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NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 04/24/2014
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/24/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

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	$960	$0	$0	$960	07/24/2014

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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

Dr. Falk Pharma **Ex. 1031**
IPR Petition USP 11,246,828

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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

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

91543 7590 04/24/2014
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

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

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

(Depositor's name)
(Signature)
(Date)

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nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/24/2014

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 03-02 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, 1_____
(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. 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
❑ Issue Fee
❑ Publication Fee (No small entity discount permitted)
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
❑ A check is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
❑ Applicant certifying micro entity status. See 37 CFR 1.29 — 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.
❑ Applicant asserting small entity status. See 37 CFR 1.27 — 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.
❑ Applicant changing to regular undiscounted fee 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)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 29 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 29 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

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 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 12/896,005	Applicant(s) PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) 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 RCE and IDS filed on 09/18/2013*.
   ☐ 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 *1-34 and 55-60*. 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

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

Continued Examination under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2013 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 09/18/2013 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Reasons for Allowance

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

Claims **1-34 and 55-60** are allowed for the reasons articulated in the notice of allowance (NOA) mailed on 06/19/2013, which are incorporated herein by reference. Applicants' IDS submitted on 09/18/2013 did not change the previous determination of patentability since the references do not disclose 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, as recited in instant claims 1 and 27.

The Rejoinder set forth in the NOA of 06/19/2013 remains in effect and is also incorporated herein by reference.

Comments

4. 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

5. Claims **1-34 and 55-60** are allowed.

6. 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 Thursday from 6:30 am to 5:00 pm.

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

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EXAMINER
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NOTIFICATION DATE	DELIVERY MODE
04/18/2014	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):

zpatdcdocketing@cooley.com

PTOL-90A (Rev. 04/07)

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ARADHANA SASAN*.

(2) *THOMAS BLINKA*.

(3) *TRUPTI JOSHI*.

(4) *RAYMOND PARKER*.

Date of Interview: *15 April 2014*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☒ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *OF RECORD*.

Identification of prior art discussed: *References in IDS filed on 9/18/13*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants' representatives discussed the references cited in the IDS filed on 9/18/13 and how these references do not teach the limitations of the topical administration of the orally disintegrating corticosteroid composition.

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.

☐ Attachment

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	12/896,005
Filing Date	10/01/2010
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	EURA-119/01US 307853-2692

This is a Request for Continued Examination (RCE) under 37 CFR 1 .114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

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

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

      ii. ☐ Other _____

   b. ☒ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☒ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a

   a. ☐ period of ___ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
   The Director is hereby authorized to charge the following fees any underpayment of fees or credit any overpayments to

   a. ☒ Deposit Account No. 50-1283 .

      i. ☒ RCE fee required under 37 CFR 1.17(e)

      ii ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	T. A. Blinka	Date	9/19/13
Name (Print/Type)	Thomas A. Blinka	Registration No.	44541

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature			
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

American LegalNet, Inc.
www.FormsWorkFlow.com

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 06/19/2013
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/19/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

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	$1780	$300	$0	$2080	09/19/2013

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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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

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

91543 7590 06/19/2013
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

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

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

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

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nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	09/19/2013

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 03-02 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
❑ Issue Fee
❑ Publication Fee (No small entity discount permitted)
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
❑ A check is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29	NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
❑ Applicant asserting small entity status. See 37 CFR 1.27	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.
❑ Applicant changing to regular undiscounted fee 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, 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.

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

91543 7590 06/19/2013
Cooley LLP
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1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/19/2013

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

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

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.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 12/896,005	Applicant(s) PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) 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 and Remarks filed on 05/31/13*.
   ☐ 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 *1-34 and 55-60*. 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: _____.

   Interim copies:

   a) ☐ All b) ☐ Some c) ☐ None of the: Interim copies of the priority documents have been 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 *Annotated 1st page of After-Final Amendment*.

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

Reasons for Allowance

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

2. 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 A1) do not teach or suggest the limitation of the disintegration time or the topical delivery of drugs.

A further prior art search did not disclose a reference that teaches 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, as recited in instant claims 1 and 27.

Therefore, the claimed invention is novel and unobvious over the prior art of record.

Rejoinder

3. Claims 1-28 and 55-60 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 29-34, directed to the process of using an allowable product, previously withdrawn from consideration as a result of a

restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 01/31/12 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Comments

4. 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

5. Claims **1-34 and 55-60** are allowed.

6. 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 Thursday from 6:30 am to 5:00 pm.

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

Receipt date: 05/31/2013 12896005 - GAU: 1615
OK TO ENTER: /A.S./
06/04/2013

Attorney Docket No. EURA-119/01US 307853-2692 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Stephen PERRETT, et al.	Confirmation No.:	8779
Application No.:	12/896,005	Group Art Unit:	1615
Filed:	October 1, 2010	Examiner:	Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

AMENDMENT/RESPONSE TO OFFICE ACTION

Dear Madam:

This paper responds to the Final Office Action mailed January 24, 2013. Applicants request that the Commissioner treat this paper as a petition for a two month extension of time, making this response timely filed on or before June 24, 2013. If the Commissioner determines that this paper is not timely, then Applicants request that the Commissioner treat this paper as a petition for any required extension of time.

In this paper:

Amendments to the Claims begin on page 2; and

Remarks begin on page 7.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Stephen PERRETT, et al.	Confirmation No.:	8779
Application No.:	12/896,005	Group Art Unit:	1615
Filed:	October 1, 2010	Examiner:	Aradhana SASAN

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In re Application of:	Stephen PERRETT, et al.	Confirmation No.:	8779
Application No.:	12/896,005	Group Art Unit:	1615
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In this paper:

Amendments to the Claims begin on page 2; and

Remarks begin on page 7.

AMENDMENTS TO THE CLAIMS

1. (Currently amended) An orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid and at least one disintegrant, wherein the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,

   wherein the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
   wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

2. (Original) The solid pharmaceutical composition of claim 1, wherein said solid pharmaceutical composition disintegrates within 30 seconds.

3. (Original) The solid pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.

4. (Original) The solid pharmaceutical composition of claim 1, further comprising an adhesive agent.

5. (Previously amended) The solid pharmaceutical composition of claim 4, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

6. (Currently amended) The solid pharmaceutical composition of claim 1, ~~further comprising a~~ wherein the at least one disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

7. (Original) The solid pharmaceutical composition of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.

8. (Original) The solid pharmaceutical composition of claim 1, which is substantially free of lubricant.

9. (Original) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.

10. (Original) The solid pharmaceutical composition of claim 9, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.

11. (Original) The solid pharmaceutical composition of claim 10, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.

12. (Original) The solid pharmaceutical composition of claim 1, further comprising at least one antiviral agent.

13. (Previously amended) The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucelotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, purine analogs, pyrimidine analogs, and uncategorized antiviral drugs.

14. (Original) The solid pharmaceutical composition of claim 12, wherein the antiviral agent selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclocvir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.

15. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).

16. (Currently amended) The pharmaceutical composition of claim 15, wherein the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing granules comprise ~~a~~ the disintegrant and a sugar alcohol and/or saccharide.

17. (Original) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm.

18. (Previously amended) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 4 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm.

19. (Previously amended) The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm.

20. (Original) The pharmaceutical composition of claim 4, wherein the adhesive agent and the corticosteroid are intimately associated.

21. (Original) The pharmaceutical composition of claim 20, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.

22. (Original) The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.

23. (Original) The pharmaceutical composition of claim 16, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.

24. (Original) The pharmaceutical composition of claim 23, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

25. (Original) The pharmaceutical composition of claim 23, wherein the ODT is in the form of a wafer or film.

26. (Original) The pharmaceutical composition of claim 16, wherein the ODT is in the form of a wafer or film.

27. (Currently amended) An orally disintegrating tablet comprising less than or equal to about 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, <u>and at least one disintegrant,</u> wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.

28. (Previously amended) The orally disintegrating tablet of claim 27, that comprises from about 2 to about 10 mg fluticasone.

29. (Withdrawn) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.

30. (Withdrawn) The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.

31. (Withdrawn) The method of claim 29, wherein said condition is eosinophilic esophagitis.

32. (Withdrawn) The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

33. (Withdrawn) The method of claim 29, wherein said condition is viral or bacterial pharyngitis.

34. (Withdrawn) The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

35-54. (Canceled)

55. (Previously presented) The solid composition of claim 1, formulated for topical administration to the upper gastrointestinal tract.

56. (Previously presented) The solid composition of claim 55, wherein the upper gastrointestinal tract is further defined as the esophagus.

57. (Previously presented) The pharmaceutical composition of claim 16, wherein the ODT further comprises a sugar alcohol, a disintegrant, and microcrystalline cellulose, wherein the drug particles comprise fluticasone, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol or saccharide or a mixture thereof.

58. (Previously presented) The orally disintegrating tablet of claim 27, that comprises from about 0.0 l mg and about 20 mg fluticasone.

59. (Previously presented) The solid pharmaceutical composition of claim 1, that comprises from about 0.0 l mg and about 20 mg fluticasone.

60. (Previously presented) The solid pharmaceutical composition of claim 1, that comprises from about 2 to about 10 mg fluticasone.

REMARKS

I. Statement of the Substance of an Interview

Applicants and their representative gratefully acknowledge the courtesy extended by Examiner Sasan during an in-person interview on April 17, 2013. The interview included a discussion of the novel and unobvious features of the pending claims. Applicants do not disagree with the Examiner's comments on the Applicant-Initiated Interview Summary mailed April 22, 2013.

II. Status of the Claims

Claims 1-34 and 55-60 are pending. Claims 35-54 are canceled. Claims 29-34 are withdrawn from consideration, and claims 1-28 and 55-60 are under examination on the merits. Applicants reserve the right to pursue the subject matter of the canceled claims in this or another application.

Claims 1, 6, 16, and 27 are amended. Support for the amendments can be found throughout the originally filed disclosure, for example, in the originally filed claims.

Applicants gratefully acknowledge that the Examiner withdrew several rejections in the previous office action.

III. Claim Rejections

Claims 1-7, 15, 27, 28, 55, 56, and 58-60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. Pub. 2009/0131386 (*Phillips*). This rejection is respectfully traversed.

