarding Article 5 of that regulation, under which the SPC confers the same rights as conferred by the basic patent and is subject to the same obligations. Accordingly, if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate (judgments of **24 November 2011, Medeva, C‑322/10, EU:C:2011:773**, paragraph 39, and of **24 November 2011, Georgetown University and Others, C‑422/10, EU:C:2011:776**, paragraph 32).
46 It follows from the above that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent, such as claimed in that patent.
47 With regard to the implementation of that rule, it must in the first place be stated that, in accordance with a principle shared by the patent laws of the Member States and reflected in Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, the claims of a patent are to be interpreted from the perspective of a person skilled in the art and, therefore, the issue whether the product which is the subject of the SPC necessarily falls under the invention covered by that patent must be assessed from that perspective.
48 To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent.
49 In the second place, having regard to the objective of Regulation No 469/2009, recalled in paragraph 39 above, for the purposes of assessing whether a product falls under the invention covered by a basic patent, account must be taken exclusively of the prior art at the filing date or priority date of that patent, such that the product must be specifically identifiable by a person skilled in the art in the light of all the information disclosed by that patent.
50 Were it to be accepted that such an assessment could be made taking into account results from research which took place after the filing date or priority date of the basic patent, an SPC could enable its holder unduly to enjoy protection for those results even though they were not yet known at the priority date or filing date of that patent, what is more outside any procedure for the grant of a new patent. That would, as pointed out in paragraphs 40 and 41 above, run counter to the objective of Regulation No 469/2009.
51 Therefore, for the purposes of determining whether a product which is the subject of an SPC is protected by a basic patent, within the meaning of Article 3(a) of that regulation, that product must be identifiable specifically by a person skilled in the art in the light of all the information disclosed by the basic patent and of the prior art at the filing date or priority date of that patent.
52 Having regard to all the foregoing considerations, a product is *'protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009 in so far as, if that product is not expressly mentioned in the claims of the basic patent, one of those claims relates to it necessarily and specifically. For that purpose, that product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by that

patent. The person skilled in the art must be able identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned.

53 Such an interpretation of Article 3(a) of Regulation No 469/2009 must also be upheld in a situation, such as that at issue in the case in the main proceedings, where the products which are the subject of a SCP are composed of several active ingredients which have a combined effect.

54 Thus, as regards the issue whether a claim such as claim 27 of the basic patent in fact covers a combination such as the TD/emtricitabine combination which is the subject of the SPC at issue, it falls to the referring court to determine whether the general expression *'other therapeutic ingredients'*, associated with the term *'optionally'*, satisfies the requirement that the claims of the basic patent must relate necessarily and specifically to the product.

55 In particular, it is for the referring court to ascertain, in accordance with the considerations in paragraphs 47 to 51 above, whether, from the point of view of a person skilled in the art, the combination of active ingredients of which the product which is the subject of the SPC at issue consists necessarily falls under the invention covered by that patent, and whether each of those active ingredients is specifically identifiable on the basis of the prior art at the filing date or priority date of that patent.

56 In the present case it is apparent, first, from the information in the order for reference that the description of the basic patent at issue contains no information as to the possibility that the invention covered by that patent could relate specifically to a combined effect of TD and emtricitabine for the purposes of the treatment of HIV. Consequently, it does not seem possible that a person skilled in the art, on the basis of the prior art at the filing date or priority date of that patent, would be able to understand how emtricitabine, in combination with TD, necessarily falls under the invention covered by that patent. The onus is nevertheless on the referring court to check whether such is indeed the case. Secondly, it is also for that court to establish whether emtricitabine is specifically identifiable by that person skilled in the art in the light of all the information contained in that patent, on the basis of the prior art at the filing date or priority date of the patent in question.

57 Having regard to all the foregoing considerations, the answer to the question referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product composed of several active ingredients with a combined effect is *'protected by a basic patent in force'* within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

Costs

58 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Article 3(a) of Regulation 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 a product composed of several active ingredients with a combined effect is *'protected by a basic patent in force'* within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

Lenaerts
Tizzano
Silva de Lapuerta
Ilešič
Da Cruz Vilaça
Fernlund
Vajda
Bonichot
Arabadjiev
Toader
Safjan
Rodin
Jürimäe

Delivered in open court in Luxembourg on 25 July 2018.

A. Calot Escobar
Registrar

K. Lenaerts
President

* Language of the case: English.

Opinion of A-G Wathelet
delivered on 25 April 2018 (1)
Case C‑121/17
Teva UK Ltd,
Accord Healthcare Ltd,
Lupin Ltd,
Lupin (Europe) Ltd,
Generics (UK) trading as *'Mylan'*
v
Gilead Sciences Inc.
(Request for a preliminary ruling from the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom))
(Reference for a preliminary ruling — Approximation of laws — Patent law — Supplementary protection certificate for medicinal products — Regulation (EC) No 469/2009 — Article 3(a) — Conditions for obtaining — Product protected by a basic patent in force — Criteria for assessment)

I. Introduction

1. This request for a preliminary ruling, lodged with the Court Registry on 8 March 2017 by the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom) concerns the interpretation of Article 3(a) 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. (2)

2. The request has been made in proceedings brought by Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lupin (Europe) Ltd and Generics (UK), trading as *'Mylan'*, against Gilead Sciences Inc. (*'Gilead'*). In the main proceedings, the applicants are challenging the validity of Gilead's supplementary protection certificate (*'SPC'*) SPC/GB05/041 for a product described in the SPC as a *'composition containing both Tenofovir disoproxil, optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine'*. The product covered by the SPC is an anti-retroviral medication used in the treatment of human immunodeficiency virus (HIV) and is marketed by Gilead under the trade mark Truvada.

3. Gilead claims that the product covered by the SPC is *'protected'* within the meaning of Article 3(a) of Regulation No 469/2009 by a European patent but the applicants in the main proceedings dispute that claim. The latter therefore contend that the SPC does not comply with Article 3(a) of that regulation.

4. The request for a preliminary ruling affords the Court a further opportunity to rule on the thorny issue of the criteria for determining whether an active ingredient (3) or combination of active ingredients of a medicinal product is *'protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009. (4)

II. Legal context

A. EU law

5. Recitals 4, 5, 9 and 10 of Regulation No 469/2009 read as follows:

'(4) At the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.
(5) This situation leads to a lack of protection which penalises pharmaceutical research.
...
(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.
(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

6. Article 1 of that regulation, headed *'Definitions'*, provides:

'For the purposes of this Regulation, the following definitions shall apply:
(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings ...;
(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;
(c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
(d) "certificate" means the [SPC];
...'

