

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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

To:

see form PCT/ISA/220

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/EP2018/073498

International filing date (day/month/year)
31.08.2018

Priority date (day/month/year)
04.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/70 A61K31/196 A61K31/33 A61K47/34 A61P29/00 A61P19/02

Applicant
LTS LOHMANN THERAPIE-SYSTEME AG

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

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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:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
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>1-30</u> |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | <u>1-30</u> |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | <u>1-30</u> |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

- D1 WO 2014/079573 A1 (UCB PHARMA GMBH [DE]; LOHMANN THERAPIE SYST LTS [DE]) 30 May 2014 (2014-05-30)
- D2 US 2004/202707 A1 (MULLER WALTER [DE]) 14 October 2004 (2004-10-14)
- D3 US 2004/234583 A1 (MULLER WALTER [DE]) 25 November 2004 (2004-11-25)
- D4 WO 2011/076879 A1 (UCB PHARMA GMBH [DE]; LOHMANN THERAPIE SYST LTS [DE]; WOLFF HANS-MICHA) 30 June 2011 (2011-06-30)

2 **Novelty**

The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1-30 is new in the sense of Article 33(2) PCT.

3 **Inventive step**

The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1-30 does involve an inventive step in the sense of Article 33(3) PCT.

- 3.1 D1 can be considered as the prior art closest to the subject-matter of claim 1, and it discloses a microreservoir type TTS which comprises a matrix layer containing a silicone adhesive, an ethanolic solution of an active substance (rotigotine) and PVP (pages 46-47, example 1; pages 69-74, claims 1-35).

The subject-matter of claim 1 differs from D1 in that the matrix layer further comprises an emulsifier as defined in claim 1. The technical effect provided by this difference is the better stability of the matrix layer and the optimization of the active agent release in the TTS. Thus, the problem to be solved is to provide an improved TTS system in terms of stability and release profile.

3.2 The application provides evidence that by using the specific emulsifier as defined in claim 1, the stability and the release profile of the active agent are improved in comparison with TTS compositions which do not comprise the above mentioned specific emulsifier (pages 28-53, examples). Thus, the solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT).

3.3 The same reasoning applies, *mutatis mutandis*, to the subject-matter of the independent claims 21-30, which therefore is also considered inventive.

4 Industrial Applicability

Claims 1-30 are considered to be industrially applicable in the sense of Article 33(4) PCT.