UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

58249 7590 02/02/2022
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
02/02/2022	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

PTOL-90A (Rev. 04/07)

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Corrected *Notice of Allowability*	**Application No.** 17/236,295	**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 IDS filed on 10/14/21.
   ☐ 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 1-30 . 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)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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NOTICE OF ALLOWANCE AND FEE(S) DUE

58249 7590 10/06/2021
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/06/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

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	$1200	$0.00	$0.00	$1200	01/06/2022

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
Commissioner for Patents
P.O. Box 1450
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)

58249 7590 10/06/2021
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
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.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

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APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/06/2022

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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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.

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Notice of Allowability	Application No. 17/236,295	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 electronic Terminal Disclaimer filed on 09/23/21.
   ☐ 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 1-30 . 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)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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, Remarks, and electronic Terminal Disclaimer filed on 09/23/21 are acknowledged.

3. Claims 1, 18-20, and 27-30 were amended.

4. Claims 1-30 are pending.

Reasons for Allowance

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

Claim Amendments

6. In light of the amendment of claim 28, the objection to this claim is withdrawn.

7. In light of the amendment of claims 29 and 30 to be dependent on claim 28, the duplicate claim warning is withdrawn.

8. In light of the amendment of claims 1, 18-20, 27, and 28 to replace "dispersing" with "disintegrating" the rejection of these claims under 35 U.S.C. 112(b) is withdrawn.

Applicant's Arguments regarding Claim Rejections - 35 USC § 103

9. Applicant's arguments (Pages 7-9, filed 09/23/21) regarding the following rejections have been fully considered and are persuasive.

   i. Rejection of claims 1-4, 13, 18-19, and 29-30 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (US 2004/0228919 A1) in view of Richards (US 4,985,418)

ii. Rejection of claims 5-17 and 20-27 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton et al. in view of Richards and Venkatesh *et al.* (US 2009/0169620 A1)

iii. Rejection of claim 28 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton et al. in view of Richards and Phillips (US 2009/0131386 A1)

10. Therefore, the rejections have been withdrawn.

Double Patenting

11. Applicant's arguments (Pages 9-10, filed 09/23/21) regarding the provisional rejection of claims 1-6, 9-21, and 28-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-9, 12-16, and 29 of copending Application No. 17/211,119; and the rejection of claims 1-22 on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 6-19, 23-26, and 36-38 of U.S. Patent No. 10,471,071 B2 have been fully considered and are persuasive. These particular double patenting rejections have been withdrawn.

Terminal Disclaimer

12. The electronic terminal disclaimer filed on 09/23/21 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.

Updated Search

13. An updated prior art search did not disclose a reference that teaches an orally disintegrating tablet comprising about 1 mg to about 6 mg of fluticasone propionate wherein upon administration a therapeutically effective amount of fluticasone propionate

is deposited topically in the upper gastrointestinal tract, and wherein the orally dispersing tablet disintegrates within 60 seconds 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

14. 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

15. Claims **1-30** 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.

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

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

Docket No.: ELLO-119/07US 342083-2008
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	1023
Application No.:	17/236,295	Group Art Unit:	1615
Filed:	April 21, 2021	Examiner:	A. Sasan

For: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

AMENDMENT/RESPONSE TO OFFICE ACTION

In response to the non-final Office Action dated June 30, 2021, Applicant submits the following Amendments and/or Remarks, and respectfully requests reconsideration of the application in view thereof.

Any extensions of time necessary to prevent abandonment of this application are hereby petitioned for under 37 C.F.R. §1.136(a), and any additional fees required (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-1283.

Amendments to the Claims are reflected in the listing of the claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

253607500 v1

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

IN THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination. Changes to any amended claims are indicated by [[double brackets]], ~~strikethrough~~ and/or underlining. This listing also reflects any cancellation and/or addition of claims.

1. (Currently Amended) An orally disintegrating tablet comprising:

(i) about 1 mg to about 6 mg of fluticasone propionate; and

(ii) at least one disintegrant;

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

wherein the orally ~~dispersing~~ disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.

2. (Original) The orally disintegrating tablet of claim 1, comprising about 1 mg to about 2 mg of fluticasone propionate.

3. (Original) The orally disintegrating tablet of claim 1, comprising about 3 mg of fluticasone propionate.

4. (Original) The orally disintegrating tablet of claim 1, comprising a sugar alcohol and/or saccharide.

5. (Original) The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise fluticasone propionate and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.

6. (Original) The orally disintegrating tablet of claim 5, wherein the rapidly dispersing granules have an average particle size of less than about 300 μm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm.

7. (Original) The orally disintegrating tablet of claim 5, wherein the drug particles have an average particle size of about 100-400 μm.

8. (Original) The orally disintegrating tablet of claim 5, the drug particles have an average particle size of about 100-400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm.

9. (Original) The orally disintegrating tablet of claim 5, comprising about 1 mg to about 2 mg of fluticasone propionate.

10. (Original) The orally disintegrating tablet of claim 5, comprising about 3 mg of fluticasone propionate.

11. (Original) The orally disintegrating tablet of claim 8, comprising about 1 mg to about 2 mg of fluticasone propionate.

12. (Original) The orally disintegrating tablet of claim 8, comprising about 3 mg of fluticasone propionate.

13. (Original) The orally disintegrating tablet of claim 1, wherein the disintegrant is crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, or combinations thereof.

14. (Original) The orally disintegrating tablet of claim 13, wherein the disintegrant is crospovidone.

15. (Original) The orally disintegrating tablet of claim 5, wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol. lactose, sucrose, maltose, or combinations thereof.

16. (Original) The orally disintegrating tablet of claim 15, wherein the sugar alcohol is mannitol.

