STOCKHOLM DISTRICT COURT
The Patent and Market Court

MINUTES
2024-11-11
Processing in Stockholm

Annex 16 Case No
PMÄ 7804-24

Proceedings in the absence of the parties

THE COURT
Counsel Peter Adamsson and Patent Attorneys Anna Hedberg and Andreas Gustafsson

MINUTE TAKER
Legal Adviser Johanna Mikkola Jäghammar

PARTIES

Complainant
Gilead Sciences Inc. 333
Lakeside Drive Foster
City, CA 94404 USA

Represented by: Michael Byström, Patent Attorney, and Marcus Eilenberg, Associate, c/o Zacco Sweden AB
Box 5581
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Counterpart
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5055
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THE CASE
Supplementary cover for medicines

APPEALED DECISION
Decision of the Swedish Patent and Registration Office of February 22, 2024 concerning supplementary protection certificate application 2290051-8, see Annex 1.

BACKGROUND

Gilead Sciences Inc (Gilead Sciences) is the holder of the European patent EP 3 347 352 (basic patent) filed on August 17, 2017. The first European marketing authorization (EU/1/22/1671) was issued on 17 August 2022 and communicated to the holder on 19 August 2022.

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Expedition time Monday - Friday 08:00-16:00

By the appealed decision, the Swedish Patent and Registration Office (PRV) granted on February 22, 2024 SPC for the product "lenacapavir or a pharmaceutically acceptable salt thereof, in particular lenacapavir sodium". The PRV has calculated that the SPC will enter into force on August 18, 2037 and can be maintained August 18, 2037.

CLAIMS AND ATTITUDE

Gilead Sciences has appealed the PRV's decision and requested that the term of the SPC be amended so that it is valid until August 19 or 20, 2037.

The PRV has the amendment of the decision.

FOUNDATIONS

As the basis for its action, **Gilead** Sciences has argued that the PRV has incorrectly calculated the period of validity because the Swedish translation 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 (SPC Regulation) is not consistent with other language versions within the EU.

The PRV has maintained that the calculation was made in accordance Article 13(1) of the SPC Regulation.

DEVELOPMENT OF THE ACTION

Gilead Sciences

Other language versions of the Regulation state that the period of validity shall refer to the time period "between" the filing date of the basic patent and the date of notification of the marketing authorization, while the Swedish version states the time elapsed "from" the filing date "to" the date of the marketing authorization. The Swedish

The translation is therefore not consistent with the other language versions. Given that the article is to be interpreted in the same way in all EU Member States, the PRV must make its assessment on the basis of the other language versions.

Determining the number of days elapsed between the filing date of the basic patent and the notification date of the marketing authorization can be done in two ways.
The end date can be included in the calculation, which means that there are three days between the dates. If the end date is not included, there are two days between the dates. It can never be one day as assessed by the PRV.

The SPC should be in force at least until August 19, 2037, taking into account recital 9 of the SPC Regulation. If the 15-year period of exclusivity is to be assessed as a time limit counting from the moment the event of notification of the marketing authorization occurs, 19 August 2022 should not be included in the period of exclusivity, in accordance with Article 3(1) of Council Regulation (EEC, Euratom)
No 1182/71 laying down rules for determining periods, dates and time limits. Consequently, the 15-year period started on August 20, 2022. Article 3(2)(c) of the same Regulation provides that the period ends on the last hour of the day of the fifteenth year which falls on the same date as the day that starts the period. On this basis, the holder is entitled to exclusivity until the end of the last hour of 20 August 2037. In case the time period is counted from the date of the event of notification of the marketing authorization, i.e. not covered by Article 3(1), but instead assessed as a time period counted from the date of notification of the marketing authorization, 19 August 2022 is the day that starts the time period and the holder is thus entitled to exclusivity until the end of the last hour of 19 August 2037.

The current practice of the PRV appears to determine the duration of a SPC calculating a 15-year period from the the medicinal product first receives authorization. However, the PRV's practice of deducting one day from the 15th anniversary of the date of issue of the marketing authorization has no basis in the SPC Regulation and is inconsistent

with the rules for calculating periods under EU law and the above-mentioned Regulation on time limits.

The current practice of the PRV is also inconsistent with the practice of other national patent offices in Europe. Similar SPCs, based on the same basic patent and sales authorization, have been granted in Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Spain, France, Greece, Hungary, Italy, Latvia, the Netherlands, Poland, Portugal and Slovenia. All other SPCs have been granted with a minimum duration of two days and no other national patent office has calculated a duration of one day.

GRP

The PRV uses the Swedish wording of the SPC Regulation when calculating the term of protection for a SPC. According to the Regulation, the term of protection shall correspond to the time that has elapsed "from" the filing date of the patent application "to" the date on which the product was approved for sale, i.e. not "" and "to". A literal interpretation of the Article does not include the filing date of the patent application and the date of the first marketing authorization, and therefore it is correctly calculated that the SPC shall enter into force on 18 August 2037 and can be maintained until 18 August 2037.