Claim 1 recites a "*solid* pharmaceutical composition" of a topically administrable corticosteroid "wherein the solid pharmaceutical composition *disintegrates within 60 seconds*

[under specified test conditions]" (emphases added). Claim 27 recites an "orally disintegrating tablet" that "*disintegrates within 60 seconds* [under the same test conditions]" (emphases added). Claims 1 and 27 are not obvious over *Phillips* at least because *Phillips* does not teach or suggest these features of claim 1.

Phillips is directed primarily to liquid dosage forms, containing, for example, isotonic agents[1] and viscosity enhancing agents[2] so as to provide a liquid composition with a high viscosity.[3]

Phillips does not teach or suggest a orally disintegrating solid pharmaceutical composition that can disintegrate within sixty seconds. *Philips* also fails to recognize the difference in employing a liquid composition versus a disintegrating solid composition comprising a corticosteroid as the former provides for greater distribution and residence of the active throughout the mouth and thus broader promotion of an undesirable affect, *i.e.*, an oral yeast infection. Thus, *Philips* provides no reason to have a rapid disintegration time, particularly one of about 60 seconds as recited in claims 1 and 27.

Thus, *Phillips*' comment that "dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus" does not equate to a suggestion that a solid composition dissolves within sixty seconds, as recited in claims 1 and 27. This is so because a dosage form can substantially dissolve or disintegrate in the mouth or esophagus in more than sixty seconds. For example, *Phillips* contains a laundry list of solid dosage forms that cannot be reasonably read as disintegrating within sixty seconds. *Philips*' list includes capsules, which cannot reasonably disintegrate within sixty seconds because they are designed to break down ezymatically in the gastrointestinal tract, and lozenges, which are retained in the mouth for longer than sixty seconds

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[1] *Phillips* at paragraph [0007]
[2] *See*, *Phillips* at paragraph [0029]
[3] *Phillips* at paragraph [0043]

before dissolving.[4] Thus, despite a statement concerning the location (i.e., mouth of esophagus) of disintegration or dissolution, *Phillips* fails to disclose any particular disintegration time, and similarly fails to recognize the importance of disintegration within sixty seconds.

Dissolution within sixty seconds is an important feature of the invention. As discussed in this Application, corticosteroids are known to suppress immune function, thus, prolonged contact of corticosteroids to the mouth or throat can lead to an oral yeast infection.[5] In order to minimize contact with the mouth, thereby minimizing the chance of an oral yeast infection, claims 1 and 27 provide a composition that disintegrates within sixty seconds; after the composition disintegrates, the remnants of the composition can be swallowed thus minimizing both the contact between the drug and the mouth and the likelihood of developing a yeast infection. *Phillips* fails to recognize the connection between residence time of a corticosteroid in the mouth and the potential for developing yeast infections. Thus, *Phillips* provides no reason to make a composition that disintegrates within sixty seconds, as recited in claims 1 and 27.

Furthermore, *Phillips'* compositions do not inherently disintegrate within sixty seconds. *Phillips* does not disclose any particular solid composition with any particular combination of components. Thus, there is no basis to assume that a composition according to *Phillips* would inherently disintegrate within sixty seconds.

Because *Phillips* does not teach or suggest, either explicitly or inherently, all of the features of claim 1, claim 1 is not obvious over *Phillips*. The remaining claims depend on claim 1 or 27, and are therefore not obvious over *Phillips* for at least the same reasons as claims 1 and 27. Applicants request that the rejection be withdrawn and the claims allowed.

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[4] *Phillips* at paragraph [0085]
[5] As-filed specification, page 1, lines 17-page 2, line 2.

Claims 8-22 and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Phillips* in view of U.S. Pat. Pub. 2009/0169620 (*Venkatesh*). This rejection is respectfully traversed.

As discussed above, *Phillips* does not teach or suggest all of the features of claims 1 and 27. *Venkatesh* does not make up for the deficiencies in *Phillips*. *Venkatesh* teaches an orally disintegrating tablet that delivers a drug, such as temazapam, *systemically*. *Venkatesh* does not teach or suggest topical delivery of drugs, and like *Phillips*, *Venkatesh* fails to recognize the importance of minimizing exposure of the oral cavity to corticosteroids in order to prevent oral yeast infections. Accordingly, the artisan would not combine the teachings of *Phillips* and *Venkatesh* to provide a solid formulation that deposits a corticosteroid topically in the upper gastrointestinal tract while minimizing the possibility of an oral yeast infection by disintegrating within 60 seconds. Applicants therefore respectfully request that the rejection be withdrawn.

Claims 8-22 and 57 depend on claim 1 or 27, and are not obvious over the cited prior art for at least the same reasons as claims 1 and 27. Applicants respectfully request that the rejection be withdrawn and the claims allowed.

Claims 23-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Phillips* in view of *Venkatesh* and U.S. Pat. Appln. 2007/0059361 (*Rawas-Qalaji*). This rejection is respectfully traversed.

As discussed above, claims 1 and 27 are not obvious over *Phillips* and *Venkatesh*. *Rawas-Qalaji* does not make up for the deficiencies in *Phillips* and *Venkatesh*, because *Rawas-Qalaji* teaches an oral formulation that rapidly delivers *systemic* epinephrine through the *oral* mucos*a* to "produce *plasma epinephrine concentrations* similar to those produced by an [Epi-

Pen injection]."[6] Thus, contrary to the current invention, which minimizes oral exposure to corticosteroids in order to prevent oral yeast infections, *Rawas-Qalaji's* goal is to provide substantial drug exposure to oral cavity to the drug in order to achieve rapid drug uptake. Further, because *Rawas-Qalaji* is concerned with dosage forms for *systemic* administration of a drug, it does not suggest that dosage form for *topical* delivery of a drug should disintegrate within any particular time, much less "within sixty seconds" as recited in claims 1 and 27. Thus, *Rawas-Qalaji*, even in combination with *Phillips* and *Venkatesh*, does not suggest that disintegration within sixty seconds is desirable for topical delivery of a corticosteroid "without significant systemic glucocorticoid or mineralocorticoid activity," as claimed in claims 1 and 27.

Claims 23-26 depend on claim 1 or 27 and are unobvious over the cited prior art for at least the same reasons as claims 1 and 27. Applicants request that the rejection be withdrawn and the claims allowed.

IV. Withdrawn Claims

Withdrawn claims 29-34 depend on or otherwise contain all of the features of claim 1 or 27. Because claims 1 and 27 are allowable, claims 29-34 should be rejoined and allowed.

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[6] *Rawas-Qalaji*, Abstract (emphasis added).

CONCLUSION

In view of the foregoing, Applicants believe that the Application is allowable.

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.

Respectfully submitted,
COOLEY LLP

Dated: May 31, 2013

By: Thomas A. Blinka
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

91543 7590 04/22/2013
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EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
04/22/2013	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):

zpatdcdocketing@cooley.com

PTOL-90A (Rev. 04/07)

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ARADHANA SASAN*.

(2) *THOMAS BLINKA*.

(3) *RAYMOND PARKER*.

(4) *ERIC SILVERMAN*.

Date of Interview: *17 April 2013*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *Phillips (US 2009/0131386 A1) & Rawas-Qalaji et al. (US 2007/0059361 A1)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Mr. Blinka presented the following arguments: (i) Philips relates to liquid formulations and only has a laundry list of dosage forms containing solid dosage forms like capsules which are intended to be ingested and lozenges which remain in the mouth for a prolonged time; (ii) Phillips does not address the problem of corticosteroids leading to yeast infections; and (iii) Phillips does not disclose disintegration time as recited in the instant claims. Regarding Rawas-Qalaji, Mr. Blinka argued that: (i) the drug (epinephrine) is a systemically active drug (not topically active); and (ii) the reason for disintegration in the dosage form of Rawas-Qalaji is different (rapid uptake of epinephrine in the mouth). Mr. Parker argued that a prima facie case of obviousness was not established. The Examiner explained the reasons for relying on Phillips and suggested adding limitations regarding "topically active" corticosteroid; orally disintegrating dosage form; adhesive agent and/or excipients in order to provide more structural components of the composition in order to tie it with the disintegration and deposition recitations. Applicants' representatives will consider filing arguments and amendments. Further consideration may be required after Applicants' response is filed .

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.

☐ Attachment

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

91543 7590 01/24/2013
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EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/24/2013	PAPER

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

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

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *06 December 2012*.

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) *1-60* is/are pending in the application.

5a) Of the above claim(s) *29-54* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-28 and 55-60* is/are rejected.

8)☐ Claim(s) _____ 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).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 12/06/12 are acknowledged.

2. Claims 29-54 were withdrawn. Claims 1, 5, 13, 18-19 and 27-28 were amended. New claims 55-60 were added.

3. Claims 1-28 and 55-60 are included in the prosecution.

Response to Amendments/Arguments

Amendment of the Specification

4. The amendment of the Specification to correct the typographical errors regarding "alginate" and "purine" as well as to correct the error regarding the USP<701>Disintegration Test are acknowledged.

Rejection of claims under 35 USC § 103(a)

5. Applicants amended claim 1 to recite that the corticosteroid is deposited topically in the upper gastrointestinal tract. In light of this amendment, Applicants' arguments (Pages 15-20, filed 12/06/12) regarding the following rejections have been fully considered and are persuasive.

- Rejection of claims 1-22 and 27-28 under 35 U.S.C. 103(a) as being unpatentable over Venkatesh et al. (US 2009/0169620 A1) in view of Brantl (US 2005/0009848 A1)
- Rejection of claims 23-26 under 35 U.S.C. 103(a) as being unpatentable over Venkatesh et al. (US 2009/0169620 A1) in view of Brantl (US 2005/0009848 A1) and further in view of Rawas-Qalaji et al. (US 2007/0059361 A1

Therefore, the rejections have been withdrawn. However, upon further consideration, and in light of the amendment, a new ground(s) of rejection is made over Phillips (US 2009/0131386 A1).

