PRV
SWEDISH PATENT AND REGISTRATION OFFICE

DECISION TO REJECT (J)

Date August 20, 2015

SPC application No. 1490055-9
Basic Patent No. 94928563.9 (0 720 599)

Höjberg A/S
St. Kongensgade 59 A
DK-1264 Köpenhamn
DANMARK

Your reference: L445SE03
Applicant: Merck Sharp & Dohme Corp.

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.
This application for a Supplementary Protection Certificate (SPC) concerns the basic patent 94928563.9 (0 720 599) which was first filed on September 14, 1994. The patent was granted by the EPO on May 19, 1999 and validated in Sweden on August 18, 1999. The basic patent's last day in force in Sweden was September 14, 2014. With reference to Article 3a of Regulation (EC) No. 469/2009, this was the last date to apply for an SPC based on this patent. The application for an SPC covering the product *ezetimibe and atorvastatin or pharmaceutically acceptable salts thereof, including atorvastatin as atorvastatin calcium trihydrate* was filed on September 12, 2014.

The application for a marketing authorization for the combination product *ezetimibe and atorvastatin* in Sweden and other EU countries was made under Directive 2001/83/EC using the Decentralized Procedure. The German authority Bundesinstitute für Arzneimittel und Medizinprodukte (BfArM) acted as reference member state and closed the approval process on September 10, 2014 with the issuance of an End of Procedure decision. From this date, all participating Member States, including Sweden, were obliged to grant national marketing authorizations for the product. A marketing authorization was issued by the Swedish Medical Products Agency on October 16, 2014.

Article 3b of Regulation (EC) No. 469/2009 states that 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 valid authorization 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.

Since the authorization to place the combination product of *ezetimibe and atorvastatin* was not granted in Sweden until October 16, 2014, the application is in violation of Article 3b. There was no valid authorization to place the product on the Swedish market as a medicinal product on September 12, 2014 when the application for SPC was made, nor on September 14, 2014 which was the last possible date to apply for an SPC using the basic patent in question. This application for an SPC must therefore be rejected.

Marie Eriksson

Louise Jonshammar

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 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

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