THE COURT'S ASSESSMENT

Legal starting points

According to recitals 3-5, the SPC Regulation aims to protect pharmaceutical inventions that are the result of long and costly research. The protection should be both sufficient to allow the pharmaceutical industry to recoup its investment and equivalent to the protection available in other technology sectors. According to recital 9, in order to obtain both a patent and a supplementary protection certificate for a medicinal product, the holder should effective protection, enjoy exclusive rights for a total of fifteen years from the date

the medicinal product was first authorized for marketing in the Community. It follows from recital 10 that protection must be proportionate. Supplementary protection certificates are therefore limited both to a maximum period of five years and to the product which has received marketing authorization as a medicinal product.

The duration of the supplementary protection certificate is governed by Article 13 of the Regulation. It follows from the requirement of uniform application of European Union law that, where a provision of European Union law does not contain an express reference to the legal systems of the Member States for the definition of a particular concept, that concept must be given an independent and uniform interpretation throughout the European Union. The Court of Justice of the European Union has held that the concepts referred to in Article 13 are not defined in that article, nor does that article refer to national law, with the result that, for the purposes of the SPC Regulation, Article 13 must be regarded as referring to an autonomous concept of European Union law which must be interpreted uniformly throughout the Union. (See judgment of the Court of Justice of the European Union in Case C-471/14 Seattle Genetics, EU:C:2015:659, paragraphs 23-27.) That article must be interpreted not only in the light of its wording, but also in the light of the scheme and purpose of the provisions of which it forms part (see judgment of the Court of Justice of the European Union in Case C-125/10 Merck Sharp & Dohme, EU:C:2011:812, paragraph 29).

The provisions of Community law are drafted in several languages and the different language versions are equally valid, so that the interpretation of a provision of EU law requires a comparison of the different language versions. The legal concepts do not necessarily have the same content in EU law and in national legal systems. The provision must be placed in context and interpreted in the light of Community law as a whole, taking into account the objectives of Community law and its state of development at the time when the provision in question is to be applied. (See judgment of the Court of Justice of the European Union in Case C-283/81 CILFIT v Ministero della Sanità, EU:C:1982:335, paragraphs 18-20.)

According to the Swedish version of Article 13(1) of the SPC Regulation, the SPC applies from the expiry of the basic patent for a

a period equal to the time elapsed from the date of filing of the application for the basic patent to the date of the first authorization to place the product on the market in the Community, less five years.

The English version of Article 13(1) reads: "The certificate 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 authorization to place the product on the market in the Community, reduced by a period of five years". Similarly, the German, French and Spanish language versions of the Article state that the period is calculated "between" the two dates in question. The explanatory memorandum to the proposed SPC Regulation also states
the period "between" the two dates (see Commission of the European Communities COM[90] 101 final - Syn 255, April 11, 1990, Explanatory memorandum, paragraph 51).

The assessment in this case

The first question that the Patent and Market Court must decide is which wording should form the basis for calculating the duration of the SPC. It is clear from both the preparatory works to the SPC Regulation and the statements of the Court of Justice of the European Union set out above that Article 13 is to be interpreted uniformly within the European Union and that the holder of the marketing authorization is not to be adversely affected by any difference in language in the Regulation. It is therefore the Court's assessment that the period referred to in Article 13(1) is the period which elapsed 'between' the two dates in question, irrespective of how the article is worded in the Swedish version. Such an interpretation is also supported by recital 4, which uses the term 'between' in the Swedish version, and by certain Swedish translations of the judgments of the Court of Justice of the European Union concerning Article 13 (see, inter alia, the judgments of the Court of Justice of the European Union in Case C-121/17 Teva UK and Others [2018] EU:C:585, paragraph 39; Case C-492/16 Incyte [2017] EU:C:995, paragraph 55; Case C-229/09 Hogan Lovells International [2010] EU:C:673, paragraph 50; and Merck Sharp & Dohme, paragraph 45).

It is undisputed in the case that the application the basic patent was filed on August 17, 2017 and that the first European marketing authorization was served on the holder on August 19

2022: the Court of Justice has clarified that the date of the first marketing authorization referred to in Article 13(1) is the date of notification of the decision to the marketing authorization holder (see Seattle Genetics, paragraph 40). The duration of the SPC is thus the period between these two dates, reduced by five years.

The precise manner in which the calculation is to be made is not clear from either the legislative text or the preparatory works. However, in the Court's view, it is an established principle that the calculation of a period between two dates is made *from* a date and that the end date is either included (*to and including*) or not (*to)*. As stated by the complainant, this method of calculation is used in the vast majority of time calculators and also in data formulas. However, the main rule is that the end date is not included in the calculation.

