SWEET COURT
Patent and Market Court
Rotel 0218

DECISION
2021-04-07
Stockholm

Target no.
PMÖÄ 1213-20

CONTESTED DECISION
Decision of the Patent and Market Court 2020-01-10 in case PMÄ 1331-17, see Annex A

PARTER

Complainant
AstraZeneca AB, 556011-7482
151 85 Södertälje

represented by: M. B., Patent Attorney

Counterparty
Swedish Patent and Registration
Office Box 5055
102 42 Stockholm

SECTOR
Supplementary protection for medicinal products

DECISION OF THE PATENT AND MARKET COURT

The Patent and Market Court rejects the appeal.

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YRKANDEN M.M.

AstraZeneca AB has requested that the Patent and Market Court set aside the contested decision and remit the supplementary protection certificate application 1490041-9 to the Patent and Registration Office for further processing.

The Patent and Registration Office (PRV) has opposed the amendment of the decision of the Patent and Market Court.

GRUNDER

In support of its appeal, AstraZeneca submits that the application for a supplementary protection certificate satisfies the conditions laid down in Article 3(a) and (c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning supplementary protection certificates for medicinal products (Regulation on supplementary protection certificates for medicinal products).

In support of its position, the PRV submits that the condition in Article 3(c) is not fulfilled.

EVIDENCE

AstraZeneca has relied on the published international patent application WO 03/099836 A1 in the Patent and Market Court.

DEVELOPMENT OF ACTION

AstraZeneca

AstraZeneca has developed its action in essentially the same way as in the Patent and Market Court, with the following additions in summary.

Article 3a

In its judgment of 25 July 2018, C-121/17, EU:C:2018:585, Teva, the European Court of Justice has clarified when a combination product is protected by a basic patent. The CJEU states that Article 3(a) of the SPC Regulation must be interpreted as meaning that a product consisting of several active ingredients with a combined effect is 'protected by a basic patent in force', within the meaning of that provision, when the combination of active ingredients of which that product consists, even if not expressly mentioned in the claims of the basic patent, is necessarily and specifically referred to in those claims.

AstraZeneca's supplementary protection certificate application is based on the basic patent EP 1 506 211 B1 (EP 211). Claim 7 of the basic patent specifically, clearly and unambiguously identifies the combination product 'dapagliflozin and metformin'. The published international patent application WO 03/099836 A1 on which the basic patent is based has always contained patent claims which specifically, clearly and unambiguously identify the combination product 'dapagliflozin and metformin'. Since the combination 'dapagliflozin and metformin' is specifically identified in the claims of the basic patent, the condition of Article 3(a), as interpreted by Teva, is fulfilled.

The concept of "the essence of the innovative activity", which has been expressed in the contested decision as the "central inventive concept" of the invention, is, as stated by the Court of Justice of the European Union in its judgment of 30 April 2020, C-650/17, EU:C:2020:327, Royalty Pharma, paragraph 32, not relevant for the interpretation of the condition in Article 3(a).

PRV

In addition to what is stated in the PRV's decision (Annex 1 to Annex A), the PRV has essentially stated the following.

Article 3a

The PRV's assessment, like AstraZeneca's, is that the patented invention necessarily comprises the product "a combination of dapagliflozin or a pharmaceutically acceptable salt thereof and metformin or a pharmaceutically acceptable salt thereof" and that the product is specifically identifiable by a person skilled in the art, i.e. Article 3(a) of the SPC Regulation is fulfilled.

Article 3c

The PRV is of the opinion that the condition in the wording of Article 3(c) is fulfilled for the product "a combination of dapagliflozin or a pharmaceutically acceptable salt thereof and metformin or a pharmaceutically acceptable salt thereof" since the previously granted SPC referred to a different product, namely "dapagliflozin and pharmaceutically acceptable salts thereof".

The PRV understands the practice developed by the European Court of Justice to mean that, in the circumstances of the present case, it would be contrary to the purpose of the SPC Regulation if a new SPC could be obtained each time a new combination of dapagliflozin and another ingredient obtained marketing authorisation, which in the present case would mean an extension of the period of validity of AstraZeneca's previously granted SPC for the product dapagliflozin (cf. e.g.e.g. judgment of the Court of Justice of the European Union of 12 December 2013, Actavis, C-443/12, EU:C:2013:833, paragraphs 29 and 30 and 34 and 35).

That the CJEU has clarified that the concept of "core inventive advance" is not relevant to the interpretation of
Article 3(a) (cf. paragraph 32 of Royalty Pharma) does not, in the view of the PRV, alter this assessment.

THE REASONS FOR THE DECISION

Introduction

The Patent and Market Court rejected AstraZeneca's appeal because the conditions of Articles 3(a) and 3(c) of the SPC Regulation were not considered to be met. Although the parties in the Patent and Market Court agree that the condition of Article 3(a) is fulfilled, it is for the Patent and Market Court to make an independent assessment on this issue. However, the parties have different views on whether the condition in Article 3(c) can be considered to be fulfilled. The Court will therefore first assess whether the condition in Article 3(a) is fulfilled and, if so, then assess whether the condition in Article 3(c) is fulfilled.

Article 3a

Article 3(a) of the Regulation on supplementary protection certificates for medicinal products requires that the product is protected by a basic patent in force before a supplementary protection certificate can be granted.

According to Article 1(b) of the Regulation, 'product' means the active ingredient or combination of active ingredients of a medicinal product. Article 1(c) defines a basic patent as a patent which protects a product as such, a method of making a product or a use of a product and which is invoked by the holder as a basis for the grant of a supplementary protection certificate.

In its assessment, the Patent and Market Court has taken into account Actavis and the judgments of the European Court of Justice of 12 December 2013, Georgetown, C-484/12, EU:C:2013:828 and of 12 March 2015, Boehringer, C-577/13, EU:C:2015:165.

Following these judgments, the Court of Justice of the European Union has given further guidance on the interpretation of the condition in Article 3(a) in the Teva and Royalty Pharma judgments.

