AWA

Patent- og Varemærkestyrelsen
Helgeshøj Allé 81
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Our Reference: 139852 15 September 2020

New SPC Application in Denmark
Applicant: Portola Pharmaceuticals, Inc.

Dear Sirs,

We enclose a request for a new SPC application in Denmark. We kindly ask you to withdraw the application fee of 3.000,00 DKK from our deposit account IPB43.

The product applied for is:
Andexanet Alfa

The product applied for is at least protected by claim 2 of the basic patent relied on for the purpose of the present application, DK/EP 3 078 743 T3.

Claim 2 of the patent refers to a pharmaceutical composition comprising a carrier and an isolated two-chain polypeptide comprising an amino acid sequence having at least 80% homology to SEQ ID NO. 13.

The INN 'andexanet alfa' as published in WHO Drug Information, Vol. 27, No. 4, 2013, pg. 402-403 (enclosed) recites the light chain amino acid sequence of SEQ ID NO. 14 and the heavy chain amino acid sequence of SEQ ID NO. 15 of the patent. Together these form the amino acid sequence of SEQ ID NO. 13 of the patent. Claim 2 also recites characteristics (i)-(iii) of the polypeptide which correspond to characteristics of andexanet alfa as described in the Summary of Product Characteristics (enclosed) at section 5.1 (page 8) under the heading

"mechanism of action". The characteristics recited in the claim and the corresponding part of the Summary of Product Characteristics describing these characteristics of andexanet alfa is set out below.

characteristic of polypeptide of the claims	**corresponding description of characteristic in Summary of Product Characteristics (section 5.1)**
(i) has reduced catalytic activity	"Andexanet alfa is a recombinant form of human FXa protein that has been modified to lack FXa enzymatic activity. The active site serine was substituted with alanine, rendering the molecule unable to cleave and activate prothrombin"
(ii) is capable of binding to a factor Xa inhibitor	"Andexanet alfa is a specific reversal agent for FXa inhibitors. The predominant mechanism of action is the binding and sequestration of the FXa inhibitor"
(iii) cannot assemble into the prothrombinase complex.	"the gamma-carboxyglutamic acid (Gla) domain was removed to eliminate the ability of the protein to assemble into the prothrombinase complex"

Andexanet alfa thus has all of the physical and functional characteristics recited in claim 2 of the patent.

The product andexanet alfa is therefore protected at least by claim 2 of the patent.

Thus the active ingredient is protected by the basic patent relied upon in the sense of Article 3(a) of the Regulation.

The medicinal product is approved by the centralized procedure having market authorisation no. EU/1/18/1345 for the active ingredient Andexanet Alfa with the tradename Ondexxya®. The decision to approve the MA is dated 26 April 2019 and the notification date of the MA is 30 April 2019. In accordance with the CJEU Judgement C471/14 (Seattle Genetics), the calculation of the term of the SPC to be based on the latter date.

The present Applicant already has an existing SPC application number CA 2019 00053 for the same product based on EP 2 193 196 which is the "parent patent" of the basic patent for the present SPC application, i.e. EP 3 078 743. The Applicant recognises, and is making no attempt to contravene, Article 3(c) of Regulation (EC) No 469/2009 (the "SPC Regulation"). The Applicant requests that the two SPC applications are considered together, and that, if the applications are considered allowable, the Applicant is given an opportunity to select which SPC application is granted.

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Thus, based on the above, we believe that all relevant requirements of the Regulation (EC) No. 469/2009 are met and look forward to receiving the certificate, or if the Patent Office finds that any deficiencies exist. We look forward to receiving a communication setting these out.

Yours sincerely,
AWA Denmark A/S

Helle Friis Svenstrup

Encl.

- SPC request form
- Copy of the first MA in DK and EEA (DK)
- Copy of the renewed first MA in DK and EEA (DK)
- Copy of the SmPC (DK)
- Copy of the publication of the MA in the OJEU – C180/1
- WHO Drug Information, Vol. 27, No. 4, 2013