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|-------------------------|-------------------------------------|-------------------------|---|------------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 17/724,019 | 04/19/2022 | Katie F. WLASCHIN | 80025US010 | 1017 |
| | 7590 05/10/202 TVE PROPERTIES CO | EXAMINER | | |
| PO BOX 33427 | 7 | MAEWALL, SNIGDHA | | |
| ST. PAUL, MN 55133-3427 | | | ART UNIT | PAPER NUMBER |
| | | | 1612 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 05/10/2023 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. 17/724,019 | Applicant(s) WLASCHIN et al. | | | | |
|---|--|---|--|--|--|--|
| Office Action Summary | Examiner | Art Unit | AIA (FITF) Status | | | |
| | SNIGDHA MAEWALL | 1612 | Yes | | | |
| The MAILING DATE of this communication ap | pears on the cover sheet with the c | orrespondenc | ce address | | | |
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| A SHORTENED STATUTORY PERIOD FOR REPL DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut | | nely filed after SIX (the mailing date of D (35 U.S.C. § 133 | 6) MONTHS from the mailing f this communication. 3). | | | |
| Any reply received by the Office later than three months after the mailir adjustment. See 37 CFR 1.704(b). | ig date of this communication, even if timely filed | d, may reduce any o | earned patent term | | | |
| Status | | | | | | |
| 1) ■ Responsive to communication(s) filed on 04 | | | | | | |
| A declaration(s)/affidavit(s) under 37 CFR | | | | | | |
| 2a) This action is FINAL . 2b) 3) An election was made by the applicant in re | This action is non-final. | ont oot forth (| during the interview | | | |
| on ; the restriction requirement and ele | | | | | | |
| 4) Since this application is in condition for allow closed in accordance with the practice under | vance except for formal matters, | , prosecution | as to the merits is | | | |
| Disposition of Claims* | | | | | | |
| 5) 🗹 Claim(s) <u>1 and 20-23</u> is/are pending in the application. | | | | | | |
| 5a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 6) 🔲 Claim(s) is/are allowed. | | | | | | |
| 7) ☑ Claim(s) <u>1 and 20-23</u> is/are rejected. | | | | | | |
| 8) 🔲 Claim(s) is/are objected to. | | | | | | |
| 9) Claim(s) are subject to restriction a | • | | | | | |
| * If any claims have been determined <u>allowable</u> , you may be e | - | - | way program at a | | | |
| participating intellectual property office for the corresponding a http://www.uspto.gov/patents/init_events/pph/index.jsp or send | | | | | | |
| | | <u>.9011</u> | | | | |
| Application Papers 10) The specification is objected to by the Exam | iner | | | | | |
| 11) The drawing(s) filed on is/are: a) | | the Examine | er. | | | |
| Applicant may not request that any objection to the | • • • • | | | | | |
| Replacement drawing sheet(s) including the correction | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for fore Certified copies: | | 9(a)-(d) or (f |). | | | |
| a)□ All b)□ Some** c)□ None of | the: | | | | | |
| 1. Certified copies of the priority docu | ments have been received. | | | | | |
| Certified copies of the priority docu | ments have been received in Ap | plication No. | ·· | | | |
| 3. Copies of the certified copies of the application from the International B | ureau (PCT Rule 17.2(a)). | received in th | nis National Stage | | | |
| ** See the attached detailed Office action for a list of the certif | fied copies not received. | | | | | |
| Attachment(s) | | | | | | |
| 1) 🔽 Notice of References Cited (PTO-892) 3) 🗌 Interview Summary (PTO-413) | | | | | | |
| 2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/ Paper No(s)/Mail Date | Paper No(s)/Mail D SB/08b) 4) Other: |)ate | | | | |
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Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined

under the first inventor to file provisions of the AIA.

Detailed Action

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all

obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 20-23 are rejected under 35 U.S.C. 103 as being unpatentable over Wlaschin et al (USP 8,460,689).

