

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 025.0012-WO00	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 16/52492	International filing date (day/month/year) 19 September 2016 (19.09.2016)	(Earliest) Priority Date (day/month/year) 18 September 2015 (18.09.2015)	
Applicant THAR PHARMACEUTICALS, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out 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)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 37
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 14-369 and 399-400
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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International application No.

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A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 31/675, A61K 31/197 (2016.01) CPC - A61K 2300/00, A61K 31/198 According to International Patent Classification (IPC) or to both national classification and IPC																							
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61K 31/675, A61K 31/197 (2016.01) CPC - A61K 2300/00, A61K 31/198 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Patents and non-patent literature (classification, keyword; search terms below) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase, Google Scholar (non-patent literature), Google Patents; search terms: API, drug, coformer, molecular complex, crystalline, amorphous, cocrystal, enteric coated, oral dosage, zoledronic acid, zoledronate, amino acid																							
C. DOCUMENTS CONSIDERED TO BE RELEVANT <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No. *</th> </tr> </thead> <tbody> <tr> <td>X --- Y</td> <td>WO 2011/097269 A9 (Thar Pharmaceuticals, Inc.) 11 August 2011 (11.08.2011), entire document, especially abstract, pg 5 para 3, pg 5 para 5, pg 6 para 3, pg 11 para 4, pg 20 para 3, pg 26 para 3, pg 28 para 2, pg 28 para 4, pg 39 para 3, pg 55 para 3, pg 59 para 2, pg 63 para 4, Table 11, Table 12, Table 13, Table 14, Table 15</td> <td>1-13, 370-378, 382-390, and 392-398 ----- 379-381 and 391</td> </tr> <tr> <td>Y</td> <td>US 2013/0303488 A1 (Tabuteau) 14 November 2013 (14.11.2013), entire document, especially abstract, para [0006], [0041], [0084]</td> <td>379-381 and 391</td> </tr> <tr> <td>A</td> <td>US 2007/0021618 A1 (Aronhime et al.) 25 January 2007 (25.01.2007), entire document</td> <td>1-13 and 370-398</td> </tr> <tr> <td>A</td> <td>US 2012/0190647 A1 (Hanna et al.) 26 July 2012 (26.07.2012), entire document</td> <td>1-13 and 370-398</td> </tr> <tr> <td>A</td> <td>US 2004/0220264 A1 (Yu et al.) 4 November 2004 (04.11.2004), entire document</td> <td>1-13 and 370-398</td> </tr> <tr> <td>A</td> <td>US 2014/0349974 A1 (Tabuteau) 27 November 2014 (27.11.2014), entire document</td> <td>1-13 and 370-398</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No. *	X --- Y	WO 2011/097269 A9 (Thar Pharmaceuticals, Inc.) 11 August 2011 (11.08.2011), entire document, especially abstract, pg 5 para 3, pg 5 para 5, pg 6 para 3, pg 11 para 4, pg 20 para 3, pg 26 para 3, pg 28 para 2, pg 28 para 4, pg 39 para 3, pg 55 para 3, pg 59 para 2, pg 63 para 4, Table 11, Table 12, Table 13, Table 14, Table 15	1-13, 370-378, 382-390, and 392-398 ----- 379-381 and 391	Y	US 2013/0303488 A1 (Tabuteau) 14 November 2013 (14.11.2013), entire document, especially abstract, para [0006], [0041], [0084]	379-381 and 391	A	US 2007/0021618 A1 (Aronhime et al.) 25 January 2007 (25.01.2007), entire document	1-13 and 370-398	A	US 2012/0190647 A1 (Hanna et al.) 26 July 2012 (26.07.2012), entire document	1-13 and 370-398	A	US 2004/0220264 A1 (Yu et al.) 4 November 2004 (04.11.2004), entire document	1-13 and 370-398	A	US 2014/0349974 A1 (Tabuteau) 27 November 2014 (27.11.2014), entire document	1-13 and 370-398
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Date of the actual completion of the international search 9 November 2016		Date of mailing of the international search report 16 DEC 2016																					
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774																					