New Rejections necessitated by Amendment

Claim Rejections - 35 USC § 103

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

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

7. Claims **1-7, 15, 27, 28, 55, 56 and 58-60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1).

The claimed invention is a solid pharmaceutical composition comprising less than or equal to about 20 mg of a corticosteroid, wherein the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within

60 seconds when tested using the USP <701> Disintegration Test, and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

Phillips teaches pharmaceutical compositions for the treatment of inflammation of the gastrointestinal tract (Abstract). The composition comprises a corticosteroid such as fluticasone propionate (Page 1, [0008]). The amount of corticosteroid is from about 100 µg to about 20 mg (Page 1, [0008] and Page 7, [0059]). The composition is formulated into solid dosage forms and administered locally (Page 12, [0083]). Phillips teaches that "… the corticosteroid is formulated readily using pharmaceutically acceptable excipients and/or auxiliaries well known in the art into dosages suitable for oral administration. Such excipients and auxiliaries enable the compositions … to be formulated as tablets, pills, dragees, capsules … for oral ingestion by a patient to be treated" (Page 12, [0084]). The solid dosage forms, such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach (Page 12, [0085] and Page 13, [0092]).

Phillips does not expressly teach an example or embodiment wherein the solid dosage form contains less than or equal to 20 mg of a corticosteroid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as fluticasone propionate, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such

as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., also as taught by Phillips, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Phillips clearly teaches that solid dosage forms containing the corticosteroid can be prepared (Page 12, [0083] – [0085]) and that interaction of the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus, is increased, in order to decrease the physiological manifestations or symptoms of gastrointestinal tract inflammation (Pages 4-5, [0036]).

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

Regarding instant claims 1 and 27, the limitation of a solid pharmaceutical composition comprising less than or equal to about 20 mg of a corticosteroid would have been obvious over the composition comprising a corticosteroid such as fluticasone propionate (Page 1, [0008]) as taught by Phillips, wherein the amount of corticosteroid is from about 100 µg to about 20 mg (Page 1, [0008], Page 7, [0059] and Page 10, [0069]), and wherein the composition is formulated into solid dosage forms such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc. (Page 12, [0083] – [0085]). The limitations of the solid pharmaceutical composition having no significant

systemic glucocorticoid or mineralocorticoid activity after oral administration and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract would have been obvious over the local administration of the solid dosage form, (Page 12, [0083]) and the compositions which contain an excipient that increases the interaction of the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus (Page 4, [0036]) as taught by Phillips. The limitation of the solid pharmaceutical composition disintegrating within 60 seconds when tested using the USP <701> Disintegration Test would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth and/or esophagus prior to reaching the stomach as taught by Phillips (Page 12, [0085] and Page 13, [0092]). The limitation of the time period for disintegration is a property associated with the solid dosage form. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding instant claim 2, the limitation of the solid pharmaceutical composition disintegrating within 30 seconds would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth and/or esophagus prior to reaching the stomach as taught by Phillips (Page 12, [0085] and Page 13, [0092]).

Regarding instant claim 3, the limitation of the corticosteroid would have been obvious over the fluticasone propionate, as taught by Phillips (Page 1, [0008]).

Regarding instant claims 4-5, the limitation of the composition further comprising an adhesive agent would have been obvious over the mucoadhesive agents including polyvinylpyrrolidone polymer, cross-linked poly(acrylic acid), cross-linked alginate gum gel, polycarboxylated vinyl polymer, as taught by Phillips (Page 6, [0046]).

Regarding instant claim 6, the limitation of the composition further comprising a disintegrant would have been obvious over the cross-linked polyvinylpyrrolidone (Page 13, [0085]); lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Regarding instant claim 7, the limitation of the composition further comprising an excipient would have been obvious over the lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips.

Regarding instant claim 15, the limitation of the orally disintegrating tablet (ODT) would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth, as taught by Phillips (Page 12, [0085] and Page 13, [0092]).

Regarding instant claims 28 and 58-60, the limitation of a solid pharmaceutical composition comprising less than or equal to about 2 to about 10 mg fluticasone would have been obvious over the composition comprising a corticosteroid such as fluticasone propionate (Page 1, [0008]), wherein the amount of corticosteroid is from about 100 µg

to about 20 mg, or from about 250 µg to about 10 mg, (Page 1, [0008], Pages 7-8, [0059] and Page 10, [0069]) as taught by Phillips.

Regarding instant claims 55 and 56, the limitation of topical administration to the upper gastrointestinal tract would have been obvious over the local administration of the solid dosage form, (Page 12, [0083]) and the compositions which contain an excipient that increases the interaction of the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus (Page 4, [0036]) as taught by Phillips.

8. Claims **8-22 and 57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Venkatesh et al. (US 2009/0169620 A1).

Phillips does not expressly teach a composition which is substantially free of lubricant.

Venkatesh et al. teach a solid pharmaceutical composition in the form of an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug, an ODT binder polymer, a sugar alcohol and/or saccharide, and a disintegrant (Abstract, Page 1, [0002] and [0006] and claims 1-23). The therapeutically effective amount of at least one drug (Page 1, [0006]); 7.5,15, mg of temazepam (Page 4, [0032]); and the corticosteroid beclomethasone (Page 3, [0029] left hand column) are disclosed. The ODT compositions disintegrate in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

ODT binder polymers including polyvinylpyrrolidone (povidone or PVP), methylcellulose and hydroxypropylcellulose are disclosed (Page 4, [0035]). Disintegrants including crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethylcellulose, and low-substituted hydroxypropylcellulose are disclosed (Abstract, Page 5, [0041]). Sugar alcohols such as mannitol, xylitol, sorbitol, maltol and maltitol; and saccharides such as lactose, sucrose and maltose are disclosed (Page 5, [0042] – [0043], [0047]). The lubricant (e.g., magnesium stearate) is not part of the composition, but is used as a processing aid, and is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression (Page 10, [0093]). Antifungal agents including fluconazole, itraconazole, nystatin and voriconazole are disclosed (Page 3, [0029]). Antiviral agents are disclosed (Page 3, [0029]). The ODT comprises drug particles and rapidly-dispersing microgranules, wherein the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant, and the drug particles comprise the drug (Page 1, [0007]). Drug particles have an average particle size of 1-400 µm (Page 6, [0062] and claim 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as fluticasone propionate, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., also as taught by Phillips, in view of the orally disintegrating tablet (ODT) comprising a therapeutically

effective amount of a drug such as the corticosteroid beclomethasone wherein the ODT disintegrates in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures, taught by Venkatesh et al., and produce the instant invention.

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

Regarding instant claim 8, the limitation of the solid pharmaceutical composition substantially free of lubricant would have been obvious over the lubricant (e.g., magnesium stearate) which is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression, as taught by Venkatesh et al. (Page 10, [0093]) since this lubricant is not part of the composition, but is used as a processing aid.

Regarding instant claims 9-11, the limitation of the solid pharmaceutical composition further comprising at least one antifungal agent would have been obvious over the antifungal agents including fluconazole, itraconazole, nystatin and voriconazole, as taught by Venkatesh et al. (Page 3, [0029]).

Regarding instant claims 12-14, the limitation of the solid pharmaceutical composition further comprising at least one antiviral agent would have been obvious over the antiviral agents, including acyclovir, as taught by Venkatesh et al. (Page 3, [0029]).

Regarding instant claim 15, the limitation of the orally disintegrating tablet (ODT) would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth, as taught by Phillips (Page 12, [0085] and Page 13, [0092]) and by the ODT, as taught by Venkatesh et al. (Abstract and Page 1, [0006]).

Regarding instant claim 16, the limitation of the ODT comprising drug particles and rapidly dispersing granules would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth (Page 12, [0085] and Page 13, [0092]) and the corticosteroid fluticasone propionate (Page 1, [0008]), as taught by Phillips, and by the ODT comprising drug particles and rapidly-dispersing microgranules, wherein the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant, and the drug particles comprise the drug (Page 1, [0007]), and wherein the drug may be a corticosteroid (Page 3, [0029] left hand column), as suggested by Venkatesh et al.

Regarding instant claim 17, the limitation of the drug particles having an average particle size of less than about 400 µm would have been obvious over the drug particles having an average particle size of 1-400 µm, as taught by Venkatesh et al. (Page 6, [0062] and claim 16). 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 having an average particle size of 300 µm or less, as taught by Venkatesh et al. (Page 5, [0045]). The limitation of the disintegrant and sugar alcohol and/or saccharide having an average particle size of less than about 30 µm would have been obvious over the average particle size of the

sugar alcohol and/or saccharide having an average particle size of 30 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 18, the limitation of the drug particles having an average particle size of less than about 4 µm would have been obvious over the drug crystals having an average particle size of about 1-25 µm, as taught by Venkatesh et al. (Page 4, [0034]). 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 having an average particle size of 300 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 19, the limitation of the corticosteroid disposed over the surface of an excipient would have been obvious over the drug coated beads and rapidly-dispersing microgranules comprising the sugar alcohol and/or saccharide in combination with the disintegrant (Page 1, [0008]), wherein the rapidly dispersing microgranules have an average particle size of 300 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 20, the limitation of the intimately associated adhesive agent and the corticosteroid would have been obvious over the corticosteroid fluticasone propionate, (Page 1, [0008]) and mucoadhesive agents including polyvinylpyrrolidone polymer, cross-linked poly(acrylic acid), cross-linked alginate gum gel, polycarboxylated vinyl polymer, as taught by Phillips (Page 6, [0046]); and by the ODT binder polymers including polyvinylpyrrolidone (povidone or PVP), methylcellulose and hydroxypropylcellulose (Page 4, [0035]), the corticosteroids, as taught by

Venkatesh et al. (Page 3, [0029] left hand column); since Venkatesh et al. teach that the drug and the ODT binder polymer are mixed and granulated together (i.e., are intimately associated) (Page 1, [0010]).

Regarding instant claims 21-22, the limitation of the corticosteroid surrounded or encapsulated by the adhesive agent (claim 21) and the limitation of the corticosteroid disposed on the surface of the adhesive agent (claim 22) would have been obvious over the drug microgranules prepared by wet or dry granulating the drug in the presence of one or more ODT binder polymers or drug-layered beads prepared by dissolving or suspending the drug in a solution of one or more drug-layering binders and coating the resulting solution onto inert core particles, as taught by Venkatesh et al. (Page 6, [0060]).

