

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/IB2024/051129

International filing date (day/month/year)
07.02.2024

Priority date (day/month/year)
07.02.2023

International Patent Classification (IPC) or both national classification and IPC
INV. A61K33/26 A61K33/42 A61P3/02 A61P7/06

Applicant
ALESCO S.R.L.

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

Authorized Officer

Scheid, Günther

Telephone No. -0



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.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
 - ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
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>1-21</u> |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | <u>1-21</u> |
| Industrial applicability (IA) | Yes: Claims | <u>1-21</u> |
| | No: Claims | |
2. Citations and explanations
- see separate sheet**

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

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

Reference is made to the following documents:

- D1 WO 2014/009806 A1 (ALESCO SRL [IT]) 16 January 2014 (2014-01-16)
- D2 WO 2016/037836 A1 (UNILEVER NV [NL]; UNILEVER PLC [GB]; CONOPCO INC DBA UNILEVER [US]) 17 March 2016 (2016-03-17)
- D3 TIAN TIAN ET AL: "Dissolution behaviour of ferric pyrophosphate and its mixtures with soluble pyrophosphates: Potential strategy for increasing iron bioavailability",
FOOD CHEMISTRY, ELSEVIER LTD, NL,
vol. 208, 23 March 2016 (2016-03-23), pages 97-102, XP029527322,
ISSN: 0308-8146, DOI: 10.1016/J.FOODCHEM.2016.03.078
- D4 COLIN I. CERCAMONDI ET AL: "Abstract",
BRITISH JOURNAL OF NUTRITION,
vol. 116, no. 3, 14 August 2016 (2016-08-14), pages 496-503,
XP055661417,
UK
ISSN: 0007-1145, DOI: 10.1017/S0007114516002191
- D5 EP 1 743 530 A1 (UNILEVER NV [NL]; UNILEVER PLC [GB]) 17 January 2007 (2007-01-17)

1 Novelty

D1 discloses (claims) a solid composition for use in the treatment of disorders or diseases related to an iron deficiency comprising or, alternatively, consisting of an iron (III) salt, sucrose esters or sucresters E473 and a lecithin,
wherein said iron (III) salt is ferric pyrophosphate; said iron (III) salt is in an amount comprised from 30 to 70%, preferably from 40 to 60% by weight,
wherein said sucrose esters or sucresters E473 are in an amount comprised from 10 to 30%, preferably from 15 to 25% by weight,

wherein said lecithin is a lecithin E322 and is selected from the group comprising the maize, sunflower or soya lecithin; said lecithin is in an amount comprised from 0.1 to 1.5, preferably from 0.4 to 1% by weight,

wherein said sucrose ester or sucrester and said lecithin are in the composition in a weight ratio comprised from 25:1 to 20:1 ; preferably in a weight ratio comprised from 20:1 to 15:1,

wherein said gelatinized or pregelatinized starch is selected from the group comprising rice starch or maize starch; said starch is in an amount comprised from 15 to 40%, preferably from 20 to 35% by weight.

D1 does not disclose a composition comprising ferric pyrophosphate and a sodium or potassium pyrophosphate salt and comprising at least one arabic gum or acacia gum.

Documents D2-D4 disclose compositions comprising ferric pyrophosphate and a sodium or potassium pyrophosphate salt, but do not comprise at least one lecithin and at least one sucrestere.

Document D5 discloses (examples 3 and 4) Gum Arabic stabilized iron(III) pyrophosphate nanoparticles, but does not disclose a composition comprising ferric pyrophosphate and a sodium or potassium pyrophosphate salt.

Therefore, subject-matter of present claims 1-21 is novel (Article 33(2) PCT).

2 Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-21 does not involve an inventive step in the sense of Article 33(3) PCT.

D1 is the closest prior art.

Subject-matter of present claims 1-21 differ essentially from D1 in that the mixtures (compositions) comprise an iron (III) pyrophosphate salt and a sodium or potassium pyrophosphate salt and in addition comprise at least one arabic gum or acacia gum.

The technical effect of the presence of the sodium or potassium pyrophosphate salt lies in the improved bioavailability of the iron contained in the compositions (see [0272] of the description).

The objective technical problem to be solved by the present application can therefore be described as the provision of compositions comprising iron (III) pyrophosphate which have an improved bioavailability of the iron.

The solution proposed in claims 1-21 of the present application cannot be considered as involving an inventive step. The concept of using sodium or potassium pyrophosphate salt in order to improve bioavailability of iron (III) has already been demonstrated in numerous disclosures of the pertinent prior art, as can be seen in D2, D3 and D4. All three documents disclose in detail, how sodium pyrophosphate salt increases bioavailability of ferric pyrophosphate. The at least one arabic gum or acacia gum appears to not add to any specific technical effect. In fact, arabic gum or acacia gum are widely known as additives and has been disclosed for example in D5 (examples 3 and 4) in the context of stabilizing iron(III) pyrophosphate nanoparticles.

3 Industrial applicability

Subject-matter of present claims 1-21 fulfils the requirements of Article 33(4) PCT.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D5 is not mentioned in the description, nor is this document / are these documents identified therein.