17. (Original) The orally disintegrating tablet of claim 5, wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.

18. (Currently Amended) The orally disintegrating tablet of claim 1, wherein the orally ~~dispersing~~ disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.

19. (Currently Amended) The orally disintegrating tablet of claim 1, wherein the orally ~~dispersing~~ disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

20. (Currently Amended) An orally disintegrating tablet comprising:

(i) about 1 mg to about 3 mg of fluticasone propionate; and

(ii) rapidly dispersing granules comprising (a) at least one disintegrant and (b) at least one sugar alcohol, saccharide, or combination thereof;

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

wherein the orally ~~dispersing~~ disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.

21. (Original) The orally disintegrating tablet of claim 20, wherein the orally disintegrating tablet comprises drug particles comprising the fluticasone propionate and at least one excipient.

22. (Original) The orally disintegrating tablet of claim 21, wherein drug particles have an average particle size of about 100-400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm, and the ratio of disintegrant to sugar alcohol and/or saccharide in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.

23. (Original) The orally disintegrating tablet of claim 22, wherein the disintegrant is crospovidone.

24. (Original) The orally disintegrating tablet of claim 23, wherein the sugar alcohol is mannitol.

25. (Original) The orally disintegrating tablet of claim 24, comprising about 1 mg to about 2 mg of fluticasone propionate.

26. (Original) The orally disintegrating tablet of claim 24, comprising about 3 mg of fluticasone propionate.

27. (Currently Amended) The orally disintegrating tablet of claim 26, wherein the orally ~~dispersing~~ disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

28. (Currently Amended) A method for treating eosinophilic esophagitis comprising administering to a patient in need thereof the orally ~~dispersing~~ disintegrating tablet according to claim 1.

29. (Currently Amended) The ~~orally dispersing tablet~~ method of claim [[1]] 28, comprising about 1 mg to about 2 mg of fluticasone propionate.

30. (Currently Amended) The ~~orally dispersing tablet~~ method of claim [[1]]28, comprising about 3 mg of fluticasone propionate.

REMARKS

Upon entry to these amendments, claims 1-30 are pending in the present application. In this response, claims 1, 18-20, 27 and 28 have been amended to correct typographical errors, and claims 29 and 30 have been amended to depend on claim 28. The amendments are made without prejudice or disclaimer. Support for the claim amendments can be found throughout the application as originally filed. No new matter is added.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Objections

Claim 28 is objected to because of an informality. Applicant has now amended claim 28, line 1, to include the article "a" before the term "patient."

Applicant respectfully requests that this objection be withdrawn.

Claim Rejections – 35 USC §112

Claims 1, 18-20 and 27-30 are rejected under 35 U.S.C. 112 as allegedly being indefinite.

In response, claims 1, 18-20, 27, and 28 have been amended to replace "dispersing" with "disintegrating."

For at least the foregoing reasons, Applicant submits that the claims are not indefinite and respectfully requests withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – 35 USC §103

The pending claims are rejected under 35 U.S.C. 103 as allegedly being unpatentable over combinations of U.S. Publication No. 2004/0228919 (hereinafter "Houghton") of U.S. Patent No. 4,985,418 (herein after "Richards"), U.S. Publication No. 2009/0169620 (hereinafter "Venkatesh"), and U.S. Publication No. 2009/0131386 (herein after "Phillips")

1. The Pending Claims are Patentable For at least the Same Reasons that the Office Allowed U.S. Patent Nos. 8,771,729; 9,486,407; and 10,632,069

The pending claims are directed to an orally disintegrating tablet comprising, *inter alia*, about 1 mg to about 6 mg of fluticasone propionate; wherein upon administration a therapeutically effective amount of **fluticasone propionate is deposited topically in the upper gastrointestinal tract**, and wherein the orally dispersing tablet **disintegrates within 60 seconds** when tested using the USP <701> Disintegration Test.

The Office has already granted several patents in this "family" with broader claims. See U.S. Patent Nos. 8,771,729; 9,486,407; and 10,632,069. The pending claims are consistent with the Office's Reasons for Allowance in these related patents. For example, in the Notice of Allowance for U.S. App. No. 12/896,005 (Now U.S. Patent No. 8,771,729), the Office allowed the application because the prior art does "not disclosure an orally disintegrating solid pharmaceutical composition having the limitations of **a topically administrable corticosteroid** and at least one disintegrant, wherein the **composition disintegrates within 60 seconds**." Similarly, in the Notice of Allowance for U.S. App. No. 15/816154 (Now U.S. Patent No. 10,632,069), the Office allowed the application because "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."

As shown above, the pending claims recite topical deposition/administration of a corticosteroid (fluticasone propionate) to the upper GI tract, and a disintegration rate of ≤ 60 seconds. Thus, Applicant requests withdrawal of the rejection and allowance of the claims.

2. The Newly Cited References Do Not Teach or Suggest the Presently Claimed Invention

Richards is directed to an enteric coated composition for colonic delivery to treat inflammatory bowel disease. See Richards, e.g., col. 3, ll. 18-31. Richards' fluticasone propionate is enterically coated so that the drug is administered to the intestine and not beforehand (i.e., it is not topically administered to the upper gastrointestinal tract as required by the pending claims). Additionally, Richards is cumulative to Brantl (US 2005/0009848), which also describes enteric coated corticosteroids. Brantl was cited and overcome in U.S. 8,771,729. See Final Rejection, mailed January 14, 2013.

Houghton is directed to compositions formulated for oromucosal delivery. See, e.g., [0032], [0047], and [0194]. In contrast, the pending claims require topical deposition of the corticosteroid in the upper gastrointestinal tract.

