Binding Copies
issued to the parties on:

FRENCH REPUBLIC
ON BEHALF OF THE FRENCH PEOPLE

COURT OF APPEAL OF PARIS

Pole 5 - Chamber 2

JUDGMENT OF SEPTEMBER 25, 2020

(n°93, 11 pages)

Number of registration in the general directory: n° RG 18/23642 - n° Portalis 35L7-V-B7C-B6VUO

Decision referred to the Court: judgment of October 25, 2018 - PARIS Regional Court – 3rd chamber 1st section - RG n°16/16178

APPEALANTS

S.A.S. TEVA SANTE, acting in the person of its legal representatives domiciled in this capacity at the registered office located at
100-110, General de Gaulle esplanade
92931 PARIS LA DEFENSE CEDEX
Registered at the RCS of Nanterre under the number 401 972 476

Company TEVA PHARMACEUTICALS EUROPE B. V. a company incorporated under Dutch law, represented by its board of directors, domiciled in this capacity at the registered office of TEVA PHARMACEUTICALS EUROPE B. V., a company incorporated under Dutch law.
Piet Heinkade 107
1019 GM AMSTERDAM
NETHERLANDS

Represented by Mr. Jean-Claude CHEVILLER, lawyer at the PARIS Bar, toque D 0945
Assisted by Me François POCHART pleading for the SCP AUGUST & DEBOUZY ET ASSOCIES, lawyer at the PARIS Bar, hat P 438

RESPONDENT

Company MERCK SHARP & DOHME CORP. a corporation incorporated under the laws of the United States of America, in the person of its legal representatives domiciled in that capacity at the registered office located at One Merck Drive, New York.
Whitehouse Station
NJ 08889 (UNITED STATES OF AMERICA)

Represented by Me Matthieu BOCCON-GIBOD of the SELARL LEXAVOUE PARIS-VERSAILLES, lawyer at the PARIS Bar, toque C 2477
Assisted by Me Laëtitia BENARD pleading for ALLEN & OVERY LLP, lawyer at the PARIS Bar, toque J 022

COMPOSITION OF THE COURT :

The case was debated on July 9, 2020, in open court, before the Court composed of :

Mrs. Anne-Marie GABER, President of the Chamber
Mrs. Laurence LEHMANN, Counsellor
Mrs. Françoise BARUTEL, Counsellor

who have deliberated

A report was presented at the hearing by Mrs. Françoise BARUTEL under the conditions provided for in Article 785 of the Code of Civil Procedure.

Clerk during the debates: Mrs. Carole TREJAUT

JUDGMENT OF THE COURT OF APPEAL :

Contradictory
By making the judgment available at the Court Registry, the parties having been notified in advance under the conditions provided for in the second paragraph of Article 450 of the Code of Civil Procedure
Signed by Laurence LEHMANN, Councillor, acting as President, replacing Mrs. Anne-Marie GABER, President, prevented, and by Mrs. Carole TREJAUT, Clerk, present at the time of making the judgment available.

Having regard to the contradictory judgment rendered on October 25, 2018 by the Paris Regional Court (3rd chamber, 1st section) ;

Having regard to the appeal filed on November 6, 2018 by Teva Pharmaceuticals Europe BV and Teva Santé (together Teva);

Having regard to the last submissions (submissions no. 4) submitted to the clerk's office, and notified electronically on 4 May 2020 by the companies Teva, appellants ;

Having regard to the final submissions (submissions no. 5) submitted to the clerk's office, and notified electronically on May 26, 2020, by the Respondent Merck Sharp & Dohme Corp ("Merck") ;

Having regard to the Closing Order of June 4, 2020,

ON THIS, THE COURT,

For a complete statement of the facts of the case and the procedure, express reference is made to the appealed decision and the above-mentioned writings of the parties.

It will simply be recalled that Merck is part of the American pharmaceutical group Merck & Co. It is active in the field of research and in particular in the field of drugs against hypercholesterolemia.

Teva Pharmaceuticals Europe BV, a company incorporated under Dutch law, presents itself as the leader in generic drugs in Europe.

