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(81) Designated States (unless otherwise indicated, for every

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HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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— with international search report (Art. 21(3))

(88) Date of publication of the international search report:

24 December 2014

(54) Title: COMPOSITIONS AND METHODS FOR THE TREATMENT OF MUCOSITIS

(57) Abstract: The invention relates to the compounds of formula I, formula II, formula III, formula IV, formula V, formula VI and formula VII or its pharmaceutical acceptable polymorphs, solvates, enantiomers, stereoisomers and hydrates thereof. The pharmaceutical compositions comprising an effective amount of compounds of formula I, formula II, formula III, formula IV, formula V, formula VI or formula VII and methods for the treatment of mucositis may be formulated for oral, buccal, rectal, topical, transdermal, transmucosal, intravenous, oral solution, parenteral administration, syrup, or injection. Such compositions may be used to treatment of mucositis and oral mucosal inflammatory or oral infectious diseases.



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2013/060719

A. CLASSIFICATION OF SUBJECT MATTER  
A61K31/17, A61P01/04, C07C251/06 Version=2014.01

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, A61P, C07C

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

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

ORBIT, IPO-INTERNAL DATABASE, STN

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 1356470 A (SEPERIC) 12 June 1974 (12-06-1974), the family member of US 4011342 A See Abstract, Claims 1, 2 & 9-14, description, column 1, lines 27-30 -----	1, 8, 15 & 29
XP	WO 2013/175377 A2 (KANDULA, MAHESH) 28 November 2013 (28.11.2013) See Claims, description, page 32-36.	1, 8, 15 & 29

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:	"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
"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	"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
"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)	"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
"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	"&" document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA/

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**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/IB2013/060719

Citation	Pub.Date	Family	Pub.Date
GB 1356470 A	12-06-1974	US 4011342 A	08-03-1977
		DE 2226590 A	14-12-1972
		FR 2140060 A	12-01-1973
		JP S4828434 A	14-04-1973
		CH 554319 A	30-09-1974
WO 2013/175377 A3 A2	28-11-2013	WO 2013/175377 A3	30-01-2014

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2013/060719

**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.: 16, 18, 20, 22, 24, 26 & 28  
because they relate to subject matter not required to be searched by this Authority, namely:  
The subject matter of claims 16, 18, 20, 22, 24, 26 & 28 relates to a method for treatment of the human or animal body, which does not require an international search by the International Searching Authority in accordance with PCT Article 17(2)(a)(i) and [Rule 39.1(iv)]1.
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:  
Claims & Reasons:

Group-1. 1, 8, 15 & 29

The subject matters of these claims relates to a compound of formula I, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

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, 8, 15 & 29.

**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.

Continuation of Observations where unity of invention is lacking(Box III)  
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Group-2. 2, 9, 17 & 30

The subject matters of these claims relates to a compound of formula II, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Group-3. 3, 10, 19 & 31

The subject matters of these claims relates to a compound of formula III, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Group-4. 4, 11 & 21

The subject matters of these claims relates to a compound of formula IV, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Group-5. 5, 12, 23 & 32

The subject matters of these claims relates to a compound of formula V, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Group-6. 6, 13, 25 & 33

The subject matters of these claims relates to a compound of formula VI, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Group-7. 7, 14, 27 & 34

The subject matters of these claims relates to a compound of formula VII, its salts, pharmaceutical composition and the use of the compound to treat mucositis.

Reasons:

These claims are related to seven different compounds, their salts, pharmaceutical composition as well as the use of the compounds to treat mucositis. Though these compounds and their composition have been used for same purpose, but the structure of these compounds are completely different from each other. There are no structurally common technical feature among these compounds. The use of these compounds is only common technical feature lies between them. However, the subject matter of the first invention is anticipated by the cited prior art document D1 (GB 1356470). The phenyl-guanidine derivative with formula I, its salts and composition are already disclosed in the cited prior art. Also the compound and its composition have been used in the same purpose. So, there are no special technical feature which co-relates these seven different inventions.

Hence the international application does not comply with the

requirement of unity of invention(Rules 13.1, 13.2 and 13.3).