The combination of Richards and Houghton cannot result in an ODT that topically delivers a therapeutically effective amount of fluticasone propionate to the upper GI tract (e.g., esophagus), because Houghton's drug is administered to the oromucosa and Richard's drug is administered to the colon.

For at least the foregoing reasons, Applicant submits that a case of obviousness has not been established, and respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

Double Patenting

Claims 1-6, 9-21 and 28-30 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1, 4-9, 12-16 and 29 of co-pending Application No. 17/211,119. Applicant requests withdrawal of this rejection for at least two reasons: (1) as discussed below with respect to the double patenting rejection over U.S. Patent No. 10,471,071 (the predecessor to Application No. 17/211,119), the Office previously determined that claims similar to the pending claims were patentably distinct from claims similar to those in co-pending Application No. 17/211,119 (because the claims in both U.S. Patent No. 10,471,071 and co-pending Application No. 17/211,119 require adsorption of the corticosteroid on a pharmaceutically acceptable carrier); and (2) the present application has an earlier effective filing date Application No. 17/211,119. MPEP 804 I.B.1.(b) states: "If a provisional nonstatutory

double patenting rejection is the only rejection remaining in an application having the earliest effective U.S. filing compared to the reference application(s), the examiner should withdraw the rejection in the application having the earliest effective U.S. filing date and permit that application to issue as a patent …"

Claims 1-22 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-40 of U.S. Patent No. 8,771,729 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 8,771,729, thereby obviating this rejection.

Claims 1-22 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-42 of U.S. Patent No. 9,486,407 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 9,486,407, thereby obviating this rejection.

Claims 1-22 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-3, 6-19, 23-26 and 36-38 of U.S. Patent No. 10,471,071 B2. The Office determined that the claims in U.S. Patent No. 10,471,071 were patentably distinct from U.S. 8,771,729 and U.S. 9,486,407. This was at least because the claims in U.S. Patent No. 10,471,071 require that a corticosteroid is adsorbed to a pharmaceutically acceptable carrier, whereas no such limitation in the claims of U.S. 8,771,729 and U.S. 9,486,407. See U.S. App. No. 14/917,125 (now U.S. Patent No. 10,471,071), Final Rejection mailed January 30, 2019. Because the pending claims also do not recite a limitation regarding adsorption of budesonide on a pharmaceutically acceptable carrier, Applicant requests withdrawal of this double patenting rejection.

Applicant respectfully requests that the double patenting rejection be held in abeyance under indication of allowable claims over the cited prior art.

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.

Dated: September 23, 2021

Respectfully submitted,
COOLEY LLP

By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

USPTO CUSTOMER NO. 58249

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

58249 7590 08/11/2021
COOLEY LLP
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1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/11/2021	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

PTOL-90A (Rev. 04/07)

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Applicant-Initiated Interview Summary	Application No. 17/236,295	Applicant(s) PERRETT et al.		
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) Status No	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
ARADHANA SASAN	Primary Examiner	Telephonic
MATTHEW SCHEIDEMAN	Attorney	
JONATHAN COUSIN	Attorney	

Date of Interview: 06 August 2021

Issues Discussed:

35 U.S.C. 103

There was a brief discussion based on the agenda regarding the claims reciting topical deposition and disintegration within 60 seconds, as well as some of the same/cumulative prior art references from previous related cases. The Examiner explained that this was done to make sure the rationale for obviousness was clear on the record in this particular case, along with making sure all the other issues (such as objections, and rejections under 112 and double patenting) were consolidated into the office action. The Examiner agreed that the arguments presented in the agenda were persuasive and the obviousness rejections would fall. Applicant's representative will consider filing a formal response. An updated search and consideration may be required once Applicant's response is received.

☑ Attachment

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Agenda for Telephonic Interview of Appl. Nos. 16/821,464 and 17/236,295 (Attorney Docket Nos. ELLO-119/06US and ELLO-119/07US)
August 6, 2021 at 10:00 AM ET

Arguments and amendments are presented for purposes of facilitating the interview only, and are not to be made part of the official record

I. PTO Representative – Examiner Aradhana Sasan

II. Applicant's Representatives – Jonathan Cousin (Reg. No. 66,418), Matthew Scheideman (Reg. No. 76, 605), Cooley LLP

III. Pending Claims:

a. Claim 1 in US 16/821,464: An orally dispersing tablet comprising: (i) about 0.5 mg to about 1 mg of budesonide; (ii) and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; (iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof; 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.

b. Claim 1 in US 17/236,295: An orally disintegrating tablet comprising: (i) about 1 mg to about 6 mg of fluticasone propionate; and (ii) at least one disintegrant; wherein upon administration a therapeutically effective amount of **fluticasone propionate is deposited topically in the upper gastrointestinal tract**, and wherein the orally dispersing tablet **disintegrates within 60 seconds** when tested using the USP <701> Disintegration Test.

IV. Discussion Points:

a. **The Office has already granted several patents in this "family" with broader claims**. See U.S. Patent Nos. 8,771,729; 9,486,407; and 10,632,069.

b. **Pending claims are consistent with the Office's Reasons for Allowance**:

i. See Notice of Allowance for US App. 12/896,005 (Now U.S. Patent No. 8,771,729): the prior art does "not disclosure an orally disintegrating solid pharmaceutical composition having the limitations of **a topically administrable corticosteroid** and at least one disintegrant, wherein the **composition disintegrates within 60 seconds**."