Teva Santé is the French subsidiary of the group, exploiting the group's specialties for France.

Merck owns European Patent No. 0 720 599 (EP 599) entitled "Hydroxy-substituted azetidinone compounds effective as hypocholesterolemic agents", filed on September 14, 1994 and published on May 19, 1999, which expired on September 14, 2014.

The purpose of this patent is to protect a new class of hypocholesterolemic compounds, hydroxy-substituted azetidinones, to which ezetimibe belongs, as well as the combination of hydroxy-substituted azetidinone and a cholesterol biosynthesis inhibitor, for the treatment and prevention of atherosclerosis.

The EP 599 patent covers 21 claims:
- Claims 1 to 8 relate to compounds of the substituted azetidinone family, including ezetimibe in claim 8 ;
- Claim 9, dependent on claims 1 to 8, relates to a pharmaceutical composition comprising a substituted azetidinone alone or in combination with a cholesterol biosynthesis inhibitor;
- Claim 10 relates to the use of a compound according to any of Claims 1 to 8 for the manufacture of a medicament for the treatment or prevention of atherosclerosis;
- Claims 11 and 12 relate to a process for the preparation of a pharmaceutical composition according to claim 9, using the compounds of claims 1 to 8, with a pharmaceutically acceptable carrier, or a cholesterol biosynthesis inhibitor;
- Claims 13 and 14 relate to the use of the hydroxy-substituted azetidinone of Claims 1 to 8 with a cholesterol biosynthesis inhibitor, for the manufacture of a medicament for the treatment or prevention of atherosclerosis or for the reduction of plasma cholesterol levels;
- Claim 15 relates to a kit consisting of separate containers, one of the containers comprising a pharmaceutical composition with a cholesterol biosynthesis inhibitor, the other a compound according to one of claims 1 to 8 ;
- Claim 16 refers to claims 9, 12 or 15, and is directed to the specific families of cholesterol biosynthesis inhibitors, namely HMG CoA reductase inhibitors, inhibitors of squalene synthesis and inhibitors of squalene epoxidase synthesis;
- Claim 17, which is dependent on claim 16, includes among the inhibitors of cholesterol biosynthesis, lovastatin, prevastatin, fluvastatin, simvastatin, C1-981, DMP-965, L-659, 699, squalestanine 1 and NB-598 ;
- Claim 18 is the use as claimed in Claim 1, 3 or 14 where the cholesterol biosynthesis inhibitor is as defined in Claim 16 or Claim 17 ;
- Claims 19, 20 and 21 relate to processes for the preparation of a compound of hydroxy-substituted azetidinones as defined in Claim 1.

The protection conferred by this patent has been extended by two applications for supplementary protection certificates (SPC) :
- the SPC n°03C0028 (n°028) granted by the INPI on February 4, 2005 on the basis of patent EP 599 and the marketing authorization (MA) of the ezetimibe product marketed under the brand name EZETROL. For France, the first marketing authorization was granted on June 11, 2003. This SPC expired on April 17, 2018.
- the SPC n°05C0040 (n°040) granted by the INPI on December 21, 2006 on the basis of patent EP 599 and the MA for the combination product of ezetimibe and simvastatin marketed under the brand name INEGY. For France, the first MA was granted on July 28, 2005. This SPC expired on April 2, 2019.

On the basis of the EP 599 patent, Merck has filed two other SPC applications:
- n°14C0065 for the composition of active ingredients "ezetimibe in combination with rosuvastatin". The INPI rejected this application by decision of February 3, 2017, and Merck withdrew its appeal against this decision.
- No. 14C0068 (No. 068) on September 12, 2014 for the active ingredient composition "ezetimibe in combination with atorvastatin". The INPI rejected this application by decision of February 5, 2018. In a decision dated January 22, 2019, the Paris Court of Appeal dismissed Merck's appeal against this decision. An appeal [to the Supreme Court] is pending.

