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(54) Title: TOPICAL PHARMACEUTICAL COMPOSITIONS OF TERBINAFINE AND PROCESSES FOR THEIR PREPARATION

(57) Abstract: The present invention relates to topical pharmaceutical compositions of terbinafine, one or more non-ionic surfactants, and one or more fatty acids or fatty alcohols, and processes for their preparation.



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## INTERNATIONAL SEARCH REPORT

International application No

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## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/107 A61K47/10 A61K47/12 A61K31/137 A61P31/10  
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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

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)

EPO-Internal, WPI Data, EMBASE, BIOSIS, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| X         | US 5 681 849 A (RICHTER FRIEDRICH [CH] ET AL) 28 October 1997 (1997-10-28)<br>cited in the application<br>esp. column 5, lines 49-64<br>the whole document<br>esp. examples 4 and 5<br>esp. claims 1-15  | 1-9,<br>12-26         |
| X         | WO 2005/013955 A2 (NOVARTIS CONSUMER HEALTH SA [CH]; LARNIER CATHERINE [CH]; STEIGER MICH)<br>17 February 2005 (2005-02-17)<br>page 1, line 1 - line 26<br>page 2, line 9 - line 22<br>page 4, line 32 - page 5, line 11<br>examples 1-4<br><br>-----<br>-/- | 1-26                  |



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 document but published on or after the international filing date

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"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

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"&amp;" document member of the same patent family

Date of the actual completion of the international search

31 October 2006

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14/11/2006

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## INTERNATIONAL SEARCH REPORT

International 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.        |
|-----------|--|------------------------------|
| X         | BUNDESVERBAND DER PHARMAZEUTISCHEN<br>INDUSTRIE E.V.: "Rote Liste 1995"<br>1995, ECV-EDITIO CANTOR, AUKLENDORF,<br>GERMANY, XP002404962<br>product nr. 20087 "Lamisil Creme"<br>-----  | 1-12,14,<br>24,25            |
| X         | US 6 455 592 B1 (LAUGIER JEAN-PIERRE [FR]<br>ET AL) 24 September 2002 (2002-09-24)<br><br>column 3, lines 1-60<br>column 4, line 21 - line 25<br>example 7<br>claims 1-3,7-9<br>-----  | 1-4,9,<br>12,14,<br>15,24,25 |
| X         | WO 99/20250 A (SOLTEC RES PTY LTD [AU];<br>DAVEY GREG [AU]; ABRAM ALBERT ZORKO [AU])<br>29 April 1999 (1999-04-29)<br>page 1, line 3 - line 4<br>page 3, line 17 - line 19<br>page 4, line 16 - line 23<br>claims 1,4,10,11<br>-----   | 1-12,14,<br>15,24            |
| X         | ALBERTI I ET AL: "In vivo assessment of<br>enhanced topical delivery of terbinafine<br>to human stratum corneum"<br>JOURNAL OF CONTROLLED RELEASE, ELSEVIER,<br>AMSTERDAM, NL,<br>vol. 71, no. 3,<br>28 April 2001 (2001-04-28), pages 319-327,<br>XP004234529<br>ISSN: 0168-3659<br>the whole document<br>page 320, right-hand column, last<br>paragraph - page 321, left-hand column,<br>paragraph 1<br>page 324, left-hand column, paragraph 1 -<br>page 324, right-hand column, paragraph 1<br>figure 6<br>----- | 1-3,<br>9-12,14,<br>15,24    |
| X         | WO 01/60345 A2 (NOVARTIS AG [CH]; NOVARTIS<br>ERFIND VERWALT GMBH [AT]; RYDER NEIL<br>STEWART) 23 August 2001 (2001-08-23)<br>page 1, paragraph 1<br>example 3<br>-----  | 1-15,24,<br>25               |
| P,X       | WO 2006/012146 A (IDEXX LAB INC [US])<br>2 February 2006 (2006-02-02)<br><br>paragraphs [0270], [0271]<br>examples 5.3,5.5<br>-----  | 1-3,<br>9-12,14,<br>15,24,25 |

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2006/050991

## Box 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:  
  
Although claims 25 and 26 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 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.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2006/050991

| Patent document<br>cited in search report |    | Publication<br>date | Patent family<br>member(s)   | Publication<br>date  |
|---|----|---------------------|--|--|
| US 5681849                                | A  | 28-10-1997          | NONE   |  |
| WO 2005013955                             | A2 | 17-02-2005          | AU 2004262934 A1<br>CA 2535235 A1  | 17-02-2005<br>17-02-2005   |
| US 6455592                                | B1 | 24-09-2002          | NONE   |  |
| WO 9920250                                | A  | 29-04-1999          | CA 2306560 A1<br>EP 1024792 A1<br>JP 2001520184 T  | 29-04-1999<br>09-08-2000<br>30-10-2001   |
| WO 0160345                                | A2 | 23-08-2001          | AT 253939 T<br>AU 5464701 A<br>BR 0108403 A<br>CA 2399971 A1<br>CN 1400909 A<br>DE 60101213 D1<br>DE 60101213 T2<br>DK 1255564 T3<br>EP 1255564 A2<br>ES 2210150 T3<br>HK 1052633 A1<br>JP 2003522783 T<br>PT 1255564 T<br>TR 200400227 T4<br>US 2003100517 A1 | 15-11-2003<br>27-08-2001<br>11-03-2003<br>23-08-2001<br>05-03-2003<br>18-12-2003<br>19-08-2004<br>09-02-2004<br>13-11-2002<br>01-07-2004<br>25-08-2006<br>29-07-2003<br>31-03-2004<br>21-04-2004<br>29-05-2003 |
| WO 2006012146                             | A  | 02-02-2006          | NONE   |  |