7. Article 3 of Regulation No 469/2009, headed *'Conditions for obtaining a certificate'*, 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 [of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use] (OJ 2001 L 311, p. 67)] ...;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.'

B. The European Patent Convention

8. Under the heading *'Extent of protection'*, Article 69 of the Convention on the Grant of European Patents, signed in Munich on 5 October 1973, in the version applicable at the material time in the main proceedings (*'the EPC'*), is worded as follows:

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

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

9. Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, which forms an integral part of the convention in accordance with Article 164(1) thereof, provides as follows in relation to Article 69:

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

10. Article 83 of the EPC, headed *'Disclosure of the invention'*, states as follows:

'The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.'

11. Article 84 of the EPC, headed *'Claims'*, provides that *'the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.'*

C. United Kingdom law

12. Article 69 of the EPC and the Protocol on its interpretation were given effect in the United Kingdom by section 125(1) and (3) of the Patents Act 1977 (*'the Patents Act 1977'*).

13. Under the heading *'Extent of invention'*, section 125 of the Patents Act 1977 provides:

'(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

...

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.'

III. The main proceedings and the question referred for a preliminary ruling

14. Gilead is a pharmaceutical company which markets an antiretroviral medicinal product indicated for the treatment of persons infected with HIV, under the name Truvada. That medicinal product contains two active ingredients, tenofovir disoproxil (*'TD'*) and emtricitabine. (5) It was granted marketing authorisation (*'MA'*) in 2005 by the European Medicines Agency (EMA).

15. Gilead holds European patent No EP 0 915 894 (*'the basic patent'*). That patent, which was applied for on 25 July 1997 with a claimed priority date of 26 July 1996, was granted on 14 May 2003 and expired on 24 July 2017. It covers, in general terms, a series of molecules which are helpful in the therapeutic treatment of a number of viral infections in humans and animals, in particular HIV.

16. The *'Summary of the Invention'* states that the invention provides compounds in accordance with two Markush formulae, formula (1a) and formula (1), and methods for preparing such compounds.

17. Claim 1 is a claim to compounds of formula (1a) and claim 2 is a claim to compounds of formula (1). Claims 3 to 24 are dependent compound claims which get progressively narrower in scope.

18. Claim 25 is an independent compound claim to TD.

19. Claim 27 is in the following terms:

'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 ingredients.' (6)

20. Claims 28 to 33 are method claims.

21. In 2008, Gilead was granted SPC SPC/GB05/041 on the basis of claim 27 of the basic patent and the MA obtained for Truvada. The SPC relates to a *'composition containing [TD], optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine'*. (7)

22. The applicants in the main proceedings, who intended to market generic versions of Truvada on the UK market once the basic patent had expired, brought proceedings before the referring court disputing the validity of that SPC.

23. In support of their action, the applicants in the main proceedings argue essentially that, in order for Article 3(a) of Regulation No 469/2009 to be satisfied, the product in question must be *'specified in the wording of the claims'* (8) and, where the claim contains a functional definition, it must *'relate, implicitly but necessarily and specifically'* to that product. (9) They

observe that emtricitabine is not specified anywhere in the wording of claim 27 and that the words *'other therapeutic ingredients'* do not specify any active ingredient, whether structurally, functionally or otherwise. *'On the contrary, they cover a virtually unlimited range of active ingredients for the treatment of many diseases. Indeed, emtricitabine was not approved for clinical use until seven years after the priority date of the Patent and there is no evidence that it was known to be efficacious at that date.'*

24. The applicants in the main proceedings also contend that claim 27 does not require the presence of any *'other therapeutic ingredients'* since such ingredients are only *'optionally'* present. According to the applicants, *'it is clear from the case-law of the [Court] that it is not enough that a claim to "A composition comprising compound A" would be infringed due to the presence of A in a combination product consisting of A and B. There is no distinction between such a claim and a claim to "A composition consisting of compound A and optionally other active ingredients"'*.

25. Gilead asserts that in order for Article 3(a) of Regulation No 469/2009 to be satisfied, it is necessary and sufficient that the product in question falls within the scope of protection of at least one claim of the basic patent applying the Extent of Protection Rules. (10) It takes the view that the combination of TD and emtricitabine does fall within the scope of protection of claim 27 of the patent under Article 69 of the EPC and under the Protocol on interpretation.

26. The referring court considers that, notwithstanding the many judgments delivered by the Court of Justice on interpretation of Article 3(a) of Regulation No 469/2009, (11) the meaning to be given to that article *'remains unclear'*. The referring court asserts that the need to make a reference to the Court of Justice is confirmed by the divergent decisions that have been reached around Europe as to the availability of an SPC on the facts of the present case and by the differing interpretations of Article 3(a) of Regulation No 469/2009 that have been adopted in the case-law of the national courts. (12)

27. The referring court states that it is not sufficient that the product falls within at least one claim of the basic patent and that *'more is required'*. The judgments of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833), of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), and of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), suggest that, in order to determine whether a *'product is protected by a basic patent'*, *'the subject matter of the invention covered by the basic patent'* or the *'core inventive advance'* must also be taken into consideration. However, the referring court submits, those judgments do not make clear the meaning and scope of those new tests, or even whether they apply to interpretation of Article 3(a) of Regulation No 469/2009. (13)

28. According to the referring court, the product must contain an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. (14)

29. In the present case, the referring court notes that emtricitabine is not mentioned in the basic patent at issue. Nor is there any evidence that emtricitabine was known to be efficacious for the treatment of HIV on the priority date claimed by that patent. In view of those considerations, the referring court hesitates to find that the TD/emtricitabine combination is protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, especially as the criteria laid down in the case-law provide but little clarification for the purpose of resolving that question.

30. In those circumstances, the High Court of Justice (England and Wales), Chancery Division (Patents Court) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No 469/2009.'

IV. Procedure before the Court of Justice

31. The referring court included with its request for a preliminary ruling a request for the case to be decided under the expedited procedure pursuant to Article 105(1) of the Court's Rules of Procedure. (15) The Court of Justice refused that request by order of 4 April 2017. (16)

32. The applicants in the main proceedings, Gilead, the United Kingdom Government, the Greek and Netherlands Governments and the European Commission submitted written observations.