With a bailiff's service of November 3, 2016, the Teva companies, which launched on the market a generic drug of ezetrol (ezetimibe alone) on April 18, 2018 and of Inegy (combination of ezetimibe and simvastatin) on April 24, 2018, sued Merck before the Paris Regional Court (Tribunal de Grande Instance), requesting the invalidity of claims 9 to 18 of EP 599 patent and of the SPC No. 040.

By judgment, including an appeal, the Tribunal de Grande Instance of Paris has in particular:
- Dismissed Merck's inadmissibility arguments based on the statute of limitations and the lack of interest to act against claims 9 to 11 of the French part of the European patent EP 599,
- Declared the Teva companies admissible in their requests,
- Rejected Teva's request to nullify claims 9 to 18 of the French part of European patent EP 599 for insufficiency of description,
- Dismissed the Teva companies' request for the nullity of SPC No. 040 and for publication,
- Ordered in solidum the Teva companies to pay the costs and to pay Merck the sum of 100,000 euros pursuant to Article 700 of the Code of Civil Procedure.

By an order of May 23, 2019, the Case management judge, who had been requested in a procedural issue to refer a question to the Court of Justice of the European Union, rejected this request.

Parallel proceedings relating to the SPC granted for the combination product ezetimibe and simvastatin are opposing Merck to various generic manufacturers before the French courts.

By orders dated February 8 and March 7, 2019, respectively, the Juge des Référés and the Case management judge of the Tribunal de Grande Instance de Paris ruled, inter alia, that the defense based on the nullity of SPC n°040 is not serious, and ordered preliminary injunction measures, communication of accounting documents and provisional condemnation in payment against Sandoz and Mylan. By judgments dated February 14, 2020, this court essentially reversed these orders.

Other parallel proceedings involving the SPC granted for the combination product ezetimibe and simvastatin also oppose Merck to various generic manufacturers in Europe.

Various courts have granted preliminary injunctions to the Merck companies, including the Oslo Court of Justice in its decision of September 21, 2018, confirmed by the Borgarting Court of Appeals on December 21, 2018, the Prague Court of Justice on August 28, 2018, the Portuguese Arbitral Tribunal on September 7, 2018, the Commercial Court of Brussels on December 21, 2018, and the Vienna Court of Justice on January 23, 2019, confirmed by the Vienna Court of Appeals on July 10, 2019.

Some courts have refused to order the requested measures and ruled that SPC No. 040 is likely to be invalid, including the Court of The Hague on June 11, 2018, the Court of Appeal of The Hague by decision of October 23, 2018, the Regional Court of Düsseldorf by decision of October 1st, 2018 confirmed by the Court of Appeal of Düsseldorf on March 15, 2019 and the Regional Court of Barcelona on September 12, 2018.

On the admissibility of the request for invalidity of claims 9 to 18 of the patent

Merck argues that the Teva companies are inadmissible to seek the invalidity of claims 9 to 18 of the patent as long as they do not challenge the validity of the broader main claims, on which the said claims depend.

The Teva Companies argue that an action for nullity of a dependent claim that served as a basis for obtaining a SPC is admissible, since the absence of a challenge to the validity of an independent claim does not constitute acquiescence in the validity of the dependent claims, and that a dependent claim may be null for a reason of its own, such as insufficiency of description.

The court observes that the question of the validity of a claim via the validity of the independent claim from which it depends does not constitute a reason of inadmissibility of the nullity action, but is a question to be decided on the merits.

The Court adopts the relevant grounds on which the first instance judges have righty declared admissible the request of the Teva companies for the nullity of claims 9 to 18 of patent EP 599, which serve as a basis for SPC no. 040, whose validity is contested, which constitutes an obstacle to the marketing by the said companies of a generic drug comprising the combination of ezetimibe and simvastatin, their interest in bringing an action for nullity having therefore been established. The judgment on this point will therefore be confirmed.

On the nullity of claims 9 to 18 of the patent for insufficiency of description

The Teva Companies argue that claims 9 to 18 are void for insufficiency of description in that :
- They are claims for therapeutic use for which Merck does not provide any pharmacological or biological tests related to these teachings;
- there is no demonstration or even assertion of the therapeutic effect and pharmacological properties of a combination of ezetimibe with simvastatin or another inhibitor;
- in the absence of data and examples relating to the combination of ezetimibe and simvastatin, the skilled person will have to determine which combination, with which inhibitor from a list of ten or so, and which dosage for the intended therapeutic use, so that he will have to conduct a genuine research program, all of which demonstrating an excessive effort revealing an insufficiency of description of the disputed claims.