Wlaschin discloses an oral moisturizing composition that also decolonized mammalian oral tissue (e.g., composition that contacted oral tissue), see title and [abstract]. Wlaschin, teaches that a significant segment of the population suffers from xerostomia (dry mouth) and as such, it is extremely important that oral treatment regiments address both the reduction of microorganisms (plaque removal and reduction of opportunistic organisms in the oral cavity), and xerostomia, see [col 1, lines 22-23] and [col 1, lines 60-63]. Wlaschin discloses that the composition comprises edible vegetable oils in an amount of at least 30 %, see [col 12, lines 14-15] and [col 33, lines 9-13]; significant amounts of water (e.g., at least 20 wt. %; e.g., 87.8 % water disclosed in the example formulations of Table 3), [col 32, lines 1-2]; nonionic surfactants, generally, [col 29, line 63] (0.1 to 10 wt. % disclosed at [col 28, lines 30-38]); 1.6 % xanthan gum (e.g.,

polymeric viscosity modifier) as disclosed in Table 3, Example Formulation # 1]. The composition was formulated as an oil-in-water emulsion with a pH of 3-8 see [col 8, lines 5-7], and [col 11, lines 16-26]. Additionally, Wlaschin generally discloses use of excipients [col 33, line 48]. Wlaschin teaches use of thickeners, humectants and excipients in column 19, lines 52-59. Claim 1 recites 5-70 % plant based oil; 35-95 % aqueous phase; 0.1-7.5 % surfactant; 0.05-3 % viscosity modifier; pH of 4.5-9.5. Wlaschin disclosed edible vegetable oils in an amount of at least 30 %; significant amounts of water (e.g., at least 20 wt. %; e.g., 87.8 % water disclosed in the example formulations of Table 3); nonionic surfactants, generally, (0.1 to 10 wt. % disclosed at [col 28, lines 30-38]); 1.6 % xanthan gum (e.g., polymeric viscosity modifier) [Table 3, Example Formulation # 1]; pH of 3-8. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a prima facie case of obviousness exists. MPEP 2144.05 A. Wlaschin discloses use of fumed silica, see [col 31, line 56]. Wlaschin discloses use of oils, including olive, cottonseed, peanut, corn, sesame, safflower, soybean oils, and the like, see [col 32, lines 54-57] natural. Further, at Table 2, Wlaschin discloses coconut oil as a comparative example of an ingredient found in commercially available oral moisturizers. Wlaschin discloses sweeteners, see [col 17, line 3]. Wlaschin discloses use of aloe vera, see [Table 1]. Wlaschin disclosed enhancer components, including sugar, at not greater than 20 % [col 25, line 38 to col 26, line, 3]. Wlaschin does not disclose a quaternary antimicrobial compound as a required ingredient. Wlaschin discloses a viscosity of at least 10,000 or in excess of 50,000 cps, see [col 11, lines 41-49]. Wlaschin discloses a physically stable compositions at 25 ° C, see [col 17, lines 23-27]. Wlaschin taught excipients at increasing amounts (e.g., Wlaschin disclosed excipients at 0.5-2 % at Tables 12-16). Since the art

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teaches treating xerostomia, it would implicitly increase lubriciousness in an oral tissue. Since the art teaches pH of 3-8. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a prima facie case of obviousness exists. MPEP 2144.05 A. Thus, it would have been obvious to one of ordinary skill to have formulated an oral composition for treating xerostomia comprising plant based oils, aqueous phase, surfactant and viscosity modifier with a pH of 3-8 which overlaps with the claimed range of 4.5 to 9.5 and thus creates case of obviousness and combining prior art elements according to their known function would have provided predictable results of oral composition for treating xerostomia, see MPEP 2143 part (I)(A).

Claim 22 is rejected under 35 U.S.C. 103 as being unpatentable over Wlaschin et al (USP 8,460,689), in view of Hunter et al (USP 6,159,459).

Wlaschin generally discloses [col 33, line 49] lubricants.

Wlaschin does not specifically disclose that the composition increased lubricity or lubriciousness, as recited in claim 22.

Hunter discloses [abstract] an oral lubricant (beta-glucan polymer) having particular usefulness for alleviating the symptoms of xerostomia. As per Hunter [col 1, lines 16-22], xerostomia, in which the salivary glands do not produce sufficient quantities of saliva, causes discomfort which can in some cases be quite severe. Without saliva, the mouth burns and the throat and tongue can undergo radical changes. Teeth can decay rapidly and the tongue can become smooth, cracked and vulnerable to infection. As such, [col 2, lines 13-23], it is most desirable to have an oral lubricating composition for human use, to relieve the discomforts and inconveniences incurred by xerostomia and dryness of the mouth. Hunter's composition [col 2, lines 13-23 and at lines 31-37] had

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