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NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 12/18/2019
Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/18/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804	4432

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	03/18/2020

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
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Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

91543 7590 12/18/2019
Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804	4432

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nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	03/18/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
SASAN, ARADHANA	1615	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US	4432
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EXAMINER				
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Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 12/18/2019				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/816,154	Applicant(s) Perrett et al.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (FITF) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendments, Remarks and Terminal Disclaimer filed on 12/06/19.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ 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.

3. ☒ The allowed claim(s) is/are 44,48-54,57-58 and 60-66. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

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)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____.	7. ☐ Other ____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____.	

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	
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DETAILED CORRESPONDENCE

Notice of Pre-AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. The Amendments and Remarks filed on 12/06/19 are acknowledged.
3. Claims 1-43, 45-47, 55-56 and 59 were cancelled.
4. Claims 44, 57-58, 60-63 and 65-66 were amended.
5. Claims 44, 48-54, 57-58 and 60-66 are pending.

Information Disclosure Statement

6. The information disclosure statement (IDS) filed on 12/06/19 is acknowledged.
The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98.
Accordingly, the examiner is considering the information disclosure statement.
Please see the attached copy of PTO-1449.

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

Claim Objection

8. In light of the amendment of claim 65 to be dependent on claim 64, the objection to claim 65 is withdrawn.

Claim Rejections - 35 USC § 103

9. Applicant amended claim 44 to recite that the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP<701> Disintegration Test. In light of this amendment, Applicant's arguments (Pages 4-5, filed

12/06/19) regarding the rejection of claims 44 and 48-66 under pre-AIA 35 U.S.C.

103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1) have been fully considered and are persuasive. Since Dohil et al. do not teach or suggest the disintegration time of the tablet, particularly disintegration within 60 seconds in simulated saliva, as recited in instant claim 44, the rejection based on Dohil et al. is withdrawn.

Terminal Disclaimer

10. The electronic terminal disclaimer filed on 12/06/19 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent Numbers 8,771,729 and 9,486,407 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting Rejection over U.S. Patent No. 10,105,315

11. Applicant's arguments (Page 5, filed 12/06/19) regarding the rejection of claims 44 and 48-66 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10-14 of U.S. Patent No. 10,105,315 (the '315 Patent) have been fully considered and are persuasive. Claims of the '315 Patent require the administration of the corticosteroid while the patient is lying down, which was critical to the method of the '315 Patent. Therefore, the double patenting rejection over the '315 Patent is withdrawn.

Updated Search

12. An updated prior art search did not disclose a reference that teaches an orally dispersing tablet comprising 0.5 mg to 5 mg of budesonide and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the

oral cavity, wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract, and wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test, as recited in the instant claims. Therefore, the claimed invention is novel and unobvious over the prior art of record.

Comments

13. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

14. Claims **44, 48-54, 57-58 and 60-66** are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARADHANA SASAN whose telephone number is (571)272-9022. The examiner can normally be reached Monday to Friday from 6:30 am to 3:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

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

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Attorney Docket No. ADAR-119/05US 325049-2804

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, et al. Confirmation No.: 4432
Application No.: 15/816,154 Group Art Unit: 1615
Filed: November 17, 2017 Examiner: Aradhana Sasan
FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.111

In response to the non-final office action dated September 9, 2019, please
amend the above-identified application, as follows:

Amendments to the Claims begin on page **2** of this paper; and

Remarks begin on page **4** of this paper.

AMENDMENT TO THE CLAIMS:

The following Listing of Claims will replace all prior versions of Listing of Claims in the application.

1.-43. (Cancelled)

44. (Currently Amended) An orally dispersing tablet comprising (i) 0.5 mg to 5 mg of a corticosteroid ~~selected from the group consisting of budesonide, fluticasone, and salts, solvates and esters thereof,~~ and (ii) at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity,

wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract, and

wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.

45-47. (Cancelled)

48. (Previously Presented) The orally dispersing tablet of claim 44, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

49. (Previously Presented) The orally dispersing tablet of claim 48, wherein the at least one disintegrant is selected from the group consisting of croscopovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

50. (Previously Presented) The orally dispersing tablet of claim 44, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, sucralose, maltose, cyclodextrin, polyvinyl pyrrolidone, magnesium stearate, and combinations thereof.

51. (Previously Presented) The orally dispersing tablet of claim 50, wherein the excipient is selected from the group consisting of mannitol, sucralose, magnesium stearate, and combinations thereof.

52. (Previously Presented) The orally dispersing tablet of claim 51, wherein the excipient is mannitol.

Attorney Docket No.: ADAR-119/05US 325049-2804
U.S. Patent Application No.: 15/816,154

53. (Previously Presented) The orally dispersing tablet of claim 51, wherein the excipient is sucralose.
54. (Previously Presented) The orally dispersing tablet of claim 51, wherein the excipient is magnesium stearate.
55. (Cancelled)
56. (Cancelled)
57. (Currently Amended) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of budesonide ~~or fluticasone propionate~~.
58. (Currently Amended) The orally dispersing tablet of claim 44, comprising about 1 mg of budesonide.
59. (Cancelled)
60. (Currently Amended) The orally dispersing tablet of claim 51, comprising about 1 mg of budesonide.
61. (Currently Amended) The orally dispersing tablet of claim 52, comprising about 1 mg of budesonide.
62. (Currently Amended) The orally dispersing tablet of claim 53, comprising about 1 mg of budesonide.
63. (Currently Amended) The orally dispersing tablet of claim 54, comprising about 1 mg of budesonide.
64. (Previously Presented) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof an orally dispersing tablet according to claim 44.
65. (Currently Amended) The method of claim ~~[[65]]~~64, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus.
66. (Currently Amended) The method of claim ~~[[65]]~~64, wherein said inflammatory condition of the gastrointestinal tract is eosinophilic esophagitis.

REMARKS

I. Status of Claims

Upon receipt of the non-final Office Action dated September 9, 2019, claims 44 and 48-66 were pending. Claims 44, 57, 58, 60-63, 65, and 66 have been amended without prejudice or disclaimer. Claims 55, 56, and 59 have been cancelled without prejudice or disclaimer. Support for the amended claims can be found throughout the as-filed specification.

No new matter is believed to have been added by way of the present amendments. Entry thereof and reconsideration of the present Application is respectfully requested.

II. Summary of Examiner Interview

On December 4, 2019, Applicant's attorney, Jon Cousin, conducted a telephonic interview with Examiner Sasan. Applicant's attorney appreciates the time, attention, and courtesy extended by Examiner Sasan. During the interview, proposed amendments to the independent claim were discussed, substantially as provided herein. Examiner Sasan indicated that the proposed amendments should overcome the current rejection, and that a further prior art search would be conducted in view of the formal response as-filed.

III. Claim Objections

The Examiner objected to claim 65 as being in improper form because it is dependent on itself. To address this issue, Applicant has amended claim 65 to depend from claim 64. Accordingly, Applicant respectfully requests the present objection be withdrawn.

IV. Claim Rejections under 35 U.S.C. § 103

The Examiner rejected claims 44 and 48-66 under 35 U.S.C. § 103 as being unpatentable over U.S. Publication No. 2009/0191275 to *Dohil et al.* ("*Dohil*").

Without acquiescing to the present rejection, and solely to expedite prosecution, Applicant has amended claim 44. Specifically, Applicant amended claim 44 to recite the tablet's disintegration rate: "wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test." As discussed during the interview, *Dohil* fails to disclose or render obvious an orally dispersing tablet that disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.

Accordingly, Applicant respectfully submits that, for at least the foregoing reasons, independent claim 44 is allowable over the cited reference. Additionally, dependent claims 48-54, 57, 58, and 60-66 are allowable at least because of their dependency on an allowable independent claim.

V. Double Patenting Rejections

Claims 27-40 are rejected on the ground of non-statutory double patenting as purportedly being unpatentable over:

- claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729;
- claims 1-5, 9-26, and 35-39 of U.S. Patent No. 9,486,407; and
- claims 1 and 10-14 of U.S. Patent No. 10,105,315.

Without conceding to the propriety of the rejection and solely to advance prosecution, Applicant submits concurrently herewith e-terminal disclaimers over U.S. Patent Nos. 8,771,729 and 9,486,407, along with the corresponding terminal disclaimer fee.

Applicant notes that during the Interview, the Examiner agreed to withdrawal the non-statutory double patenting rejection over U.S. Patent No. 10,105,315. As discussed during the interview, the claims in U.S. Patent No. 10,105,315, are directed to a method of treating eosinophilic esophagitis in which the corticosteroid is administered “*while the patient is lying down.*” As discussed in the prosecution history of U.S. Patent No. 10,105,315, such a method was not obvious over the present claims and specification.

Accordingly, Applicant believes the obviousness-type double patenting rejections are overcome and respectfully requests withdrawal of the present rejection.

CONCLUSION

Having addressed each of the foregoing rejections, it is respectfully submitted that a full and complete response has been made to the outstanding Office Action and as such, the application is in condition for allowance. Notice to that effect is respectfully requested.

If the Examiner believes, for any reason, that a personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283.

Respectfully submitted,
COOLEY LLP

Dated: December 6, 2019

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804	4432
91543	7590	09/09/2019	EXAMINER	
Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			09/09/2019	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zIPPatentDocketingMailboxUS@cooley.com

DETAILED CORRESPONDENCE

Notice of Pre-AIA or AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. The remarks, amendments, and Request for Continued Examination filed on 06/10/19 are acknowledged.
3. Claims 1-43 and 45-47 were cancelled. Claim 44 was amended. New claims 48-66 were added.
4. Claims 44 and 48-66 are included in the prosecution.

Continued Examination under 37 CFR 1.114

5. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/10/19 has been entered.

