PRV
SWEDISH PATENT AND REGISTRATION OFFICE

DECISION TO GRANT SPC

Date March 24, 2015

SPC application No. 1490064-1
Basic Patent No. 05704765.6 (1 713 823)

Zacco Sweden AB
Box 5581
114 85 Stockholm

Your reference: P41405142SE00
Applicant: Medivir AB, Blasieholmsgatan 2, 111 48 Stockholm

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 Supplementary Protection Certificate for medicinal products, grants Supplementary Protection Certificate (SPC) for the product *Simeprevir, or a pharmaceutically acceptable salt thereof, including simeprevir sodium.* The product is protected by the basic patent 05704765.6 (1 713 823).

The SPC enters into force on 2025-01-29 and can be upheld no longer than 2029-05-13.

This decision will be published in the Swedish Patent Gazette No. 16/2015.

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 2025-01-31.

Reason for the decision
You have applied for a Supplementary Protection Certificate (SPC) for the product *Simeprevir, or a pharmaceutically acceptable salt thereof, including simeprevir sodium.* With the application, you filed a request that the Swedish Patent and Registration Office (PRV) shall apply Article 13 of Council Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products (the Regulation) so that the period of the SPC is calculated from the day the marketing authorisation holder was notified of the European Commission decision to grant the marketing authorisation (2014-05-16) and not from the day the Commission decided to grant the marketing authorisation (2014-05-14). The reason for your request is that the UKIPO has changed its practice and is calculating the duration of an SPC based on the date of notification. This practice has been followed by other patent offices in Europe, and with reference to recitals 7, 9 and 10 of the Regulation, as well as to Article 13 of the Regulation, the maximum term of

protection must end on the same day throughout the Community. An inconsistent approach must not be taken in this regard.

As a condition for obtaining an SPC, Article 3b of the Regulation states that a valid authorisation to place the product on the market as a medicinal product must have been granted at the date of the application, in the member state where the application is made.

Article 13.1 of the Regulation 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 for the first authorisation to place the product on the market in the Community, reduced by a period of five years.

The Regulation gives no further guidance as to how Article 13 shall be interpreted and applied.

The preparatory works to the Regulation (COM (90)101 final – SYN 255), paragraph 16, reads:

> The proposal for a Regulation provides for a simple, transparent system which can easily be applied by the parties concerned. It therefore does not lead to excessive bureaucracy. There is no need for any new administrative body and the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations. [...] The adoption of a standard system to calculate the duration of the protection given by the certificate without abstraction of certain information specific to the case (date of granting the authorisation, date of filing the patent application, date of expiry of the patent) means that the calculation is easy to make.

Article 8 of the Regulation requires that the SPC application shall contain, among other information, the number and date of the first authorisation to place the product on the market, as referred to in Article 3b, and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation (Article 8.1 a iv).

The application shall also contain a copy of the authorisation as referred to in Article 3b, in which the product is identified, containing in particular the number and *date of the authorisation* and a summary of the product characteristics (Article 8.1 b). If the authorisation referred to in point b is not the first authorisation for placing the product on the market as a medicinal product in the Community, the application shall contain information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication (Article 8.1 c).

Article 9.2 d of the Regulation, in Swedish, states that the authority shall publish the number and date *of issue* (*dagen för utfärdande)* of the authorisation referred to in Article 3b, and in Article 9.2 e it is stated that the publication, where relevant, shall contain the number and date *of issue* (*utfärdandedagen)* of the first authorisation to place the product on the market in the Community. The parts of the Article that are quoted in italics do indeed not correspond to the wording of the Regulation in, for instance, English, French or German. However, none of the languages prevail over the others. According to settled case-law, the various language versions of a provision of Community law must be uniformly interpreted, and thus, in the case of divergence between those versions, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part (Court of Justice of the European Union, judgment on 9 January 2003, case No. C-257/00, Givane et al., REG 2003, page I345, paragraph 37, with quoted case law).

It is clear from the judgment of the Court of Justice of the European Union on 11 December 2003 in case No. C-127/00, Hässle AB vs. Ratiopharm GmbH, REG 2003, s. I-14781, paragraph 57, that a word that appears in more than one article within the Regulation cannot be construed as having a different meaning unless there is proper justification for different interpretations depending on which provision of the Regulation it appears in.

If the national authority is to apply Article 13.1 as you request, the law applicable for the first authorisation to place the product on the market in the Community must be known to the authority, specifically the legal provisions regarding the day of entry into force of the relevant marketing authorisation. Also, if that day is not the day of the decision, the authority needs information on when the event occurred which triggered entry into force of that specific marketing authorisation. When you filed your SPC application you informed the PRV that the relevant marketing authorisation entered into force when it was notified to the marketing authorisation holder, and that the date of notification was 2014-05-16.