Regarding instant claim 57, the limitation of the ODT further comprising a sugar alcohol, a disintegrant and microcrystalline cellulose would have been obvious over the dosage forms which substantially dissolve or disintegrate in the mouth (Page 12, [0085] and Page 13, [0092]), the corticosteroid fluticasone propionate (Page 1, [0008]), the sugar alcohols mannitol and sorbitol (Page 13, [0086]), the disintegrant cross-linked polyvinylpyrrolidone (Page 13, [0085]), and microcrystalline cellulose (Page 10, [0071]) as taught by Phillips, and by the ODT comprising drug particles and rapidly-dispersing microgranules, wherein the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant, and the drug particles comprise the drug (Page 1, [0007]), and wherein the drug may be a corticosteroid (Page 3, [0029] left hand column), as suggested by Venkatesh et al.

9. Claims **23-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Venkatesh et al. (US 2009/0169620 A1) and further in view of Rawas-Qalaji et al. (US 2007/0059361 A1).

Claim 23 is drawn to the ODT comprising a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.

Phillips and Venkatesh et al. are discussed above.

Phillips and Venkatesh et al. do not expressly teach the ODT comprising a lyophilized matrix.

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

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a corticosteroid such as fluticasone propionate, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., also as taught by Phillips, in view of the orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug such as the corticosteroid beclomethasone wherein the ODT disintegrates in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration

Test procedures, taught by Venkatesh et al., further in view of freeze-dried fast-disintegrating tablets for oral (buccal) administration, as taught by Rawas-Qalaji et al., and produce the instant invention.

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

Regarding instant claims 23-24, the limitation of the lyophilized matrix would have been obvious over the freeze-dried ODTs taught by Rawas-Qalaji et al. (Page 4, [0046] – [0047]). The limitation of the lyophilized matrix comprising the corticosteroid in combination with at least one excipient would have been obvious over the fluticasone propionate, (Page 1, [0008]) and excipients lactose, sucrose, mannitol and sorbitol (Page 13, [0086]) as taught by Phillips; the corticosteroid (Page 3, [0029] left hand column) and excipients including sugar alcohols such as mannitol, xylitol, sorbitol, maltol and maltitol; and saccharides such as lactose, sucrose and maltose, as taught by Venkatesh et al. (Page 5, [0042] – [0043], [0047]).

Regarding instant claims 25-26, the limitation of the wafer or film would have been obvious over the wafer ODTs taught by Rawas-Qalaji et al. (Page 4, [0047]).

Conclusion

10. No claims are allowed.

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

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

12. 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 Thursday from 6:30 am to 5:00 pm.

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

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

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Stephen PERRETT, et al.	Confirmation No.:	8779
Application No.:	12/896,005	Group Art Unit:	1615
Filed:	October 1, 2010	Examiner:	Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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AMENDMENT/RESPONSE TO OFFICE ACTION

This paper responds to the non-final Office Action dated June 6, 2012 for which a period of a response extends through December 6, 2012 with a three-month extension of time that is hereby requested. Thus, this paper is timely filed.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims begin on page 5 of this paper.

Remarks/Arguments begin on page 14 of this paper.

IN THE SPECIFICATION:

Please replace the paragraph beginning on page 2, line 8 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In one embodiment, the present invention is directed to a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds ~~in simulated saliva~~ when tested using the USP <701> Disintegration Test, and/or which disintegrates within 60 seconds when placed in the oral cavity of a human.

Please replace the paragraph beginning on page 7, line 3 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In one embodiment, the present invention provides a solid pharmaceutical composition which comprises less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity, and wherein the solid pharmaceutical composition disintegrates within 60 seconds ~~in simulated saliva~~ when tested using the USP <701> Disintegration Test. In another embodiment, the solid pharmaceutical compositions of the present invention disintegrate within 60 seconds in the oral cavity of the patient, e.g., human. In still other embodiments, the solid pharmaceutical compositions of the present invention disintegrate within 30 seconds ~~in simulated saliva~~ (using the USP <701> Disintegration Test), or in the oral cavity of a patient. In still other embodiments, the solid or liquid pharmaceutical compositions of the present invention topically provide a therapeutically

effective amount of a corticosteroid to inflamed tissues of the gastrointestinal tract, after oral administration to a patient in need thereof.

Please replace the paragraph beginning on page 15, line 10 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In one embodiment, the solid pharmaceutical compositions of the present invention include an adhesive agent. Suitable adhesive agents include sucrose aluminum sulfate complex, chitosan and derivatives thereof (e.g., trimethylchitosan, chitosan salts), polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, Eudragit® polymers (E, L, S, NE, RL, and RS grades), carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked ~~alignate~~ alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

Please replace the paragraph beginning on page 16, line 16 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In another embodiment, pharmaceutical compositions of the present invention include an antiviral agent. Antiviral agents which may be included in the solid pharmaceutical compositions of the present invention include interferons, nucleoside and nucleotide reverse

transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, guanosine analogs, ~~puridine~~ purine analogs, pyrimidine analogs, and other "uncategorized" antiviral drugs recognized in the art which do not fall within any of the above classes (e.g. foscarnet and miltefosine). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abacavir, aciclovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, durunavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate, etravirine, famciclovir, fosamprenavir, ganciclocvir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, loviride, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon α-2a, pegylated interferon α-2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegrvir, ritonavir, ribavirin, rimantadine, rlipivirine, saquinavir, stampidine, stavudine, tenofovir, tipranavir, TNX-355, trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

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 strikethrough and underlining. This listing also reflects any cancellation and/or addition of claims.

1. (Currently amended) A solid pharmaceutical composition comprising less than or equal to about 20 mg of a corticosteroid, wherein the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,

   wherein the solid pharmaceutical composition disintegrates within 60 seconds ~~in simulated saliva fluid~~ when tested using the USP <701> Disintegration Test, and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

2. (Original) The solid pharmaceutical composition of claim 1, wherein said solid pharmaceutical composition disintegrates within 30 seconds.

3. (Original) The solid pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.

4. (Original) The solid pharmaceutical composition of claim 1, further comprising an adhesive agent.

5. (Currently amended) The solid pharmaceutical composition of claim 4, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked

polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked ~~alignate~~ alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

6. (Original) The solid pharmaceutical composition of claim 1, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

7. (Original) The solid pharmaceutical composition of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.

8. (Original) The solid pharmaceutical composition of claim 1, which is substantially free of lubricant.

9. (Original) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.

10. (Original) The solid pharmaceutical composition of claim 9, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.

11. (Original) The solid pharmaceutical composition of claim 10, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.

12. (Original) The solid pharmaceutical composition of claim 1, further comprising at least one antiviral agent.

13. (Currently amended) The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucelotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, ~~puridine~~ purine analogs, pyrimidine analogs, and uncategorized antiviral drugs.

14. (Original) The solid pharmaceutical composition of claim 12, wherein the antiviral agent selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclocvir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.

15. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).

16. (Original) The pharmaceutical composition of claim 15, wherein the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise ~~the~~ corticosteroid, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol and/or saccharide.

17. (Original) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 400 μm, the rapidly dispersing granules have

an average particle size of less than about 300 μm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm.

18. (Currently amended) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 4 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm~~, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm~~.

19. (Currently amended) The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm~~, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm~~.

20. (Original) The pharmaceutical composition of claim 4, wherein the adhesive agent and the corticosteroid are intimately associated.

21. (Original) The pharmaceutical composition of claim 20, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.

22. (Original) The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.

23. (Original) The pharmaceutical composition of claim 16, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.

24. (Original) The pharmaceutical composition of claim 23, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

25. (Original) The pharmaceutical composition of claim 23, wherein the ODT is in the form of a wafer or film.

26. (Original) The pharmaceutical composition of claim 16, wherein the ODT is in the form of a wafer or film.

27. (Currently amended) An orally disintegrating tablet comprising less than or equal to about 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, wherein the orally disintegrating tablet disintegrates within 60 seconds ~~in simulated saliva fluid~~ when tested using the USP <701> Disintegration Test, and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

28. (Currently amended) The orally disintegrating tablet of claim 27, ~~wherein the orally disintegrating tablet~~ that comprises from about ~~0.05-0.3~~ 2 to about 10 mg fluticasone.

29. (Withdrawn) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.

30. (Withdrawn) The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.

31. (Withdrawn) The method of claim 29, wherein said condition is eosinophilic esophagitis.

32. (Withdrawn) The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

33. (Withdrawn) The method of claim 29, wherein said condition is viral or bacterial pharyngitis.

34. (Withdrawn) The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

35. (Withdrawn) A substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid.

36. (Withdrawn) The liquid pharmaceutical composition of claim 35 wherein the liquid is selected from the group consisting of pharmaceutically acceptable alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, ethyl butyrate, dibutyl malonate, tributyl citrate, tri-n-hexyl acetylcitrate, diethyl succinate, diethyl glutarate, diethyl malonate, triethyl citrate, triacetin, tributyrin, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, caprolactam, N,N-diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, 1,3-dimethyl-3,4,5,6-tetrohydro-2(1H)-pyrimidinone, and combinations thereof.

37. (Withdrawn) The liquid pharmaceutical composition of claim 36 wherein the liquid is selected from the group consisting of alcohols, oils; glycols; glycol ethers; pyrrolidones; polyethylene glycols, glycerol and combinations thereof.

38. (Withdrawn) The liquid pharmaceutical composition of claim 37 wherein the liquid is selected from the group consisting of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof.

39. (Withdrawn) The liquid pharmaceutical composition of claim 35, further comprising a phase change agent dissolved or suspended in said liquid, wherein after administration to a patient, said composition undergoes a change in physical properties of the composition upon contact with the gastrointestinal tract of said patient, whereby contact of the corticosteroid with the gastrointestinal tract of the patient is enhanced and/or prolonged.

40. (Withdrawn) The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition precipitates onto the mucosa of the gastrointestinal tract of the patient, whereby deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

41. (Withdrawn) The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition forms a gel on contact with the mucosa of the gastrointestinal tract of the patient, whereby the deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

42. (Withdrawn) The liquid pharmaceutical composition of claim 35, wherein after administration to a patient, said composition increases in viscosity upon contact with the mucosa of the gastrointestinal tract of the patient, whereby the residence time of the corticosteroid on the mucosa of the intestinal tract is prolonged.

43. (Withdrawn) The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a poorly water-soluble polymer.