Information Disclosure Statement

6. The information disclosure statements (IDS) filed on 06/10/19 and 08/07/19 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements. Please see the attached copies of PTO-1449.

Response to Amendments/Arguments

Claim Objections

7. In light of the cancellation of claims 28-43 and 45-47, the objections to these claims are rendered moot.

8. However, a new objection to newly added claim 65 is presented below.

Rejection of claims under 35 USC § 112, second paragraph

9. In light of the cancellation of claims 45-47, the rejection of these claims under 35 USC § 112, second paragraph, is rendered moot.

Rejection of claims under 35 USC § 102(b)

10. Applicant's arguments (Pages 4-5, filed 06/10/19) with respect to the rejection of claims 42 and 44 under 35 USC § 102(b) as being anticipated by Dohil et al. (US 2009/0191275 A1) have been fully considered and are persuasive.

Therefore the rejection of 12/10/18 is withdrawn.

Claim Objections

11. Claim **65** is objected to under 37 CFR 1.75(c) as being in improper form because it is dependent on itself. See MPEP § 608.01(n). For examination purposes, claim 65 is construed to be dependent on claim 64. Appropriate correction is required.

Claim Rejections - 35 USC § 103

12. The following is a quotation of pre-AIA 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 44 and 48-66 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1).**

Instant claim 44 is drawn to an orally dispersing tablet comprising 0.5 mg to 5 mg of a corticosteroid selected from the group consisting of budesonide, fluticasone, and salts, solvates and esters thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract.

Dohil et al. disclose a pharmaceutical composition wherein budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus; and the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus ([0062]). The dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients ([0021], [0033]). Dohil et al. disclose that their methods are useful for preventing or alleviating symptoms and inflammation associated with other diseases or conditions of the gastrointestinal tract, for example, the upper gastrointestinal tract, where it is beneficial to target a particular target site, rather than

provide systemic therapy ([0009]), e.g., the esophagus ([0035], [0044], [0056]). The budesonide is administered in oral form in a formulation with increased coating, e.g., viscosity and/or mucoadhesive characteristic is deliver to the esophagus in an effective dose to reduce the inflammation of the esophagus ([0036]).

Dohil et al. disclose a composition that has an effective volume which coats or at least partially coats the esophagus, and delivers the composition to the affected areas, including the esophagus ([0056]).

Dohil et al. do not expressly disclose an embodiment of the orally dispersing lozenge wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract, as recited in instant claim 44.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition wherein budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus; the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus, and the dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients, as taught by Dohil et al., administer the orally dispersing lozenge to a subject in need thereof and achieve the deposition of the corticosteroid in the upper gastrointestinal tract, for example, the esophagus, as suggested by Dohil et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Dohil et al. clearly disclose the solid orally dispersing dosage form, i.e., a lozenge that

contains budesonide in a dosage of 250 µg to about 10 mg in the presence of excipients ([0021], [0033], [0036]). Dohil et al. also clearly disclose the deposition of the corticosteroid once the composition is administered orally ([0056]). One of ordinary skill in the art would have found it obvious that once the orally dispersing lozenge containing 250 µg to about 10 mg budesonide and excipients is administered orally to a subject orally, the lozenge will disperse in the mouth of the subject and be deposited in the upper GI tract, e.g., the esophagus.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 44, the limitations of the orally dispersing tablet would have been obvious over the lozenge that contains budesonide in a dosage of 250 µg to about 10 mg in the presence of excipients ([0021], [0033], [0036]), which may be dissolved in the mouth, thus reaching and coating the esophagus; and the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus ([0056], [0062]), as taught by Dohil et al.

Regarding instant claims 48-49, the limitations of the disintegrant would have been obvious over the disintegrating agents, cross-linked polyvinylpyrrolidone (or crospovidone), mannitol, sorbitol, lactose, and sucrose ([0070]), as taught by Dohil et al.

Regarding instant claims 50-53, the limitations of the excipient would have been obvious over the lactose, sucrose, sucralose, mannitol and sorbitol ([0070]), as taught by Dohil et al.

Regarding instant claim 54, the limitation of magnesium stearate would have been obvious over the magnesium stearate ([0091]), as taught by Dohil et al.

Regarding instant claims 55-63, the limitations of the orally dispersing tablet comprising from about 1 mg to about 3 mg of budesonide or fluticasone propionate would have been obvious over the budesonide ([0062]), wherein the dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients ([0021], [0033]), and fluticasone propionate ([0049]), as taught by Dohil et al. According to MPEP 2144.05, "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists."

Regarding instant claims 64-66, the limitations of the method for treating an inflammatory condition of the gastrointestinal tract (instant claim 64), inflammation of the esophagus (instant claim 65), and eosinophilic esophagitis (instant claim 66), would have been obvious over the treatment of inflammation of the gastrointestinal tract, including the esophagus, for example eosinophilic esophagitis, as taught by Dohil et al. ([0009] – [0010], [0019], [0028], and [0037]).

Response to Arguments

14. In light of the cancellation of claims 28-43 and 45-47 the rejection with respect to these claims is rendered moot.

15. Applicant's arguments (Pages 5-9, filed 06/10/19) with respect to the rejection of claim 44 under 35 USC § 103(a) as being unpatentable over Dohil et al., and as the

rejection now applies to new claims 48-66, have been fully considered but are not persuasive.

Applicant argues that "... at the time of Applicant's invention, liquid dosage forms, such as those exemplified in Dohil and in the evidence of record⁵, were the standard of care for treating inflammation of the upper GI tract, because such liquid dosage forms ensured that a therapeutically effective amount of the corticosteroid "reach[ed] the targeted and/ or inflamed portion of the gastrointestinal tract ..."⁶ Applicant argues that there is no motivation to formulate a corticosteroid in Dohil's "lozenge or other similar tablet" to treat inflammation of the upper GI tract, or a reasonable basis to believe that such a composition would successfully deposit a "therapeutically effective amount" of corticosteroid on the upper GI tract, as required by the present claims.

This is not persuasive because Dohil et al. clearly disclose the solid orally dispersing dosage form, i.e., a lozenge that contains budesonide in a dosage of 250 µg to about 10 mg in the presence of excipients ([0021], [0033], [0036]). Dohil et al. also clearly disclose the deposition of the corticosteroid once the composition is administered orally ([0056]). One of ordinary skill in the art would have found it obvious that once the orally dispersing lozenge containing 250 µg to about 10 mg budesonide and excipients is administered orally to a subject orally, the lozenge will disperse in the mouth of the subject and be deposited in the upper GI tract, e.g., the esophagus.

Applicant argues that "... there is no lozenge or similar tablet exemplified in Dohil, let alone clinical data showing that such dosage forms actually deposit a "therapeutically effective amount" of corticosteroid on the upper GI tract, as required by

the present claims. Rather, Dohil is directed to liquid dosage forms ... out of the 177 paragraphs in Dohil, only 10 paragraphs mention a solid dosage form ...”

This is not persuasive because, as discussed above, Dohil et al. disclose not only an orally dispersing lozenge but also the deposition of the corticosteroid in the upper GI tract. One of ordinary skill in the art would have found it obvious that once the orally dispersing lozenge containing 250 µg to about 10 mg budesonide and excipients is administered orally to a subject orally, the lozenge will disperse in the mouth of the subject and be deposited in the upper GI tract, e.g., the esophagus.

Applicant argues that at the time of present invention, liquid dosage forms were the standard of care, and that the skilled artisan would have no motivation to modify the standard of care and select a solid dosage form from Dohil.

This is not persuasive because Dohil et al. disclose the preparation of orally dispersing lozenges which contain the corticosteroids recited in the instant claims.

Applicant argues that a lozenge or tablet does not deliver a bolus dose of the corticosteroid, and that lozenges dissolve over a much longer timeframe. Applicant argues that there is no way to know from Dohil if such a lozenge containing 0.5-5 mg of a budesonide or fluticasone would deliver a "therapeutically effective dose" of the corticosteroid to the esophagus.

This is not persuasive because instant claims do not recite any limitation regarding a bolus dose. Instant claims are also silent regarding the dispersion time period of the orally dispersing tablet. The lozenge disclosed by Dohil intrinsically disperses orally and based on the teaching of the deposition of the corticosteroid in the upper GI tract, e.g., the esophagus, one of ordinary skill in the art would have found that

once the orally dispersing lozenge of Dohil was administered, the corticosteroid would be deposited in the esophagus of the subject. The features upon which applicant relies (i.e., bolus dose and dispersion time) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the skilled artisan also would not have formulated a corticosteroid in Dohil's tablet, because tablets are conventionally swallowed whole and delivered to the stomach where the drug is released.

This is not persuasive because Dohil et al. clearly disclose a lozenge ([0062]) which is not swallowed but kept in the oral cavity to disperse over a period of time. One of ordinary skill in the art would know that the lozenge taught by Dohil et al. will not be swallowed and travel to the stomach in order to be released. Dohil et al. disclose the advantage of providing the active ingredient to the target site instead of providing systemic therapy ([0009]).

Applicant argues that "The skilled artisan, being aware of the side effects associated with oral administration of topical corticosteroids, would not have been motivated to (nor would have found it obvious to) increase the time the oral cavity is exposed to the topical corticosteroid, by formulating the corticosteroid in a lozenge or other similar tablet that disperses in the mouth over an extended period of time (e.g., compared to a liquid), as doing so would have reasonably increased the risk of developing candidiasis."

This is not persuasive because instant claims do not recite any time period that the orally dispersing tablet can be held in the mouth of a subject.

Applicant argues that there is no evidence in Dohil that a corticosteroid in an ODT would even contact the upper GI tract, let alone deposit a therapeutically effective amount of the drug on the upper GI tract, as required by the present claims.

