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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/277,789	10/20/2011	Robert A. Ashley	512-53 DIV/CON II	4179

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

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PAPER

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

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 13/277,789	<b>Applicant(s)</b> ASHLEY, ROBERT A.	
	<b>Examiner</b> SUSAN TRAN	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on \_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5)  Claim(s) 21-40 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5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.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) 21-40 is/are rejected.
- 8)  Claim(s) \_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/01/12</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claims 21, 23, 25-28, 30, 32-35 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583.***

Perricone teaches a method for the treatment of pustule and papule. The method comprises orally administering an antibiotic compound. See column 5, lines 40-45; column 6, lines 20-24; and column 8, lines 24-29.

Perricone does not expressly teach the claimed amount of antibiotic compound, as well as the claimed antibiotic such as doxycycline.

Pflugfelder teaches a method for treating conditions associated with rosacea. The method comprises orally administering a tetracycline compound in a sub-antimicrobial amount that ranges from about 20% to about 80% of the normal antibiotic therapeutic dose of the particular tetracycline compound. See abstract; column 4, lines 1-10; and column 5, lines 1-12. Tetracycline compound includes doxycycline is found in column 6, line 5; and claim 3.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the method of Perricone to administer antibiotic

compound in a sub-antimicrobial amount in view of the teachings of Pflugfelder. This is because: 1) Pflugfelder teaches the use of an antibiotic compound for the treatment of rosacea related conditions is known in the art; 2) Pflugfelder teaches that long term administration of antibiotic compound in a sub-antimicrobial amount will minimized tetracycline advert side-effects such as nausea, vomiting, diarrhea, and epigastric pain (column 1, lines 48-63); and 3) Perricone teaches the desirability for administering antibiotic compound in a lower dosage amount to eliminate advert side-effect such as nausea, GI upset, yeast infection, and interactions with other medication (column 8, lines 30-40).

***Claims 24, 25, 31, 32, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583 and Sheth et al. US 5,300,304.***

Perricone is relied upon for the reasons stated above. The reference is silent with respect to the once-a-day sustained release dosage.

Sheth teaches a pulsatile once-a-day dosage form of a non-toxic acid tetracycline compound for the treatment of acne. See abstract; columns 5-6; and claims.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition of Perricone to include a once-a-day antibiotic composition because Sheth teaches an antibiotic once-a-day dosage form is known in the art.

***Claims 22, 29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583 and Heesch US 2002/0165220 A1.***

Perricone is relied upon for the reasons stated above. Perricone does not teach the hyclate salt of doxycycline.

Heesch teaches a tetracycline compound useful for the treatment of acne includes doxycycline. Heesch further teaches that doxycycline hyclate exhibits better advantage over the doxycycline compound. See abstract; paragraphs 0093-0094 and claims.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition of Perricone to include the hyclate salt of the antibiotic compound in view of the teachings of Heesch. This is because doxycycline monohydrate (hyclate) provides lower dosage requirement, and because Perricone teaches the desirability for lower antibiotic dosage.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN TRAN whose telephone number is (571)272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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