33. The applicants in the main proceedings, Gilead, the United Kingdom Government, the Greek and Latvian Governments and the Commission presented oral argument at the hearing on 20 February 2018.

V. Analysis

A. Observations of the parties

34. The applicants in the main proceedings contend that the Court of Justice had answered substantially the same question concerning Article 3(a) of Regulation No 469/2009 in its judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773). In their view, that article must be interpreted as precluding the grant of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application.

35. According to the applicants in the main proceedings, the Court's case-law subsequent to that judgment has restated the same criteria and given the same reasons for adopting it. They maintain that it is plain, in the present case, that the SPC does not satisfy the requirements under Article 3(a) of Regulation No 469/2009, because emtricitabine is not referred to anywhere in the patent, whether by name, by reference to its chemical structure or otherwise.

36. The applicants in the main proceedings also contend that it *'is clear that the scope of protection of claim 27 is not limited to a pharmaceutical composition containing two (or more) therapeutic ingredients, but extends to a pharmaceutical composition containing a*

single therapeutic ingredient consisting of a compound falling within claims 1 to 25. As the referring court held, the presence or absence of another therapeutic ingredient is irrelevant to any assessment of whether a pharmaceutical composition falls within claim 27, and thus to whether dealings in such a pharmaceutical composition infringe that claim of the patent.'

37. Gilead argues that a product is protected by a basic patent in force, in accordance with Article 3(a) of Regulation No 469/2009, if the product falls within the scope of protection of a claim of the basic patent in force, as determined in accordance with Article 69 of the EPC or national legislation derived from that article. Gilead submits that there is no further or additional requirement under EU law. In its view, the approach advocated by the referring court must be rejected because it has no basis in Regulation No 469/2009, is inconsistent with the case-law of the Court of Justice, and has been proposed in the past by the referring court and rejected by the Court of Justice.

38. The United Kingdom Government points out that in paragraph 41 of the judgment of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833), the Court stated that *'the basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent …'*. The United Kingdom of Great Britain and Northern Ireland submits that this *'core inventive advance'* test is a workable approach which properly reflects the balance between the competing interests underlying Regulation No 469/2009 because it does not require national intellectual property offices to undertake an assessment of inventive step akin to assessing the validity of the contested patent. That government notes that the referring court has suggested that *'technical contribution'* can be taken as equivalent to identifying an *'inventive advance'*. Nevertheless, according to the United Kingdom Government, some care is needed in linking these concepts, because the term *'technical contribution'* arises in a number of different contexts in the case-law of the Boards of Appeal of the European Patent Office (EPO) and it is likely to lead to confusion and legal uncertainty if the test to be applied under Regulation No 469/2009 is tied too closely to that case-law. (17)

39. The United Kingdom Government is therefore of the view that the appropriate test comprises three stages as follows:

'(i) the first step is to determine whether the product falls within the scope of at least one claim of the patent. The claims must relate either explicitly, or implicitly (but necessarily and specifically), to the active ingredient or ingredients in question;

(ii) the second step is to determine the core inventive advance of the basic patent, and

(iii) finally, (a) if the product contains a single active ingredient, it must be determined whether that active ingredient embodies the core inventive advance identified in step (ii); or (b) if the product contains a combination of active ingredients, it must be determined whether the combination itself, as distinct from one or more of the ingredients, embodies the core inventive advance identified in step (ii)' (see paragraph 38 of its observations).

40. The Netherlands Government takes the view that a *'product is protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009 if the product is specified in the claims of the basic patent. According to that government, the product is so specified if a person skilled in the art would have recognised, both in the light of the description and of that person's general knowledge as at the priority date, that the active ingredient for which a supplementary certificate is sought is among the substances mentioned in the claims. However, according to the Netherlands Government, in order to determine whether a combination product (in this instance, the combination of TD and emtricitabine) is protected by a basic patent in force, the combination product must also be capable of being regarded as the core inventive advance. (18)

41. In the present case, the Netherlands Government considers that what is therefore required is not only that a person skilled in the art should recognise that the expression *'other therapeutic ingredients'* mentioned in claim 27 refers to emtricitabine. It is also necessary, according to that government, to assess whether that ingredient, in combination with the active ingredient TD, is the subject of the invention covered by the patent. If the combination of TD and emtricitabine does not form part of the core inventive advance, according to the Netherlands Government the condition under Article 3(a) of Regulation No 469/2009 is not satisfied.

42. The Greek Government contends that it is clear from the Court's case-law that in the case of a combination medicinal product composed of at least two active ingredients, as with the product at issue, (19) in order for an SPC to be granted, the inventive advance of the patent must form part of the combination, as referred to in the claims of the patent. Therefore, in a case such as the present one, no SPC is to be granted for a medicinal product consisting of an active ingredient or a combination of active ingredients which does not embody the inventive advance of the basic patent.

43. At the hearing on 20 February 2018, the Latvian Government contended that the expression *'protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009 had to be interpreted strictly in order to meet the objectives of that regulation and to protect not only the interests of manufacturers of patented pharmaceutical products, but also those of manufacturers of generic medicinal products and consumers. That government argues that the active ingredient must be clearly mentioned in the claims of the basic patent, as interpreted in accordance with Article 69 of the EPC. However, the Latvian Government does not believe that criterion to be sufficient. In its view, there must be an additional test, that is to say, whether the active ingredient in question constitutes the core inventive advance of the basic patent. According to that government, in the case of a

combination of active ingredients, that combination must constitute the core inventive advance.

44. The Commission points out that in paragraph 28 of the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773), the Court of Justice held that *'Article 3(a) of Regulation No 469/2009 [had to] be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application.'*

45. According to the Commission, claim 27 is unduly broad, open-ended and generic in its drafting. In its view, whilst that wording might have sufficed under proper scrutiny in the era of the judgment of 16 September 1999, Farmitalia (C‑392/97, EU:C:1999:416), under the Extent of Protection Rules, it would not meet the standard laid down in the Court's more recent case-law.

46. The Commission submits in that regard that the terms *'comprising'* and *'optionally'* militate against that standard as they are by choice broad and open-ended.

