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, acting 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

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).

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

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.'

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

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.'

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];

…'

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.'

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].'

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.'

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

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:

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.'

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.

…'

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

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).

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.

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.

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.

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.'

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'.

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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).

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).

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).

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).

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.

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).

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.

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.

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).

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.

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).

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).

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.

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'.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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 K. Lenaerts

Registrar President

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* Language of the case: English.