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ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))*
- *of inventorship (Rule 4.17(iv))*

Published:

- *with international search report (Art. 21(3))*

- (88) **Date of publication of the international search report:**
8 May 2014

(54) **Title:** COMPOSITIONS COMPRISING FUSIDIC ACID AND PACKAGES THEREFOR

(57) **Abstract:** Described are solid pharmaceutical compositions of fusidic acid, and pharmaceutically acceptable salts thereof, dosage units of the pharmaceutical compositions, and packages for pharmaceutical compositions of fusidic acid, and pharmaceutically acceptable salts thereof, which increase stability against the degradation of the fusidic acid, and pharmaceutically acceptable salts thereof. Also described are uses of the pharmaceutical compositions and dosage units in treating diseases.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/39219

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 31/56 (2012.01) USPC - 514/182 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) USPC - 514/182 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC - 424/400; 514/169, 514/170, 514/171 (see search terms below) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) *** Databases: WEST (PGPB, USPT, USOC, EPAB, JPAB); Google, Google Scholar *** Search Terms Used: CEM-102, Pereira, fusidic acid, Fucidin, Fucithalmic, mannitol, mannite, mg, container, packaging, infection, excipient, HDPE, high density polyethylene, glass, terephthalate, Oxy-Guar, TOPAS, oxygen, impermeable, resistant,		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2011/0009375 A1 (JONES) 13 January 2011 (13.01.2011) para [0006]-[0008], [0103], [0106], [0108], [0110], [0119], [0125]	1, 5-9 and 58-60 ----- 2-4 and 10-14
X --- Y	US 2009/0258069 A1 (BURNIER et al.) 15 October 2009 (15.10.2009) para [0007], [0133], [0135], [0138], [0146], [0149], [0211], [0252]	1 and 16 ----- 15 and 17-18
Y	US 2003/0004321 A1 (TUINMAN et al.) 02 January 2003 (02.01.2003) para [0092], [0094]	2-4 and 10-14
Y	WO 2010/122491 A1 (SRINIVASAN et al.) 28 October 2010 (28.10.2010) pg 1, ln 6-13; pg 3, ln 16- pg 4, ln 5.	15 and 17-18
☐ Further documents are listed in the continuation of Box C. ☐		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 26 September 2012 (26.09.2012)		Date of mailing of the international search report 09 OCT 2012
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. 571-273-3201		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/39219

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.:
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:
see extra sheet

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.:
1-18 and 58-60

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/39219

Attachment to Box No. III: Lack of unity invention

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-18 and 58-60, directed to compositions and dosage units comprising fusidic acid, or a pharmaceutically acceptable salt thereof, which are packaged into oxygen resistant and/or oxygen impermeable containers; wherein claims 1-18 and 58-61 further relate to specific dosage ranges and concentrations of the fusidic acid, as well as the combination of fusidic acid with other agents, such as mannitol, in specific weight ratios.

Group II: Claims 19-57 and 61, directed to packaged articles comprising fusidic acid, or a pharmaceutically acceptable salt thereof, packaged into oxygen resistant and/or oxygen impermeable containers; wherein claims 19-57 further relate to specific protective properties of the packaging materials, including fusidic acid degradation resulting from storage in packaged articles.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The groups I-II as described above share the technical features of being related to articles and dosage units comprising fusidic acid, or a pharmaceutically acceptable salt thereof, which are packaged into oxygen resistant and/or oxygen impermeable containers. However, these shared technical features fail to make a contribution over the prior art US 2010/0078336 A1 to Reyhan et al., which discloses the placement of fusidic acid in a medical dosage device (para [0007], with para [0043], 'fusidic acid') which is enclosed in a package made of polymeric materials, such as HDPE, which 'substantially inhibit moisture and oxygen permeation' into the device (para [0053], with para [0037]).

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims of the various groups I-II as defined above do not share any special technical feature that is an advance over the prior art. The 1,2-diphenylpyrrole derivatives of the claims are known in the art. See US 6,887,893 B1 to Kurakata et al. (3 May 2005), summary of the invention. HER2 inhibitors are also known in the art. See US U2007/0142346 A1 to Johnson et al. (21 June 21, 2007) for example (see abstract). Both references teach the disclosed compounds for the treatment of cancer.

Groups I-II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.