47. As regards the referring court's proposed core inventive advance test and whether or not it can be applied for the purposes of Article 3(a) of Regulation No 469/2009, the Commission submits that it could be argued that the Court has already alluded to that test in paragraph 41 of its judgment of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833). It notes that that judgment relates, however, to Article 3(c) of Regulation No 469/2009 in a context where an earlier SPC had been issued to the applicant for the same product and a second SPC was requested for a combination that included that product. The Commission adds that the Court declined to answer the first question in that case, which related to Article 3(a) of that regulation.

B. Preliminary observations

48. The reason given for adopting Regulation No 469/2009 is that the period of effective protection under a patent is insufficient to cover the investment put into pharmaceutical research and the regulation therefore seeks to make up for that insufficiency by creating an SPC for medicinal products. (20)

49. Regulation No 469/2009 establishes a uniform solution at European Union level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Union. (21)

50. Indeed, Article 2 of Regulation No 469/2009 provides that any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative licensing procedure (22) may, under the terms and conditions provided for in that regulation, be the subject of an SPC.

51. Article 3 of Regulation No 469/2009 accordingly lays down four cumulative requirements for obtaining an SPC. Only the first requirement, laid down in Article 3(a) of that regulation, that the product must be *'protected by a basic patent in force'*, is at issue in the present case.

52. Under Article 5 of Regulation No 469/2009, any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations.

53. Article 13(1) of Regulation No 469/2009 provides that the SPC is to take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of five years. Article 13(2) of Regulation No 469/2009 states that *'notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect'*. (23)

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

1. Medeva and the importance of the claims

54. As stated in paragraph 32 of the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773), and given that, under Article 5 of Regulation No 469/2009, any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations, it follows that Article 3(a) of Regulation No 469/2009 precludes an SPC being issued where it relates to active ingredients which are not specified (24) in the wording of the claims in that basic patent. (25)

55. In paragraph 30 of the order of 25 November 2011, Daiichi Sankyo (C‑6/11, EU:C:2011:781) the Court also held that *'Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the SPC application.'* (26)

56. To my mind, the terms *'specify'* and *'identify'* are synonyms that the Court of Justice uses interchangeably.

57. The Court has therefore emphasised the key role played by the claims for the purposes of determining whether a product is protected by a basic patent within the meaning of Article 3(a) of Regulation No 469/2009.

2. The rules for interpreting claims — The rules relating to the extent of the invention — Article 69 of the EPC

58. The Court of Justice has clearly ruled that the rules for determining what is protected by a basic patent for the purpose of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, as distinct from those relating to infringement proceedings. (27)

59. As a simple illustration of the difference between the rules relating to the extent of the invention and those relating to infringement proceedings, a medicinal

product composed of active ingredients A+B would infringe a patent and give rise to infringement proceedings even if the claims of the patent related only to active ingredient A.
60. On the other hand, it is clear that active ingredient B, which is not specified anywhere in the claims, does not fall within the extent of the invention and is not *'protected'* by the patent in question within the meaning of Article 69 of the EPC and the Protocol on its interpretation and of Article 125 of the Patents Act 1977.
61. Indeed, although Regulation No 469/2009 is intended to establish a uniform solution at Union level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State, the Court has nevertheless held that, since patent law is not harmonised at Union level, the extent of patent protection can be determined only in the light of the non-European Union rules governing patents. (28)
62. In paragraph 40 of the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), the Court held that it had no jurisdiction to interpret the provisions of the EPC, since, unlike the Member States, the European Union has not acceded to the convention and the Court could not, therefore, provide further guidance to the referring court concerning the manner in which it should determine the extent of the claims of a patent issued by the EPO.
63. To my mind, it is that tension between two separate legal regimes that characterises the SPC system set up by Regulation No 469/2009 and gives rise to difficulties in interpreting and applying certain provisions of that regulation, in particular Article 3(a). (29)

3. The Court's case-law post Medeva

64. The question being asked in this case is whether it is sufficient that a product falls within at least one claim of the basic patent under the Extent of Protection Rules applicable to the patent in order to be a product protected by a basic patent within the meaning of Article 3(a) of Regulation No 469/2009, or whether other additional criteria must be applied.
65. To resolve that doubt, the referring court proposes that it should be ascertained not only whether the product falls within at least one claim of the basic patent under the Extension of Protection Rules, but also whether the product embodies the inventive advance of the basic patent.
66. That question has arisen in response to certain guidance provided in the Court's case-law subsequent to the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773).
67. In paragraph 41 of its judgment of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833), the Court held that *'the basic objective of Regulation No 469/2009 [was] to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent'*. (30)
68. It should be noted, however, that that judgment is not relevant in the present case because it concerns only Article 3(c) of Regulation No 469/2009, which is not at issue in the present case, (31) the Court having stated clearly that there was no need to rule on the question referred in that case relating to Article 3(a) of that regulation.
69. In the case which gave rise to the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), the Court was asked whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as *'protected by a basic patent in force'* within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula (32) in the patent claims.
70. Paragraph 44 of the same judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), indicates that *'where the active ingredient is covered by a functional formula (33) in the claims of a patent issued by the EPO, Article 3(a) of that regulation does not, in principle, preclude the grant of an SPC for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.'* (34)
71. Lastly, in paragraph 38 of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), the Court held that *'in order for a basic patent to protect "as such" an active ingredient within the meaning of Articles 1(c) and 3(a) of Regulation No 469/2009, that active ingredient [had to] constitute the subject matter of the invention (35) covered by that patent.'* (36)
72. To my mind, it is clear from the Court's case-law, in particular the judgments of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773), of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), and of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), that the only means of determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) of Regulation No 469/2009 is to be found only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else. (37)
73. Any other additional criterion, such as the requirement proposed by the referring court that the active ingredient embody *'the inventive advance of the patent'* runs the risk, in my view, of giving rise to confusion with the criteria for determining whether an invention is patentable. (38) The question whether a

product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 is not the same as the question whether that product is patentable, which is a matter exclusively for national or treaty law.
74. Nevertheless, merely because a substance might fall within the protection of the claims of a patent under Article 69 of the EPC and the Protocol on its interpretation and the provisions of relevant national law, such as Article 125 of the Patents Act 1977, does not necessarily imply that that substance is a product protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009.
75. Indeed, the fact that a substance or combination of substances falls within the scope of protection of a patent, in particular under Article 69 of the EPC and the Protocol on its interpretation and the provisions of relevant national law is a necessary but not sufficient condition for it to be a product protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009.