44. (Withdrawn) The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a thermosensitive polymer whose aqueous viscosity changes in the range of about 15 – 40°C.

45. (Withdrawn – Currently amended) The liquid pharmaceutical composition of claim 39, wherein said phase change agent increases in viscosity upon contact with the fluids of the oropharynx.[.]

46. (Withdrawn) The liquid pharmaceutical composition of claim 39, wherein the phase change agent is a polymer selected from the group consisting of poly(N-isopropylacrylamide), poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol) and mixtures thereof.

47. (Withdrawn) The pharmaceutical composition of claim 35, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, tixocortol, beclomethasone, and salts, solvates, and esters thereof.

48. (Withdrawn) The pharmaceutical composition of claim 41, wherein said liquid is water-miscible and said phase change agent is a bio-gelling polymer having a low water-solubility.

49. (Withdrawn) The pharmaceutical composition of claim 48, wherein said water-miscible solvent is selected from the group consisting of ethanol, isopropyl alcohol, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol, propylene glycol, polyethylene glycol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, and combinations thereof.

50. (Withdrawn) The pharmaceutical composition of claim 48, wherein said bio-gelling polymer is selected from the group consisting of polylactides, polyglycolides, polycaprolactones, polydioxannones, polycarbonates, polyhydroxybutyrates, polyalkyene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, cellulose derivatives, cellulose esters, methacrylic acid and methacrylate polymers, and copolymers, terpolymers and mixtures thereof.

51. (Withdrawn) The pharmaceutical composition of claim 51, wherein said bio-gelling polymer is ethylcellulose.

52. (Withdrawn) The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 50%.

53. (Withdrawn) The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 100%.

54. (Withdrawn) The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 200%.

55. (New) The solid composition of claim 1, formulated for topical administration to the upper gastrointestinal tract.

56. (New) The solid composition of claim 55, wherein the upper gastrointestinal tract is further defined as the esophagus.

57. (New) The pharmaceutical composition of claim 16, wherein the ODT further comprises a sugar alcohol, a disintegrant, and microcrystalline cellulose, wherein the drug particles comprise fluticasone, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol or saccharide or a mixture thereof.

58. (New) The orally disintegrating tablet of claim 27, that comprises from about 0.0 l mg and about 20 mg fluticasone.

59. (New) The solid pharmaceutical composition of claim 1, that comprises from about 0.0 l mg and about 20 mg fluticasone.

60. (New) The solid pharmaceutical composition of claim 1, that comprises from about 2 to about 10 mg fluticasone.

REMARKS

I. Status of the Claims

Claims 1-54 are pending with claims 29-54 withdrawn from consideration as drawn to unelected subject matter. Claims 1, 5, 13, 18, 19, 27, 28, and 45 are amended. New claims 55-60 are added. Support for these amended claims can be found in the specification as originally filed. See, *e.g.*, page 3, lines 9-13 and lines 22-25; page 5, lines 12-19; page 10, lines 10-14 and line 19 through page 11, line 17; page 20, lines 8-9; and page 22, lines 15-18. In addition, two claims are amended to correct typographical errors: claim 5 (correction of "alignate" to "alginate") and claim 13 (correction of "puridine" to "purine"). Further, claims 1 and 27 have been amended to delete the phrase "simulated saliva" which was mistakenly referred to as the testing medium for the USP <701> Disintegration Test as discussed below in Section III. No new matter is added by these amendments. Entry and consideration of the amended claim set is respectfully requested.

II. Interview Summary

Applicants thank Examiner Sasan for the in-person interview conducted with Applicants' representatives Tom Blinka and Tamara Kale on October 24, 2012. Applicants do not disagree with the characterization of the interview as provided in the Interview Summary.

III. Amendment to the Specification

The typographical errors noted above in Section I regarding "alignate" and "puridine" have also been corrected in the Specification.

An obvious error in the Specification regarding the USP <701> Disintegration Test was discovered and is corrected in the amendment submitted herein.

It is standard knowledge that this test is run in the presence of water. See Appendix 1 (*The United States Pharmacopeial Convention,* <701 Disintegration >, August 1, 2008 and comments from the USP website regarding the same). However, at three locations in the Specification, "simulated saliva" is mistakenly referred to as the testing medium. This is corrected herein by amendment.

No new matter is added by this amendment per M.P.E.P. § 2163(I)(B) ("An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.") (internal citation omitted). Entry of the amendment is respectfully requested.

IV. The Obviousness Rejection of Claims 1-22, 27, and 28 Is Overcome

Claims 1-22, 27 and 28 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Publ. Appl. No. 2009/0169620 ("*Venkatesh*") in view of U.S. Publ. Appl. No. 2005/0009848 ("*Brantl*").

As discussed with Examiner Sasan during the October 2012 interview, the presently claimed compositions comprising corticosteroids having no significant systemic glucocorticoid or mineralocorticoid activity after oral administration are useful for the treatment, such as topical treatment, of conditions associated with inflammation of the gastrointestinal tract, particularly the esophagus. See, *e.g.*, Specification, page 1, lines 7-9; page 2, lines 3-6; and page 5, lines 12-19. As the Specification explains, "[t]opical administration of a corticosteroid for conditions associated with inflammation of the gastrointestinal tract is desirable because it results in fewer side-effects than systemic corticosteroid administration." Specification, page 5, lines 14-16; see also the Background of the Invention at pp 1-2 of the Specification.

Venkatesh describes orally disintegrating tablets (ODTs) that may comprise a laundry list of various suitable drugs, including corticosteroids, that are intended for rapid disintegration. See Abstract and paras. [0022] and [0023]. *Venkatesh* does not particularly highlight that drugs should be used relative to whether they have or do not have significant systemic activity. See paras. [0027]-[0030]. Of the corticosteroids listed, only one, beclomethasone, does not have significant systemic activity yet the several other corticosteroids listed do have such activity (*e.g.*, hydrocortisone, prednisone, prednisolone, methylprednisolone, betamethasone, dexamethasone). See para. [0029] (more specifically, page 3, col. 1). *Venkatesh* makes no comment on any preference for choosing corticosteroids from the laundry list, and does not provide direction for selecting beclomethasone in particular from the list of corticosteroids. Accordingly, to the extent *Venkatesh* suggests use of drugs, let alone corticosteroids, *Venkatesh* provides no preference of drugs or even corticosteroids having systemic activity versus those that do not have any systemic activity and if anything, relative to active corticosteroids, it is the systemically acting ones that dominate. These teachings are in contrast to the claimed corticosteroid-containing compositions that exhibit no significant systemic activity.

Furthermore, in contrast to the amended claims, *Venkatesh* does not teach a composition comprising a corticosteroid wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract. Yet the present Specification makes it clear that the compositions, upon administration, deposit corticosteroid topically in the upper gastrointestinal tract. See, *e.g.*, page 5, lines 12-19.

Brantl is primarily directed to oral compositions comprising an antiviral for treatment of inflammatory bowel disease. See Abstract. As a first point, *Brantl* is <u>not</u> directed to ODTs and a

rapid disintegration composition. In addition, *Brantl's* compositions only optionally further comprise a corticosteroid in addition to the antiviral, and fluticasone is mentioned (para. [0065]).

As a second point, as discussed with Examiner Sasan in the October 2012 interview, *Brantl* notes that when employing compositions comprising corticosteroids for oral administration, it is preferable that the dosage form is enterically coated so that the agent dissolves in the intestine and not beforehand. See, *e.g.*, paras. [0033] and [0058] ("These corticosteroids act only topically, i.e., only on the mucosa of the intestine. However, this does not preclude their oral co-administration, as it is possible to prepare oral formulations with a suitable coating that permits release only in the intestine, such as an enteric coating."); see also Example 3. To permit release only in the intestine, *Brantl*'s enteric coatings surround the entire dosage form. That the dosage forms are entirely coated is implied in para. [0058] as well as in Example 3, where the Entocort EC® capsule[1] is employed because budesonide was used in the composition.

A. There Is No Apparent Reason to Combine the Art as Suggested

In view of *Brantl's* teaching for treating the mucosa of the intestine and delay of release of active therefore, Applicants submit that a skilled artisan would find no reason to combine the references in the manner asserted by the Examiner. Only the present invention contemplates the rapid disintegration of a composition exhibiting no significant systemic glucocorticoid or mineralocorticoid activity. The rapidly disintegrating ODT of *Venkatesh* would be taught against by *Brantl's* focus on treating an intestinal bowel disease, particularly when *Brantl's*

[1] Entocort EC® is a capsule that is covered by U.S. Patent No. 5,643,602. See Appendix 2 (District Court of Delaware Filing regarding Entocort EC® litigation, particularly page 3, part C). The enteric coating of Entocort EC® completely encloses the inner, corticosteroid-containing contents. See US '602, col. 6, lines 1-14 and Appendix 2, particularly pp 5-8.

compositions that contain corticosteroids are preferably enterically coated in full and *Venkatesh*'s compositions do not discuss enteric coatings whatsoever. That is, *Brantl's* corticosteroid-containing compositions are fully enterically coated to slow down release of the drug and to assist in targeted release in the intestine; by contrast, *Venkatesh's* corticosteroid-containing compositions are designed for rapid disintegration. Thus, a skilled artisan having *Venkatesh* would not be motivated to import therein the teachings of *Brantl*. This counsels against an obviousness conclusion.[2]

Indeed, if one were to modify *Venkatesh* with the enterically-coated compositions of *Brantl*, the rapid disintegration properties of the *Venkatesh* compositions would be compromised. This further counsels against an obviousness rejection based on a combination of the two.[3]

B. Improper Hindsight Cannot Be Used to Support an Obviousness Rejection

KSR did not change the principle that use of hindsight when assessing claims is impermissible.[4] However, only through improper hindsight knowledge may one arrive at the presently claimed invention based on the cited art. In particular, one would have to: (a) select a corticosteroid out of a large list of optional, equally suitable components of *Venkatesh*'s ODTs despite that reference's emphasis on the sleep aid temazepam; (b) select non-systemically active beclomethasone from the several corticosteroids listed in *Venkatesh* although all other corticosteroids listed are systemically active; (c) turn to *Brantl* for its teaching of a non-

---

[2] *See KSR Int'l Co. v. Teleflex Inc.* 550 U.S. 398, 418 (2007) (there should be an "explicit" analysis regarding "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.") (emphasis added).