In Teva, paragraph 57, the CJEU explained that Article 3(a) must be interpreted as meaning that a product consisting of several active ingredients with a combined effect is 'protected by a basic patent in force', within the meaning of that provision, where the combination of active ingredients of which that product consists, even if not expressly mentioned in the claims of the basic patent, is necessarily and specifically referred to in those claims of the patent. In making this assessment, account shall be taken of whether, in the light of the state of the art at the date of filing of the application or at the date of priority of the basic patent, a person skilled in the art would consider that

- a combination of these active ingredients necessarily, in the light of the description and drawings in this patent, are covered by the invention which the patent protects, and that
- each of these active ingredients can be specifically identified, in the light of all the circumstances described in this patent.

The CJEU then stated in Royalty Pharma, inter alia. In Teva, the CJEU clearly relied on an interpretation of Article 3(a) of the SPC Regulation, in which the concept of 'the essence of the innovative activity' is not relevant. Article 3(a) of the Regulation must be interpreted as meaning that a product is protected by a basic patent in force, within the meaning of that provision, where it corresponds to a general functional definition used in one of the claims of the basic patent and necessarily falls within the scope of the invention which the patent protects, without, however, being individualised as a concrete embodiment of the patent, provided that it can be specifically identified by a person skilled in the art, in the light of all the information disclosed by the patent, on the basis of his general knowledge in the field concerned on the date of filing or the date of priority and in the light of the state of the art on that date. (See paragraphs 32 and 43.)

The provision of Article 3(a) is fulfilled

The Patent and Market Court states the following. Claim 1 of the basic patent specifically mentions the active ingredient dapagliflozin. Claim 7, which is connected to claim 1, relates to a pharmaceutical combination which is claimed to contain the active ingredient metformin and consequently, due to the connection of claim 7 to claim 1, also dapagliflozin according to claim 1. The Patent and Market Court therefore considers that a person skilled in the art would consider that a combination of the ingredients dapagliflozin and metformin is necessarily covered by the invention protected by the patent and that each of the active ingredients is specifically identifiable by the basic patent.

For these reasons, the Court of Appeal, unlike the Court of First Instance, concludes that the condition of Article 3(a) is fulfilled.

Article 3c

Article 3(c) of the Regulation on supplementary protection certificates for medicinal products requires that a supplementary protection certificate has not already been granted for the product (see the judgment of the Court of Appeal of 28 February 2011 in Case No 07-278, p. 5).

In Actavis, the Court of Justice of the European Union interpreted Article 3(c) and stated, in the circumstances of the main proceedings, that. Where, on the basis of a patent protecting an innovative active ingredient and an authorisation to market a medicinal product containing that ingredient as the sole active ingredient, a patentee has already obtained a supplementary protection certificate for that active ingredient enabling him to oppose the use of that active ingredient alone or in combination with other active ingredients, Article 3(c) of the Regulation on supplementary protection certificates for medicinal products must be interpreted as precluding the patentee - on the basis of the same patent but on the basis of a subsequent marketing authorisation for another medicinal product containing that active ingredient in combination with an innovative active ingredient - from refusing to grant a supplementary protection certificate to a medicinal product containing that active ingredient.

another active ingredient, which is not as such protected by the said patent - obtains a second supplementary protection certificate for this combination of active ingredients (see paragraph 43).

In Actavis, the CJEU further declared that Article 3(c) had not been fulfilled regardless of whether the combination of the active ingredients as such was protected by the basic patent and Article 3(a) thus fulfilled (see paragraph 44).

The provision of Article 3(c) is not fulfilled

The Patent and Market Court considered that "dapagliflozin" constitutes the innovative ingredient of the basic patent and constitutes the central inventive concept. However, the Patent and Market Court stated that for this product a prior SPC has already been granted based on the basic patent in question, so that a second SPC for another product consisting of dapagliflozin does not fulfil the condition of Article 3(c) of the SPC Regulation. The Court noted that, in addition, the prior SPC could already have prevented other manufacturers from supplying and marketing both dapagliflozin and combinations of dapagliflozin and other ingredients.

The Patent and Market Court notes that supplementary protection for the combination product containing the ingredients dapagliflozin and metformin has not previously been granted and agrees with the parties that the condition in the wording of Article 3(c) is fulfilled.

The question is then whether Article 3(c) nevertheless precludes the grant of a supplementary protection certificate for the said combination product in the light of the interpretation of Article 3(c) by the Court of Justice of the European Union.

AstraZeneca has previously been granted a supplementary protection certificate for the product dapagliflozin. With this SPC, AstraZeneca has had the possibility to oppose the use of dapagliflozin alone or in combination with other active ingredients, e.g. metformin. By having this possibility, AstraZeneca has already been compensated for the delay in the commercialisation of the invention which has

arising from the time elapsed between the date of filing of a patent application and the date of obtaining the first marketing authorisation (see Actavis, paragraphs 31 and 40). The Court of Justice of the European Communities considers, in the light of the Court of Justice's ruling in Actavis, that Article 3(c) therefore precludes the grant of supplementary protection for the product dapagliflozin and metformin in combination.

For these reasons, the Patent and Market Court comes to the same conclusion as the Patent and Market Court, namely that Article 3(c) precludes the grant of supplementary protection. The appeal must therefore be dismissed.

Summary

Unlike the Court of First Instance and taking into account recent case law of the Court of Justice of the European Union, the Court of First Instance has come to the conclusion that Article 3(a) of the Supplementary Protection Certificate Regulation is fulfilled, i.e. a product containing the active ingredients dapagliflozin and metformin has been considered protected by the basic patent in question. However, the Court of First Instance of the European Union, like the Court of First Instance of the European Union and for partly the same reasons, has come to the conclusion that the wording of Article 3(c) of the Regulation is in itself fulfilled, but that the condition of the Article - that supplementary protection has not already been granted for the product - cannot be considered fulfilled in view of the interpretation of the Article by the Court of Justice of the European Union.