The Merck Company argues that :
- it is up to the person who claims that the invention is not sufficiently described to prove it, and that in this case the Teva companies do not dispute that a drug containing ezetimibe, alone or in combination with other active ingredients, has at least the effect provided by ezetimibe as well as additional effects from the other compounds, and that therefore the combination product of ezetimibe and simvastatin will have at least the effect of treating atherosclerosis and reducing cholesterol levels so that evidence of insufficiency of description is not reported ;
- the patent describes the combination in relation to its therapeutic indication, mentions simvastatin as a preferred inhibitor and gives the dosage of the inhibitor in combination with ezetimibe ;
-the information described in the patent relating to the mechanism of action of the new class of hydroxy-substituted azetidinone compounds combined with the general knowledge of the skilled person on the mechanism of action of HMG-COA reductase inhibitors such as simvastatin made it plausible that the combination product of ezetimibe and simvastatin would be useful in the treatment and prevention of atherosclerosis.

The court recalled that an invention is sufficiently described when the skilled person is able, on reading the description and taking into account his normal professional knowledge, after, if need be, reasonable trial and error, to execute the invention.

It is not disputed in this case that the skilled person, as the 1st instance judges judges correctly defined, is a pharmacologist with specific knowledge in the field of drugs treating hypercholesterolemia.

It is also not discussed that the main claims 1 to 8 relating to the family of substituted azetidinomas as hypocholesterolemic agents in the treatment and prevention of atherosclerosis are sufficiently described. The validity of these claims is not disputed.

Claims 9 to 15 and 18, whose nullity is requested, are claims dependent on main claims 1 to 8. Claim 16 is dependent on Claim 9, and Claim 17 is dependent on Claim 16, so both Claims 16 and 17 are also dependent on main Claims 1 to 8.

With respect to the insufficiency of description opposed to dependent claims 9 to 18, the first instance judges correctly noted that the patent mentions that:
- inhibition of cholesterol biosynthesis by HMG CoA reductase inhibitors has been shown to be an effective way to reduce plasma cholesterol and atherosclerosis and that combination therapy with an HMG CoA reductase inhibitor and a bile acid sequestrant has been shown to be more effective in human hyperlipidemic patients than either agent alone (page 3),
- Inhibitors of cholesterol biosynthesis for use in the combination of the present invention include inhibitors of HMG CoA reductase, inhibitors of squalene synthesis and inhibitors of HGM CoA reductase, and among these, lovastatin, pravastatin and simvastatin are the preferred inhibitors (page 10 and 11) ;
- for combinations of the invention where hydroxy-substituted azetidinone is administered in combination with a cholesterol biosynthesis inhibitor, the daily dose is 0.1 to 80 mg/kg mammalian weight per day ; for HMG CoA reductase inhibitors, the dose is approximately 10 to 40 mg per dose, once or twice daily, resulting in a total daily dose of approximately 10 to 80 mg per day, the exact dose of any component of the combination to be administered being determined by the treating physician and depending on the potency of the compound administered, the age, weight, condition and response of the patient (page 32).

They deduced with relevant rationale, which the court adopts and completes, that the combination of hydroxy-substituted azetidinones with other inhibitors of cholesterol biosynthesis such as HMG CoA reductase inhibitors and in particular simvastatin for the treatment and prevention of atherosclerosis is sufficiently described by the skilled person with his general knowledge at the filing date of the patent application, in particular on the mechanism of action of HMG-COA reductase inhibitors such as simvastatin, was able to reproduce the invention without being forced to perform a research program by himself, so that the Teva companies must be dismissed from their request of nullity, and the judgment under appeal will be upheld on this ground.