4. The degree of specificity or abstraction of the claims

76. As patents often contain a range of claims varying in their degree of specificity or abstraction, (39) the real question which arises in the present case is with what degree of specificity or abstraction a product is *'specified'* in the claims of the basic patent within the meaning of Article 3(a) of Regulation No 469/2009.
77. In paragraph 39 of its judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), the Court held that it is not always necessary for the purposes of Article 3(a) of Regulation No 469/2009 that the active ingredient be referred to literally by its name or chemical structure in the claims of a basic patent and that a functional definition of an active ingredient in the claims of a basic patent could, in certain circumstances, be sufficient. (40)
78. On the other hand, it is apparent from paragraphs 36 to 39 and 41 of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), that the fact that a basic patent contains a claim relating to a specifically named active ingredient may, in certain circumstances, not be sufficient.
79. However, that judgment should be read with caution given the singular facts it dealt with. The active ingredient at issue was not in fact specified in the patent as initially granted. A new claim relating to that active ingredient was purportedly added to the basic patent retrospectively after it had been granted, following a procedure to amend the basic patent, (41) with the intention, in my view, of obtaining an SPC.
80. As I indicated in point 74 of this Opinion, it is not sufficient merely that a product falls within the scope of protection of a patent (42) for it to be regarded as a protected product within the meaning of Article 3(a) of Regulation No 469/2009. It is common knowledge that claims are often (deliberately and ingeniously) drafted in broad, (43) vague, generic and stereotypical (44) terms so that they cover multiple substances.
81. To my mind, a product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be specifically, precisely and individually identifiable (45) in the wording of the patent claims.
82. The name of the active ingredient or its chemical composition does not need to be referred to expressly in the claims, (46) provided that the active ingredient is specifically and precisely identifiable as at the priority date of the patent.
83. If, for example, a substance claimed in a patent consists of several variants, (47) the product protected by the patent within the meaning of Article 3(a) of Regulation No 469/2009 does not necessarily encompass all those variants. As at the priority date of the patent, a variant must be specifically and precisely identifiable in the wording of the patent claims in order for it to be *'a product protected by the patent'* within the meaning of Article 3(a) of Regulation No 469/2009. (48)
84. In paragraph 35 of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), the Court held that *'the objective pursued by Regulation No 469/2009 [was] not to compensate the holder fully for the delay to the marketing of his invention or to compensate for such delay in connection with the marketing of that invention in all its possible commercial forms, including in the form of combinations based on the same active ingredient'*. (49)

5. Application to the facts of the main proceedings

85. In the main proceedings, it is common ground that the active ingredient emtricitabine is not expressly named in the claims of the basic patent.
86. However, it is apparent from the request for a preliminary ruling that Gilead obtained the SPC in question in the main proceedings for an anti-viral medicinal product containing two active ingredients, namely TD and emtricitabine, on the basis of claim 27 of the basic patent. That claim in fact refers to a pharmaceutical composition *'comprising'*a compound according to any one of claims 1 to 25, that is to say, in the present case, TD under claim 25, and *'optionally other therapeutic ingredients.'*
87. To my mind, and subject to verification by the referring court, as the active ingredient emtricitabine is claimed solely through the use of completely indeterminate expressions such as *'comprising'* and *'optionally other therapeutic ingredients'*, (50) terms which may cover multiple substances that are not specifically and precisely identifiable on the priority date of the patent, (51) the combination containing the active ingredients TD and emtricitabine, that is to say, the medicinal product marketed under the name Truvada, is not protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009,

even though that combination may fall within the protection of claim 27 of the patent at issue in the main proceedings under Article 69 of the EPC and the Protocol on its interpretation and section 125 of the Patents Act 1977.

88. It would appear, subject once again to verification by the referring court, that, on 26 July 1996, the claimed priority date of the patent at issue in the main proceedings, it would not have been obvious to a person skilled in the art that the active ingredient emtricitabine was specifically and precisely identifiable in the wording of the claims of that patent.

VI. Conclusion

89. In the light of all the foregoing, I propose that the Court should answer the question referred for a preliminary ruling by the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom) as follows:

Article 3(a) 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 precludes the grant of a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent. The fact that a substance or combination of substances falls within the scope of protection of the basic patent is a necessary, but not sufficient, requirement for it to constitute a product protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009. A product is protected by a patent within the meaning of Article 3(a) of that regulation if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent. In the case of a combination of active ingredients, each active ingredient in that combination must be specifically, precisely and individually identifiable in the wording of the claims of the basic patent.

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1 Original language: French.

2 OJ 2009 L 152, p. 1.

3 In paragraph 25 of its judgment of 15 January 2015, Forsgren (C‑631/13, EU:C:2015:13), the Court of Justice ruled that *'the term "active ingredient", for the purposes of applying Regulation No 469/2009, concerns substances producing a pharmacological, immunological or metabolic action of their own.'*

4 It should be noted that two other requests for preliminary rulings concerning interpretation of Article 3(a) of Regulation No 469/2009 are currently pending before the Court of Justice. See the request for a preliminary ruling in Case C‑650/17, QH, lodged at the Court Registry on 21 November 2017 by the Bundespatentgericht (Federal Patent Court, Germany) (OJ 2018 C 52, p. 20) and the request for a preliminary ruling in Case C‑114/18, Sandoz and Hexal, lodged at the Court Registry on 14 February 2018 by the Court of Appeal (United Kingdom).

5 According to the referring court *'emtricitabine appears to have been first described in an article in November 1992. This article reported, inter alia, data for emtricitabine from in vitro anti-HIV studies. There is no evidence that it was known in July 1996 that emtricitabine was an effective agent for the treatment of HIV in humans, still less that this was common general knowledge to the person skilled in the art to whom the Patent is addressed. The European Medicines Agency first approved emtricitabine in October 2003, over seven years later'*, (see paragraphs 6 and 7 of the request for a preliminary ruling).