This is not persuasive because Dohil et al. disclose the benefits of targeting the upper GI tract as opposed to systemic therapy ([0009], [0035], [0036], and [0044]). The coating of the esophagus, and delivery of the composition to the affected areas, for example, the lower esophagus, the upper esophagus, the esophagus, or a portion of the esophagus, is clearly disclosed by Dohil et al. ([0056]).

Applicant argues that they surprisingly and unexpectedly discovered that an ODT can topically deposit a therapeutically effective amount of fluticasone or budesonide (or salts, solvates, or esters thereof) on the upper GI tract.

This is not persuasive because the topical deposition of a corticosteroid to the upper GI tract, e.g., the esophagus, is disclosed by Dohil et al. ([0056]).

Therefore, the obviousness rejection of 12/10/18 based on Dohil et al. is maintained.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

17. Claims 44 and 48-66 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729 B2 ("the '729 Patent").

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that instant claims specifically recite budesonide or a salt, solvate, or ester thereof whereas claims of the '729 Patent recite a topically administrable corticosteroid. However, claims 3 and 27 of the '729 Patent recite budesonide. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and arrive at the claimed invention of the '729 Patent.

Therefore, instant claims and claims of the '729 Patent are not patentably distinct over each other.

18. **Claims 44 and 48-66 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 9-26 and 35-39 of U.S. Patent No. 9,486,407 B2 (“the ‘407 Patent”).**

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the ‘407 Patent recite a method of treating an inflammatory condition of the gastrointestinal tract and a topically administrable corticosteroid whereas instant claims specifically recite budesonide or a salt, solvate, or ester thereof. However, instant claims 64-66 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Furthermore, claims 3 and 37 of the ‘407 Patent also recite budesonide or salts, solvates and esters thereof. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the ‘407 Patent.

Therefore, instant claims and claims of the ‘407 Patent are not patentably distinct over each other.

19. **Claims 44 and 48-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10-14 of U.S. Patent No. 10,105,315 B2 (“the ‘315 Patent”).**

Please note that the ‘315 Patent and the application under examination (the instant application SN: 15/816,154) name different inventive entities but are commonly assigned.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the ‘315 Patent recite a method of topically treating eosinophilic esophagitis (EoE) in a patient in need thereof with an oral corticosteroid whereas instant claims are drawn to an orally dispersing tablet, as stated above. However, instant claims 64-66 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Instant claim 66 particularly recites the treatment of EoE. Furthermore, in the ‘315 Patent, claim 10 recites budesonide and fluticasone, claim 11 recites a solid composition, and claim 12 recites an orally disintegrating composition.

Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the

instant claims and arrive at the claimed method and ODT as recited in the claims of the '315 Patent.

Therefore, instant claims and claims of the '315 Patent are not patentably distinct over each other.

Response to Arguments

20. Applicant's arguments (Pages 9-10, filed 06/10/19) regarding the double patenting rejections over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729; over claims 1-5, 9-26 and 35-39 of U.S. Patent No. 9,486,407; and over claims 1 and 10-14 of U.S. Patent No. 10,105,315 have been fully considered.

Applicant requests that the double patenting rejections be held in abeyance until patentable subject matter is determined.

Applicant's request have been fully considered but since there are still pending art rejections in the present application, the double patenting rejections will be maintained until terminal disclaimers are filed.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARADHANA SASAN whose telephone number is (571)272-9022. The examiner can normally be reached Monday to Friday from 6:30 am to 3:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

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

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	15816154	Filing Date	2017-11-17	Docket Number (if applicable)	ADAR-119/05US 325049-280	Art Unit	1615
First Named Inventor	Stephen PERRETT			Examiner Name	Sasan Aradhana		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other

Petition for Three-Month Extension of Time + fee

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 501283

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	Jonathan M. Cousin/	Date (YYYY-MM-DD)	2019-06-10
Name	Jonathan M. Cousin	Registration Number	66418

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 4432
et al.
Application No.: 15/816,154 Group Art Unit: 1615
Filed: November 17, 2017 Examiner: ARADHANA, Sasan
FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO FINAL REJECTION AND REQUEST FOR CONTINUED
EXAMINATION UNDER 37 C.F.R. § 1.114**

This paper is filed in response the Final Office Action (FOA), mailed on January 10, 2019. Filed herewith is a request for a three month extension of time. Thus, this response is timely filed by June 10, 2019. Also filed herewith is a Request for Continued Examination under 37 C.F.R. § 1.114. It is respectfully requested that the outstanding Office Action be reconsidered in view of the following remarks.

Amendments to the Claims begin on page 2 of this paper; and

Remarks begin on page 4 of this paper.

AMENDMENT TO THE CLAIMS:

The following Listing of Claims will replace all prior versions of Listing of Claims in the application.

1.-43. (Cancelled)

44. (Currently amended) An orally dispersing tablet comprising ~~less than or equal to 0.5 mg to 5~~ [[20]] mg of a corticosteroid selected from the group consisting of budesonide, fluticasone, and salts, solvates and esters thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity,

wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract.

45-47. (Cancelled)

48. (New) The orally dispersing tablet of claim 44, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

49. (New) The orally dispersing tablet of claim 48, wherein the at least one disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

50. (New) The orally dispersing tablet of claim 44, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, sucralose, maltose, cyclodextrin, polyvinyl pyrrolidone, magnesium stearate, and combinations thereof.

51. (New) The orally dispersing tablet of claim 50, wherein the excipient is selected from the group consisting of mannitol, sucralose, magnesium stearate, and combinations thereof.

52. (New) The orally dispersing tablet of claim 51, wherein the excipient is mannitol.

53. (New) The orally dispersing tablet of claim 51, wherein the excipient is sucralose.

54. (New) The orally dispersing tablet of claim 51, wherein the excipient is magnesium stearate.

55. (New) The orally dispersing tablet of claim 44, wherein said corticosteroid is budesonide.
56. (New) The orally dispersing tablet of claim 44, wherein said corticosteroid is fluticasone propionate.
57. (New) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of budesonide or fluticasone propionate.
58. (New) The orally dispersing tablet of claim 44, comprising 1 mg of budesonide.
59. (New) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of fluticasone propionate.
60. (New) The orally dispersing tablet of claim 51, comprising 1 mg of budesonide.
61. (New) The orally dispersing tablet of claim 52, comprising 1 mg of budesonide.
62. (New) The orally dispersing tablet of claim 53, comprising 1 mg of budesonide.
63. (New) The orally dispersing tablet of claim 54, comprising 1 mg of budesonide.
64. (New) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof an orally dispersing tablet according to claim 44.
65. (New) The method of claim 65, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus.
66. (New) The method of claim 65, wherein said inflammatory condition of the gastrointestinal tract is eosinophilic esophagitis.

REMARKS

I. Status of Claims

Upon entry of the present amendments, claims 44 and 48-66 are pending. Claims 27-43 and 45-47 have been cancelled, and replaced with new claims 48-66. Support for new claims 48-66 can be found in the claims as originally filed and throughout the specification.

Claim 44 has been amended to recite a specific dose of the corticosteroid (i.e., “about 0.5 mg to about 5 mg”). Support for this amendment is found in paragraph [0033] of the application as filed.

No new matter is believed to have been added by way of the present amendments.

II. Claim Objections

The Examiner objected to claim 28-43 “as being an improper dependent claim because they are directly or indirectly dependent on a succeeding claim ... and not on a proceeding claim.” Claims 28-43 have been cancelled, and replaced with new claims 48-66 which depend, directly or indirectly, on preceding claim 44, thus rendering this rejection moot.

The Examiner objected to claims 34 and 45-47 for various formality reasons. Claims 34 and 45-47 have been cancelled, thus rendering this rejection moot. New claims 52 and 53 replace cancelled claims 45 and 46, and new claims 52 and 53 include “the” after the term “wherein” and before “excipient.” New claim 54 replaces cancelled claim 47, and new claim 54 includes “is” after “excipient.” Therefore, new claims 52-54 address the objections to cancelled claims 45-47.

III. Claim Rejections under 35 U.S.C. § 102

The Examiner rejected claims 42 and 44 is anticipated under 35 U.S.C. § 102(a) and (e) by US Pub. No. 2009/0191275 (*Dohil*). Specifically, the Examiner alleges that *Dohil* discloses a lozenge containing 250 µg to about 10 mg of budesonide, which dissolves in the mouth and coats the oesophagus. Applicant respectfully disagrees.

To be anticipated, the claimed subject matter must be disclosed “clearly and unequivocally” in the reference. In re Arkley, 455 F.2d 586, 587 (C.C.P.A 1972) (“Thus, for the instant [anticipation] rejection . . . to have been proper, the . . . reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound

without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”).

Here, *Dohil* does not clearly and unambiguously disclose an orally dispersing tablet containing “0.5 mg to 5 mg” of budesonide as required by amended claim 44. More specifically, the only exemplified composition is a liquid composition containing water, and either sucralose or maltodextrin. *See* paragraphs [0103], [0104], [0110], [0126], and [0128]. There is no exemplified or specific embodiment of an orally dispersing tablet containing “0.5 mg to 5 mg” of budesonide as required by amended claim 44.

While paragraph [0062] mentions a budesonide-containing lozenge (among other solid dosage forms), no dose is disclosed in paragraph [0062]. Instead, the Examiner cites to paragraphs [0021] and [0033] for the dosage of 250 µg to about 10 mg. But, these paragraphs are not directly related to the budesonide-containing lozenge of paragraph [0062]. Rather, when read in context, paragraph [0021] refers to the dosage of budesonide used in a liquid composition (“In certain embodiments, the pharmaceutical composition provided herein has a volume of about 2 mL to about 20 mL ... comprises about 250 µg to about 10 mg of corticosteroid). Similarly, paragraph [0033] refers to the dose of budesonide when combined with the viscosity enhancing agent in the liquid composition described in paragraph [0030]. To be clear, paragraphs [0021] and [0033] do not disclose the dose of budesonide in the budesonide-containing lozenge of paragraph [0062].