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ii. See also Notice of Allowance for US App. 15/816154 (Now U.S. Patent 10,632,069): "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"

c. **Prior art cited in US 16/821,464 (Phillips, US 2009/0131386 A1 and Venkatesh, US 2009/0169620) was previously overcome in U.S. Patent No. 8,771,729:**

i. See Notice of Allowance for US App. 12/896,005 (Now U.S. Patent No. 8,771,729): "Applicants amended claims 1 and 27 to recite the limitations of "orally disintegrating" and "at least one disintegrant". In light of the amendments, Applicants' arguments (filed 05/31/13) regarding the importance of the disintegration within 60 seconds and how this minimizes the chance of an oral yeast infection were persuasive. **Phillips (US 2009/0131386 A1) does not teach or suggest an orally disintegrating solid pharmaceutical composition (or an orally disintegrating tablet) that disintegrates within 60 seconds.** Although Phillips teaches solid dosage forms, this reference is silent with respect to any disintegration time. **Venkatesh et al. (US 2009/0169620 A1)** and Rawas-Qalaji et al. (US 2007/0059361 A 1) **do not teach or suggest the limitation of the disintegration time or the topical delivery of drugs.**"

d. Prior art cited in US 17/236,295 in a rejection of the claims under 35 USC 103 (Richards (US4,985,418) and Houghton (US 2004/0228919 A1)) is cumulative to art previously overcome and does not lead to the claimed invention.

i. Richards is directed to an enteric coated composition for colonic delivery to treat inflammatory bowel disease. Richards' fluticasone propionate is enterically coated so that the drug is administered to the intestine and not beforehand (i.e., not the upper gastrointestinal tract).

1. Richards is cumulative to Brantl (US 2005/0009848), which was cited and overcome in U.S. 8,771,729. See Final Rejection, mailed January 14, 2013.

ii. Houghton is directed to oromucosal delivery, and teaches that oromucosal delivery is beneficial when the drug can't be administered to the GI tract
    1. The pending claims require delivery to the upper GI tract
iii. The combination cannot result in an ODT that delivers the drug to the esophagus, because Houghton's drug is absorbed in the oral mucosa and Richard's drug is administered to the colon.

Sasan, Aradhana

From: Scheideman, Matthew H <mscheideman@cooley.com>
Sent: Thursday, August 5, 2021 4:53 PM
To: Sasan, Aradhana
Cc: Cousin, Jonathan
Subject: Interview Agenda and Discussion Points (for Interview 8/6 at 10AM ET)
Attachments: Interview Agenda and Discussion Points (to Examiner Sasan).docx

CAUTION: This email has originated from a source outside of USPTO. **PLEASE CONSIDER THE SOURCE** before responding, clicking on links, or opening attachments.

Hi Examiner Sasan,

Please find attached a summary of discussion points for tomorrow's interview.

Look forward to speaking with you.

Best regards,

Matt

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

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COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/30/2021	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

PTOL-90A (Rev. 04/07)

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Office Action Summary	Application No. 17/236,295	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 --

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 04/21/21.

☐ 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) 1-30 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) 1-30 is/are rejected.

8) ☑ Claim(s) 28 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: _____.

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. Claims 1-30 are pending and are included in the prosecution.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on 05/27/21 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 attached copy of PTO-1449.

Claim Objections

4. Claim **28** is objected to because of the following informalities: In claim 28, line 1, the article "a" should be added before the term "patient." Appropriate correction is required.

Duplicate Claims

5. Applicant is advised that should claim **2** be found allowable, claim **29** will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

6. Also, should claim **3** be found allowable, claim **30** will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 608.01(m). Appropriate correction is required.

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Claim Rejections - 35 USC § 112

7. 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.

8. Claims **1**, **18-20**, and **27-30** 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.

9. Claim **1** recites the limitation "... wherein the orally **dispersing** tablet ..." in line 6 (emphasis added). The preamble of claim 1 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

10. Claims **18** and **19** recite the limitation "... wherein the orally **dispersing** tablet ..." in line 1 of each claim (emphasis added). Claims 18 and 19 are dependent on claim 1, and the preamble of claim 1 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

11. Claim **20** recites the limitation "... wherein the orally **dispersing** tablet ..." in line 7 (emphasis added). The preamble of claim 20 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

12. Claim **27** recites the limitation "... wherein the orally **dispersing** tablet ..." in line 1 (emphasis added). Claim 17 is ultimately dependent on claim 20, and the preamble of

claim 20 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

13. Claims **28-30** recite the limitation "... the orally **dispersing** tablet ..." (in line 2 of claim 28, in line 1 of each of claims 29 and 30) (emphasis added). Claims 28-30 are dependent on claim 1, and the preamble of claim 1 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

14. 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 negatived 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.

15. **Claims 1-4, 13, 18-19, and 29-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (US 2004/0228919 A1) in view of Richards (US 4,985,418)**.

Instant claim 1 is drawn to an orally disintegrating tablet comprising:

(i) about 1 mg to about 6 mg of fluticasone propionate; and

(ii) at least one disintegrant;

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

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

Houghton *et al.* teach a fast-dispersing solid dosage form suitable for oromucosal administration of a pharmaceutically active substance which contains a saccharide matrix (Abstract, claims 1-11). The solid dosage form is a compressed fast dispersing tablet ([0001], [0212]). The active substance is present in the matrix both in the form of microcapsules and in the form of molecules in direct contact with the matrix ([0208]-[0210]). The solid dosage form disintegrates quickly in the mouth ([0070], [0072], [0172]), the disintegrating time is less than 60 seconds ([0072], [0223], claims 21, 53-58). Pharmaceutically active substances include corticosteroids, and fluticasone propionate ([0095] and [0114]). Disintegrants including mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046], [0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]) are disclosed.

Houghton *et al.* do not teach the dosage of about 1 mg to about 6 mg of fluticasone propionate.