6 According to the referring court, *'claim 27 requires the presence in the pharmaceutical composition of a compound falling within any of claims 1 to 25 together with a pharmaceutically acceptable carrier. The significance of the words "comprising" and "optionally" is that claim 27 permits, but does not require, the presence of other ingredients, both therapeutic and non-therapeutic. The scope of protection of claim 27 is therefore not limited to a pharmaceutical composition containing two (or more) therapeutic ingredients, but extends to a pharmaceutical composition containing a single therapeutic ingredient consisting of a compound falling within claims 1 to 25. It follows that the presence or absence of another therapeutic ingredient is irrelevant to any assessment of whether a pharmaceutical composition falls within claim 27, and thus to whether dealings in such a pharmaceutical composition infringe that claim of the Patent.'* According to that court, *'the decision whether to include claims like [claim 27] at all in a patent of this nature, and if so how to draft such claims, are matters for the choice of the patent proprietor. In practice, the decision will be taken by the patent attorney who drafts the patent application based on legal, rather than scientific or technical, considerations'* (see paragraphs 22 and 20 respectively of the request for a preliminary ruling).

7 According to the referring court, *'it is common ground that emtricitabine is not mentioned or referred to in the Patent'* (see paragraph 15 of the request for a preliminary ruling).

8 See the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773).

9 See the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835).

10 See the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835, paragraphs 32 and 39).

11 The referring court cites the judgments of 16 September 1999, Farmitalia (C‑392/97, EU:C:1999:416); of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773); of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833); of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835); and of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), and also the orders of 25 November 2011, Yeda Research and Development

Company and Aventis Holdings (C‑518/10, EU:C:2011:779), University of Queensland and CSL (C‑630/10, EU:C:2011:780), and Daiichi Sankyo (C‑6/11, EU:C:2011:781).

12 In paragraph 93 of the request for a preliminary ruling, the referring court notes that *'applications for an SPC for the combination of TD and emtricitabine have been rejected by the Swedish patent office and Patent Appeals Court, albeit prior to Medeva, by the Dutch Patent Office and the Greek Patent Office, but in Spain the application was granted following a decision of the Madrid Administrative Court. An application was also granted in Germany following a decision of the Federal Patent Court, again prior to Medeva. But more recently the German Patent Office refused an application by Gilead for an SPC for a triple combination of TD, emtricitabine and efavirenz.'* Furthermore, in its judgment No 10607 of 6 August 2014, the Varhoven administrativen sad (Supreme Administrative Court, Bulgaria) examined whether the product Atripla was protected by basic patent No BG 62612 for the purposes of granting an SPC. The SPC in question related to three active ingredients: efavirenz, emtricitabine and tenofovir disoproxil, whilst the basic patent covered only the first two active ingredients; tenofovir disoproxil was not mentioned. The Varhoven administrativen sad (Supreme Administrative Court) noted that emtricitabine and tenofovir disoproxil were the individual components of the product at issue and did not comprise a new active substance which could be described as an HIV reverse transcriptase nucleotide analogue. That court concluded that the composition of the three active ingredients in question comprising the product Atripla was not protected by the basic patent and, accordingly, upheld the decision of the patent office refusing to issue the relevant SPC. Further, in its judgment of 22 March 2017, 3.Pfv.IV.21.502/2016/3, the Kúria (Supreme Court, Hungary) confirmed the decisions delivered by the lower courts following an action brought against a decision of the National Intellectual Property Office (*'the NIPO'*). By that decision, the NIPO had refused the application for an SPC to protect the medicinal product Atripla, consisting of a combination of three active ingredients, in particular efavirenz, emtricitabine and tenofovir disoproxil fumarate, which had been granted marketing authorisation. According to the NIPO, that combination was not protected by a basic patent, because the claim in the relevant basic patent mentioned expressly only efavirenz. The requirement for granting a certificate set out in Article 3(a) of Regulation No 469/2009 was therefore not satisfied as regards the combination. The lower courts confirmed the NIPO's refusal in that respect. In addition, two joined cases are currently pending before the High Court (Ireland), brought by Gilead Sciences Inc and Gilead Biopharmaceutics Ireland UC against Mylan SAS Generices (UK) Ltd and McDermott Laboratories Ltd, on the one hand, and, on the other hand, by the same applicants against Teva B.V. and Norton (Waterford) Ltd, concerning Irish SPC No 2005/021 for the medicinal product Truvada.

13 The judgment of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833), concerns interpretation of Article 3(c) of Regulation No 469/2009 and the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), concerns interpretation of Article 3(a) and (c) of that regulation.

14 The referring court states that: *'where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent. Thus in a case such as the present, where the inventive advance of the Patent consists generally of the compounds of formulae (1) and (1a), including specifically TD, a medicinal product whose active ingredient is TD is protected by the Patent within the meaning of Article 3(a) because it embodies the inventive advance of the Patent. A medicinal product whose active ingredients are TD and another therapeutic agent such as emtricitabine in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from TD, does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which ... can be manipulated by the patent attorney who drafts it, but of its substance. By contrast, if Gilead (or another inventor) were to obtain a patent for an invention consisting of a combination of TD and substance X which surprisingly had a synergistic effect in treating HIV, then a medicinal product whose active ingredients were TD and X would be protected by that patent since it would embody the inventive advance of that patent. ... This interpretation of Article 3(a) would accord with the object of the SPC Regulation, which is to encourage invention in the field of medicinal products by compensating inventors for the delay in exploiting their inventions due to the need to obtain regulatory approval, and not to confer unjustified monopolies'* (see paragraph 97 of the request for a preliminary ruling).

15 The referring court argued that, should the case not benefit from such a procedure, the case could not be resolved before expiry of the patent at issue in the main proceedings. According to the referring court, this would inevitably put back the date on which generic medicinal products would be available for National Health Service England and would, in turn, entail higher costs and place a greater strain on the budget of the latter.

16 The Court of Justice found that invoking economic interests, including those liable to have an impact on public finances, does not justify use of the expedited procedure. Furthermore, according to the Court of Justice, the referring court had not referred to any imminent risk to public health that might constitute an exceptional circumstance such as to justify the use of the expedited procedure. The Court held that it was clear from the order for reference that whilst, according to the referring court, use of the ordinary procedure to deal with the present case would delay the date of availability of generic medicinal products, it would

nevertheless not affect the health of the patients concerned, who would continue to be treated by means of Truvada.

17 See, inter alia, the various uses of the term *'identified'* in the Case Law of the Boards of Appeal of the European Patent Office, 8th edition, July 2016, available at the following address: https://www.epo.org/law-practice/case-law-appeals/case-law_fr.html.

18 That follows, according to the Netherlands Government, from the judgments of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), and of 12 December 2013, Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833), which concerned combination products.

