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(54) Title: PHARMACEUTICAL COMPOSITIONS COMPRISING A 7-(2-AMINOETHYL)-BENZOTHIAZOLONE AND A GLUCOCORTICOID

(57) Abstract: The present invention provides a pharmaceutical composition, pharmaceutical product or kit comprising a first active ingredient (A) being 4-hydroxy-7-[2-[2-[3-[2-phenylethoxy]propylsulphonyl]ethylamino]ethyl]-1,3-benzothiazol-2(3H)-one or a pharmaceutically acceptable salt thereof, and a second active ingredient (B) being a glucocorticoid, for use in the treatment of obstructive airways diseases.

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# INTERNATIONAL SEARCH REPORT

Inter I Application No  
PCT/GB 00/03112

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/58 A61K31/57 A61K31/43

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 7 A61K

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 practical, search terms used)

EMBASE, CHEM ABS Data, MEDLINE, EPO-Internal, CANCERLIT, BIOSIS, PAJ, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                        | Relevant to claim No. |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y          | WO 93 24473 A (BROWN ROGER CHARLES<br>;CHESHIRE DAVID RANULF (GB); FISON PLC<br>(GB);) 9 December 1993 (1993-12-09)<br>cited in the application<br>page 7, line 22 - line 29; example 6<br>----                                                                           | 1-17                  |
| A          | IKEDA A. ET AL: "Pharmacological<br>treatment in acute exacerbations of<br>chronic obstructive pulmonary disease."<br>DRUGS AND AGING, (1998) 12/2 (129-137). ,<br>XP000986468<br>page 132, column 2, paragraph 6 -page<br>132133, column 2, paragraph 1<br>-----<br>-/-- | 1-17                  |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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 document 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.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

27 February 2001

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15/03/2001

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# INTERNATIONAL SEARCH REPORT

Inter Application No  
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| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT |                                                                                                                                                                                                                                                                                             |                       |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Category *                                           | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                          | Relevant to claim No. |
| A                                                    | LURIE A. ET AL: "Long-term management of reversible obstructive airways disease in adults."<br>LUNG, (1990) 168/SUPPL. (154-167). ,<br>XP000986437<br>page 158, paragraph 2<br>---                                                                                                          | 1-17                  |
| A                                                    | BARNES P.J.: "New therapies for chronic obstructive pulmonary disease."<br>THORAX, (1998) 53/2 (137-147). ,<br>XP000986442<br>page 139, column 1, paragraph 52<br>---                                                                                                                       | 1-17                  |
| Y                                                    | KERSTJENS H A ET AL: "Influence of treatment on peak expiratory flow and its relation to airway hyperresponsiveness and symptoms. The Dutch CNSLD Study Group."<br>THORAX, (1994 NOV) 49 (11) 1109-15. ,<br>XP000986460<br>page 1109, column 1<br>page 1112, column 2, paragraph 5<br>----- | 1-17                  |

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1, 2, 4,-10, 12-15, 17

Present claims 1, 2, 4,-10, 12-15 and 17 relate to a compound defined by reference to a desirable characteristic or property, namely a glucocorticoid.

The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the compounds mentioned in claims 3, 11 or 16, with due regard to the therapeutic applications mentioned in the claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter i Application No

PCT/GB 00/03112

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
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