APPEAL

There is no reason to make an exception to the general rule that the decision of the Patent and Market Court may not be appealed (see Chapter 1, Section 3, paragraph 3 of the Patent and Market Courts Act, 2016:188). This decision may therefore not be appealed.

The decision was taken by Peter Strömberg, former judge of the Court of Appeal, Anders Brinkman, Judge-Rapporteur, Sara Ulfsdotter, Judge of the Court of Appeal and Marianne Bratsberg, former Patent Attorney.

STOCKHOLM DISTRICT COURT
Patent and Market Court

MINUTES
2020-01-10
Handling in Stockholm

Annex 6
Target no.
PMÄ 1331-17

Proceedings in the absence of the parties

RIGHT
Mr Alexander Ramsay, Counsellor, Ms Yvonne Siösteen, Judge-Rapporteur, and Ms Anna Hedberg, Patent Attorney

RECORDING SECRETARY
Referees

PARTER

Complainant
AstraZeneca AB

Counterparty
Patent and Registration Office
PRV Stockholm
Box 5055
102 42 Stockholm

SECTOR
Supplementary protection for medicinal products

CONTESTED DECISION
Decision of the Patent and Registration Office (PRV) 2016-11-23 regarding the Supplementary Protection Certificate application 1490041-9, see Annex 1.

BACKGROUND

AstraZeneca AB filed an application with the PRV on 14 July 2014 for a supplementary protection certificate for medicinal products relating to the product "a combination of dapagliflozin or a pharmaceutically acceptable salt thereof and metformin or a pharmaceutically acceptable salt thereof".

The European patent EP 0373664.2 with publication number EP 1 506 211 B1 relating to "C-aryl glucoside SGLT2 inhibitors and method" was cited as the basic patent. The application stated that the product is disclosed in claims 5, 6 and 7. Dapagliflozin

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08:00-16:00 STOCKHOLM DISTRICT COURT **MINUTES**

Annex 6

was cited as a specific compound in claims 1 and 2. Metformin was cited as a specific compound in claim 7.

For the wording of the patent claims in Swedish translation see Annex 2.

Before the PRV, the applicant relied on the fact that the medicinal product 'XIGDUO-dapagliflozin/metformin' was authorised for sale as a medicinal product in Sweden on 16 January 2014 (EU/1/13/900) as the first marketing authorisation for the product under Article 3(d) 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 (the 'SPC Regulation').

By the contested decision, the PRV rejected the application for a supplementary protection certificate. The reason given by the PRV was that AstraZeneca had already obtained a supplementary protection certificate for the product 'dapagliflozin and pharmaceutically acceptable salts thereof' through SPC 1390017-0 based on the same basic patent as above and the marketing authorisation for the medicinal product Forxiga. According to Article 3(c) of the SPC Regulation, one of the conditions for obtaining a SPC is that a SPC has not already been granted for the product.

The PRV considered, with reference to the case law of the European Court of Justice, that it is in principle possible to obtain a second supplementary protection certificate based on the same basic patent. However, it is a precondition that each product is protected as such by the basic patent (see judgments of the Court of Justice of the European Union of 12 December 2013 in C-443/12, EU:C:2013:83, Actavis v Sanofi (Actavis) and C-484/12, EU:C:2013:828, Georgetown University v Octrooicentrum Nederland, (Georgetown)).

According to the PRV, the patent holder has already been compensated, through the earlier supplementary protection, for the delay in the sale of what constitutes "the core inventive advance".

The PRV therefore considered that the SPC application did not meet the condition of Article 3(c) of the

the Supplementary Protection Order.

APPEAL

AstraZeneca has applied to the Patent and Market Court for the grant of Supplementary Protection Certificate No 1490041-9 in respect of the product 'a combination of dapagliflozin or a pharmaceutically acceptable salt thereof and metformin or a pharmaceutically acceptable salt thereof' (hereinafter 'dapagliflozin and metformin').

GRUNDER

AstraZeneca maintains in support of its application that its application for supplementary protection for 'dapagliflozin and metformin' satisfies the condition laid down in Article 3(c) of the SPC Regulation.

DEVELOPMENT OF ACTION

In support of its action, AstraZeneca submits essentially the following.

The combination of dapagliflozin and metformin in the present application is a clearly distinguishable invention from the monotherapy invention of dapagliflozin alone. The basic patent protects dapagliflozin and also a second invention; the combination of dapagliflozin and metformin.

The specific combination is identified in claim 7 of the basic patent which is directed to the combination of an SGLT2 inhibiting compound, which is identified in claim 1 as dapagliflozin or a pharmaceutically acceptable salt thereof, a stereoisomer thereof, or a prodrug ester thereof and metformin. Metformin is also the first identified antidiabetic agent to appear in the list of antidiabetic agents in claim 7.

From the description it appears that a combination of dapagliflozin with another antidiabetic agent can generate antihyperglycemic results that are greater than what is possible to obtain from these drugs individually and greater than the total additive antihyperglycemic effects generated by these drugs, see paragraph [0054] of the basic patent. This points to a clear expectation that dapagliflozin in combi- nation with another antidiabetic agent, in particular metformin, would act synergistically.

The specific combination of dapagliflozin and metformin is thus a separate invention protected by the basic patent. It represents a fundamental innovative advance in its own right. The patentee could have filed a separate divisional patent application for the combination of dapagliflozin and metformin. The fact that this was not done should not prevent the grant of a second supplementary protection based on the basic patent.

The product required research and development, including clinical trials, which resulted in further delays before marketing authorisation could be granted for the combination product.

An analogous situation regarding a combination product has been considered and discussed in the UK decision (BL 0/117/16) issued by the UKIPO on 12 January 2016. The product "ezetimibe and atorvastatin" was considered "protected as such" by the basic EP patent.
0 720 599 B1.

