

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2023/053959

International filing date (day/month/year)
16.02.2023

Priority date (day/month/year)
17.02.2022

International Patent Classification (IPC) or both national classification and IPC
INV. A61K31/454 A61K9/08 A61K47/40 A61P37/08

Applicant
FAES FARMA, S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-31</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-31</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-27</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

1. The relevant prior art documents are referred to as D1 and D2 as in the order of appearance in the International Search Report (ISR). Unless otherwise indicated, reference is made to the passages of said documents cited in the ISR.

2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Rule 43*bis*.1(a)(i) and (b) PCT):

(N) The subject-matter of independent claims 1, 19, 20, 24 and 28 is regarded as novel (Article 33(2) PCT).

D1 discloses ophthalmic aqueous solutions for treatment of an ocular allergic condition comprising 0.4-1.0% w/v of bilastine, 5-15% w/v of various beta-cyclodextrins, and having a pH between 5-8. These ranges overlap with the corresponding ranges defined in present claim 1.

Further, claim 1 defines an aqueous *parenteral* pharmaceutical composition, wherein parenteral is selected from *intravenous or intramuscular*. This imposes certain functional restrictions on the composition.

The ophthalmic composition of D1 comprises viscosity agents (MC, gellan, Na hyaluronate) rendering it unsuitable for parenteral applications selected from intravenous or intramuscular. The compositions of D1 are not in a form suitable for intravenous or intramuscular applications.

Hence, claim 1 is novel over D1.

The subsidiary independent claims 19, 20, 24 and 28 (medical uses and method of treatment using the composition of claim 1) are also novel for same reasons.

(IS) The subject-matter of independent claims 1, 19, 20, 24 and 28 is considered to involve an inventive step (Article 33(3) PCT) for the following reasons.

Claim 1 differs from D1 in that the aqueous composition of bilastine is an intravenous (IV) or intramuscular (IM) parenteral composition. This imposes certain functional restrictions on the composition, notably the exclusion of a gelling agent (claim 2).

Further, claims 5 and 6 define higher concentrations of bilastine than those used in ophthalmic applications of D1.

In the application, it is credibly shown by evidence (clinical data: efficacy, safety, tolerability; cf. application, in particular example 5) that these distinguishing features can be associated with a therapeutic effect in the treatment of acute type I hypersensitivity reactions by IV or IM administration once daily (see claims 21, 23, 25, 27, 29 and 31). On this basis, an inventive step can be recognised. The prior art neither indicates nor suggests medical uses by IV or IM administration. As mentioned above, the ophthalmic composition of D1 comprises viscosity agents rendering it functionally unsuitable for a use by IV or IM injection.

(IA) The subject-matter of claims 1-27 is considered to be industrially applicable (Article 33(4) PCT). The possibility of industrial application is beyond any doubt.

The subject-matter of claims 28-31 falls under the provisions of Article 34(4)(a)(i) and Rule 67.1(iv) PCT.

3. Reservation statement regarding patentability (claims 28-31):

The patentability of claims to methods of medical treatment (present claims 28-31) can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.