19 Truvada.

20 See the judgment of 24 November 2011, Georgetown University and Others (C‑422/10, EU:C:2011:776, paragraph 25). *'The standard term of patent protection is 20 years, calculated from the date of application for registration of the invention. If an authorisation to place medicinal products on the market … is granted following the filing of an application to have the patent registered, manufacturers of medicinal products will be unable commercially to exploit their position of exclusivity in relation to the patented active ingredients of that medicinal product during the period which elapses between the application to have the patent registered and the authorisation to place the medicinal product concerned on the market. Since, in the view of the European Union legislature, that would make the period of effective protection under the patent insufficient to cover the investment in research and to generate the resources needed to maintain a high level of research, Regulation No 469/2009 grants those manufacturers the possibility to extend their rights to exclusivity in the patented active ingredients of a medicinal product by applying for [an SPC] to cover a period not exceeding 15 years from the time at which the medicinal product concerned first obtains authorisation to be placed on the market within the European Union.' 'Those rules are intended to achieve a balance between the various interests at stake in the pharmaceutical sector. Those interests include, on the one hand, the interests of the undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector and therefore favour an extension of the term of protection for their inventions in order to be able to recoup the investment costs. On the other hand, there are the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines. It is also relevant in this connection that, in general, the marketing of generic medicinal products has the effect of lowering the prices of the relevant medicinal products. Against that background, the interests of patients lie between the interests of the undertakings and institutions conducting research and those of the producers of generic medicines. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. The same applies to State public health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in slightly modified form under the protection of certificates but without genuine innovation and thereby artificially driving up expenditure in the health sector.'* (see Opinion of Advocate General Trstenjak in Medeva in C‑322/10 and C‑422/10, EU:C:2011:476, points 76 and 77).

21 See the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659, paragraph 26 and the case-law cited), and the order of 25 November 2011, Yeda Research and Development Company and Aventis Holdings (C‑518/10, EU:C:2011:779, paragraph 36).

22 Under Directive 2001/83 or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1).

23 The protection conferred by an SPC begins the day following expiry of the basic patent. It is apparent from paragraph 42 of the order of the President of the Court of 14 November 2013, Astrazeneca (C‑617/12, EU:C:2013:761), and paragraph 30 of the order of 13 February 2014, Merck Canada (C‑555/13, EU:C:2014:92), that the holder of both a patent and an SPC should not be able to enjoy more than 15 years of exclusivity from the first authorisation to place the medicinal product concerned on the market in the Union.

24 See also, to that effect, the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835, paragraph 34).

25 The Court has accordingly held, in particular, that, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, an SPC cannot be granted on the basis of such a patent for one of the active ingredients considered in isolation. See, in that respect, the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773, paragraph 26), and the order of 25 November 2011, Yeda Research and Development Company and Aventis Holdings (C‑518/10, EU:C:2011:779, paragraph 38).

26 Emphasis added. See, also, to that effect, the orders of 25 November 2011, University of Queensland and CSL (C‑630/10, EU:C:2011:780, paragraph 31), and Yeda Research and Development Company and Aventis Holdings (C‑518/10, EU:C:2011:779,

paragraph 39). In the order of 25 November 2011, University of Queensland and CSL (C‑630/10, EU:C:2011:780, paragraphs 38 to 40), the Court found that a patent protecting the process by which a *'product'* within the meaning of Regulation No 469/2009 is obtained could, in accordance with Article 2 of the regulation, enable an SPC to be granted. If the law applicable to such a patent so provides, an SPC granted on the basis of that patent will also extend the protection of the process by which the product is obtained to the product thus obtained. However, just as Article 3(a) of Regulation No 469/2009 precludes the grant of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent, where the basic patent relied on in support of an SPC application relates to the process by which a product is obtained, that provision also precludes an SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from that process.

27 See the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835, paragraphs 33 and 37).

28 See the judgments of 16 September 1999, Farmitalia (C‑392/97, EU:C:1999:416, paragraph 27), and of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773, paragraph 23), and the order of 25 November 2011, Yeda Research and Development Company and Aventis Holdings (C‑518/10, EU:C:2011:779, paragraph 35). It is apparent from the request for a preliminary ruling that, in the main proceedings, the national rules for interpreting claims are those set out in section 125 of the Patents Act 1977. See, to that effect, the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835, paragraph 32). Under section 125(3) of the Patents Act 1977, the Protocol on the Interpretation of Article 69 of the EPC applies for the purposes of applying section 125(1) of that Act.

29 *'Although the SPC regime creates a distinct, new form of intellectual property right, rather than simply extending the period of protection guaranteed by existing patents, it is, nonetheless, closely connected with the national systems under which pharmaceutical patent rights are initially granted and protected. Thus, in substantive terms, a certificate can only be granted if a product is protected by a basic patent and the protection conferred by a certificate must be within the limits of that conferred by the basic patent. The certificate holder enjoys the same rights and is subject to the same limitations and obligations as affected the basic patent'*, see Opinion of Advocate General Fennelly in Farmitalia (C‑392/97, EU:C:1999:277, point 21).

30 Emphasis added. I confess to a certain amount of difficulty in distinguishing between the *'core inventive advance that is the subject of the basic patent'* and the invention disclosed by the claims.

31 Under that article, a product can be the subject of one SPC only. In paragraph 33 of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), the Court held that *'it is possible, in principle, on the basis of a patent which protects several different "products", to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is "protected" as such by that "basic patent" within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation'*. I would observe here that the referring court stated in the request for a preliminary ruling that *'in addition to Truvada, Gilead markets a monotherapy for the treatment of HIV under the trade mark Viread which has only TDF as the active ingredient. Gilead obtained the first [MA] for Viread on 5 February 2002 … Gilead has not obtained an SPC for Viread, presumably because the period which elapsed between the date of filing of the application for the Patent and the date of that marketing authorisation was less than five years (so that the term of any SPC would have been negative)'* (see paragraph 24 of the request for a preliminary ruling).

32 *'A claim may broadly define a feature in terms of its function, i.e. as a functional feature, even where only one example of the feature has been given in the description, if the skilled person would appreciate that other means could be used for the same function'* (https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_6_5.htm).

