

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/TR2015/050208

International filing date (day/month/year)
28.11.2015

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/00 A61K9/12 A61K31/4174 A61K31/573 A61P17/00 A61P31/10

Applicant
PHARMACTIVE ILAC SAN. VE TIC. A.S.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form PCT/ISA/210

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-8</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-8</u>
Industrial applicability (IA)	Yes: Claims	<u>1-8</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

- D1 VERALDI STEFANO: "Isoconazole nitrate: a unique broad-spectrum antimicrobial azole effective in the treatment of dermatomycoses, both as monotherapy and in combination with corticosteroids", MYCOSES, vol. 56, no. Suppl. 1, Sp. Iss. SI, May 2013 (2013-05), pages 3-15
- D2 HAVLICKOVA B ET AL: "The advantages of topical combination therapy in the treatment of inflammatory dermatomycoses", MYCOSES, WILEY-BLACKWELL PUBLISHING LTD, GB, vol. 51, no. Suppl. 4, 1 September 2008 (2008-09-01), pages 16-26, XP008122342, ISSN: 0933-7407
- D3 HERMS E ET AL: "Once daily administration of isoconazole as a cream, solution and spray: comparative studies of patients with dermatomycoses", ZEITSCHRIFT FÜR HAUTKRANKHEITEN 15 MAY 1988, vol. 63, no. 5, 15 May 1988 (1988-05-15), pages 377-384, XP009188847, ISSN: 0301-0481
- D4 WO 2015/138650 A1
- D5 WO 2011/026076 A2

2 The present application meets the criteria of Article 33(2) PCT, because the subject-matter of claims is new.

None of the cited documents discloses a topical spray composition comprising diflucortolone and isoconazole.

3 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claims 1-8 does not involve an inventive step.

D1 or D2 are regarded as being the prior art closest to the subject-matter of the present claims. These documents refer to the known combination of isoconazole nitrate and diflucortolone valerate in the form of a cream for the treatment of dermatomycoses.

The subject-matter of independent claim 1 differs from known D1/D2 in that the composition is in the form of a spray.

No special technical effect seems to derive from this difference.

The problem to be solved by the present invention may therefore be regarded as the provision of an alternative topical pharmaceutical form of the known combination of active ingredients.

The solution proposed in claim 1 of the present application, namely the formulation in the form of a spray, cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Starting from D1 or D2 and looking for an alternative pharmaceutical form, it would be obvious for the skilled man to try to formulate isoconazole nitrate and diflucortolone in the form of a spray. It should be noticed that the skilled man knows that isoconazole (alone) has already been formulated in the form of a spray (see D3) and that corticosteroids, among others diflucortolone, can also be formulated in the form of sprays (see D4 and D5).

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.