[3] See M.P.E.P. § 2143.01(V) ("If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.").

[4] *KSR*, 550 U.S. at 421 (cautioning against hindsight bias distortion in assessing obviousness) (see also *Mintz v. Dietz & Watson*, No. 2010-1341, slip op. at 9, 13 (Fed. Cir., May 30, 2012) (characterizing hindsight as "forbidden" and "prohibited").

systemically active corticosteroid, fluticasone, to substitute for beclomethasone although it is an optional component of yet another large list, despite that reference's emphasis on antivirals; and then (d) disregard *Brantl*'s teachings regarding coating the entire corticosteroid-coated dosage form with an enteric coating despite *Venkatesh*'s lack of enteric coatings. None of the references provide any apparent reason for reading the references in this selective manner and Applicants submit that only with the benefit of improper hindsight can this conclusion be reached.

The foregoing demonstrates there is no apparent reason to combine the cited references such that the obviousness rejection is overcome. Withdrawal of the rejection is therefore respectfully requested.

V. The Obviousness Rejection of Claims 23-26 Is Overcome

Claims 23-26 are rejected under 35 U.S.C. § 103(a) as obvious over *Venkatesh* in view of *Brantl* and further in view of U.S. Publ. Appl. No. 2007/0059361 ("*Rawas-Qalaji*"). *Rawas-Qalaji* is drawn to fast-disintegrating epinephrine tablets for buccal or sublingual administration. See Abstract. *Rawas-Qalaji* is said to supply the teachings of claims 23-26 regarding lyophilized matrices and ODT wafer/films.

Rawas-Qalaji does nothing to address the deficiencies of *Venkatesh* and *Brantl* noted above. For example, this reference fails to mention corticosteroids, much less fluticasone, nor does this reference provide any apparent reason to employ fluticasone in its epinephrine-containing compositions, particularly when epinephrine was chosen by *Rawas-Qalaji* for *e.g.*, anaphylaxis (see, e.g., para. [0009]), a condition not mentioned in either of *Venkatesh* or *Brantl*. Withdrawal of the obviousness rejection is therefore respectfully requested.

VI. The New Claims Are Not Obvious

New claims 55-60 are not obvious in view of the cited art. In particular, Applicants note that claims 55-56 are directed to compositions formulated for topical administration to the upper gastrointestinal tract. Nothing in *Brantl* would suggest that its dosage forms are appropriate for such formulations and indeed, this reference teaches away from such formulations because *Brantl* specifically recommends enteric coatings when corticosteroids are employed in order to target the drug to the intestine. That a reference teaches away is sufficient on its own to defeat a *prima facie* case of obviousness[5], and Applicants therefore submit that no combination of *Venkatesh* and *Brantl* renders these claims obvious.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that no further impediments exist to the allowance of this application and, therefore, requests an indication of allowability. However, the Examiner is requested to call the undersigned if any questions or comments arise.

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.

[5] *See Winner Int'l. Royalty Corp. v. Wang*, 202 F.3d 1340, 1349-50 (Fed. Cir. 2000); see also M.P.E.P. §§ 2141.02 and 2145 (prior art must be considered as a whole, including any disclosure that teaches away from the claimed invention).

Dated: December 6, 2012

Respectfully submitted,
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EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/26/2012	PAPER

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

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

PTOL-90A (Rev. 04/07)

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ARADHANA SASAN*.

(2) *THOMAS BLINKA*.

(3) *TAMARA KALE*.

(4)_____.

Date of Interview: *24 October 2012*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1-28*.

Identification of prior art discussed: *Venkatesh et al. (US 2009/0169620 A1) and Brantl (US 2005/0009848 A1)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Mr. Blinka presented: (i) background information about the composition and its use for a local, topical effect rather than a systemic effect; (ii) arguments regarding Venkatesh - how this reference does not teach that the composition has no systemic activity after oral administration; and (iii) arguments regarding Brantl - although this reference teaches corticosteroids, they are only used as optional components and when they are used they act topically - but only in the intestine. The Examiner inquired if adhesion of the composition was required for the local/topical effect. Mr. Blinka discussed the adhesion in terms of the particles of the composition. Mr. Blinka will consider filing amendments and arguments which reflect the distinguishing features of the composition. Further search and consideration of the claims will be required after amendments and arguments are filed .

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.

☐ Attachment

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

91543 7590 06/06/2012
Cooley LLP
ATTN: Patent Group
777 6th Street, N.W., Suite 1100
Washington, DC 20001

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/06/2012	PAPER

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

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

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *03 April 2011*.

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) *1-54* is/are pending in the application.

5a) Of the above claim(s) *29-54* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-28* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/05/11*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Restriction Response

1. Applicants' provisional election with traverse of Group I (claims 1-28) in the reply filed on April 3, 2012 is acknowledged. The traversal is on the ground(s) that the Examiner has not satisfied the requirements for the restriction requirement among Groups I-III and the Examiner has to prove with specificity that the inventions in the instant application are both independent and distinct to issue a Restriction Requirement. Applicants argue that the Examiner only proffers that the inventions are distinct, and provides not a scintilla of rationale regarding how the inventions are independent.

This is not persuasive because the inventions are independent and distinct, as discussed in the restriction requirement of 01/31/12. The process for using the product as claimed (Invention II) can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast. Inventions I and III are independent and distinct because the claims of Invention I do not require a substantially non-aqueous liquid pharmaceutical composition since they are drawn to a solid pharmaceutical composition.

Applicants argue that the Examiner's allegation that there would be an undue search burden without the Restriction requirement is without merit and the Examiner has not, in fact, provided any definitive (specificities) statement as to why an undue burden would result from the search and examination of the full set of claims, but has only proffered generalities. Applicants submit that search queries should be readily fashionable without an undue burden.

This is not persuasive because not only have the inventions acquired a separate status in the art in view of their different classification and due to their recognized divergent subject matter; the prior art applicable to one invention would not likely be applicable to another invention; and the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. The separate groups recite independent and distinct inventions as further indicated by separate status in the art as products versus methods, and separate searches would be required for each, therefore constituting an undue search burden.

The restriction requirement is still deemed proper and is therefore made FINAL.

2. Applicants' submission (that when the claims directed to the elected invention are in condition for allowance, the nonelected invention(s) that require all the limitations of an allowable claim should be considered for rejoinder) is acknowledged.

3. Claims 29-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

4. Claims 1-28 are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statement (IDS) filed on April 5, 2011 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

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

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

7. Claims **1-22 and 27-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatesh et al. (US 2009/0169620 A1) in view of Brantl (US 2005/0009848 A1).

The claimed invention is a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

Venkatesh et al. teach a solid pharmaceutical composition in the form of an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug, an ODT binder polymer, a sugar alcohol and/or saccharide, and a disintegrant (Abstract,

Page 1, [0002] and [0006] and claims 1-23). The therapeutically effective amount of at least one drug (Page 1, [0006]); 7.5,15, mg of temazepam (Page 4, [0032]); and the corticosteroid beclomethasone (Page 3, [0029] left hand column) are disclosed. The ODT compositions disintegrate in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures (Page 4, [0039], Page 9, [0080] – [0082] and [0085]). ODT binder polymers including polyvinylpyrrolidone (povidone or PVP), methylcellulose and hydroxypropylcellulose are disclosed (Page 4, [0035]). Disintegrants including crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethylcellulose, and low-substituted hydroxypropylcellulose are disclosed (Abstract, Page 5, [0041]). Sugar alcohols such as mannitol, xylitol, sorbitol, maltol and maltitol; and saccharides such as lactose, sucrose and maltose are disclosed (Page 5, [0042] – [0043], [0047]). The lubricant (e.g., magnesium stearate) is not part of the composition, but is used as a processing aid, and is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression (Page 10, [0093]). Antifungal agents including fluconazole, itraconazole, nystatin and voriconazole are disclosed (Page 3, [0029]). Antiviral agents are disclosed (Page 3, [0029]). The ODT comprises drug particles and rapidly-dispersing microgranules, wherein the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant, and the drug particles comprise the drug (Page 1, [0007]). Drug particles have an average particle size of 1-400 µm (Page 6, [0062] and claim 16).

Venkatesh et al. do not expressly teach that the amount of the corticosteroid in the solid pharmaceutical composition is less than or equal to 20 mg and that the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration.

Brantl teaches oral administration of systemically inactive corticosteroids that act exclusively or almost exclusively by the topical route (Page 3, [0033] and Page 6, [0058]) including 3 mg of budesonide (Page 3, [0033]), fluticasone or pharmaceutically acceptable salts thereof (Page 8, [0065]). Antiviral agents including acyclovir, brivudine, famciclovir, ganciclovir, penciclovir, trifluridine, valacyclovir and valgancyclovir are disclosed (Page 3, [0025]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug such as the corticosteroid beclomethasone wherein the ODT disintegrates in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures, taught by Venkatesh et al., in view of the oral administration of systemically inactive corticosteroids that act exclusively or almost exclusively by the topical route including 3 mg of budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both Venkatesh et al. and Brantl disclose the use of corticosteroids in orally

administered dosage forms and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141. One of ordinary skill in the art would be motivated to combine Brantl with Venkatesh et al. in order to reduce the systemic side effects of corticosteroids by using systemically inactive corticosteroids that exert their effect locally, as taught by Brantl (Page 6, [0058]).