Richards teaches fluticasone propionate administered by the oral route in a tablet form (Abstract, claims 1-2). The effective amount of fluticasone propionate administered by the oral route is from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2). Example 1 discloses a tablet for oral

administration which contains 5.0 mg/tablet of fluticasone propionate (micronised) (Col. 4, lines 24-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a fast-dispersing tablet which disintegrates quickly in the mouth, has a disintegrating time of less than 60 seconds, contains a saccharide matrix, and fluticasone propionate as the pharmaceutically active substance, as taught by Houghton *et al.*, in view of the effective amount of fluticasone propionate when administered by the oral route of 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit, and 5.0 mg/tablet, as taught by Richards, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both Houghton *et al.* and Richards are drawn to tablet dosage forms that contain fluticasone propionate. MPEP 2144.06 states: "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the dosage of fluticasone propionate of 1 mg to 10 mg per tablet, as taught by Richards, in the fast dispersing tablet dosage form taught by Houghton *et al.* with a reasonable expectation of success in producing a functional tablet since Richards teaches that this is the effective amount of fluticasone propionate per tablet. Furthermore, each tablet/dosage form is taught to be useful for the same purpose, *i.e.*, oral administration of fluticasone propionate, and it is *prima facie* obvious

to combine said compositions to form a third composition to be used for the very same purpose.

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 1, the limitation of an orally disintegrating tablet would have been obvious over the fast-dispersing tablet suitable for oromucosal administration of a pharmaceutically active substance (Abstract, claims 1-11, [0001], [0212]) which disintegrates quickly in the mouth ([0070], [0072], [0172]), as taught by Houghton *et al.*

Regarding instant claim 1, the limitation of about 1 mg to about 6 mg of fluticasone propionate would have been obvious over the overlapping effective amount of fluticasone propionate administered by the oral route of from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2), and Example 1 which is a tablet for oral administration containing 5.0 mg/tablet of fluticasone propionate (micronised) (Col. 4, lines 24-42), as taught by Richards. 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 1, the limitation of at least one disintegrant would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046],

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

[0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]), as taught by Houghton *et al.*

Regarding instant claim 1, the limitation of "wherein upon administration a therapeutically effective amount of fluticasone propionate is deposited topically in the upper gastrointestinal tract" would have been obvious over the oral administration of the fast dispersing tablet containing fluticasone propionate taught by Houghton *et al.* (Abstract, claims 1-11, [0001], [0212]) in view of the effective amount of fluticasone propionate taught by Richards (Col. 3, line 66 to Col. 4, line 2 , Example 1 - Col. 4, lines 24-42) since the same composition containing the same components are disclosed. The effect of depositing a therapeutically effective amount of fluticasone propionate in the upper gastrointestinal tract is a property associated with the composition and would occur once the fast dispersing tablet of the prior art is orally administered to a patient. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Regarding instant claim 1, the limitation of wherein the orally dispersing tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test would have been obvious over the disintegrating time of less than 60 seconds ([0072], [0223], claims 21, 53-58), as taught by Houghton *et al.*

Regarding instant claims 2 and 29, the limitations of about 1 mg to about 2 mg of fluticasone propionate would have been obvious over the overlapping effective amount of fluticasone propionate administered by the oral route of from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2),

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

as taught by Richards. 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 3 and 30, the limitations of about 3 mg of fluticasone propionate would have been obvious over the overlapping effective amount of fluticasone propionate administered by the oral route of from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2), and Example 1 which contains 5.0 mg/tablet of fluticasone propionate (micronised) (Col. 4, lines 24-42), as taught by Richards. 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 4, the limitation of a sugar alcohol and/or saccharide would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046], [0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]), as taught by Houghton *et al.*

Regarding instant claim 13, the limitation of the disintegrant would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046], [0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]), as taught by Houghton *et al.*, and by the croscarmellose

sodium (crosslinked carboxymethyl cellulose sodium) (Example 1 – Col. 4, lines 24-40), as taught by Richards.

Regarding instant claim 18, the limitation of wherein the orally dispersing tablet disintegrates within 60 seconds when tested in simulated saliva using the USP <701> Disintegration Test would have been obvious over the disintegrating time of less than 60 seconds ([0072], [0223], claims 21, 53-58), as taught by Houghton *et al.*

Regarding instant claim 19, the limitation of wherein the orally dispersing tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test would have been obvious over the disintegrating time of less than 30 seconds ([0072], [0223]), as taught by Houghton *et al.*

16. **Claims 5-17 and 20-27 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (US 2004/0228919 A1) in view of Richards (US 4,985,418), as applied to claims 1-4, 13, 18-19, and 29-30 above, in view of Venkatesh *et al.* (US 2009/0169620 A1)**.

Instant claim 5 is drawn to the orally disintegrating tablet (ODT) of claim 1, wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise fluticasone propionate and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.

The teachings of Houghton *et al.* and Richards are discussed above.

Houghton *et al.* and Richards do not expressly teach that the ODT comprises drug particles and rapidly dispersing granules as recited in instant claim 5.

Venkatesh *et al.* teach an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of at least one drug; 0.5-3% of an ODT binder polymer; a sugar alcohol and/or saccharide; and a disintegrant (Abstract, claims 1-23). The ODT comprises drug particles and rapidly-dispersing microgranules, wherein the drug particles comprise the drug and an ODT binder polymer, and the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant ([0007]). The drug particles also include other excipients such as a filler, a diluent and/or a disintegrant ([0035]),

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a fast-dispersing tablet which disintegrates quickly in the mouth, has a disintegrating time of less than 60 seconds, contains a saccharide matrix, and fluticasone propionate as the pharmaceutically active substance, as taught by Houghton *et al.*, in view of the effective amount of fluticasone propionate when administered by the oral route of 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit, and 5.0 mg/tablet, as taught by Richards, further in view of an orally disintegrating tablet (ODT) containing drug particles which comprise the drug and an ODT binder polymer, and rapidly dispersing microgranules which comprise the sugar alcohol and/or saccharide in combination with the disintegrant, as 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 all the references are drawn to tablet formulations for the oral delivery of pharmaceutically active drugs. It is obvious to combine prior art elements according to known methods to

yield predictable results. Please see MPEP 2141. Moreover, Venkatesh *et al.* teaches the inclusion of steroidal drugs ([0029]), just as taught by Houghton *et al.* and Richards.