When the SPC for dapagliflozin alone expires, it will be possible for third parties to use dapagliflozin in other ways and in other combinations. If the remaining SPC is granted, the SPC will continue, but it will only protect the combination of dapagliflozin and metformin; it will not protect all combinations of dapagliflozin.

Similar applications for supplementary protection as in the present application have been granted for the product 'dapagliflozin and metformin' in the following countries. Bulgaria, Greece, Cyprus, Spain, Slovakia, Denmark, Slovenia, Luxembourg, Italy, Estonia, Lithuania, Latvia and Malta.

COURT'S ASSESSMENT

A basic purpose of supplementary protection is to extend the patent term of the patented invention, i.e., like the patent, it should protect the addition to the technology that the invention has contributed. However, the extended protection is limited to the specific product authorised to be marketed as a medicinal product.

When assessing the authorisation of a supplementary protection certificate for a medicinal product, the concept of product is of central importance. The product is defined in Article 1 of the SPC Regulation and this product definition also applies to the product in Article 3 of the same Regulation which sets out the conditions for obtaining a SPC.

Article 1(b) defines the product as the active ingredient or combination of active ingredients of a medicinal product.

Furthermore, Article 1(c) defines a basic patent as a patent which protects *a product as such*, a method of producing a product or a use of a product and which is invoked by the proprietor as a basis for the grant of supplementary protection.

According to Article 3(a), one of several conditions for supplementary protection is that the product is protected by a valid basic patent and according to Article 3(c), another condition is that no supplementary protection has previously been granted for the product, (cf. the judgment of the Court of Appeal in case 07-278 concerning a translation error of the term "medicinal product" in the Swedish version.)

Supplementary protection has already been granted for the product 'dapagliflozin' based on the basic patent EP 1 506 211 B1, which is also invoked as the basic patent in the application now before the Court.

In cases C-484/12 (Georgetown), paragraph 30, and C-577/13 (Boehringer), paragraph 33, the CJEU has ruled that it is in principle possible to obtain several SPCs for different products based on the same basic patent. However, each product as such must be "protected" by a "basic patent" within the meaning of Article 3(a) in conjunction with Article 1(b) and (c) of the SPC Regulation, see paragraph 33 in Boehringer.

However, according to the CJEU, the aim of the SPC Regulation is not to fully compensate for the delay in the commercialisation of an invention or to compensate for all possible forms of commercialisation of the invention, including combinations of the same active ingredient, see CJEU judgment of 12 March 2014 in C-577/13, EU:C:2015:165, Actavis v Boehringer Ingelheim Pharma (Boehringer), paragraphs 35 and 37 and C-443/12 (Actavis), paragraphs 30 and 40.

In Boehringer, the question was whether a supplementary protection certificate could be granted for a product consisting of an active ingredient, which constituted the subject-matter of the invention, in combination with another ingredient. The CJEU held in that case that in order for an active ingredient to be considered 'protected as such', it must constitute the subject-matter of the invention covered by the patent, see paragraph 38. Furthermore, the ECJ held that, in the circumstances of the case, the prior supplementary protection of the active ingredient which is the subject matter of the invention, based on the same basic patent, prevents a combination with another active ingredient which is not the subject matter of the invention.
for the invention.

In Actavis, the CJEU ruled that it is not possible to obtain a second supplementary protection certificate if a first supplementary protection certificate has already been granted for an active ingredient, and this ingredient is combined in a product with another active ingredient that is not "protected

as such' of the basic patent, see Actavis, paragraph 43), see paragraph 33 in C-577/13 (Boehringer).

Thus, for an active ingredient to be considered protected by the basic patent under Article 1(c) and Article 3(a) of the SPC Regulation, it must constitute 'the subject-matter of the invention' covered by the patent, cf. paragraph 38 of Boehringer. As stated above, a fundamental condition of the SPC Regulation is that a supplementary protection certificate should be granted for the contribution to the technology made by the invention.

In Boehringer, the CJEU stated that all the interests involved, including the pharmaceutical industry and public health, should be taken into account. The CJEU considered that it would be contrary to the balancing exercise to allow the successive placing on the market of the active ingredient together with an unlimited number of other active ingredients which are not the subject matter of the invention covered by a basic patent to confer the right to several supplementary protection certificates, see paragraph 36.

According to Boehringer, point 38, the second ingredient in a combination of two ingredients must be protected as such in order to obtain a supplementary protection certificate for the combination. The Court must therefore consider whether metformin meets the requirement of being 'protected as such', within the meaning of the SPC Regulation, by EP 1 506 211 B1. If not, the earlier SPC for the product 'dapagliflozin' precludes the patentee from being granted a second SPC for the product 'dapagliflozin and metformin'.

AstraZeneca argues that the basic patent covers and protects more than one invention; that it protects both dapagliflozin and a second invention consisting of the combination of dapagliflozin and metformin. According to AstraZeneca, dapagliflozin is therefore not 'the sole subject matter'. AstraZeneca has argued that the combination of dapagliflozin and metformin has a synergistic effect compared to dapagliflozin alone and therefore the product 'dapagliflozin and metformin' constitutes a separate invention which is 'protected as such' by the basic patent. Thus, AstraZeneca considers that a supplementary protection for

the product 'dapagliflozin' would not be an obstacle to a new supplementary protection certificate for this second product based on the same basic patent.

The Court notes that metformin is only one of a large number of other known antidiabetic substances mentioned in the description which may possibly be combined with dapagliflozin, see claim 7 and page 14, lines 16-29 and lines 34-35. In the description on page 14, line 34-page 15, line 8, a biguanide such as metformin or phenformin, sulfonylureas such as glyburide, glimepiride and others are mentioned as preferred. However, all of these antidiabetic compounds are generally known to the skilled person to be used in the treatment of diabetes.

In Boehringer, the European Court of Justice has ruled that a supplementary protection certificate for a combination of two ingredients cannot be granted in the following cases. The basic patent contains a claim directed to the product comprising the one active ingredient which alone constitutes the subject matter of the invention for which the patentee already has a supplementary protection and additional claims relating to a product containing a combination of active ingredients and an additional ingredient which does not constitute the subject matter of the invention, see paragraphs 39 and 41.