On the request for nullity of the SCP and referral to the CJEU

Merck argues that a referral to the CJEU is justified in the present case on the interpretation of :
* Article 3 (a) of the Regulation in that :
- the two-part test of the Gilead C121/17 decision of the CJEU of July 25, 2018 should only be applied in cases where the product is implicitly but necessarily targeted in the patent claims so that where a combination of active ingredients is explicitly claimed in the patent, as in the present case, there is no need to apply the said test, the conditions of Article 3(a) being immediately satisfied ;
- the case law of the CJEU does not require the patent to expressly present the combination product as a distinct invention; the mere fact that the combination product is presented as "another aspect of the invention" does not prevent it from being an invention within the meaning of the Gilead decision, and there is nothing in the Regulation to indicate that distinct SPCs can only be granted for distinct products on condition that the said products are qualified as distinct inventions in the basic patent ;
- Gilead decision, while using the term "combined effect", does not impose to fulfill Article 3(a) the disclosure in the basic patent of research results demonstrating this combined effect;
* Article 3(c) of the Regulation in that :
- teachings of the Sanofi decision are not applicable in the present case because, unlike the combinations referred to in the Sanofi case, the combination of ezetimibe and simvastatin is a subject matter of the invention claimed in the EP 599 patent;
- the concept of product must be the same for article 3(a) and 3(c).

In the alternative, Merck argues that :
- the combination of the active ingredients of ezetimibe and simvastatin constitutes a "product" within the meaning of the SPC Regulation ;
- this combination product is explicitly mentioned in claim 17 of the contested patent so that it is protected by a patent in force pursuant to Article 3(a) of the said Regulation ;
- the combination "product" ezetimibe and simvastatin, which is described in the patent and is an object of the invention, has not already been the subject of an SPC so that it meets the requirements of Article 3(c) of the Regulations ;
- the Georgetown University decision C[484/12] of the CJEU of December 12, 2013 recognizes that several inventions may be present in the same basic patent and that the grant of an SPC for a first product protected by a basic patent does not preclude the grant of an SPC for a second product also protected by that patent, so that SPC No. 040 is valid;
- the patent discloses a combined effect of ezetimibe and simvastatin in that it states that the invention also consists of the combination of hydroxy-substituted azetidinone with HMG CoA reductase inhibitors to reduce plasma cholesterol levels for the treatment and prevention of atherosclerosis and discloses the dosages of the HMG CoA reductase inhibitors, the skilled person necessarily understands that, due to lowers amounts of cholesterol delivered to the liver by ezetimibe, smaller doses of statins are required to achieve an equivalent or improved effect compared to the statin administration alone, thereby reducing the risk of adverse events associated with high doses of statins.

The Teva companies argue in substance that the combination product of ezetimibe and simvastatin constitutes a mere variation of the invention and not a distinct product from ezetimibe alone, for which the patentee has already obtained a SPC, and which allowed him to it to oppose the marketing of ezetimibe combined with any other product, in addition to the fact that the marketing authorization of July 28, 2005 was not the first marketing authorization obtained for the product, so that SPC No. 040 is null. In the alternative, they request that a question be referred to the CJEU.

The Court points out that Article 3 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the SPC for medicinal products provides: "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
(a) the product is protected by a basic patent in force;
(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Article 1 of that Regulation defines "product" as "the active ingredient or composition of active ingredients of a medicinal product", and "basic patent" as "a patent which protects a product as such, (...)".

In the present case, a first SPC was granted on February 4, 2005 to Merck on the basis of the basic patent EP 599 for the ezetimibe product alone. The disputed SPC No. 040 is the second SPC granted under the same basic patent on December 21, 2006 for the [combination] of matter product of ezetimibe and simvastatin.

The aforementioned articles of the Regulation must be interpreted in the light of the case law of the CJEU, in particular in the present case with regard to the Sanofi C 443/12 decision dated December 12, 2013, which deals with similar facts to those of the present case, in which the holder of a patent has obtained on the basis of this patent protecting an innovative active principle and a MA for a medicine containing it as a single active principle, a SPC for this active principle, then a second SPC on the basis of the same patent and a MA for a different medicine containing said active principle in [combination] with another active principle, which, as such, is not protected by the patent.