Thus, by arbitrarily selecting doses from unrelated paragraphs, the Examiner is engaged in exactly the “picking and choosing” prohibited in *Arkley*. Here, as in *Arkley*, there is “nothing in the teachings relied upon by the Patent Office which ‘clearly and unequivocally’ directs those skilled in the art to make this selection [of 0.5 mg to 15 mg of budesonide for an orally dispersing tablet].”¹

Applicant respectfully requests withdrawal of the present rejection.

IV. Claim Rejections under 35 U.S.C. § 103

The Examiner rejected claims 28-33 and 36-47 as obvious under 35 U.S.C. § 103 over *Dohil*. The Examiner also rejected claims 28-47 as obvious under 35 U.S.C. § 103 over *Dohil* in view of U.S. Publication 2007/0059361 (“*Rawas-Qalaji*”).

Applicant notes that claims 28-43 and 45-47 have been cancelled, thus rendering this

¹ *Arkley*, 455 F.2d at 588.

rejection moot. However, Applicant will address the rejection as it applies to claim 44 and as it may apply to the currently pending claims.²

The claimed invention is, *inter alia*, an orally dispersing tablet (ODT) containing 0.5-5 mg of a topical corticosteroid (budesonide or fluticasone, or salts, solvates, or esters thereof), which topically deposits a “therapeutically effective amount” of the corticosteroid on the upper gastrointestinal (GI) tract after administration to topically treat inflammation. Because fluticasone and budesonide (and salts, solvates and esters thereof) act topically (i.e., they do not act systemically), these corticosteroids must be delivered topically to the tissue of the upper GI tract to treat inflammation.³ However, it was “difficult to deliver an effective dose of corticosteroid to the targeted area of the esophagus.”⁴ As such, at the time of Applicant’s invention, liquid dosage forms, such as those exemplified in *Dohil* and in the evidence of record⁵, were the standard of care for treating inflammation of the upper GI tract, because such liquid dosage forms ensured that a therapeutically effective amount of the corticosteroid “reach[ed] the targeted and/or inflamed portion of the gastrointestinal tract ...”⁶

The Examiner contends that *Dohil* teaches a “lozenge or other similar tablet” containing 250 µg to about 10 mg of budesonide and excipients. According to the Examiner, “it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention”⁷ because *Dohil* teaches that “the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.”⁸

Applicant respectfully disagrees. As discussed below, there is no motivation to formulate a corticosteroid in *Dohil*’s “lozenge or other similar tablet” to treat inflammation of the upper GI tract, or a reasonable basis to believe that such a composition would successfully deposit a “therapeutically effective amount” of corticosteroid on the upper GI tract, as required by the present claims.

As a first point, there is no lozenge or similar tablet exemplified in *Dohil*, let alone

² Because claims directed to a lyophilized composition were deleted, *Rawas-Qalaji* will not be addressed in the present response.

³ Applicant’s specification, page 4, lines 9-21

⁴ U.S. Pub. 2007/0111978, paragraph [0007].

⁵ See also U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; U.S. Pub. 2009/0131386; U.S. Pub. 2007/0111978; Kumari and Rajendran, *Indian Journal of Otolaryngology and Head & Neck Surgery*, 60(3): 199-201 (2008); and Teitelbaum, et al. *Gastroenterology* (2002), 122(5): 1216-1225.

⁶ U.S. Pub. 2009/0131386, paragraph [0060]

⁷ NFOA, page 4.

⁸ FOA, page 7.

clinical data showing that such dosage forms actually deposit a “therapeutically effective amount” of corticosteroid on the upper GI tract, as required by the present claims. Rather, *Dohil* is directed to liquid dosage forms containing, for example, surfactants⁹ that promote efficient dispersion of a corticosteroid in a liquid composition, buffering agents¹⁰ that maintain the pH of a liquid composition, and viscosity enhancing agents¹¹ that provide a liquid composition with a high viscosity.¹² In fact, out of the 177 paragraphs in *Dohil*, only 10 paragraphs mention a solid dosage form. The other 167 paragraphs are directed primarily to liquid dosage forms and the viscosity of such dosage forms. Importantly, *Dohil* teaches that the liquid dosage form exemplified in Examples 1 and 2 administers “an effective dose to reduce the inflammation of the esophagus.”¹³

1. No Motivation to Select a Solid Dosage Form

As discussed above, at the time of the present invention, liquid dosage forms¹⁴ were the standard of care¹⁵ because such dosage forms were well-known to deliver “an effective dose to reduce the inflammation of the esophagus.”¹⁶ There is no teaching or suggestion in *Dohil* that liquid dosage forms were ineffective, and no problems identified in *Dohil* that solid dosage forms could address but liquid dosage forms could not. Indeed, the evidence of record establishes the opposite – that liquid dosage forms were efficacious.¹⁷ As such, the skilled artisan would have no motivation to modify the standard of care and select a solid dosage form from *Dohil*.

Indeed, at the time of the claimed invention, it would have been counterintuitive to formulate budesonide or fluticasone (or salts, solvates, or esters thereof) in a solid dosage form, such as *Dohil*’s lozenge, to treat inflammation of the upper GI tract for the following reasons. First, fluticasone or budesonide must topically contact the inflamed tissue of the upper GI tract, and *Dohil*’s liquid ensures topically topical delivery of the corticosteroid to the inflamed tissue of the upper GI tract.¹⁸ More specifically, the liquid advantageously provides a bolus dose of

⁹ *Dohil*, paragraph [0087]

¹⁰ *Dohil*, paragraph [0081]

¹¹ *See, Dohil*, paragraph [0021]

¹² *See, Dohil*, paragraphs [0073] and [0097]-[0101]

¹³ *Dohil*, paragraph [0034]

¹⁴ *See Dohil*, Examples 1-5

¹⁵ *See also* U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017)

¹⁶ *Dohil*, paragraph [0034]

¹⁷ *See, e.g., Dohil*, Examples 1-5.

¹⁸ *Dohil*, Examples 1-5

the corticosteroid to the targeted area of the upper GI tract in a single swallow.¹⁹ In contrast, a lozenge or tablet does not deliver a bolus dose of the corticosteroid, and thus does not have the same advantage as the liquid formulation. Lozenges dissolve over a much longer timeframe, and repeated swallowing throughout the much longer timeframe would be necessary to deliver the entire dose. In contrast to a liquid, only a fraction of the total dose would be administered to the esophagus with each swallow. Thus, per swallow a smaller concentration of the corticosteroid contacts the esophagus compared to a liquid composition. There is no way to know from *Dohil* if such a lozenge containing 0.5-5 mg of a budesonide or fluticasone would deliver a “therapeutically effective dose” of the corticosteroid to the esophagus.

Further, as discussed in Applicant’s response filed February 23, 2019, the skilled artisan also would not have formulated a corticosteroid in *Dohil*’s tablet, because tablets are conventionally swallowed whole and delivered to the stomach where the drug is released. That is, drug release from tablets conventionally occurs after the tablet passes through the upper GI tract, and therefore a therapeutically effective amount of the drug does not contact the upper GI tract. In contrast, a drug in a liquid dosage form would be exposed to tissue in the upper GI tract as the composition is swallowed.

Lastly, topical contact of corticosteroids with oral mucosa is well-known to cause side-effects. Specifically, oral corticosteroids are known to suppress the immune response in the oral cavity causing candidiasis (also known as thrush).²⁰ The skilled artisan, being aware of the side effects associated with oral administration of topical corticosteroids, would not have been motivated to (nor would have found it obvious to) increase the time the oral cavity is exposed to the topical corticosteroid, by formulating the corticosteroid in a lozenge or other similar tablet that disperses in the mouth over an extended period of time (e.g., compared to a liquid), as doing so would have reasonably increased the risk of developing candidiasis.

Therefore, because liquid formulations were well-known to deliver “an effective dose to reduce the inflammation of the esophagus”²¹, and because lozenges and other similar tablets increase the risk of a candidiasis infection (because such dosage forms reside in the oral cavity

¹⁹ See paragraph [0057] “In specific embodiments, a volume sufficient to coat the esophagus is a volume that provides a bolus when orally administered to an individual.

²⁰ See, e.g., Applicant’s specification, paragraph [00105]; Teitelbaum, et al. *Gastroenterology*, 2002; 122:1216-1225, disclosed in the IDS submitted on December 20, 2017

²¹ *Dohil*, paragraph [0034]

for a prolonged period of time compared to a liquid that is swallowed immediately), the skilled artisan would not have used an ODT, but would have used a liquid dosage form instead.

2. No Reasonable Basis to Expect an ODT could Topically Deposit a Therapeutically Effective Amount of a Corticosteroid on the Upper Gastrointestinal Tract

As discussed above, only liquid dosage forms were known to topically deposit a therapeutically effective amount of corticosteroid on the upper GI tract. *See Dohil* Examples 1-5 and the clinical data showing the efficacy of the liquid dosage forms. *See also* paragraph [0034] which describes the efficacy of the liquid dosage forms: “It has been found that by administering Budesonide in oral form, in a formulation with increased fluid viscosity, that the corticosteroid was delivered to the esophagus in an effective dose to reduce the inflammation of the esophagus.” There is no evidence in *Dohil* (or any other reference of record) that a corticosteroid in an ODT would even contact the upper GI tract, let alone deposit a therapeutically effective amount of the drug on the upper GI tract, as required by the present claims. Indeed, there is no reasonable expectation that claimed ODT would topically deposit a therapeutically effective amount of a corticosteroid on the upper GI tract. The only efficacious prior art formulation is a liquid that deliver a bolus dose of the corticosteroid in a single swallow, whereas *Dohil*’s lozenge or tablet would deliver only a fraction of the dose with each swallow. Applicant is aware of no prior art ODT that delivered any drug to the upper GI tract. Accordingly, at the time of the present invention, the skilled artisan could not have predicted that an ODT would topically deposit a therapeutically effective amount of a corticosteroid on the upper GI tract, as required by the present claims.