According to the assessment of the Patent and Market Court, the central inventive concept of the basic patent is dapagliflozin. Neither in the patent description nor otherwise has any effect resulting from the combination of metformin and dapagliflozin been suggested which adds anything to the central inventive concept. A mere assertion of a synergistic effect that would result from a combination with known antidiabetic substances, such as metformin, cannot be considered to constitute a technical contribution beyond the scope of the central inventive concept. The product 'dapagliflozin and metformin' cannot therefore be regarded as an invention which, under the SPC Regulation, can form the basis for extended patent protection. The Court finds that metformin is not protected as such within the meaning of paragraph 38 of Boehringer. The condition in Article 3(a) that the product be protected by a basic patent in force is therefore not met.

Therefore, a supplementary protection certificate cannot be granted for the product 'dapagliflozin and metformin'.

The fact that the combination of dapagliflozin and metformin required research and development, including clinical trials, which resulted in further delays before the marketing authorisation for the product "dapagliflozin and metformin" could be issued does not change this assessment. Nor does what other courts and authorities have decided with regard to the granting of a supplementary protection certificate for the product
"dapagliflozin and metformin" and the product "ezetimibe and atorvastatin" changes the Court's assessment.

In the Court's view, 'dapagliflozin', as described above, constitutes the innovative ingredient of EP 1 506 211 B1 and constitutes the central inventive concept and is therefore a product protected as such by the basic patent EP 1 506 211 B1 within the meaning of the Supplementary Protection Regulation. However, this product has already been granted a previous SPC 1390017-9 based on the basic patent in question, so that a second SPC for another product consisting of dapagliflozin does not fulfil the condition of Article 3(c) of the SPC Regulation. In addition, it can be noted that the previous SPC could already have prevented other manufacturers from supplying and marketing dapagliflozin as well as combinations of dapagliflozin and other ingredients.

In the light of the above, the Court considers that it is not possible under the SPC Regulation to obtain an additional SPC based on the basic patent and for the product "dapagliflozin and metformin".

The appeal must therefore be dismissed.

DECISION

The Patent and Market Court rejects the appeal.

HOW TO APPEAL, see Annex 3 (PMD 13)

Written appeal, addressed to the Patent and Market Court, must be received by the Patent and Market Court no later than 2020-01-31

Permission to appeal is required.

Yvonne Siösteen

Protocol exhibited

PRV
SWEDISH PATENT AND REALSTRATION OFFICE

DECISION TO REJECT

Date 2016-11-23

SPC application No. 1490041-9
Basic Patent No. 03736643.2 (1 506 211)

ZACCO SWEDEN AB
BOX 5581
114 85 STOCKHOLM

Your reference: P41403370SE00
Applicant: AstraZeneca AB, 151 85 Sodertiilje SE.

Decision
The Swedish Patent and Registration Office (PRV) rejects your application for a Supplementary Protection Certificate for a medicinal product, with reference to Article 10.2 of Regulation (EC) No 469/2009.

Reason for the decision

The application

The present application for a Supplementary Protection Certificate for a medicinal product is directed to the product 'A combination of dapagliflozin or a pharmaceutically acceptable salt thereof and metformin or a pharmaceutically acceptable salt thereof'.

As basic patent for the present application, the applicant relies on 03736643.2 (1 506 211) concerning "C-aryl Glucoside SGLT2 Inhibitors and Method".

The applicant refers to the marketing authorisation EU/1/13/900 of 2014-01-16 as the first authorisation to place the product on the Swedish market as a medicinal product. This authorisation relates to the medicinal product Xigduo.

Articles lb and 3c of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (hereinafter referred to as the SPC Regulation)

Article lb defines that "product" for the purpose of the SPC Regulation means "the active ingredient or combination of active ingredients of a medicinal product".

Article 3 of the SPC Regulation specifies the conditions that must be met in order for a certificate to be issued. A certificate shall, therefore, only be granted if the following conditions are met in the Member State in which the application is submitted and at the date of said 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.

Summary of the applicant's arguments

In a statement of remarks dated 2015-02-20 the applicant was given the opportunity to respond to PRV's position that the application does not meet the condition laid down in article 3c of the SPC Regulation. The statement of remarks prompted an answer, dated 2015-06-17, in which the applicant argues that the application fulfils all the requirements of article 3 of the SPC Regulation, wherefore a certificate should be issued.

In the answer, the applicant refers to the rulings in C-443/12 (Actavis) and C-484/12 (Georgetown). It is pointed out that both of the decisions initially comment that it is possible to obtain more than one SPC per patent.

In C-443/12, paragraph 29, it is stated that it is possible 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 the 'basic patent' within the meaning of article 3a of Regulation No 469/2009, in conjunction with articles 1b and le of that regulation.

The applicant emphasizes that the facts of the present application are different from those in C-443/12. The applicant contends that the active ingredient metformin and the combination of the two active ingredients dapagliflozin and metformin is protected as such by the basic patent 03736643.2 (1 506 211).

This is in contrast to C-443/12, which was concerned with a patent, EP045451 l, which related to irbesartan. In EP0454511 the second active ingredient is defined in purely functional terms, in the only claim directed to a composition containing irbesartan in association with a second active ingredient.

The applicant points out that, in the present case, the specific combination of dapagliflozin and metformin is identified in claim 7. In contrast to C-443/12 the second active ingredient is not merely identified in a functional sense. Furthermore, in paragraph [0055] of the description of the basic patent it is envisaged that a combination of compound of structure I, which encompasses dapagliflozin, with another antidiabetic agent could produce "antihyperglycemic results greater than that possible from each of these medicaments alone and greater than the combined additive antihyperglycemic effects produced by these medicaments". The applicant means that this statement points to a clear expectation that a compound such as dapagliflozin in combination with another antidiabetic agent, notably metformin, would act synergistically. The applicant notes that it is generally understood that a synergistic effect would be considered to be inventive over the use of the compounds alone or when their individual effects are merely combined.