Regarding instant claims 5 and 21, the limitation of the drug particles comprising fluticasone propionate and at least one excipient would have been obvious over the active substance which is present in the matrix in the form of microcapsules ([0208]-[0210]) wherein the active substance is fluticasone propionate ([0095] and [0114]), and the microcapsules contain the active substance and a first encapsulating agent which includes excipients such as poly-lactide, gelatines, soy protein, gums, polysaccharides and starches ([0211]), as taught by Houghton *et al.*, and by the drug particles which comprise the drug and an ODT binder polymer ([0007]), wherein the drug particles also include other excipients such as a filler, a diluent and/or a disintegrant ([0035]), as taught by Venkatesh *et al.*

Regarding instant claims 5 and 20, the limitations of the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide would have been obvious over the rapidly-dispersing microgranules comprising the sugar alcohol and/or saccharide in combination with the disintegrant ([0007]), as taught by Venkatesh *et al.*

Regarding instant claims 6, 8, and 22, the limitation of the rapidly dispersing granules having an average particle size of less than about 300 µm would have been obvious over the average particle size of the rapidly dispersing microgranules of 300 µm or less ([0045]), as taught by Venkatesh *et al.* The limitation of each of the disintegrant and sugar alcohol and/or saccharide having an average particle size of about 1-30 µm would have been obvious over the granulation of one or more sugar alcohols,

saccharides or mixture thereof, each of which has an average particle diameter of not more than about 30 µm ([0079]), as taught by Venkatesh *et al.*

Regarding instant claims 7, 8, and 22, the limitations of the drug particles having an average particle size of about 100-400 µm would have been obvious over the drug particles having a mean particle size of about 100-400 µm (claims 16 and 18), as taught by Venkatesh *et al.*

Regarding instant claims 9, 11, 20 and 25, the limitations of about 1 mg to about 2 mg of fluticasone propionate (instant claims 9, 11, and 25), and about 1 mg to about 3 mg of fluticasone propionate (instant claim 20) would have been obvious over the overlapping effective amount of fluticasone propionate administered by the oral route of from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2), as taught by Richards. 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 10, 12, and 26, the limitation of about 3 mg of fluticasone propionate would have been obvious over the overlapping effective amount of fluticasone propionate administered by the oral route of from 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit (Col. 3, line 66 to Col. 4, line 2), and Example 1 which contains 5.0 mg/tablet of fluticasone propionate (micronised) (Col. 4, lines 24-42), as taught by Richards. 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."

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Regarding instant claim 13, the limitation of the disintegrant would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046], [0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]), as taught by Houghton *et al.*, the croscarmellose sodium (crosslinked carboxymethyl cellulose sodium) (Example 1 – Col. 4, lines 24-40), as taught by Richards, and by the crospovidone ([0041]), as taught by Venkatesh *et al.*

Regarding instant claims 14 and 23, the limitation of the disintegrant which is crospovidone would have been obvious over the crospovidone ([0041]), as taught by Venkatesh *et al.*

Regarding instant claim 15, the limitation of the sugar alcohol and/or saccharide would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), sorbitol (Abstract, [0034], [0042], [0046], [0090], [0091], [0262], [0272], [0280], [0306], [0309], [0311], claims 1, 7, 45, and 46), maltitol, lactose, and sucrose ([0086]), as taught by Houghton *et al.*

Regarding instant claims 16 and 24, the limitation of the sugar alcohol which is mannitol would have been obvious over the mannitol ([0038], [0041], [0086], [0087], [0262], [0272], [0280], [0306], [0309], [0311], claims 4, 8, 47, and 48), as taught by Houghton *et al.*

Regarding instant claims 17 and 22, the limitation of the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing granules of from about 90/10 to about 99/01 would have been obvious over the ranges of maltodextrin (disintegrant), which is 3-40% (w/w) ([0040]) and the sorbitol (sugar alcohol), which is

0.01-10% (w/w) ([0042]), as taught by Houghton *et al.* The calculated ratio when the disintegrant is 40% w/w and the sugar alcohol is 0.44% w/w (within the disclosed range of 0.01-10%) is 90.9/1.

Regarding instant claim 20, the limitation of an orally disintegrating tablet would have been obvious over the fast-dispersing tablet suitable for oromucosal administration of a pharmaceutically active substance (Abstract, claims 1-11, [0001], [0212]) which disintegrates quickly in the mouth ([0070], [0072], [0172]), as taught by Houghton *et al.*

Regarding instant claim 20, the limitation of "wherein upon administration a therapeutically effective amount of fluticasone propionate is deposited topically in the upper gastrointestinal tract" would have been obvious over the oral administration of the fast dispersing tablet containing fluticasone propionate taught by Houghton *et al.* (Abstract, claims 1-11, [0001], [0212]) in view of the effective amount of fluticasone propionate taught by Richards (Col. 3, line 66 to Col. 4, line 2 , Example 1 - Col. 4, lines 24-42) since the same composition containing the same components are disclosed. The effect of depositing a therapeutically effective amount of fluticasone propionate in the upper gastrointestinal tract is a property associated with the composition and would occur once the fast dispersing tablet of the prior art is orally administered to a patient. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Regarding instant claim 20, the limitation of wherein the orally dispersing tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test

would have been obvious over the disintegrating time of less than 60 seconds ([0072], [0223], claims 21, 53-58), as taught by Houghton *et al.*

Regarding instant claim 27, the limitation of wherein the orally dispersing tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test would have been obvious over the disintegrating time of less than 30 seconds ([0072], [0223]), as taught by Houghton *et al.*

17. **Claim 28 is are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (US 2004/0228919 A1) in view of Richards (US 4,985,418), as applied to claims 1-4, 13, 18-19, and 29-30 above, in view of Phillips (US 2009/0131386 A1)**.