The Regulation does not require that the applicant states, in the SPC application, which date the marketing authorisation was notified to the marketing authorisation holder. Article 8 only requires the applicant to state *the date of the first authorisation*, which can be interpreted either as the date on which the marketing authorisation entered into force or the date of issue of the marketing authorisation.

It is the understanding of the PRV that the objective behind the requirement to file the documents prescribed in Article 8.1b and 8.1c is that the applicant shall prove the information relevant to Article 8.1a iv. Hence, the documents shall prove the date of the first marketing authorisation in the member state of application as well as in the Community, and serve to identify the product for the SPC.

The date of notification is, for obvious reasons, not included in the marketing authorisation decision. The date of notification – at least with respect to decisions issued by the European Commission after examination from the European Medicine's Agency (EMA) – is however published in the official publication of the marketing authorisation decision. If the first marketing authorisation according to Article 3b also is the first authorisation to place the product on the market as a medicinal product within the Community, the applicant is not required by Article 8 of the Regulation to file a copy of this publication.

Hence, if it is the date of notification which is relevant to the application of Article 13.1, the applicant is not always required, according to Article 8, to submit documentation to prove which day the marketing authorisation holder was notified of the decision. Without such requirement, the patent authority has no possibility to apply Article 10.3 of the Regulation and ask the applicant to prove the date of notification.

The interpretation of Article 13.1 you propose could easily be applied by the national authority with regards to marketing authorisations issued by the European Commission. In respect of marketing authorisations issued by other, national, medicine's authorities within the Community, the patent authority would face a burdensome administration in finding out when the relevant marketing authorisation entered into force (day of decision, day of notification, or another day) according to the law applicable in the country of issuance, and when this day occurred. If this was not immediately clear from the copy of the official publication filed with reference to Article 8.1c, the patent authority would have considerable difficulty in applying Article 13.1 in a consistent and non-bureaucratic way.

It is the view of the PRV that Article 13.1 of the Regulation cannot be applied inconsistently to the effect that only when calculating the period of an SPC based on a marketing authorisation from the Commission, the calculation sets out from the date of notification of the decision. If Article 13.1 is to be interpreted as you suggest, the applicant should be obliged to submit information on, and to prove, when the marketing authorisation entered into force as well as the actual date of entry into force, when the first authorisation to place the product on the market in the Community is not the same authorisation as referred to in Article 3b. It is the understanding of the PRV that no such requirement exists and therefore, that the patent authority has no possibility to ask the applicant to rectify this as an irregularity according to Article 10.3 of the Regulation.

It is the view of the PRV that "the date of the first authorisation to place the product on the market in the Community" in Article 13.1 must be interpreted as meaning the date of the decision of the first marketing authorisation. Only with that interpretation can the national patent authorities apply Article 13.1 in a consistent, non-bureaucratic and administratively simple way. Further, the

copy which is to be submitted according to Article 8.1b serves as sufficient evidence when this marketing authorisation is the first authorisation to place the product on the market in the Community. This interpretation also gives a systematic meaning to the requirements of information and documents to be filed in the application. The Swedish wording of Article 9.2 is also supported by this systematic meaning.

The application for a Supplementary Protection Certificate for the product *Simeprevir, or a pharmaceutically acceptable salt thereof, including simeprevir sodium* fulfills the conditions set out in Article 3 of the Regulation. In view of the above reasoning, PRV calculates the duration of the certificate using the date of decision of the first authorisation to place the product on the market in the Community, i.e. 2014-05-14. The PRV therefore grants the SPC application 1490064-1 for the product *Simeprevir, or a pharmaceutically acceptable salt thereof, including simeprevir sodium* with the duration from 2025-01-29 until 2029-05-13.

Andreas Gustafsson

This decision has been made in consultation with Louise Jönshammar, lawyer.

How to appeal against this decision

This decision can be appealed at the Court of Patent Appeals (Patentbesvärsrätten). If you wish to appeal against the decision, you must write to the Court of Patent Appeals. State which decision you wish to appeal against and in what way you want the decision to be altered. The appeal must be submitted to The Swedish Patent and Registration Office not later than within two months from the date of the decision, or the appeal will not be tried.
Submit the appeal to:
Patentbesvärsrätten
Patent- och registreringsverket
Box 5055
SE-102 42 Stockholm
SWEDEN

exp 150324 m rek post lg