

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: see form PCT/ISA/220

PCT

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

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/EP2022/053190	International filing date (day/month/year) 10.02.2022	Priority date (day/month/year) 11.02.2021
International Patent Classification (IPC) or both national classification and IPC INV. A61K8/06 A61Q15/00 A61K8/26 A61K8/33 A61K8/37 A61K8/85 A61K8/92		
Applicant LA SUPERQUIMICA, S.A.		

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:  European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Bader, Karl Günther Telephone No. +49 30 25901-0
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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>1-16</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-16</u>
Industrial applicability (IA)	Yes: Claims	<u>1-16</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 DATABASE GNPD [Online] MINTEL; 28 April 2004 (2004-04-28), anonymous: "Protección Interactiva Roll-On Deodorant for Men", XP055581590, Database accession no. 268708

D2 WO 2017/114786 A1 (OREAL [FR]) 6 July 2017 (2017-07-06)

D3 WO 2018/111664 A1 (COLGATE PALMOLIVE CO [US]) 21 June 2018 (2018-06-21)

2 Independent claims:

1. A pharmaceutical or cosmetic water-in-oil emulsion composition comprising:
(a) a therapeutically or cosmetically effective amount of one or more antiperspirant active ingredients;
(b) one or more film-forming agents selected from the group consisting of capryloyl glycerine/sebacic acid copolymer; polyester-7 (and) neopentyl glycol diheptanoate; ethylcellulose (and) diisopropyl adipate; VP/acrylates/lauryl methacrylate copolymer; VP/eicosene copolymer; triacontanyl PVP; and pentyleneglycol (and) shellac; and
(c) one or more emollients selected from the group consisting of dicaprylyl ether; PPG-14 butyl ether; triheptanoin (and) (C₁₃-C₁₆) isoparaffin; heptyl undecylenate (and) (C₁₃-C₁₅) alkane; triheptanoin (and) (C₁₃-C₁₅) alkane; diisooctyl succinate; neopentyl glycol diheptanoate; diheptyl succinate; isododecane; dipropylheptyl carbonate; caprylyl caprylate/caprate; propylheptyl caprylate; cetearyl isononanoate; undecane (and) tridecane; (C₁₂-C₁₅)alkyl benzoate, dibutyl adipate; coco-caprylate; dicaprylyl carbonate; PPG-15 stearyl ether; coco-caprylate/caprate; caprylic/capric triglyceride; cocoglycerides; octyldodecanol, isopropyl myristate and isopropyl palmitate;
(d) together with one or more pharmaceutically or cosmetically acceptable excipients or carriers.

16. The water-in-oil emulsion composition as defined in any of the claims 1-15 for use in therapy;
or alternatively the use of water-in-oil emulsion composition in cosmetic; particularly as antiperspirant and deodorant agent.

- 3 The applicant has requested to have the present application processed under PCT Direct (PCT Guidelines B-IV, 1.2.1). Account taken of the applicant's comments submitted with the PCT Direct letter of 02-10-2022, this Authority considers that the claims do not meet the requirements of the PCT for the following reasons:
- 4 The present application does meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 appears new.
- D1 does indeed not explicitly state which type of emulsion is formed.
- D2 discloses indeed anhydrous compositions, excluding the formation of a W/O emulsion.
- 5 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 does not involve an inventive step.
- 5.1 D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses:
- A cosmetic emulsion composition comprising:
- (a) a cosmetically effective amount of one or more antiperspirant active ingredients;
- D1 discloses a cosmetic water-in-oil emulsion composition comprising:
- (a) Aluminium Chlorohydrate
 - (b) VP/eicosene copolymer or triacontanyl PVP
 - (c) PPG-15 Stearyl Ether
 - (d) together with one or more cosmetically acceptable excipients or carriers.
- 5.2 The subject-matter of claim 1 therefore differs from this known emulsion in that it is a W/O type.
- 5.3 The application provides details and effects of a very specific solution involving only capryloyl glycerine/sebacic acid copolymer and dicaprylyl ether/PPG-14 butyl ether. In view of the large structural variation of the individual alternatives for (b) and (c) any effect shown for this specific combination cannot be credibly extended over the scope of all combinations claimed, this even disregarding the fact that not all compounds falling under (a) might be compatible with the system involving (b) and (c).
- 5.4 Consequently the problem to be solved is considered as provision of an alternative AP composition.
- 5.5 The solution is the use of an W/O emulsion as basis.

- 5.6 The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The effects achieved appear not related with the type of emulsion. Consequently the solution is rather residing in the combination of a film forming polymer, an emollient and an AP active, which is already disclosed in the prior art for similar systems. While it is appreciated that the type of emulsion formed by a given combination of emulsifiers is dependent on the HLB of the emulsifiers in the system, as a matter of fact the overall HLB value of the combination is critical. D1 does not disclose amounts and thus the overall HLB cannot be calculated in that case. However from the position of the PPG-15 stearyl ether in the MINTEL list it can be derived in a mere relative manner that it is in somewhat an excess to the other emulsifiers, in the absence of absolute values the type of emulsion can of course not be derived, but the option of the formation of a W/O emulsion indeed is not excluded prima facie. Given that water is clearly in excess in D1 and in the absence of a larger oil body in the list in D1 located before e.g. the emulsifiers, it still appears very likely that D1 indeed discloses a W/O emulsion rather than an O/W emulsion. In any case the skilled man would now how to adjust the relative amounts in order to obtain the desired emulsion type.

- 5.7 Consequently the subject matter of the claims lacks an inventive step.