Instant claim 28 is drawn to a method for treating eosinophilic esophagitis comprising administering to a patient in need thereof the orally dispersing tablet according to claim 1.

The teachings of Houghton *et al.* and Richards are discussed above.

Houghton *et al.* and Richards do not expressly teach the treatment of eosinophilic esophagitis as recited in instant claim 5.

Phillips teaches the treatment of inflammation of the gastrointestinal tract, including the treatment of eosinophilic esophagitis (Abstract, [0018], claims 1, 24, and 25). The method includes the administration of the corticosteroid fluticasone propionate ([0015], claims 1, 2, and 19). The corticosteroid is formulated as tablets for oral ingestion by a patient to be treated ([0084]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a fast-dispersing tablet which disintegrates quickly in the mouth, has a disintegrating time of less than 60 seconds, contains a saccharide matrix, and fluticasone propionate as the pharmaceutically active substance, as taught by Houghton *et al.*, in view of the effective amount of fluticasone propionate when administered by the oral route of 1 mg to 10 mg per dosage unit, preferably 1 mg to 5 mg per dosage unit, and 5.0 mg/tablet, as taught by Richards, further in view of the treatment of inflammation of the gastrointestinal tract, including the treatment of eosinophilic esophagitis by the administration of the corticosteroid fluticasone propionate, as taught by Phillips, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because all the references are drawn to tablet formulations for the oral delivery of pharmaceutically active drugs, including fluticasone propionate. 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 found it obvious to administer the fluticasone propionate ODT of Houghton *et al.* to a patient and have a reasonable expectation of success in treating eosinophilic esophagitis in the patient.

Regarding instant claim 28, the limitation of treating eosinophilic esophagitis would have been obvious over the treatment of eosinophilic esophagitis taught by Phillips (Abstract, [0018], claims 1, 24, and 25).

Double Patenting

18. 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.

19. **Claims 1-6, 9-21, and 28-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-9, 12-16, and 29 of copending Application No. 17/211,119 ("the '119 Application")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally disintegrating tablet (ODT) comprising a corticosteroid, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claim 1 of the '119 Application recites a topically acting corticosteroid whereas instant claim 1 recites about 1 mg to about 6 mg of fluticasone propionate. However, claims 4 and 6-8 of the '119 Application recite fluticasone and fluticasone propionate. Claim 5 of the '119 Application recites an overlapping range for the dosage of the corticosteroid, *i.e.*, about 0.5 mg to about 3 mg.

One of ordinary skill in the art would have found it obvious to use the fluticasone propionate recited in the dependent claims of the '119 Application and arrive at the claimed invention.

Therefore, instant claims and claims of the '119 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.

20. **Claims 1-22 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 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 disintegrating tablet (ODT) comprising a corticosteroid, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '729 Patent recite less than or equal to about 20 mg of a topically administrable corticosteroid, whereas instant claims recite about 1 mg to about 6 mg of fluticasone propionate.

However, claims 3 and 27 of the '729 Patent recite fluticasone, and claim 28 of the '729 Patent recites an overlapping range of about 2 mg to about 10 mg fluticasone.

One of ordinary skill in the art would have found it obvious to use the fluticasone propionate recited in the dependent claims of the '729 Patent and arrive at the claimed invention.

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

21. **Claims 1-22 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-42 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 disintegrating tablet (ODT) comprising a corticosteroid, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claim 1 of the '407 Patent recites method of treating an inflammatory condition of the gastrointestinal (GI) tract whereas instant claim 1 is drawn to an orally disintegrating tablet (ODT).

However, instant claim 28 is drawn to a method for treating eosinophilic esophagitis, which is an inflammatory condition of the GI tract.

Another difference is that claim 1 of the '407 Patent recites less than or equal to about 20 mg of a topically administrable corticosteroid, whereas instant claims recite about 1 mg to about 6 mg of fluticasone propionate.

However, claims 3, 33, 34, 37 and 42 of the '407 Patent recite fluticasone, and claim 42 of the '407 Patent recites an overlapping range of about 0.01 to about 20 mg of fluticasone.

One of ordinary skill in the art would have found it obvious to use the fluticasone recited in the dependent claims of the '407 Patent and arrive at the claimed invention.

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

22. **Claims 1-22 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 6-19, 23-26, and 36-38 of U.S. Patent No. 10,471,071 B2 ("the '071 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally disintegrating tablet (ODT) comprising a corticosteroid, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claim 1 of the '071 Patent recites a topically acting corticosteroid whereas instant claim 1 recites about 1 mg to about 6 mg of fluticasone propionate. However, claims 8 and 17-19 of the '071 Patent recite fluticasone and fluticasone propionate. Claim 17 of the '071 Patent recites an overlapping range for the dosage of the corticosteroid, *i.e.*, about 0.05 mg to about 15 mg.

One of ordinary skill in the art would have found it obvious to use the fluticasone propionate recited in the dependent claims of the '071 Patent and arrive at the claimed invention.

