PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.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.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2019/025639	03.04.2019	30.11.2018

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/46 A61K9/00 A61K9/20

Applicant
AMERILAB TECHNOLOGIES, INC.

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 43*bis*.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 notifed the International Bureau under Rule 66.1*bis*(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:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Couckuyt, Philippe Telephone No. +31 70 340-0

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 43*bis*.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 13*ter*.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 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.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 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-27
	No:	Claims	
Inventive step (IS)	Yes:	Claims	17, 27
	No:	Claims	1-16, 18-26
Industrial applicability (IA)	Yes:	Claims	1-27
	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

Reference is made to the following documents:
D1: WO-2011130440
D2: WO-2005072759
D3: WO-2014018569
D4: CN-103098926
D5: XP055603953
D6: EP-2879522
D7: WO-2010057372

V.1 Novelty (Article 33(2) PCT)

The present application meets the criteria of Article 33(2) PCT, because the subject-matter of claims 1-27 is new.

Document D1 discloses an effervescent tablet an effervescent agent (acid-base) includes 20-30% binder (none defined crystalline dextrose, lactose), a flavor agent including a solid substrate component (carrier) in addition to the flavor component like arabic gum used as emulsifying polymer, a sweetener such as stevia, an oil component, Hardness 3-10 kp and dissolution in less then 210 sec. Also method of making these tablets: sieved, mixing ingredients, tableting with tableting punches (see p.6 l.1- p.12 l. 24 and claims).

Accordingly, the subject-matter of claims 1-27 is new over D1.

Document D2 discloses an effervescent tablet an effervescent agent (acid-base) includes 15-50% binder (none defined crystalline dextrose, sucrose), a sweetener such as stevia, an oil component, natural and synthetic flavors used, Hardness 5-10 kp and disintegration in less then 2,5 mins. No arabic gum present. Further method of making these tablets: sieved, mixing ingredients, tableting with tableting punches (see p.7 l.10 - p.8 l.19 and claims).

Accordingly, the subject-matter of claims 1-27 is new over D2.

Document D3 discloses an effervescent tablet with carriers like micro crystalline dextrose and stevia as sweetener (see [00182-00198] and claims). No specific effervescent agent, nor arabic gum mentioned.

Accordingly, the subject-matter of claims 1-27 is new over D3.

Document D4 disclose an effervescent tea flavor table comprising 35% ~ 40% instant tea powder, 8% ~ 10% of anhydrous citric acid, 25% ~ 30% sugar, 4% ~ 6% gum arabic, ~19.5% 18.5% anhydrous sodium bicarbonate, includes method for preparing the oolong tea effervescent tablet with fast (undefined) disintegration time. No crystalline sugar present and undefined tablet hardness (see claims).

Accordingly, the subject-matter of claims 1-27 is new over D4.

Document D5 discloses the application of gum arabic in the food industry where it is use as flavor agent and as stabilizer of citrus oil emulsions, and in the pharmaceutical industry.

Accordingly, the subject-matter of claims 1-27 is new over D5.

Document D6 discloses a sweetener composition in the form of a tablet comprising at least one food or beverage ingredient and as sweetener monk fruit extract (see p.5 l.2-3 and claims).

Accordingly, the subject-matter of claims 1-27 is new over D6.

Document D7 discloses rice hulls used as filler (not as lubricant) in plant nutrition effervescent tablets (see claims 1, 12-15).

Accordingly, the subject-matter of claims 1-27 is new over D7.

V 2. Inventive step

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-16 does not involve an inventive step in the sense of Article 33(3) PCT.

Claims 1-16: Document D1 constitutes the closest prior art since it discloses an effervescent tablet an effervescent agent (acid-base) includes 20-30% binder (none defined crystalline dextrose, sucrose), a flavor agent including a solid substrate component (carrier) in addition to the flavor component like arabic gum used as emulsifying polymer, 2% sweetener such as stevia, an oil component, Hardness 3-10 kp and dissolution in less then 210 sec.

The subject-matter of claim 1 differs from the subject-matter of D1 in that according to the present claim the binder is selected from the group consisting of crystalline dextrose, crystalline sucrose, crystalline fructose, and combinations thereof, whereas in D1 the binder is dextrose or sucrose and not crystalline and is therefore new.

The problem to be solved by the present invention may therefore be regarded as to provide an alternative effervescent tablet that includes Stevia.

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 commercial products of dextrose (also called glucose) on the market is always available in its 'crystalline form' and mostly as 'monohydrate' rather than in anhydrous form. Also sucrose and fructose are standard available in 'crystalline form', so this is so obvious that is is not even mentioned anymore in patent descriptions.

Claims 2-16: Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step. In claims 2-16 a slight formulation change is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.
Consequently, the subject-matter of claims 2-16 lacks an inventive step (Article 33(3) PCT).

2.2 Claim 17

The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claim 17 does involve an inventive step in the sense of Article 33(3) PCT.

Document D1 constitutes the closest prior art since it discloses an effervescent tablet an effervescent agent (acid-base) includes 20-30% binder (none defined crystalline dextrose, lactose), a flavor agent including a solid substrate component (carrier) in addition to the flavor component like arabic gum used as emulsifying polymer, a sweetener such as stevia, an oil component, and a different lubricant. Hardness 3-10 kp and dissolution in less then 210 sec. Also method of making these tablets: sieved, mixing ingredients, tableting with punches. No rice hulls present.

The subject-matter of claim 17 differs from the subject-matter of D1 in that according to the present claim the lubricant is derived from multi-component integral lubricant comprising rice hulls particles, whereas in D1 a different lubricant is used and is therefore new (Article 33(2) PCT).

The technical effect of this difference is shown in the Tables 1-3 where different flavors comprising gum Arabic combined with NuMag Natural lubricant generate the desired hardness and disintegration time.

The problem to be solved by the present invention may be regarded as to provide an improved effervescent tablet that includes Stevia.

The solution to this problem proposed in claim 17 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Although these features have already been employed separately for different purpose in a similar effervescent tablets. It would not be obvious to the person skilled in the art, to apply these features with corresponding effect to the effervescent tablet according to document D1, thereby arriving at an effervescent tablet according to claim 17.

Therefore, the subject-matter of claim 17 does involve an inventive step.

2.3 claims 18-26

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 18-26 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D1 constitutes the closest prior art since it discloses mass production of effervescent tablets via a tableting process of similar tablets.

The subject-matter of claim 18 differs from the subject-matter of D1 in that according to the present claim the binder used in the method of making effercent tablets is selected from the group consisting of crystalline dextrose, crystalline sucrose, crystalline fructose, and combinations thereof, whereas in D1 the binder is dextrose or sucrose and not crystalline and is therefore new.

The problem to be solved by the present invention may therefore be regarded as to provide an alternative effervescent tablet that includes Stevia.

The solution proposed in claim 18 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
- The commercial products of dextrose (also called glucose) on the market is always available in its 'crystalline form' and mostly as 'monohydrate' rather than in anhydrous form. Also sucrose and fructose are standard available in 'crystalline form', so this is so obvious that is is not even mentioned anymore in patent descriptions.

Consequently, the subject-matter of claims 18-26 lacks an inventive step (Article 33(3) PCT).

2.4 claim 27

The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claim 27 does involve an inventive step in the sense of Article 33(3) PCT.

The same reasoning applies as for claim 17, mutatis mutandis, to the subject-matter of the corresponding dependent claim 27, which therefore is also considered inventive.

V 3. Industrial applicability

The subject-matter of claims 1-27 meets the requirements of industrial applicability.