According to the Patent and Market Court, this reasoning is supported by the Court of Justice of the European Union's calculation of the duration of the SPC in Merck Sharp & Dohme. The case concerned the period between July 5, 2002 and March 21, 2007 and the Court stated that the SPC in this case, with a six-month pediatric extension, would have a term of protection of two months and 16 days (see Merck Sharp & Dohme, paragraph 44. See also the judgment of the Court of Justice of the European Union in Case C-617/12 AstraZeneca, EU:C:2014:28, paragraph 28). As stated by the appellant, the period would have been calculated at two months and 15 days if the calculation had been based on the Swedish wording. Similarly, the term of protection would have been two months and 17 days if the end date had been included.

The calculation of the term of validity shall therefore in this case, in the event of a uniform interpretation of Article 13 of the SPC Regulation under EU law, refer to the period between August 17, 2017 and August 19, 2022, reduced by five years. This means that the SPC shall apply for one additional day beyond what has been determined by the PRV. The SPC shall thus enter into force on August 18, 2037 and can be maintained until
August 19, 2037.

DECISIONS

The Patent and Market Court amends the decision of the Swedish Patent and Registration Office of February 22, 2024 concerning supplementary protection application No. 2290051-8 in that

the additional protection shall enter into force on August 18, 2037 and may be maintained August 19, 2037.

APPEAL, see Annex 2 (PMD-13)

Written appeal, addressed to the Patent and Market Court of Appeal, must be received by the Patent and Market Court no later than December 2, 2024. Leave to appeal is required.

Johanna Mikkola Jäghammar

Minutes shown /

PRV
SWEDISH PATENT AND REGISTRATION OFFICE

DECISION TO GRANT SPC

Date 2024-02-22

SPC application No. 2290051-8
Basic Patent No. 17758388.7 (3 347 352)

Zacco S\ eden AB Box
5581
114 85 Stockholm

Your reference: SPC450910SE00
Applicant: Gilead Sciences, Inc, 333 Lakeside Drive, Foster City, CA 94404, USA, US

Decision
The Swedish Patent and Registration Office, with reference to Article 10.1 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the Supplemental' Protection Certificate for medicinal products, grants Supplementary Protection Certificate (SPC) for the product "lenacapavir or a pharmaceutically acceptable salt thereof, in particular lenacapavir sodium". The product is protected by the basic patent 17758388.7 (3 347 352).

The SPC enters into force on 2037-08-18 and can be upheld no longer than 2037-08-18.

This decision will be published in the Swedish Patent Gazette No. 2024/11.

Information on annual fees
For each new fee year that the SPC is in force. an annual fee must be paid. The first annual fee is due on 2037-08-31.

*
Elias Pershagen
Patent Examiner

SVERIGES DOMSTOLAR

How to appeal

Decisions in cases, Patent and Market Court PMD-13

If you want any part of the decision to be changed, you can appeal. Find out how do this here.

Appeal in writing within 3 weeks

Your appeal must reach the court within 3 weeks of the date of the decision.
The deadline for appeals is on the last page of the decision.

Here's how to do it

1. Write the name and case number of 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 of Appeal should hear your appeal (read more about leave to appeal below).

   If you raise new factsexplain why you did not raise them before.
3. Tell us what evidence you want to refer to. Explain what you want to show with each piece of evidence. Include written evidence that is not already in the case.

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

   If you want to re-interview someone who has already been interviewed or have a new view (e.g. visit a place), tell them and explain why.

   Also let us know if you want the other party to come in person to a meeting.
4. Provide your name and social security number or organization number.

   Provide up-to-date and complete information on where the court can reach you: postal addresses, email addresses and phone numbers.

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

What happens next?

The Patent and Market Court checks that the appeal was received in time. If it is received too late, the Court rejects the appeal. This means that the decision stands.

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

If you have previously received letters by simplified service, the Patent and Market Court can also send letters in this way.

Leave to appeal to the Patent and Market Court of Appeal

When the appeal is received by the Patent and Market Court of Appeal, the court first decides whether to hear the case.

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

- The Court considers that there are grounds for doubting the correctness of the judgment of the Patent and Market Court.
- The Court considers that it is not possible to assess whether the Patent and Market Court has ruled correctly without taking up the case.
- The Court needs to hear the case to provide guidance to other courts on the application of the law.
- The Court considers that there are exceptional reasons to reopen the case for some other reason.

If you are *not* granted leave to appeal, the appealed decision will stand. It is therefore important to include everything you want to argue in your appeal.

Want to know more?

If you have any questions, please contact the Patent and Market Court. The address and telephone number can be found on the first page of the decision.

More information is available at www.domstol.se.

Instructions for appeals **PMD-13 - Decisions in cases** - Produced by Domstolsverket, Avd. for Judicial Development - 2018-11