Furthermore, the applicant refers to paragraph 42 in C-443/12 which states that " ... On the other hand, if a combination consisting of an innovative active ingredient in respect of which an SPC has already been granted and another active ingredient, which is not protected as such by the patent in question, is the subject of a new basic patent within the meaning of Article 1(c) of that regulation, the new patent could, in so far as it covered a totally separate innovation, confer entitlement to an SPC for that new combination that is subsequently placed on the market.". The applicant means that this statement recognises that if a specific combination meets the requirements of being inventive this would permit the grant of a SPC to such a new combination when subsequently placed on the market.

The applicant stresses that the specific combination of dapagliflozin and metformin is protected as such by the basic patent and is a separate innovation in its own right. It represents a further inventive advance, which was subject to a further delay to its commercial exploitation by the reason of the requirement to do additional research and development in order to achieve the marketing authorisation for Xigduo. Therefore, the combination is fully deserving its own SPC.

Reasoning

The present application for a Supplementary Protection Certificate is directed to a combination of two active ingredients, namely to the combination of dapagliflozin and metformin.

The applicant has previously already been granted a certificate, with application number 1390017-0, for the product 'Dapagliflozin and pharmaceutically acceptable salts thereof' based on the basic patent

03736643.2 (1 506 211) and the marketing authorisation for the medical product Forxiga. Accordingly, the applicant has already been granted a SPC for one of the active ingredients based on the same basic patent as he relies on for the present application.

According to article 3c of the SPC Regulation a certificate must not be issued for products that already have been the subject of a certificate.

The Court of Justice of the European Union (CJEU) provides guidance on the interpretation of article 3c in the rulings of C-443/12 (Actavis), C-484/12 (Georgetown) and C-577/13 (Actavis - Boehringer).

In both C-443/12 and C-484/12 it is made clear that it is possible, on the basis of a patent which protects several 'products', to obtain several SPCs in relation to each of those products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of article 3a.

The Court, however, explains that even if the condition laid down in article 3a of the SPC Regulation is satisfied, for the purpose of article 3c, 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 it, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent (see C-443/12, paragraphs 29-30).

Furthermore, in paragraphs 34-35 of C-443/12 the Court points out that during the period in which the first SPC was valid, the holder of the SPC was entitled to oppose, on the basis of the basic patent, certain uses of irbesartan. It follows that the first SPC allowed the SPC holder to oppose the marketing of a medicinal product containing irbesartan in combination with hydrochlorothiazide (the combination the second SPC was relating to) for a similar therapeutic use.

Moreover, the CJEU makes clear that, article 13 of the SPC Regulation dictates that upon expiry of the initial SPC, the holder thereof may no longer, in connection with the basic patent used as the basis for grant of the SPC, oppose the marketing by third parties of the active ingredient which was the subject of the protection conferred by that SPC. This means that, after that date, it must be possible for third parties to place on the market not only medicinal product consisting of the formerly protect active ingredient but also any medicinal product containing the active ingredient in combination with another active ingredient that is not protected as such by the basic patent or any other patent. The second SPC may in fact confer upon its holder, albeit partially or indirectly,

further protection for irbesartan, extending de facto the protection it enjoyed as a result of the grant of the first SPC relating to that active ingredient. The CJEU explains that this situation confirms that a SPC, such as the second SPC at issue in case C-443/12 cannot be issued (see paragraphs 36-37 of C-443/12).

Finally, the CJEU points out that it should be recalled that the basic objective of the SPC Regulation is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent. Article 3c of the SPC Regulation precludes a patent holder from obtaining, on the basis of one and the same basic patent, more than one SPC in connection with a single active ingredient, since such a SPC would in fact be connected wholly or in part, with the same product (see paragraphs 39-43 of C-443/12).

Many of the points made by the CJEU in the ruling ofC-443/12 is repeated in C-484/12 (see paragraphs 37-40). However, in the case at hand in C-484/12 the basic patent protected both a combination of active ingredients (which included HPV-16) as well as HPV-16 as an active ingredient individually within in the meaning of article 3a, i.e. HPV-16 is protected as such. The Court makes clear that article 3c of the SPC Regulation, therefore, must be interpreted as not, in principle, precluding the proprietor from obtaining a SPC for both the combination and for HPV-16 individually, on the basis of that patent and the same marketing authorisation. The Court concludes that even if the protection conferred by two such SPCs were to overlap, they would, in principle, expire on the same date (see paragraph 35).

In the latter ruling of C-577/13 the CJEU again explains 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 the basic patent (see paragraph 33). The Court initially notes that the expression 'as such' must be given an autonomous interpretation in the light of the objectives pursued by the regulation and the overall scheme of which that expression forms part (see paragraph 32). After stressing the underlying purpose of the SPC Regulation the Court concludes that it follows that in order for a basic patent to protect 'as such' an active ingredient within the meaning of articles le and 3a of the SPC Regulation, that active ingredient must constitute the subject matter of the invention covered by the patent (see paragraph 38).

PRV notes that the case at hand in C-577/13 has many similarities with the present case. The answer to questions 2 and 3 are therefore considered highly relevant. The CJEU, in their answer, explains that articles 3a and 3c of the SPC Regulation must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an

active ingredient which constitutes the sole subject matter of the invention, for which the holder of that patent has already obtained a SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination (see paragraph 39).