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

Regarding instant claims 1 and 27, the limitation of a solid pharmaceutical composition would have been obvious over the solid pharmaceutical composition, i.e., the ODT, as taught by Venkatesh et al. (Abstract and Page 1, [0006]). The limitation of the composition comprising less than or equal to 20 mg of a corticosteroid would have been obvious over the therapeutically effective amount of at least one drug (Page 1, [0006]); 7.5,15, mg temazepam (Page 4, [0032]); and the corticosteroid beclomethasone (Page 3, [0029] left hand column) as taught by Venkatesh et al.; in view of the 3 mg of budesonide, as taught by Brantl (Page 3, [0033]). It is noted that “less than" 20 mg of a corticosteroid includes 0 mg or no corticosteroid. The limitation of the composition having no significant systemic glucocorticoid or mineralocorticoid activity after oral administration would have been obvious over the oral administration of systemically inactive corticosteroids that act exclusively or almost exclusively by the

topical route (Page 3, [0033] and Page 6, [0058]) including budesonide, fluticasone or pharmaceutically acceptable salts thereof (Page 8, [0065]) as taught by Brantl. The limitation of the solid pharmaceutical composition disintegrating within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test would have been obvious over the ODT compositions which disintegrate in about 60 seconds or less or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures, as taught by Venkatesh et al. (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

Regarding instant claim 2, the limitation of the solid pharmaceutical composition disintegrating within 30 seconds would have been obvious over the ODT compositions which disintegrate in about 30 seconds or less on contact with saliva in the buccal cavity, as taught by Venkatesh et al. (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

Regarding instant claim 3, the limitation of the corticosteroid would have been obvious over the corticosteroid beclomethasone, as taught by Venkatesh et al. (Page 3, [0029] left hand column); and by the corticosteroids including budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl (Page 3, [0033], Page 6, [0058] and Page 8, [0065]).

Regarding instant claims 4-5, the limitation of the composition further comprising an adhesive agent would have been obvious over the ODT binder polymers including polyvinylpyrrolidone (povidone or PVP), methylcellulose and hydroxypropylcellulose, as taught by Venkatesh et al. (Page 4, [0035]).

Regarding instant claim 6, the limitation of the composition further comprising a disintegrant would have been obvious over the disintegrants including crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethylcellulose, and low-substituted hydroxypropylcellulose, as taught by Venkatesh et al. (Abstract, Page 5, [0041]).

Regarding instant claim 7, the limitation of the composition further comprising an excipient would have been obvious over the excipients including sugar alcohols such as mannitol, xylitol, sorbitol, maltol and maltitol; and saccharides such as lactose, sucrose and maltose, as taught by Venkatesh et al. (Page 5, [0042] – [0043], [0047]).

Regarding instant claim 8, the limitation of the solid pharmaceutical composition substantially free of lubricant would have been obvious over the lubricant (e.g., magnesium stearate) which is sprayed only into the die cavities and on punch surfaces, wherein the excess is vacuumed off prior to compression, as taught by Venkatesh et al. (Page 10, [0093]) since this lubricant is not part of the composition, but is used as a processing aid.

Regarding instant claims 9-11, the limitation of the solid pharmaceutical composition further comprising at least one antifungal agent would have been obvious over the antifungal agents including fluconazole, itraconazole, nystatin and voriconazole, as taught by Venkatesh et al. (Page 3, [0029]).

Regarding instant claims 12-14, the limitation of the solid pharmaceutical composition further comprising at least one antiviral agent would have been obvious

over the antiviral agents taught by Venkatesh et al. (Page 3, [0029]) and the antiviral agents including acyclovir, brivudine, famciclovir, ganciclovir, penciclovir, trifluridine, valacyclovir and valgancyclovir, as taught by Brantl (Page 3, [0025]).

Regarding instant claim 15, the limitation of the orally disintegrating tablet (ODT) would have been obvious over the ODT, as taught by Venkatesh et al. (Abstract and Page 1, [0006]).

Regarding instant claim 16, the limitation of the ODT comprising drug particles and rapidly dispersing granules would have been obvious over the ODT comprising drug particles and rapidly-dispersing microgranules, wherein the rapidly-dispersing microgranules comprise the sugar alcohol and/or saccharide in combination with the disintegrant, and the drug particles comprise the drug (Page 1, [0007]), and wherein the drug may be the corticosteroid beclomethasone (Page 3, [0029] left hand column), as suggested by Venkatesh et al.; and by the corticosteroids including budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl (Page 3, [0033], Page 6, [0058] and Page 8, [0065]).

Regarding instant claim 17, the limitation of the drug particles having an average particle size of less than about 400 µm would have been obvious over the drug particles having an average particle size of 1-400 µm, as taught by Venkatesh et al. (Page 6, [0062] and claim 16). 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 having an average particle size of 300 µm or less, as taught by Venkatesh et al. (Page 5, [0045]). The limitation of

the disintegrant and sugar alcohol and/or saccharide having an average particle size of less than about 30 µm would have been obvious over the average particle size of the sugar alcohol and/or saccharide having an average particle size of 30 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 18, the limitation of the drug particles having an average particle size of less than about 4 µm would have been obvious over the drug crystals having an average particle size of about 1-25 µm, as taught by Venkatesh et al. (Page 4, [0034]). 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 having an average particle size of 300 µm or less, as taught by Venkatesh et al. (Page 5, [0045]). The limitation of the disintegrant and sugar alcohol and/or saccharide having an average particle size of less than about 30 µm would have been obvious over the average particle size of the sugar alcohol and/or saccharide having an average particle size of 30 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 19, the limitation of the corticosteroid disposed over the surface of an excipient would have been obvious over the drug coated beads and rapidly-dispersing microgranules comprising the sugar alcohol and/or saccharide in combination with the disintegrant (Page 1, [0008]), wherein the rapidly dispersing microgranules have an average particle size of 300 µm or less, and the sugar alcohol and/or saccharide have an average particle size of 30 µm or less, as taught by Venkatesh et al. (Page 5, [0045]).

Regarding instant claim 20, the limitation of the intimately associated adhesive agent and the corticosteroid would have been obvious over the ODT binder polymers including polyvinylpyrrolidone (povidone or PVP), methylcellulose and hydroxypropylcellulose (Page 4, [0035]) and the corticosteroid beclomethasone, as taught by Venkatesh et al. (Page 3, [0029] left hand column); and by the corticosteroids including budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl (Page 3, [0033], Page 6, [0058] and Page 8, [0065]) since Venkatesh et al. teach that the drug and the ODT binder polymer are mixed and granulated together (i.e., are intimately associated) (Page 1, [0010]).

Regarding instant claims 21-22, the limitation of the corticosteroid surrounded or encapsulated by the adhesive agent (claim 21) and the limitation of the corticosteroid disposed on the surface of the adhesive agent (claim 22) would have been obvious over the drug microgranules prepared by wet or dry granulating the drug in the presence of one or more ODT binder polymers or drug-layered beads prepared by dissolving or suspending the drug in a solution of one or more drug-layering binders and coating the resulting solution onto inert core particles, as taught by Venkatesh et al. (Page 6, [0060]).

Regarding instant claim 28, the limitation of the ODT comprising about 0.05-0.3 mg fluticasone would have been obvious over the therapeutically effective amount of at least one drug as taught by Venkatesh et al. (Page 1, [0006]) in view of the fluticasone taught by Brantl (Page 3, [0033], Page 6, [0058] and Page 8, [0065]). One of ordinary skill in the art would find it obvious to determine the therapeutically effective amount of

fluticasone based on the purity of the active ingredient and the concentration of fluticasone in the salt.

8. Claims **23-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatesh et al. (US 2009/0169620 A1) in view of Brantl (US 2005/0009848 A1) and further in view of Rawas-Qalaji et al. (US 2007/0059361 A1).

Claim 23 is drawn to the ODT comprising a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.

Venkatesh et al. and Brantl are discussed above.

Venkatesh et al. and Brantl do not expressly teach the ODT comprising a lyophilized matrix.

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

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug such as the corticosteroid beclomethasone wherein the ODT disintegrates in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures, taught by Venkatesh et al., in view of the oral

administration of systemically inactive corticosteroids that act exclusively or almost exclusively by the topical route including 3 mg of budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl, further in view of freeze-dried fast-disintegrating tablets for oral (buccal) administration, as taught by Rawas-Qalaji et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both Venkatesh et al. and Rawas-Qalaji et al. are drawn to ODTs and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141. One of ordinary skill in the art would have been motivated to prepare the ODT of Venkatesh et al. by freeze-drying or lyophilizing a matrix because they provide fast oral disintegration.

Regarding instant claims 23-24, the limitation of the lyophilized matrix would have been obvious over the freeze-dried ODTs taught by Rawas-Qalaji et al. (Page 4, [0046] – [0047]). The limitation of the lyophilized matrix comprising the corticosteroid in combination with at least one excipient would have been obvious over the corticosteroid beclomethasone, as taught by Venkatesh et al. (Page 3, [0029] left hand column); by the corticosteroids including budesonide, fluticasone or pharmaceutically acceptable salts thereof, as taught by Brantl (Page 3, [0033], Page 6, [0058] and Page 8, [0065]) and the excipients including sugar alcohols such as mannitol, xylitol, sorbitol, maltol and maltitol; and saccharides such as lactose, sucrose and maltose, as taught by Venkatesh et al. (Page 5, [0042] – [0043], [0047]).

Regarding instant claims 25-26, the limitation of the wafer or film would have been obvious over the wafer ODTs taught by Rawas-Qalaji et al. (Page 4, [0047]).

Conclusion

9. No claims are allowed.

10. 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 Thursday from 6:30 am to 5:00 pm.

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/
Examiner, Art Unit 1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Stephen Perrett *et al.*
Serial No.	:	12/896,005
Filed	:	October 1, 2010
For	:	Orally Administered Corticosteroid Compositions
Examiner	:	SASAN, ARADHANA
Art Unit	:	1615
Confirmation No.	:	8779

FILED VIA EFS-WEB
ON APRIL 3, 2012

RESPONSE TO RESTRICTION REQUIREMENT
AND PETITION FOR EXTENSION OF TIME

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

Dear Sirs:

This paper is a response to a Restriction Requirement in an Office Action mailed January 31, 2012, setting a one-month period for reply. Applicants discuss below their election, with traverse, of Group I, which Applicants believe encompasses claims 1-28.

This paper is also a Petition for Extension of Time, for which the Commissioner is hereby authorized to charge any required fee, or to credit any overpayment in fees, to Deposit Account 50-1283.

PETITION FOR EXTENSION OF TIME

Pursuant to the provisions of 37 C.F.R. §1.136(a)(3), Applicants hereby petition for an extension of time of **two (2) months** in responding to the Office Action mailed January 31, 2012. Granting of Applicants' request would serve to extend Applicants' due date from February 29, 2012 to April 30, 2012.

Enclosed is authorization to charge **$560.00** to satisfy the fee for a two (2) month extension of time for a large entity. The Commissioner is hereby authorized to charge any additional fee for this paper that may be required, or credit any overpayment, to Account No. 50-1283.