However, Applicant surprisingly and unexpectedly discovered that an ODT can topically deposit a therapeutically effective amount of fluticasone or budesonide (or salts, solvates, or esters thereof) on the upper GI tract.

V. Double Patenting Rejections

A. Over U.S. Patent No. 8,771,729

The Examiner rejected claims 27-40 on the ground of non-statutory double patenting over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

B. Over U.S. Patent No. 9,486,407

The Examiner rejected claims 27-40 on the grounds of non-statutory double patenting over claims 1-5, 9-26, and 35-39 of U.S. Patent No. 9,486,407. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

C. Over U.S. Patent No. 10,105,315

Lastly, the Examiner provisionally rejected claims 27-40 on the grounds of non-statutory obviousness-type double patenting over claims 1 and 10-14 of U.S. Patent No. 10,105,315. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

CONCLUSION

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

Dated: June 10, 2019

Respectfully submitted,
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Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			SASAN, ARADHANA	
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DETAILED CORRESPONDENCE

Notice of Pre-AIA or AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. The Amendments and Remarks filed on 09/28/18 are acknowledged.
3. Claims 1-26 were previously cancelled. Claim 27 was cancelled; claims 28, 30, 32-34, 36 and 38-40 were amended; and new claims 41-47 were added on 09/28/18.
4. Claims 28-47 are pending and are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statement (IDS) filed on 09/28/18 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Response to Amendments/Arguments

Claim Objections

6. In light of the cancellation of claim 27, the objection to this claim is rendered moot.
7. In light of the amendment of claim 38, the objection to this claim is withdrawn.

Rejection of claims under 35 USC § 103(a)

8. Applicant's arguments (see Pages 5-9, filed 09/28/18) with respect to the following rejections have been fully considered.

- i. Rejection of claims 27-32 and 36-40 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1)
 - ii. Rejection of claims 27-33 and 36-40 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips in view of Venkatesh et al. (US 2009/0169620 A1)
 - iii. Rejection of claims 27-32 and 34-40 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips in view of Rawas-Qalaji et al. (US 2007/0059361 A1)
9. Applicant's arguments were persuasive. Therefore, the rejections have been withdrawn.
10. Applicant cancelled claim 27 and added new independent claim 44. New claim 44 does not recite the limitation regarding the disintegration of the tablet which is faster than the rate of oral disintegration of a conventional solid oral dosage form; but does recite fluticasone and the limitation regarding a "therapeutically effective amount" of the corticosteroid is deposited in the upper gastrointestinal tract.
11. However, upon further consideration of new claim 44, a new ground(s) of rejection is made in view of Dohil et al. (US 2009/0191275 A1).
12. Since the new ground(s) of rejection were necessitated by Applicant's amendment, this action is made FINAL.

New Objections & Rejections Necessitated by Amendment

Claim Objections

13. Claims **28-43** and **45-47** are objected to for the following reasons.
14. Claims **28-43** are objected to under 37 CFR 1.75(c) as being in improper form because they are directly or indirectly dependent on a succeeding claim, i.e., on claim

44, and not on a preceding claim. See MPEP § 608.01(n). Appropriate correction is required.

15. Claims **34 and 45-47** are objected to because of the following informalities:

- i. In claim **34**, line 1, the term "**claim**" should be added before "44."
- ii. In claims **45 and 46**, the article "**the**" should be added after the term "wherein" and before the term "excipient."
- iii. In claim **47**, the term "**is**" should be added after the term "excipient."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

16. The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims **45-47** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

- i. Claim **45** recites the limitation "... wherein excipient is mannitol."
- ii. Claim **46** recites the limitation "... wherein excipient is sucralose."
- iii. Claim **47** recites the limitation "... wherein the excipient magnesium stearate ..."

Each of claims 45, 46 and 47 are dependent on claim 44. Claim 44 does not recite any "excipient." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. **Claims 42 and 44 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Dohil et al. (US 2009/0191275 A1).**

Instant claim 44 is drawn to an orally dispersing tablet comprising less than or equal to 20 mg of a corticosteroid selected from the group consisting of budesonide, fluticasone, and salts, solvates and esters thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract.

Dohil et al. disclose a pharmaceutical composition wherein budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus; and the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus ([0062]). The dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients ([0021], [0033]). The budesonide is administered in oral form in a

formulation with increased coating, e.g., viscosity and/or mucoadhesive characteristic is deliver to the esophagus in an effective dose to reduce the inflammation of the esophagus ([0036]).

Therefore, the limitations of claims 42 and 44 are anticipated by Dohil et al.

Claim Rejections - 35 USC § 103

20. The following is a quotation of pre-AIA 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. **Claims 28-33 and 36-47 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1).**

Claim 28 is drawn to the orally dispersing tablet of claim 44, further comprising an adhesive agent.

The teaching of Dohil et al. is discussed above.

Dohil et al. does not exemplify or teach a specific embodiment wherein the budesonide containing lozenge contains an adhesive agent.

However, Dohil et al. disclose the use of excipients including adhesive agents polyvinylpyrrolidone, sodium carboxymethylcellulose ([0013]), as well as gums such as Ghatti gum, guar gum, xanthan gum ([0021]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition wherein budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus; the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus, and the dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients, as taught by Dohil et al., in view of the use of adhesive agents such as polyvinylpyrrolidone, sodium carboxymethylcellulose, Ghatti gum, guar gum, and xanthan gum, also as taught by Dohil et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Dohil et al. not only disclose the inclusion of adhesive agents polyvinylpyrrolidone, sodium carboxymethylcellulose ([0013]), as well as gums such as Ghatti gum, guar gum, xanthan gum ([0021]), but they also disclose that the budesonide is administered in oral form in a formulation with increased coating, e.g., viscosity and/or mucoadhesive characteristic is deliver to the esophagus in an effective dose to reduce the inflammation of the esophagus ([0036]).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 28-29, the limitations of the orally dispersing tablet further comprising an adhesive agent (instant claim 28) and the adhesive agent the budesonide or salt, solvate or ester thereof being intimately associated (instant claim 29) would have been obvious over the adhesive agents polyvinylpyrrolidone, sodium carboxymethylcellulose ([0013]), as well as gums such as Ghatti gum, guar gum, xanthan gum ([0021]), as taught by Dohil et al.

Regarding instant claims 30-31, the limitations of the composition further comprising a disintegrant would have been obvious over the disintegrating agents, cross-linked polyvinylpyrrolidone (or crospovidone), mannitol, sorbitol, lactose, and sucrose ([0070]), as taught by Dohil et al.

Regarding instant claims 32, 41, 45 and 46, the limitations of the composition further comprising an excipient would have been obvious over the lactose, sucrose, sucralose, mannitol and sorbitol ([0070]), as taught by Dohil et al.

Regarding instant claim 33, the limitation of the orally dispersing tablet which is free of lubricant would have been obvious over the lubricant which is an optional component ([0080]), as taught by Dohil et al.

Regarding instant claims 36-38, the limitations of the method for treating an inflammatory condition of the gastrointestinal tract (instant claim 36), inflammation of the esophagus (instant claim 37), and eosinophilic esophagitis (instant claim 38), would have been obvious over the treatment of inflammation of the gastrointestinal tract,

including the esophagus, for example eosinophilic esophagitis, as taught by Dohil et al. ([0009] – [0010], [0019], [0028], and [0037]).

Regarding instant claims 39-40 and 43, the limitation of the orally dispersing tablet comprising from 0.01 mg to 20 mg of budesonide or fluticasone propionate would have been obvious over the budesonide ([0062]), the dosage of budesonide is from 250 µg to about 10 mg in the presence of excipients ([0021], [0033]), and fluticasone propionate ([0049]), as taught by Dohil et al. According to MPEP 2144.05, “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists.”

Regarding instant claim 47, the limitation of magnesium stearate would have been obvious over the magnesium stearate ([0091]), as taught by Dohil et al.

22. Claims 28-47 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1) in view of Rawas-Qalaji et al. (US 2007/0059361 A1).

Instant claim 34 is drawn to the orally dispersing tablet of claim 44, wherein the tablet comprises a lyophilized matrix, wherein the lyophilized matrix comprises the budesonide or solvate or ester thereof in combination with at least one excipient.

The teaching of Dohil et al. is discussed above.

Dohil et al. do not expressly teach that the orally dispersing tablet comprises a lyophilized matrix.

Rawas-Qalaji et al. teach freeze-dried (lyophilized) fast-disintegrating tablets for oral (buccal) administration, wherein the ODT is in the form of a wafer (Abstract and Page 4, [0046] – [0047]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical composition wherein budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus; the lozenge or other similar tablet would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus, and the dosage of budesonide is from 250 μ g to about 10 mg in the presence of excipients, as taught by Dohil et al., in view of the use of adhesive agents such as polyvinylpyrrolidone, sodium carboxymethylcellulose, Ghatti gum, guar gum, and xanthan gum, also as taught by Dohil et al., further in view of freeze-dried (lyophilized) fast-disintegrating tablets for oral (buccal) administration, as taught by Rawas-Qalaji et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Dohil et al. and Rawas-Qalaji et al. are drawn to dosage forms that dissolve or disperse in the mouth, and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141. One of ordinary skill in the art would have been motivated to prepare the orally dispersing lozenge of Dohil et al. by freeze-drying or lyophilizing a matrix, as taught by Rawas-Qalaji et al. because the latter disclose that this provides fast oral disintegration (Abstract and [0046] – [0047]).