Case C 443/12 concerns a patent covering a family of compounds including irbesartan, an antihypertensive active principle, and also covering pharmaceutical compositions comprising several active principles in combination, one of which is a compound according to the invention, and the other may be a diuretic, in particular, the claim 20 of said patent relating to a pharmaceutical composition comprising irbesartan in combination with a diuretic. On the basis of said patent, Sanofi obtained a first SPC relating to the irbesartan product alone, then a second SPC relating to the combination of irbesartan with a diuretic, in this case hydrochlorothiazide (hctz).

Merck argued that this Sanofi case law is not applicable to the case at hand in that the product in question concerned the combination of irbesartan with hctz, and that the patent did not contain a claim expressly mentioning hctz, so that if the two-part test in Gilead C121/17 had been applied, the combination product at issue would not have been considered as protected as such by the basic patent within the meaning of Article 3 a) of the Regulation, since the htcz was neither expressly mentioned nor necessarily and specifically targeted.

The Court observes that the CJEU, in its Sanofi decision C443/12, after reminding in recital 29 that a patent protecting several distinct "products" can, in principle, allow to obtain several SPCs in connection with each of those distinct products, provided in particular that each of them is "protected" as such by that "basic patent" within the meaning of Article 3(a) of the Regulation, then specified in recital 30 that " even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that regulation, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, each time he places on the market of a Member State a medicinal product containing, on the one hand, the principle active ingredient, protected as such by its basic patent, and, on the other hand, another active ingredient, which is not protected as such by the said patent. It follows that the Sanofi case-law, "even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied " is applicable to the present case with regard to the application of Article 3(c) of the Regulation.

Merck then argues that the CJEU Gilead decision C121/17 of July 25, 2018 and Royalty Pharma C 650/17 of April 30, 2020 do not require that the basic patent present the combination product as a distinct invention.

The court observes that Gilead and Royalty Pharma decisions clarified previous CJEU decisions in cases where one of the active ingredients in a combination is not designated by its chemical name or structure but only by its functional characteristics, which is not the case for the product at stake, concern situations where the SPC granted for the combination product is the first (and sole) SPC granted on the basis of the basic patent, and not, as in the present case, the second, so that the notion of "distinct product" protected as such by the basic patent, mentioned in recitals 29 and 30 of the CJEU decisions Georgetown University C 484/12 and Sanofi C 443/12 of December 12, 2013, is not applicable there.

In these decisions C 484/12 and C 443/12 relating to cases where, as in the present case, the same basic patent could be considered as protecting several products within the meaning of Article 3(a), the CJEU recognized the possibility of granting several SPCs on the basis of a single basic patent, provided that the said patent covers several distinct products.

In the case at hand, it is therefore a question of verifying whether from the point of view of a skilled person, on the basis of his general knowledge at the filing date of the basic patent, and considering the description used to interpret the claims, pursuant to Article 69 of the European Patent Convention and its Interpretative Protocol, the combination product of ezetimibe and simvastatin, the subject matter of the second contested SPC, constitutes a product distinct from ezetimibe alone, protected by the patent as such.

The court notes in this regard that the description of the EP 599 patent comprises, after presenting the background of the invention, a part entitled "Summary of the invention", paragraphs 9 to 13 of which set out in the form of Markush formula I the new hypocholesterolemic compounds, the hydroxy-substituted azetidinones, which is the subject of the invention, for the treatment and prevention of atherosclerosis, and then states in paragraph [17] "In yet another aspect, the invention relates to a kit comprising in one container an effective amount of a hydroxy-substituted azetidinone cholesterol absorption inhibitor of formula I, an inhibitor of the cholesterol biosynthesis and a pharmaceutically acceptable carrier.