33 The patent at issue in that case concerned the discovery of a new protein. That patent, inter alia, disclosed and claimed that protein. It is apparent from the patent claims that the patent also related to antibodies that bind specifically to that protein. Eli Lilly wished to market a pharmaceutical composition containing as an active ingredient an antibody that bound specifically to the new protein. It brought an action for a declaration that any SPC relying, for its legal basis, on the patent in question would be invalid. It argued in that regard that that antibody was not covered by a *'basic patent'* within the meaning of Article 3 of Regulation No 469/2009, in so far as the patent claim in question was too broadly drafted for it to be possible for that antibody to be regarded as being *'specified'* in the wording of the claims of that patent. Thus, according to Eli Lilly, in order for an SPC to be granted on the basis of the patent in question, the patent would have to contain a structural definition of the active ingredients and the claims would have to be significantly more specific.

34 Emphasis added. The referring court considers that paragraph 44 of the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), is ambiguous. It states at paragraph 81 of the request for a preliminary ruling that *'although the Court does clearly state that Article 3(a) does not preclude a product being protected by a basic patent by virtue of a functional definition, it then says that this is only permitted where the claims 'relate, implicitly but necessarily and specifically'* to the product in question. What does this mean? How are national authorities

supposed to apply this test? The Court does not explain. All that can be said with confidence is that, once again, the Court appears to be suggesting that something more is required than [that] the product falls within the scope of the basic patent applying the Extent of Protection Rules, but without making it clear what more.'

35 In paragraph 37 of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), the Court held that *'in view of the interests referred to in recitals 4, 5, 9 and 10 in the preamble to Directive 469/2009, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject matter of the invention covered by the basic patent'*.

36 Emphasis added. According to the referring court, that form of words is ambiguous. That court states that *'it nevertheless remains unclear what is required in order for Article 3(a) to be satisfied'*.

37 Despite the fact that the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), makes no reference to the wording of the claims of the patent granted, in my view, any process to determine the *'subject matter of the invention covered by a patent'* would require interpretation of the wording of those claims.

38 In order to be patentable, an invention must be novel, involve an inventive step and be susceptible to industrial application.

39 Apart from functional formulae, it should also be noted that, in the field of medicinal products, Markush formulae, which cover classes of chemical compounds, are often used in the claims of a patent. In Case T 1020/98 — 3.3.1, the EPO Board of Appeal stated that *'special problems are caused by the exceptional length of the claims, by the fact that the [Markush] formula consists entirely of variables, and by the number of variables, mostly defined in terms of other variables'* (http://www.epo.org/law-practice/case-law-appeals/recent/t981020fp1.html#q).

40 Even though it is not always necessary for the purposes of Article 3(a) of Regulation No 469/2009 that the active ingredient be referred to literally by its name or chemical structure in the claims of a basic patent, it is apparent, in my view, in particular from that paragraph 39 of the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), and the use of the expressions *'implicitly but necessarily'* and *'specifically'*, that the Court in fact intended to limit interpretation of the wording of claims to a certain degree of specificity or abstraction.

41 It can be seen from the facts of that case that the United Kingdom Intellectual Property Office (*'the UK IPO'*) had indicated to the applicant for the SPC that, with regard to certificates for products comprising a combination of active ingredients, the combination must be expressly claimed in order for it to be regarded as requiring protection as such. As the basic patent belonging to Boehringer Ingelheim Pharma (*'Boehringer'*) contained only claims which related to one of the product's active ingredients, namely the telmisartan component, the UK IPO suggested that Boehringer should apply to amend that basic patent to insert a claim to the combination of telmisartan and hydrochlorothiazide. Boehringer then applied to amend the relevant basic patent, as granted, by subsequently inserting a claim relating, inter alia, to a pharmaceutical combination of telmisartan and hydrochlorothiazide solely in order to obtain an SPC. To my mind, it is plain from the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), that the Court was unimpressed by such tactics.

42 Within the meaning, in particular, of Article 69 of the EPC.

43 As Markush formulae and functional formulae attest.

44 As borne out by the use of claims such as claim 27 of the patent in issue in the main proceedings. Claims of this kind are drafted so broadly that they could potentially cover any combination of TD with another chemical substance. I would point out that in paragraph 97 of the request for a preliminary ruling the referring court states *'the wording of the claims of the basic patent ... can be manipulated by the patent attorney who drafts it ...'*. It should be noted that, as regards the patentability of an invention, an issue over which the Court does not have jurisdiction, I am not seeking to call into question that practice.

45 See, to that effect, the judgment of 24 November 2011, Medeva (C‑322/10, EU:C:2011:773, paragraph 26), and the order of 25 November 2011, Yeda Research and Development Company and Aventis Holdings (C‑518/10, EU:C:2011:779, paragraph 38).

46 Besides the fact that the Court has previously ruled out such a requirement in paragraph 39 of its judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835), in my view that requirement is too strict and restrictive, because it does not take sufficient account of the interests of the proprietor of the patent and the need to foster the development and marketing of medicinal products. In the light of the judgment of 12 March 2015, Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165), subsequent tactical amendments of the patent, for the purpose of obtaining an SPC, are irrelevant.

47 In my view, a mere reference in the wording of the claims, such as a reference to a *'diuretic'* or a *'non-steroidal anti-inflammatory'* is not sufficient.

48 See, to that effect, paragraph 39 of the judgment of 12 December 2013, Eli Lilly and Company (C‑493/12, EU:C:2013:835). I believe that more than one variant of a chemical substance may be claimed provided that,

on the priority date of the patent, each variant is specifically and precisely identifiable.

49 Emphasis added.

50 Which are the only terms that might relate to the active ingredient emtricitabine.

51 Or even substances not yet invented on the priority date of the patent. The active ingredient emtricitabine is not specifically identifiable as such from claim 27 of the patent at issue in the main proceedings. See, to that effect, the judgment of 12 December 2013, Eli Lilly and Company (C-493/12, EU:C:2013:835, paragraph 36). In my view, an interpretation of Article 3(a) of Regulation No 469/2009 as including substances that are not specifically and precisely identifiable would undermine the objective of that regulation, which is to mitigate the insufficient period available to cover the investment put into research for new medicinal products (as referred to in recital 4 of that regulation), because it confers a benefit on the patent holder even though that patent holder had not made any investment in research relating to those substances. See, to that effect, paragraph 43 of the judgment of 12 December 2013, Eli Lilly and Company (C-493/12, EU:C:2013:835).