Regarding instant claims 34-35, the limitation of the lyophilized matrix would have been obvious over the freeze-dried ODTs taught by Rawas-Qalaji et al. (Page 4,

[0046] – [0047]). The limitation of the lyophilized matrix comprising the budesonide in combination with at least one excipient would have been obvious over the budesonide ([0027]) and excipients lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Maintained Rejections

Double Patenting

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

24. Claims 28-47 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729 B2 (“the ‘729 Patent”).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient, wherein upon administration budesonide,

or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that instant claims specifically recite budesonide or a salt, solvate, or ester thereof whereas claims of the '729 Patent recite a topically administrable corticosteroid. However, claims 3 and 27 of the '729 Patent recite budesonide. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and arrive at the claimed invention of the '729 Patent.

Therefore, instant claims and claims of the '729 Patent are not patentably distinct over each other.

25. Claims 28-47 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 9-26 and 35-39 of U.S. Patent No. 9,486,407 B2 (“the ‘407 Patent”).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '407 Patent recite a method of treating an inflammatory condition of the gastrointestinal tract and a topically administrable corticosteroid whereas instant claims specifically recite budesonide or a salt, solvate, or

ester thereof. However, instant claims 36-38 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Furthermore, claims 3 and 37 of the '407 Patent also recite budesonide or salts, solvates and esters thereof. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the '407 Patent.

Therefore, instant claims and claims of the '407 Patent are not patentably distinct over each other.

26. Claims 28-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10-14 of U.S. Patent No. 10,105,315 B2 (issued from Application No. 15/680,301 ("the '315 Patent")).

Please note that the '315 Patent issued from Application No. 15/680,301, which was used in the provisional ODP rejection in the Office Action of 06/28/18. Since the '301 Application has now issued as the '315 Patent, the provisional ODP rejection is modified to a rejection over the '315 Patent.

Also, please note that the '315 Patent and the application under examination (the instant application SN: 15/816,154) name different inventive entities but are commonly assigned.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least

one pharmaceutically acceptable ingredient, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '315 Patent recite a method of topically treating eosinophilic esophagitis (EoE) in a patient in need thereof with an oral corticosteroid whereas instant claims are drawn to an orally dispersing tablet, as stated above. However, instant claims 36-38 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Instant claim 38 particularly recites the treatment of EoE. Furthermore, in the '315 Patent Application, claim 10 recites budesonide and fluticasone, claim 11 recites a solid composition, and claim 12 recites an orally disintegrating composition.

Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the '315 Patent.

Therefore, instant claims and claims of the '315 Patent Application are not patentably distinct over each other.

Response to Arguments

27. Applicant's arguments (Pages 9-10, filed 09/28/18) regarding the double patenting rejections of claims 27-40 over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729; over claims 1-5, 9-26 and 35-39 of U.S. Patent No. 9,486,407;

and over claims 1 and 10-14 of copending Application No. 15/680,301 (as it now applies to the rejection over U.S. Patent No. 10,105,315) have been fully considered.

Applicant requests that the double patenting rejections be held in abeyance until patentable subject matter is determined.

Applicant's request have been fully considered but since there are still pending art rejections in the present application, the double patenting rejections will be maintained until terminal disclaimers are filed.

Conclusion

28. No claims are allowed.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARADHANA SASAN whose telephone number is

(571)272-9022. The examiner can normally be reached Monday to Friday from 6:30 am to 3:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

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

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 4432
et al.
Application No.: 15/816,154 Group Art Unit: 1615
Filed: November 17, 2017 Examiner: ARADHANA, Sasan
FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL REJECTION UNDER 37 C.F.R. 1.111

This paper is filed in response the Non-Final Office Action (NFOA), mailed on June 28, 2019. Thus, this response is timely filed by September 28, 2018. It is respectfully requested that the outstanding Office Action be reconsidered in view of the following remarks.

Amendments to the Claims begin on page **2** of this paper; and

Remarks begin on page **5** of this paper.

Electronic Acknowledgement Receipt	
EFS ID:	33860056
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin
Filer Authorized By:	
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	28-SEP-2018
Filing Date:	17-NOV-2017
Time Stamp:	13:11:59
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ADAR-119_05US_Response.pdf	229339	yes	10
			041586df42db60bdc4795af0e66f1323fe937c24		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Arguments/Remarks Made in an Amendment	5	10
	Claims	2	4
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Warnings:			
Information:			
Total Files Size (in bytes):		229339	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

REMARKS

I. Status of Claims

Upon entry of the present amendments, claims 28-44 are pending. Claims 41-47 are newly added. New claim 44 is similar to previous claim 27 (now cancelled), except that the “Disintegration Test” has been removed and fluticasone has been added. Additionally, new claim 44 now clarifies that the orodispersable tablet deposits a “therapeutically effective amount” of the corticosteroid on the upper GI tract. New claims 41-43 and 45-47 identify specific excipients and corticosteroids in the claimed orally dispersing tablet. Claims 28, 30, 32, 33, 34, 36, 39, and 40 have been amended to depend on new claim 44. Claim 38 has been amended to correct a typographical error. Claims 39 and 40 were amended to add “fluticasone, propionate” for consistency with new claim 44. Claim 40 has also been amended to correct the range to “1 mg to 20 mg.” Claim 27 has been cancelled. Support for these amendments can be found in the claims as originally filed and throughout the specification.

No new matter is believed to have been added by way of the present amendments.

II. Claim Objections

The Examiner objected to claim 27 because the “period following ‘Disintegration Test’ [in line 5] should be replaced by a comma.”¹ Claim 27 has been cancelled, rendering this objection moot.

The Examiner objected to claim 38 because the “comma at the end of the sentence should be replaced by a period.”² Claim 38 has been amended in the manner requested by the Examiner.

III. Claim Rejections under 35 U.S.C. § 103

The Examiner alleges that claims 27-32 and 36-40 are obvious under 35 U.S.C. § 103 over U.S. Publication 2009/0131386 (“*Phillips*”). The Examiner also alleges that claims 27-33 and 36-40 are obvious over *Phillips* in view of U.S. Publication 2009/0169620 (“*Venkatesh*”), and claims 27-32 and 34-40 are obvious over *Phillips* in view of U.S. Publication 2007/0059361 (“*Rawas-Qalaji*”). Applicants respectfully disagree and traverse the rejection, thus obviating the rejection.

The claimed invention is directed to an orally dispersing **tablet** (ODT) containing a

¹ NFOA, page 2, paragraph 6.i.

² NFOA, page 2, paragraph 6.ii.

topical corticosteroid (budesonide or fluticasone, or salts, solvates, or esters thereof), which topically deposits a “therapeutically effective amount” of the corticosteroid on the upper gastrointestinal (GI) tract after administration to topically treat inflammation. Because fluticasone and budesonide (and salts, solvates and esters thereof) act topically (i.e., they do not act systemically), these corticosteroids must be delivered topically to the tissue of the upper GI tract to treat inflammation.³ Prior to Applicant’s invention, liquid dosage forms, such as those disclosed in *Phillips* and in the evidence of record⁴, were the standard of care to treat inflammation of the upper GI tract, because such liquid dosage forms allowed the corticosteroid to “reach the targeted and/or inflamed portion of the gastrointestinal tract ...”⁵.

As discussed below, the combination of prior art does not provide a reasonable motivation to formulate an ODT with a corticosteroid to treat inflammation of the upper GI tract, or a reasonable basis to believe that such composition would successfully deposit a “therapeutically effective amount” of corticosteroid on the upper GI tract.

A. Rejection of Claims 27-32 and 36-40 under 35 U.S.C. § 103 over *Phillips*

The Examiner alleges that *Phillips* teaches “solid dosage forms ...” “for the treatment of inflammation the gastrointestinal tract.”⁶ According to the Examiner, because *Phillips* teaches “excipients and auxiliaries [that] enable the compositions ... to be formulated as tablets, pills, dragees, capsules ...” “such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach”⁷ it would have been obvious to prepare a solid dosage form such “as tablets, dragee cores, etc., ...”⁸

While *Phillips* does mention solid dosage forms, *Phillips* is directed primarily to liquid dosage forms containing, for example, preservatives,⁹ isotonic agents,¹⁰ surfactants¹¹ that promote efficient dispersion of a corticosteroid in a liquid composition,¹² and viscosity

³ Applicant’s specification, page 4, lines 9-21

⁴ See also U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017).

⁵ *Phillips*, paragraph [0060]

⁶ NFOA, page 3.

⁷ NFOA, page 4.

⁸ NFOA, page 4.

⁹ *Phillips* at, e.g., paragraphs [0009], [0031], [0035], and [0075]

¹⁰ *Phillips* at, e.g., paragraphs [0007], [0010], [0015], [0031] and [0034]

¹¹ *Phillips* at, e.g., paragraph [0010], [0031], [0033], and [0073]

¹² *Phillips* at, e.g., paragraph [0031]

enhancing agents¹³ that provide a liquid composition with a high viscosity.¹⁴ To this end, *Phillips* teaches that a liquid dosage form allows for the corticosteroid to “reach the targeted and/or inflamed portion of the gastrointestinal tract ...”,¹⁵ and the viscosity of the liquid dosage form is critical to achieving the necessary contact (“increased viscosity of the composition allows the composition to be in contact with the esophagus for an extended period of time following administration.”¹⁶). Indeed, out of the 122 paragraphs in *Phillips*, only 6 paragraphs mention a solid dosage form. The other 118 paragraphs are directed solely to liquid dosage forms. This is because, at the time of the present invention, liquids dosage forms were the standard of care for the treatment of inflammation of the upper GI tract.