Therefore, instant claims and claims of the '071 Patent are not patentably distinct over each other.

Conclusion

23. No claims are allowed.

24. 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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008	1023

58249 7590 06/04/2021
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/04/2021	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

PTOL-90A (Rev. 04/07)

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/236,295	**Applicant(s)** PERRETT et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 21 April 2021 IS **GRANTED** .

   The above-identified application has met the requirements for prioritized examination
   A. ☑ for an original nonprovisional application (Track I).
   B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

   A. filing a **petition for extension of time** to extend the time period for filing a reply;

   B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

   C. filing a **request for continued examination** ;

   D. filing a notice of appeal;

   E. filing a request for suspension of action;

   F. mailing of a notice of allowance;

   G. mailing of a final Office action;

   H. completion of examination as defined in 37 CFR 41.102; or

   I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

U.S. Patent and Trademark Office
PTO-2298 (Rev. 02-2012)

Dr. Falk Pharma Ex. 1039
IPR Petition - USP 9,486,407

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	1023
Application No.:	17/236,295	Group Art Unit:	1615
Filed:	April 21, 2021	Examiner:	Not Yet Assigned

For: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

RESPONSE TO NOTICE TO FILE MISSING PARTS

In response to the Notice to File Missing Parts dated April 28, 2021, Applicant herein submits the payment of the additional claim fees of $1000 as an undiscounted entity (i.e., 10 additional total claims over 20).

Please note that the instant application was filed on April 21, 2021 under prioritized examination ("Track 1") practice. Since the excess claim fee is timely paid, without any extension of time request, Applicant believes that the prioritized examination ("Track 1") request should continue to be considered.

Applicant believes no further fee is due with this response. However, if a fee is due, the Director 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.

Dated: May 4, 2021

Respectfully submitted,
COOLEY LLP

COOLEY LLP
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Reg. No. 66,418

249850307 v1

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/236,295	04/21/2021	Stephen PERRETT	ELLO-119/07US 342083-2008

CONFIRMATION NO. 1023

FORMALITIES LETTER

OC000000125207147

58249
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

Date Mailed: 04/28/2021

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing.

Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- Additional claim fees of $ **1000** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **1000** for **10** total claims over 20.
- $(**0**) previous unapplied payment amount.
- $ **1000** TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/lnguyen/

WHAT IS CLAIMED IS:

1. An orally disintegrating tablet comprising:

(i) about 1 mg to about 6 mg of fluticasone propionate; and

(ii) at least one disintegrant;

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

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

2. The orally disintegrating tablet of claim 1, comprising about 1 mg to about 2 mg of fluticasone propionate.

3. The orally disintegrating tablet of claim 1, comprising about 3 mg of fluticasone propionate.

4. The orally disintegrating tablet of claim 1, comprising a sugar alcohol and/or saccharide.

5. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise fluticasone propionate and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.

6. The orally disintegrating tablet of claim 5, wherein the rapidly dispersing granules have an average particle size of less than about 300 μm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm.

7. The orally disintegrating tablet of claim 5, wherein the drug particles have an average particle size of about 100-400 μm.

8. The orally disintegrating tablet of claim 5, the drug particles have an average particle size of about 100-400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm.

9. The orally disintegrating tablet of claim 5, comprising about 1 mg to about 2 mg of fluticasone propionate.

10. The orally disintegrating tablet of claim 5, comprising about 3 mg of fluticasone propionate.

11. The orally disintegrating tablet of claim 8, comprising about 1 mg to about 2 mg of fluticasone propionate.

12. The orally disintegrating tablet of claim 8, comprising about 3 mg of fluticasone propionate.

13. The orally disintegrating tablet of claim 1, wherein the disintegrant is crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, or combinations thereof.

14. The orally disintegrating tablet of claim 13, wherein the disintegrant is crospovidone.

15. The orally disintegrating tablet of claim 5, wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol. lactose, sucrose, maltose, or combinations thereof.

16. The orally disintegrating tablet of claim 15, wherein the sugar alcohol is mannitol.

17. The orally disintegrating tablet of claim 5, wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.

18. The orally disintegrating tablet of claim 1, wherein the orally dispersing tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.

19. The orally disintegrating tablet of claim 1, wherein the orally dispersing tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

20. An orally disintegrating tablet comprising:

(i) about 1 mg to about 3 mg of fluticasone propionate; and

(ii) rapidly dispersing granules comprising (a) at least one disintegrant and (b) at least one sugar alcohol, saccharide, or combination thereof;

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

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

21. The orally disintegrating tablet of claim 20, wherein the orally disintegrating tablet comprises drug particles comprising the fluticasone propionate and at least one excipient.

22. The orally disintegrating tablet of claim 21, wherein drug particles have an average particle size of about 100-400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm, and the ratio of disintegrant to sugar alcohol and/or saccharide in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.

23. The orally disintegrating tablet of claim 22, wherein the disintegrant is crospovidone.

24. The orally disintegrating tablet of claim 23, wherein the sugar alcohol is mannitol.

25. The orally disintegrating tablet of claim 24, comprising about 1 mg to about 2 mg of fluticasone propionate.

26. The orally disintegrating tablet of claim 24, comprising about 3 mg of fluticasone propionate.

27. The orally disintegrating tablet of claim 26, wherein the orally dispersing tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

28. A method for treating eosinophilic esophagitis comprising administering to patient in need thereof the orally dispersing tablet according to claim 1.

29. The orally dispersing tablet of claim 1, comprising about 1 mg to about 2 mg of fluticasone propionate.

30. The orally dispersing tablet of claim 1, comprising about 3 mg of fluticasone propionate.