In the present case, the applicant has already been granted a certificate, 1390017-0, for dapagliflozin. This SPC entitles the applicant to oppose, on the basis of the basic patent 03736643.2 (1 506 211), certain uses of dapagliflozin, such as the marketing of a medicinal product similar to Xigduo, containing dapagliflozin in combination with metfonnin.
Furthermore, the core inventive advance of the basic patent appears to be dapagliflozin as such. Metformin is a substance known to exist since at least 1922. It was introduced as a medication in France 1957 and is in the public domain. Metformin is, in the present case, not protected as such by the basic patent within the meaning of the SPC Regulation. PRV has noted the applicant's comments in relation to paragraph 42 of the ruling of C-443/12, namely that the combination of dapagliflozin and metformin is a specific combination that meets the requirements of being inventive. However, the circumstances in the case at hand is different from those described in said paragraph since the applicant relies on the same basic patent, not a new patent - covering a totally separate innovation. It should be recalled that the basic objective of the SPC Regulation is to compensate for the delay to the marketing of what constitutes the core inventive advance. According to PRV's assessment the first SPC, 1390017-0, has already afforded the applicant such compensation. Moreover, the granting of a second SPC relating to the combination of dapagliflozin and metformin would, de facto extend, albeit partially or indirectly, the protection that dapagliflozin enjoys as a result of the grant of the first SPC. The CJEU has clearly pointed out that this is not consistent with the purpose of the SPC Regulation.

Accordingly, PRV cannot see that the condition laid down in article 3c of the SPC Regulation, interpreted in the light of the rulings of C-443/12 (Actavis), C-484/12 (Georgetown) and C-577/13 (Actavis - Boehringer), is fulfilled.

Conclusion

The present application does not meet the condition specified in article 3c of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009. Accordingly, no Supplementary Protection

Certificate can be issued based on the present application. The application is therefore rejected.

Carolina Palmcrantz

Senior Patent Examiner

Andreas Gustafsson
Senior Patent
Examiner

How to appeal
This decision can be appealed to the national Patent and Market Court. If you wish to appeal against the decision, you must do it in writing. Address the appeal to the Patent and Market Court, but send it to the Swedish Patent and Registration Office, i.e. to PRV, Box 5055, SE-102 42 Stockholm, SWEDEN.

State the following in the appeal:

- Your name and address
- Which decision you wish to appeal against and the application number
- Why the decision is incorrect in your opinion
- In what way you want the decision to be altered

The appeal must be submitted to PRV within **two (2) months** from the date of the decision. Unless PRV alters the decision in the way you require, we will forward the appeal to the Patent and Market Court, provided the appeal has been submitted in time. Please note that the language of proceedings before the Patent and Market Court is Swedish.

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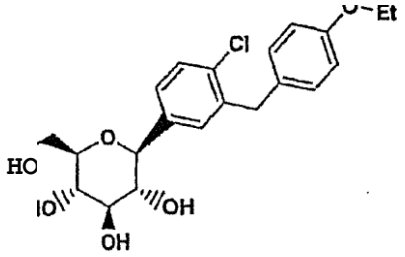
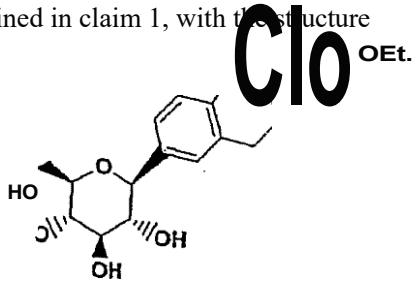
PATENTKRAY

1. Unification with the structure



or a pharmaceutically acceptable salt, a stereoisomer thereof or a prodrug ester thereof.

2. Association as defined in claim 1, with the structure



5 3. A composition comprising a compound as claimed in claim 1, and a pharmaceutically acceptable ingredient therefor.

4. A pharmaceutical combination comprising an SGLT2 inhibitor compound as defined in claim 3, and an antidiabetic agent other than an SGLT2 inhibitor, an agent for treating the complications of diabetes, an antiobesity agent, an antihypertensive agent, an
10 antiplatelet agent, an antiatherosclerotic agent and/or a lipid-lowering agent.

5. A pharmaceutical combination as set forth in claim 4, comprising nine SGLT2 inhibitor compounds and an antidiabetic agent.

6. A combination as defined in claim 5, wherein the antidiabetic agent is 1, 2, 3 or more of a bituanide sulfonylurea, a glucosidase inhibitor, a PPAR y-agonist, a PPAR o/y-
15 dual agonist, an aP2 inhibitor, a DP4 inhibitor, an insulin sensitizer, a gluc:agon-like peptide-1 (GLP-1), insulin, a meglitinide, a PTP1B inhibitor, a glycogen phosphorylase inhibitor and/or a gluc:os-6-phosphatase inhibitor.

7. Combination as defined in claim 6, wherein the antidiabetic agent is 1, 2, 3 or more of methfonnine, glyburide, glimepiride, glipyride, glipizi, chlorpropamide, gliclazide, acarbos, miglitol, pioglitazone, troglitazone, rosiglitazone, insulin, GI-262570, isaglitazone, JTT-501, NN-2344,--L895645;--YM..440;---R--l-t9702;-A:J%17;----rep-irglintd, nateglinide, KAD1129, AR-HO39242, GW-409544, KRP297, AC2993, LY315902 and/orNVP-DPP-728A.

8. Combination as defined in claim 5, wherein the SGLT2 inhibitor association is present in a weight relationship to the antidiabetic agent in the range from about 0.01 to about 300:1.

9. Combination as defined in claim 4, wherein the antiobesity agent is a b ta 3 adrenergic agonist, a lipase inhibitor, a serotonin (and dopamine) reuptake inhibitor, a thyroid receptor beta compound and/or an anorectic agent.

10. Combination as defined in claim 9, wherein antiobesity agent ether listate, ATL-962, AJ9677, L750355, CP331648, sibutramine, topiramate, ax.akin, dexamfetamine, phentermine, phenylpropanolamine and/or mazindol.

11. A combination as defined in claim 4, wherein the lipid-lowering agent is an MfP inhibitor, an HMG CoA reductase inhibitor, a scavenger synthase inhibitor, a :fibrinic acid derivative, a regulator of LDL receptor activity, a lipoxygenase inhibitor or an ACAT inhibitor.