Furthermore, many of the solid dosage forms disclosed in *Phillips* cannot be reasonably read as dispersing in the oral cavity as required by the present claims. Specifically, *Phillips*’ list includes capsules, which cannot reasonably disperse in the oral cavity because they are designed to break down enzymatically in the GI tract.¹⁷ Thus, despite a statement concerning the location (i.e., mouth or esophagus) of disintegration or dissolution, *Phillips* fails to provide any reasonable guidance concerning orally dispersing tablets. Rather, *Phillips* describes in detail numerous excipients which can be used in liquid dosage forms to achieve the contact with the inflamed tissue and the viscosity that *Phillips* teaches are essential to a therapeutically effective treatment.

1. No Motivation to Select a Solid Dosage Form

As discussed above, at the time of the present invention, liquid dosage forms¹⁸ effectively treated inflammation of upper GI tract – and this was the standard of care. There is no teaching or suggestion in *Phillips* that liquid dosage forms were ineffective, or that there were particular problems that solid dosage forms could address but liquid dosage forms cannot. As such, the skilled artisan would have no motivation to modify the standard of care and select a solid dosage form from *Phillips*.

¹³ See, *Phillips*, paragraph [0029]

¹⁴ See, *Phillips*, paragraph [0043]

¹⁵ *Phillips*, paragraph [0060]

¹⁶ *Phillips*, paragraph [0021]; see also paragraphs [0029] and [0039], and paragraphs [0040]-[0044]

¹⁷ *Phillips* at paragraph [0085]

¹⁸ *Phillips*, paragraph [0060]; See also U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017)

Indeed, at the time of the claimed invention, it would have been counterintuitive to formulate budesonide or fluticasone (or salts, solvates, or esters thereof) in a solid dosage form, such as a tablet, to treat inflammation of the upper GI tract. As discussed above, fluticasone and budesonide must topically contact the inflamed tissue of the upper GI tract to treat inflammation. However, tablets are conventionally swallowed whole and delivered to the stomach where the drug is released – that is, drug release from tablets conventionally occurs after the tablet passes through the upper GI tract and therefore a therapeutically effective amount of the drug does not contact the upper GI tract. In contrast, a drug in a liquid dosage form would be exposed to tissue in the upper GI tract as the composition is swallowed. Because the claimed corticosteroids necessarily must be topically deposited onto the upper GI tract to treat inflammation, at the time of the present invention it would have been more reasonable to use a liquid dosage form, rather than a solid dosage form. Accordingly, the skilled artisan would not have been motivated to formulate a topical corticosteroid (fluticasone or budesonide, and salts, solvates and esters thereof) in a solid dosage form.

2. There was No Reasonable Basis to Expect an ODT could Topically Deposit a Therapeutically Effective Amount of a Corticosteroid on the Upper Gastrointestinal Tract

As discussed above, *Phillips* teaches that liquid dosage forms effectively treat inflammation of the upper GI tract by allowing the corticosteroid to “reach the targeted and/or inflamed portion of the gastrointestinal tract ...”¹⁹ and with a viscosity sufficient “to be in contact with the esophagus for an extended period of time following administration.”²⁰ There is no evidence in *Phillips* (or any other reference of record) that a corticosteroid in an ODT would even contact the upper GI tract, let alone deposit a therapeutically effective amount of the drug, as required by the present claims. Indeed, the only dosage form disclosed in *Phillips* that could reasonably have been expected to topically deposit a therapeutically effective amount of corticosteroid on the upper GI tract was a liquid dosage form. To this end, Applicant is aware of no prior art ODT that was formulated to deliver any drug to the upper GI tract. Accordingly, at the time of the present invention, the skilled artisan could not have predicted that an ODT would topically deposit a therapeutically effective amount of a corticosteroid on the upper GI tract.

However, Applicant surprisingly and unexpectedly discovered that an ODT can

¹⁹ *Phillips*, paragraph [0060]

²⁰ *Phillips*, paragraph [0021]; see also paragraphs [0029] and [0039], and paragraphs [0040]-[0044] teaches

topically deposit a therapeutically effective amount of fluticasone or budesonide (or salts, solvates, or esters thereof) on the upper GI tract.

B. Rejection of Claims 27-33 and 36-40 as obvious over *Phillips* in view of U.S. Publication 2009/0169620 (“*Venkatesh*”)

The Examiner cites to *Venkatesh* as allegedly teaching an ODT that is free of lubricant as recited in claim 33.²¹ This rejection is respectfully traversed.

As discussed above, *Phillips* does not render new claim 44 obvious. *Venkatesh* does not cure the deficiencies in *Phillips*. This is because *Venkatesh* teaches an ODT that delivers a drug, such as temazepam, *systemically*, not topically as required by the present claims. Indeed, *Venkatesh* does not teach or suggest topical delivery of drugs. Accordingly, the artisan would not combine the teachings of *Phillips* and *Venkatesh* to provide a solid formulation that deposits a corticosteroid topically in the upper GI tract.

C. Rejection of Claims 27-32 and 34-40 over *Phillips* in view of *Rawas-Qalaji*

The Examiner cites to *Rawas-Qalaji* as allegedly teaching an orally dispersing tablet that comprises a lyophilized matrix.²²

As discussed above, new claim 44 is not obvious over *Phillips* and *Venkatesh*. *Rawas-Qalaji* does not cure the deficiencies in *Phillips* and *Venkatesh*, because *Rawas-Qalaji* teaches an oral formulation that rapidly delivers *systemic* epinephrine through the *oral* mucosa to “produce *plasma epinephrine concentrations* similar to those produced by an [Epi-Pen injection].”²³ Thus, contrary to the claimed invention, which topically (i.e., not systemically) treats inflammation of the upper GI tract by depositing the corticosteroid onto the upper GI tract after the drug is swallowed, *Rawas-Qalaji*’s goal is to provide a systemic therapy by promoting absorption of the drug through the oral mucosa. That is, *Rawas-Qalaji* drug is not intended to be swallowed. Because *Rawas-Qalaji* is concerned with dosage forms for *systemic* administration of a drug, it does not suggest that dosage form for *topical* delivery of a drug.

IV. Double Patenting Rejections

A. Over U.S. Patent No. 8,771,729

The Examiner rejected claims 27-40 on the ground of non-statutory double patenting over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729. Without addressing the

²¹ NFOA, page 8.

²² NFOA, page 10.

²³ *Rawas-Qalaji*, Abstract (emphasis added).

merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

B. Over U.S. Patent No. 9,486,407

The Examiner rejected claims 27-40 on the grounds of non-statutory double patenting over claims 1-5, 9-26, and 35-39 of U.S. Patent No. 9,486,407. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

C. Over U.S. Patent App. No. 15/680,301

Lastly, the Examiner provisionally rejected claims 27-40 on the grounds of non-statutory obviousness-type double patenting over claims 1 and 10-14 of copending Application No. 15/680,301. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until patentable subject matter is determined.

CONCLUSION

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

Dated: September 28, 2018

Respectfully submitted,
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AMENDMENT TO THE CLAIMS:

The following Listing of Claims will replace all prior versions of Listing of Claims in the application.

1.-26. (Cancelled)

27. (Cancelled)

28. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44, further comprising an adhesive agent, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyarylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

29. (Previously presented) The orally dispersing tablet of claim 28, wherein the adhesive agent and the budesonide or salt, solvate, or ester thereof are intimately associated.

30. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

31. (Previously presented) The orally dispersing tablet of claim 30, wherein the at least one disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

32. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol,

lactose, sucrose, sucralose, maltose, cyclodextrin, polyvinyl pyrrolidone, magnesium stearate, and combinations thereof.

33. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44, which is free of lubricant.

34. (Currently amended) The orally dispersing tablet of ~~27~~ 44, wherein the tablet comprises a lyophilized matrix, wherein the lyophilized matrix comprises the budesonide or solvate or ester thereof in combination with at least one excipient.

35. (Previously presented) The orally dispersing tablet of claim 34, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, sucralose, maltose, cyclodextrin, polyvinyl pyrrolidone, and combinations thereof.

36. (Currently amended) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof an orally dispersing tablet according to claim ~~27~~ 44.

37. (Previously presented) The method of claim 36, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus.

38. (Currently amended) The method of claim 36, wherein said inflammatory condition of the gastrointestinal tract is eosinophilic esophagitis.

39. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44, comprising from 0.01 mg to 20 mg of budesonide or fluticasone propionate.

40. (Currently amended) The orally dispersing tablet of claim ~~27~~ 44 comprising from ~~2~~ 1 mg to 20 mg budesonide or fluticasone propionate.

41. (New) The orally dispersing tablet of claim 32, wherein excipient is selected from the group consisting of mannitol, sucralose, magnesium stearate, and combinations thereof.

42. (New) The orally dispersing tablet of claim 44, wherein said corticosteroid is budesonide.

43. (New) The orally dispersing tablet of claim 44, wherein said corticosteroid is fluticasone propionate.

44. (New) An orally dispersing tablet comprising less than or equal to 20 mg of a corticosteroid selected from the group consisting of budesonide, fluticasone, and salts, solvates and esters thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity,

wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract.

45. (New) The orally dispersing tablet of claim 44, wherein excipient is mannitol.

46. (New) The orally dispersing tablet of claim 44, wherein excipient is sucralose.

47. (New) The orally dispersing tablet of claim 44, wherein the excipient magnesium stearate.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zIPPatentDocketingMailboxUS@cooley.com

Office Action Summary	Application No. 15/816,154	Applicant(s) Perrett et al.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA Status No

-- 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 MONTHS 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 02/23/18.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were 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) 27-40 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) 27-40 is/are rejected.
- 8) ☒ Claim(s) 27 and 38 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
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) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

DETAILED CORRESPONDENCE

Notice of Pre-AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. The amendment filed on 02/23/18 is acknowledged.
3. Claims 1-26 were cancelled.
4. New claims 27-40 were added and are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed on 12/20/17 and 04/16/18 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements. Please see attached copies of PTO-1449.

