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A61K 9/08 (2006.01) *A61P 1/00* (2006.01)

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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(54) Title: PHARMACEUTICAL COMPOSITIONS FOR RECTAL ADMINISTRATION

(57) Abstract: The present invention relates to a pharmaceutical composition, in particular a composition formulated for enema administration, wherein the composition comprises metronidazole or a pharmacologically acceptable derivative thereof in an amount to effectively treat both acute and chronic pouchitis and/or proctitis.



WO 2013/012662 A3

A. CLASSIFICATION OF SUBJECT MATTER*A61K 31/4164(2006.01)i, A61K 9/08(2006.01)i, A61P 1/16(2006.01)i, A61P 1/00(2006.01)i*

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)

A61K 31/4164; A61K 31/606; A61K 31/415; A61K 31/535; G01N 33/50; A61K 47/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: metronidazole, nitroimidazole, flagyl, enema, pouchitis, proctitis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 04957918A A (MARTIN, NEIL F. et al.) 18 September 1990 See claims 1-13, columns 3 and 4.	1-6,21
Y	US 2009-0233888 A1 (LIN, HENRY C.) 17 September 2009 See claims 1,2,5 and 7.	1-6,21
Y	Bo Shen, et al., A Randomized Clinical Trial of Ciprofloxacin and Metronidazole to Treat Acute Pouchitis. Inflammatory Bowel Diseases. 2001, Vol. 7(4), pages 301-305. See summary, page 302 : left column: lines 1-12.	1-6,21
Y	WO 2004-017962 A2 (S.L.A. PHARMA AG et al.) 04 March 2004 See claims 1-47.	1-6,21



Further documents are listed in the continuation of Box C.



See patent family annex.

* 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

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"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

29 JANUARY 2013 (29.01.2013)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/046395**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.: 7-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 7-20 pertain to methods for treatment of the human by therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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:

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 an additional fee, this Authority did not invite payment of any additional fee.
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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/046395

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Information on patent family members

International application No.

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