The mains claims 1 to 8 relate to compounds of the substituted azetidinone family, including ezetimibe in claim 8, the dependent claim 9 teaching, also for the treatment and prevention of atherosclerosis, the combination of a hydroxy-substituted azetidinone and a cholesterol biosynthesis inhibitor, claim 16 indicating that the inhibitor of cholesterol biosynthesis is selected from a group consisting of HMG CoA reductase inhibitors, inhibitors of squalene synthesis and squalene epoxidase inhibitors, and claim 17 teaching that the cholesterol biosynthesis inhibitor is selected from a group consisting of lovastatin, prevastatin, fluvastatin, simvastatin, CI-981 [atorvastatin], DMP-965, L-659, 699, squalestatin 1 and NB-598.

The description of the patent, which uses the singular to designate the invention, and uses the formula "in yet another aspect" to present the combination of a hydroxy-substituted azetidinone, object of the invention, with a cholesterol biosynthesis inhibitor, refers indifferently for hydroxy-substituted azetidinones alone and for their combination with a cholesterol biosynthesis inhibitor, to an effect "for the treatment and prevention of atherosclerosis or for the reduction of plasma cholesterol levels" without any indication of the specific therapeutic effect that distinguishes the product composed of ezetimibe alone from those comprising the combination of ezetimibe and a cholesterol biosynthesis inhibitor such as simvastatin, so that the skilled person, who was aware in the prior art of the possibility of combining two anticholesterolemic drugs having different mechanisms of action (paragraph 8 of the patent - an HMG CoA reductase inhibitor and a bile acid sequestrant), and who was familiar with statins, and in particular simvastatin, which have been commonly used since the late 1980s for the treatment of hypercholesterolemia, will not consider that the combination of ezetimibe with simvastatin, as the one with the 9 other active ingredients also covered by claim 17, in particular atorvastatin, for which Merck, on the basis of the same reasoning, filed a third SPC on September 12, 2014, constitutes a distinct product protected by the basic patent as such.

In the Sanofi aforementioned decision, to the question referred by the referring court as to whether "in a situation where many products are protected by a basic patent in force, does Article 3(c) of the Regulation preclude the patent proprietor from obtaining a certificate for each of the protected products, the CJEU, after having recalled in recital 40 that " the objective of that regulation is 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 forms, including in the form of combinations based on that active ingredient", said : " in circumstances (…) where, on the basis of a patent protecting an innovative active ingredient and an MA for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained an SPC for that active ingredient, Article 3(c) of Regulation No 469/2009 must be interpreted as precluding the holder of that patent from obtaining, on the basis of that same patent but an MA for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent, a second SPC relating to that combination of active ingredients".

In the present proceeding, as in the Sanofi case, the EP 599 patent protecting the active ingredient of hydroxy-substituted azetidinones as such, and in particular ezetimibe, has already led to the grant of a SPC on this active ingredient to its holder, and this first SPC relating to ezetimibe alone allowed Merck to oppose to the marketing of a drug containing ezetimibe in combination with a statin such as simvastatin and having a therapeutic indication similar to that of the drug Ezetrol.

It follows from all of these elements that there is no need for a CJEU referral and that the cumulative conditions laid down in Article 3(a) and (c) of the Regulation are not met, so that CCP No. 040 must be annulled. The judgment under appeal will therefore be overturned on the latter ground.

However, the Teva companies' requests for publication under penalty payment will not be granted, and the first instance judgment is confirmed on this point.

FOR THESE REASONS,

Confirms the appealed decision in all its provisions, except that it dismissed Teva Pharmaceuticals Europe BV and Teva Santé's application for the nullity of SPC no. 05C0040 and ordered them to pay the costs pursuant to Article 700 of the Code of Civil Procedure;

Ruling again within this limit,

Declares the supplementary protection certificate FR05C0040 null and void;

Says that this judgment will be transmitted to the National Institute of Intellectual Property (INPI) by the most diligent party, once it has become final;

Rejects all other claims of the parties contrary to the motivation ;

Orders Merck Sharp & Dohme Corp. to pay the costs of first instance and appeal, which may be recovered in accordance with the provisions of article 699 of the Code of Civil Procedure, and in view of article 700 of the said Code, orders it to pay Teva Pharmaceuticals Europe BV and Teva Santé for the non-recoverable costs of first instance and appeal, a total amount of EUR 150,000.

The Clerk P/ the President unable to attend