REMARKS

Reconsideration and withdrawal of the restriction requirement is respectfully requested in view of the remarks herein.

The January 31, 2012, Office Action required restriction to one of the following inventions under 35 USC 121:

Group I: Claims 1-28, drawn to a solid pharmaceutical composition and an orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid, classified in class 424, subclass 464.

Group II: Claims 29-34, drawn to a method for treating an inflammatory condition of the gastrointestinal tract, classified in class 514, subclass 171.

Group III: Claims 35-54, drawn to a substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid, classified in class 514, subclass 167.

The Office Action bases the restriction on the inventions of Groups I and II being distinct as follows:

> Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast.

The Office Action further alleges that

> Inventions I and III are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are mutually exclusive because the claims of Invention I do not require a substantially non-aqueous liquid pharmaceutical composition

> since they are drawn to a solid pharmaceutical composition. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

According to the Office Action,

> Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast.

In addition to the Examiner noting that the inventions were distinct, the Examiner also stated that there would be a serious search and examination burden if restriction were not required.

Applicants traverse the Examiner's restriction requirement and request reconsideration. Applicants submit that the Examiner has not satisfied the requirements for the restriction requirement among Groups I-III. 35 U.S.C. § 121 states that "[i]f two or more independent ***and*** distinct inventions are claimed in one application, the Director **may require** the application to be restricted to one of the inventions ... ". (Emphasis added) Furthermore, 37 C.F .R. § 1.141 states that "[t]wo or more independent ***and*** distinct inventions may not be claimed in one national application ... ". (Emphasis added) Thus, the Examiner has to prove with specificity that the inventions in the instant application are both independent ***and*** distinct to issue a Restriction Requirement. However, in the Office Action, the Examiner only proffers that the inventions are distinct, and provides not a scintilla of rationale regarding how the inventions are independent.

Consequently, as § 121 requires that inventions be both independent ***and*** distinct to support a Restriction Requirement, and the Examiner has failed to show both elements are met, then the Restriction Requirement is improper. In view of the aforesaid, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement.

Applicants also submit that the Examiner's allegation that the there would be an undue search burden without the Restriction requirement is without merit. Applicants submit that the Examiner has not, in fact, provided any definitive (specificities) statement as to why an undue

burden would result from the search and examination of the full set of claims, but has only proffered generalities. According to USPTO classification, Class 514 is an integral part of Class 424 and it incorporates all the definitions and rules as to subject matter of Class 424 (http://www.uspto.gov/web/patents/classification/uspc514/defs514.htm). Applicants submit that search queries should be readily fashionable without an undue burden. Searching for a method of treating an inflammatory condition of the gastrointestinal tract would inevitably include a search for a solid pharmaceutical composition and a substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid. Therefore, it would not place an unnecessary burden on the Examiner to search and examine inventions of groups I, II and III as a whole.

Provisional Group Election

To comply with the Examiner's Restriction Requirement, Applicants provisionally elect, with traverse, Group I, claims 1-28. Applicants also affirm their right to file one or more divisional applications with respect to any other non-elected subject matter.

Rejoinder

Applicants further submit that when the claims directed to the elected invention are in condition for allowance, the nonelected invention(s) that require all the limitations of an allowable claim should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected product invention and a nonelected method of use invention. MPEP 821.04.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement is requested. Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

Respectfully submitted,

By: [signature] Reg. no. 44,541

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12/896,005	10/01/2010	Stephen Perrett	EURA-119/01US 307853-2692	8779

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Washington, DC 20001

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/31/2012	PAPER

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

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

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No.	Applicant(s)	
	12/896,005	PERRETT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☒ Responsive to communication(s) filed on *01 October 2010*.

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) *1-54* 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) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-28, drawn to a solid pharmaceutical composition and an orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid, classified in class 424, subclass 464.

   II. Claims 29-34, drawn to a method for treating an inflammatory condition of the gastrointestinal tract, classified in class 514, subclass 171.

   III. Claims 35-54, drawn to a substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid, classified in class 514, subclass 167.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast.

4. Inventions I and III are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are mutually exclusive because the claims of Invention I do not require a substantially non-aqueous liquid pharmaceutical composition since they are drawn to a solid pharmaceutical composition. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast.

6. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design and mode of operation. The inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

7. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species

8. This application contains claims directed to the following patentably distinct species of inflammatory conditions of the gastrointestinal tract

- Inflammation of the esophagus
- Eosinophilic esophagus
- Inflammation of the glottis, epiglottis, tonsils, or oropharynx
- Viral pharyngitis
- Bacterial pharyngitis
- Gastroesophageal reflux disease (GERD)

- nonerosive reflux disease (NERD)
- erosive esophagitis

If applicant selects Group II, one species of the inflammatory conditions of the gastrointestinal tract (claims 30-34) must be chosen to be fully responsive.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. The etiologies of the conditions as well as the portions of the gastrointestinal tract affected by the conditions are distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

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 on Mon thru Thurs: 6:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. 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/
Examiner, Art Unit 1615

WHAT IS CLAIMED IS:

1. A solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

2. The solid pharmaceutical composition of claim 1, wherein said solid pharmaceutical composition disintegrates within 30 seconds.

3. The solid pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.

4. The solid pharmaceutical composition of claim 1, further comprising an adhesive agent.

5. The solid pharmaceutical composition of claim 4, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alignate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

6. The solid pharmaceutical composition of claim 1, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

7. The solid pharmaceutical composition of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.

8. The solid pharmaceutical composition of claim 1, which is substantially free of lubricant.

9. The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.

10. The solid pharmaceutical composition of claim 9, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.

11. The solid pharmaceutical composition of claim 10, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.

12. The solid pharmaceutical composition of claim 1, further comprising at least one antiviral agent.

13. The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucelotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, puridine analogs, pyrimidine analogs, and uncategorized antiviral drugs.

14. The solid pharmaceutical composition of claim 12, wherein the antiviral agent selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclocvir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.

15. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).

16. The pharmaceutical composition of claim 15, wherein the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol and/or saccharide.

17. The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 400 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm.

18. The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 4 μm, the rapidly dispersing granules have an average particle size of less than about 300 μm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm.

19. The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm.

20. The pharmaceutical composition of claim 4, wherein the adhesive agent and the corticosteroid are intimately associated.

21. The pharmaceutical composition of claim 20, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.

22. The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.

23. The pharmaceutical composition of claim 16, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.

24. The pharmaceutical composition of claim 23, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

25. The pharmaceutical composition of claim 23, wherein the ODT is in the form of a wafer or film.

26. The pharmaceutical composition of claim 16, wherein the ODT is in the form of a wafer or film.

27. An orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, wherein the orally disintegrating tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

28. The orally disintegrating tablet of claim 27, wherein the orally disintegrating tablet comprises about 0.05-0.3 mg fluticasone.

29. A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.

30. The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.

31. The method of claim 29, wherein said condition is eosinophilic esophagitis.

32. The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

33. The method of claim 29, wherein said condition is viral or bacterial pharyngitis.

34. The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

35. A substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid.

36. The liquid pharmaceutical composition of claim 35 wherein the liquid is selected from the group consisting of pharmaceutically acceptable alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone, 2-pyrrolidone,

glycerol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, ethyl butyrate, dibutyl malonate, tributyl citrate, tri-n-hexyl acetylcitrate, diethyl succinate, diethyl glutarate, diethyl malonate, triethyl citrate, triacetin, tributyrin, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, caprolactam, N,N-diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, 1,3-dimethyl-3,4,5,6-tetrohydro-2(1H)-pyrimidinone, and combinations thereof.

37. The liquid pharmaceutical composition of claim 36 wherein the liquid is selected from the group consisting of alcohols, oils; glycols; glycol ethers; pyrrolidones; polyethylene glycols, glycerol and combinations thereof.

38. The liquid pharmaceutical composition of claim 37 wherein the liquid is selected from the group consisting of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof.

39. The liquid pharmaceutical composition of claim 35, further comprising a phase change agent dissolved or suspended in said liquid, wherein after administration to a patient, said composition undergoes a change in physical properties of the composition upon contact with the gastrointestinal tract of said patient, whereby contact of the corticosteroid with the gastrointestinal tract of the patient is enhanced and/or prolonged.

40. The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition precipitates onto the mucosa of the gastrointestinal tract of the patient, whereby deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

41. The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition forms a gel on contact with the mucosa of the gastrointestinal tract of the patient, whereby the deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

42. The liquid pharmaceutical composition of claim 35, wherein after administration to a patient, said composition increases in viscosity upon contact with the mucosa of the

gastrointestinal tract of the patient, whereby the residence time of the corticosteroid on the mucosa of the intestinal tract is prolonged.

43. The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a poorly water-soluble polymer.

44. The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a thermosensitive polymer whose aqueous viscosity changes in the range of about 15 – 40°C.

45. The liquid pharmaceutical composition of claim 39, wherein said phase change agent increases in viscosity upon contact with the fluids of the oropharynx..

46. The liquid pharmaceutical composition of claim 39, wherein the phase change agent is a polymer selected from the group consisting of poly(N-isopropylacrylamide), poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol) and mixtures thereof.

47. The pharmaceutical composition of claim 35, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, tixocortol, beclomethasone, and salts, solvates, and esters thereof.

48. The pharmaceutical composition of claim 41, wherein said liquid is water-miscible and said phase change agent is a bio-gelling polymer having a low water-solubility.

49. The pharmaceutical composition of claim 48, wherein said water-miscible solvent is selected from the group consisting of ethanol, isopropyl alcohol, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol, propylene glycol, polyethylene glycol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, and combinations thereof.

50. The pharmaceutical composition of claim 48, wherein said bio-gelling polymer is selected from the group consisting of polylactides, polyglycolides, polycaprolactones, polydioxannones, polycarbonates, polyhydroxybutyrates, polyalkyene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene

succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, cellulose derivatives, cellulose esters, methacrylic acid and methacrylate polymers, and copolymers, terpolymers and mixtures thereof.

51. The pharmaceutical composition of claim 51, wherein said bio-gelling polymer is ethylcellulose.

52. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 50%.

53. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 100%.

54. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 200%.