Claim Objections

6. Claims **27** and **38** are objected to because of the following informalities:
 - i. In claim **27**, line 5, the period following "Disintegration Test" should be replaced by a comma.
 - ii. In claim **38**, the comma at the end of the sentence should be replaced with a period.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of pre-AIA 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 27-32 and 36-40 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1).

Instant claim 27 is drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein said tablet disintegrates faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract.

Phillips teaches pharmaceutical compositions for the treatment of inflammation of the gastrointestinal tract (Abstract). The composition comprises a corticosteroid such as budesonide ([0027]). The amount of corticosteroid is from about 100 µg to about 20 mg (Page 1, [0008] and Page 7, [0059]). The composition is formulated into solid dosage forms and administered locally (Page 12, [0083]). Phillips teaches that "... the corticosteroid is formulated readily using pharmaceutically acceptable excipients and/or

auxiliaries well known in the art into dosages suitable for oral administration. Such excipients and auxiliaries enable the compositions ... to be formulated as tablets, pills, dragees, capsules ... for oral ingestion by a patient to be treated" (Page 12, [0084]). The solid dosage forms, such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach (Page 12, [0085] and Page 13, [0092]).

Phillips does not expressly teach an example or embodiment wherein the solid dosage form contains less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as budesonide, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, etc., which are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth prior to reaching the stomach, also as taught by Phillips, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Phillips clearly teaches that solid dosage forms containing the corticosteroid can be prepared (Page 12, [0083] – [0085]), along with the corticosteroid budesonide ([0027]), and the dosage forms substantially dissolving or disintegrating in the mouth prior to reaching the stomach (Page 12, [0085] and Page 13, [0092]). Phillips also teaches that interaction of the composition with a surface of the gastrointestinal tract, e.g., the

mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus, is increased, in order to decrease the physiological manifestations or symptoms of gastrointestinal tract inflammation (Pages 4-5, [0036]). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing a functional orally dispersing tablet containing the corticosteroid budesonide such that the tablet dissolves or disintegrates in the mouth before reaching the stomach.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 27, the limitations of an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and the tablet disintegration rate which is faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test, would have been obvious over the composition comprising a corticosteroid such as budesonide ([0027]) as taught by Phillips, wherein the amount of corticosteroid is from about 100 µg to about 20 mg (Page 1, [0008], Page 7, [0059] and Page 10, [0069]), and wherein the composition is formulated into solid dosage forms such as tablets, dragee cores, etc., such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach (Page 12, [0083] - [0085] and Page 13, [0092]). The limitation of the faster disintegration rate is a property associated

with the solid dosage form and inseparable from it. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product. The limitations of the budesonide, or the salt, solvate or ester thereof deposited topically in the upper gastrointestinal tract would have been obvious over the local administration of the solid dosage form (Page 12, [0083]), and the compositions which contain an excipient that increases the interaction of the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus (Page 4, [0036]) as taught by Phillips.

Regarding instant claims 28-29, the limitations of the orally dispersing tablet further comprising an adhesive agent (instant claim 28) and the adhesive agent the budesonide or salt, solvate or ester thereof being intimately associated (instant claim 29) would have been obvious over the mucoadhesive agents including polyvinylpyrrolidone polymer, cross-linked poly(acrylic acid), cross-linked alginate gum gel, and polycarboxylated vinyl polymer, used in the dosage form with corticosteroids such as budesonide, as taught by Phillips ([0027] and Page 6, [0046]).

Regarding instant claims 30-31, the limitations of the composition further comprising a disintegrant would have been obvious over the cross-linked polyvinylpyrrolidone (Page 13, [0085]), lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Regarding instant claim 32, the limitation of the composition further comprising an excipient would have been obvious over the lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Regarding instant claims 36-38, the limitations of the method for treating an inflammatory condition of the gastrointestinal tract (instant claim 36), inflammation of the esophagus (instant claim 37), and eosinophilic esophagitis (instant claim 38), would have been obvious over the treatment of inflammation of the gastrointestinal tract, including the esophagus, for example eosinophilic esophagitis, as taught by Phillips ([0090]).

Regarding instant claims 39-40, the limitation of the orally dispersing tablet comprising from 0.01 mg to 20 mg budesonide would have been obvious over the composition comprising a corticosteroid such as budesonide ([0027]), wherein the amount of corticosteroid is from about 100 µg to about 20 mg, or from about 250 µg to about 10 mg, (Page 1, [0008], Pages 7-8, [0059] and Page 10, [0069]) as taught by Phillips. According to MPEP 2144.05, "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists."

9. Claims 27-33 and 36-40 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Venkatesh et al. (US 2009/0169620 A1).

Instant claim 33 is drawn to the orally dispersing tablet of claim 27, which is free of lubricant.

The teaching of Phillips is discussed above.

Phillips does not expressly teach an orally dispersing tablet which is substantially free of lubricant.

Venkatesh et al. teach a solid pharmaceutical composition in the form of an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug, an ODT binder polymer, a sugar alcohol and/or saccharide, and a disintegrant (Abstract, Page 1, [0002] and [0006] and claims 1-23). The use of a corticosteroid (beclomethasone) is disclosed (Page 3, [0029] left hand column). The lubricant (e.g., magnesium stearate) is not part of the composition, but is used as a processing aid, and is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression (Page 10, [0093]). The ODT compositions disintegrate in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as budesonide, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, etc., which are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth prior to reaching the stomach, also as taught by Phillips, in view of the orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug such as a corticosteroid wherein the ODT disintegrates in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the

buccal cavity, as measured by using the USP <701> Disintegration Test procedures, taught by Venkatesh et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both Phillips and Venkatesh et al. disclose the use of corticosteroids in orally administered tablet dosage forms, and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141.

Regarding instant claim 33, the limitation of the orally dispersing tablet which is free of lubricant would have been obvious over the lubricant (e.g., magnesium stearate) which is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression, as taught by Venkatesh et al. (Page 10, [0093]), since this lubricant is not part of the composition, but is used as a processing aid.

10. Claims 27-32 and 34-40 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Rawas-Qalaji et al. (US 2007/0059361 A1).

Instant claim 34 is drawn to the orally dispersing tablet of claim 27, wherein the tablet comprises a lyophilized matrix, wherein the lyophilized matrix comprises the budesonide or solvate or ester thereof in combination with at least one excipient.

The teaching of Phillips is discussed above.

Phillips does not expressly teach that the orally dispersing tablet comprises a lyophilized matrix.

Rawas-Qalaji et al. teach freeze-dried (lyophilized) fast-disintegrating tablets for oral (buccal) administration, wherein the ODT is in the form of a wafer (Abstract and Page 4, [0046] – [0047]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as budesonide, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, etc., which are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth prior to reaching the stomach, also as taught by Phillips, in view of freeze-dried (lyophilized) fast-disintegrating tablets for oral (buccal) administration, as taught by Rawas-Qalaji et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Phillips and Rawas-Qalaji et al. are drawn to ODTs and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141. One of ordinary skill in the art would have been motivated to prepare the ODT of Phillips by freeze-drying or lyophilizing a matrix, as taught by Rawas-Qalaji et al. because the latter disclose that this provides fast oral disintegration (Abstract and [0046] – [0047]).

Regarding instant claims 34-35, the limitation of the lyophilized matrix would have been obvious over the freeze-dried ODTs taught by Rawas-Qalaji et al. (Page 4, [0046] – [0047]). The limitation of the lyophilized matrix comprising the budesonide in combination with at least one excipient would have been obvious over the budesonide

([0027]) and excipients lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

12. Claims 27-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 15-27, 29-31 and 35-36 of U.S. Patent No. 8,771,729 B2 ("the '729 Patent").

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein said tablet disintegrates faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test, wherein upon administration budesonide, or the salt, solvate, or

ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that instant claims specifically recite budesonide or a salt, solvate, or ester thereof whereas claims of the '729 Patent recite a topically administrable corticosteroid. However, claims 3 and 27 of the '729 Patent recite budesonide. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and arrive at the claimed invention of the '729 Patent.

Therefore, instant claims and claims of the '729 Patent are not patentably distinct over each other.

13. Claims 27-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 9-26 and 35-39 of U.S. Patent No. 9,486,407 B2 (“the ‘407 Patent”).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein said tablet disintegrates faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '407 Patent recite a method of treating an inflammatory condition of the gastrointestinal tract and a topically administrable corticosteroid whereas instant claims specifically recite budesonide or a salt, solvate, or ester thereof. However, instant claims 36-38 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Furthermore, claims 3 and 37 of the '407 Patent also recite budesonide or salts, solvates and esters thereof. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the '407 Patent.

Therefore, instant claims and claims of the '407 Patent are not patentably distinct over each other.

14. Claims 27-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10-14 of copending Application No. 15/680,301 ("the '301 Application").

Please note that the copending application (the '301 Application) and the application under examination (the instant application SN: 15/816,154) name different inventive entities but are commonly assigned.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet

in the oral cavity, wherein said tablet disintegrates faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test, wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '301 Application recite a method of topically treating eosinophilic esophagitis (EoE) in a patient in need thereof with an oral corticosteroid whereas instant claims are drawn to an orally dispersing tablet, as stated above. However, instant claims 36-38 also recite a method for treating an inflammatory condition of the gastrointestinal tract. Instant claim 38 particularly recites the treatment of EoE. Furthermore, in the '301 Application, claim 10 recites budesonide, claim 11 recites a solid composition, and claim 12 recites an orally disintegrating composition.

Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the '301 Application.

Therefore, instant claims and claims of the '301 Application are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARADHANA SASAN whose telephone number is (571)272-9022. The examiner can normally be reached Monday to Friday from 6:30 am to 3:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

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

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615