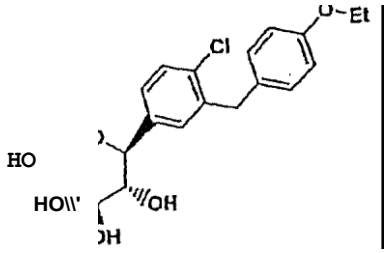
12. Combination as defined in claim 11, wherein the lipid anchoring agent is pravastatin, lovastatin, simvastatin, atorvastatin, cerivastatin, fluvastatin, nisvastatin, visastatin, atavastatin, rosuvastatin, fenofibrate, gemfibrozil, clofibrate, avasimib, TS-962, MD-700 and/or LY295427.

13. A combination as defined in claim 11, wherein the SGLT2 inhibitor is present in a weight ratio to the lipid-suppressing agent in the range of from about 0.01 to about 300:1.

14. Indication for the :preparation of a medicinal product for the treatment or prevention of the development or occurrence of diabetes, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, hyperinsulinemia, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids or glycerol, hyperlipidemia, obesity, hypertriglyceridemia, syndrome X,

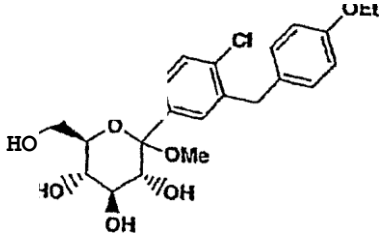
diabetic complications, atherosclerosis or hypertension, or to increase the level of high-density lipoproteins, of a compound defined in claim 1.

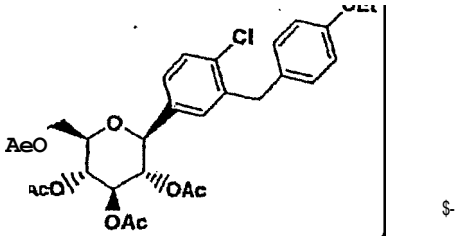
1stSr-uktur &nV-dmgas defined in patent c:rav 14, dttr SGLT2-inhibitorforemngen bar

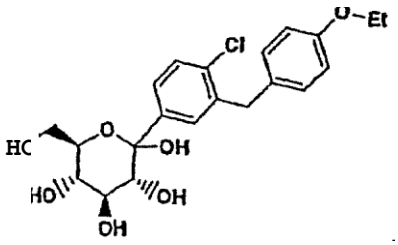


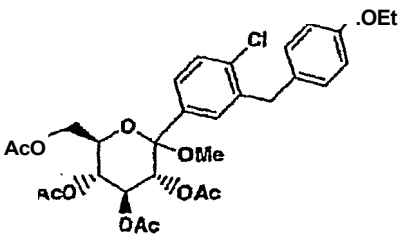
16. Advice in the preparation of a medicament for the treatment of type II diabetes of a compound as defined in claim 1 alone or in combination with another antidiabetic agent, an agent for treating the complications of diabetes, an antiobesity agent, an antihypertensive agent, an antithrombotic agent, an antiatherosclerotic agent and/or a hypolipidemic agent.

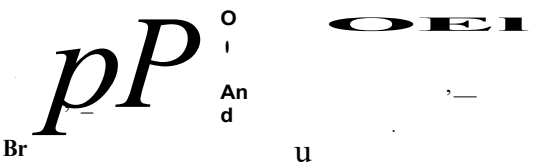
17. Association with the structure

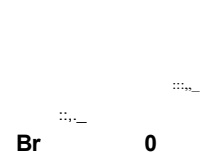












or a pharmaceutically acceptable salt thereof, any stereoisomer of diirav or a prodrug ester of diirav.

SVERIGES DOMSTOLAR

How to appeal

Decisions in cases, Patent and Market Court PMD-13

If you want any part of the decision changed, you can appeal. Here's how to do it.

Appeal in writing within 3 weeks

Your appeal must be received by the court within 3 weeks of the date of the decision. The deadline for appeal is on the last page of the decision.

How to do it

1. Write the name and case number for the Patent and Market Court.
2. Explain why you think the decision should be changed. Tell us what change you want and why you think the Patent and Market Court should hear your appeal (read more about leave to appeal below).

   If you bring up new information, explain why you did not bring this up before.
3. Tell us what you want to refer to. Explain what you want to show with each piece of evidence. Send written evidence that is not already in the case.

   You may not be able to present new evidence. If you want to do so, you should explain why you did not present the evidence before.

   If you want to have new interviews with someone who has already been interviewed or a new view (for example, a visit to a place), you should tell them and explain why.

   Also tell us if you want the other party to come in person to a meeting.
4. Provide your name and your organisation number.

   Provide up-to-date information on where the court can reach you: postal addresses, e-mail addresses and telephone numbers.

   If you have a representative, also provide contact details of the representative.
5. Sign the appeal or have your representative do it.
6. Send or submit the appeal to the Patent and Market Court. You will find the address in the decision.

What happens next?

The Patent and Market Court checks that the appeal has been filed in time. If it is filed too late, the court will reject the appeal. This means that the decision stands.

If the appeal is filed in time, the Patent and Market Court will forward the appeal and all documents in the case to the Patent and Market Court.

If you have previously received by simplified service, the Supreme Court of Patents and Markets can also send letters in this way.

Leave to appeal to the Patent and Market Court

When the appeal is lodged with the Patent and Market Court, the court first decides whether the case should be reopened.

The Patent and Market Court grants leave to appeal in four different cases.

- The Court considers that there is reason to doubt that the Patent and Market Court has ruled correctly.
- The Court considers that it is not possible to assess whether the Patent and Market Court has ruled correctly without reopening the case.
- The Court needs to take up the case in order to provide guidance to other courts in the application of the law.
- The Court considers that there are exceptional grounds for taking up the case for some other reason.

If you *do not* obtain leave, the decision under appeal will stand. It is therefore important to include everything you want to say in your appeal.

Want to know more?

Contact the Patent and Market Court if you have any questions. The address and telephone number are on the first page of the decision.

More information is available at www.domstol.se.