UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	02/15/2022	11246828	ELLO-119/06US 342083-3260	9443

58249 7590 01/26/2022

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 31 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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 Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Stephen PERRETT, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi M. Venkatesh, Vandalia, OH;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

ELLODI PHARMACEUTICALS, L.P., Lawrenceville, NJ;

Dr. Falk Pharma Ex. 1049
IPR Petition - USP 10,632,069

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

PTO/SB/08a (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	3,705,172	12-05-1972	Buchel, et al.	
	2.	3,929,768	12-30-1975	Brattsand, et al.	
	3.	4,080,448	03-21-1978	Mirsky	
	4.	4,335,121	06-15-1982	Phillipps, et al.	
	5.	4,363,806	12-14-1982	Bergstrom, et al.	
	6.	4,472,393	09-18-1984	Shapiro	
	7.	5,135,740	08-04-1992	Katz & Cheng	
	8.	5,278,175	01-11-1994	Ray, et al.	
	9.	5,403,893	04-04-1995	Tanaka, et al.	
	10.	5,446,070	08-29-1995	Mantelle, J.A.	
	11.	5,482,934	01-09-1996	Calatyud, et al.	
	12.	5,776,433	07-07-1998	Tzou, et al.	
	13.	6,316,027	11-13-2001	Johnson, et al.	
	14.	6,596,298	07-22-2003	Leung, et al.	
	15.	6,740,332	05-25-2004	Zyck, et al.	
	16.	7,033,606	04-25-2006	Besse, et al.	
	17.	8,580,300	11-12-2013	Wilhelm, et al.	
	18.	8,679,545	03-25-2014	Dohil, et al.	
	19.	8,771,729	07-08-2014	Perrett, et al.	
	20.	9,387,167	07-12-2016	Perrett et al.	
	21.	9,486,407	11-08-2016	Perrett, et al.	
	22.	9,782,347	10-10-2017	Dohil, et al.	
	23.	9,849,084	12-26-2017	Perrett, et al.	
Change(s) applied to document, /P.H./ 11/8/2021	24.	9,867,780	01-16-2018 [8]	Greinwald, et al.	
	25.	10,105,315	10-23-2018	Meltzer, et al.	
	26.	10,176,301	01-08-2019	Hill, et al.	
	27.	10,272,037	04-30-2019	Dohil, et al.	
	28.	10,471,071	11-12-2019	Gosselin, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16821464	17-Mar-2020	Stephen PERRETT	ELLO-119/06US 342083-32	9443

TITLE OF INVENTION :

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	1615	451000	

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$1200	$0	$1200	27-Jan-2022	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
58249 COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington DC 20004 UNITED STATES 202-842-7800 zIPPatentDocketingMailboxUS@cooley.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

○ 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.

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee

☐ I authorize USPTO to apply my previously paid issue fee to the current fees due

☐ Publication Fee

☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____

☐ Advance Order - # of copies _____

☐ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____ . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. COOLEY, LLP
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

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.

Name	City	State	Country	Category
ELLODI PHARMACEUTICALS, L.P.	Lawrenceville	NEW JERSEY	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Jonathan M. Cousin/	**Date**	01-05-2022
Name	Jonathan M. Cousin	**Registration Number**	66418

Electronic Patent Application Fee Transmittal

Application Number:	16821464
Filing Date:	17-Mar-2020
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/Carolina Pimentel
Attorney Docket Number:	ELLO-119/06US 342083-3260

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt

EFS ID:	44669508
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	05-JAN-2022
Filing Date:	17-MAR-2020
Time Stamp:	11:48:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1200
RAM confirmation Number	E202215B48201480
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	62164 e4e5a0e98bd415acf93e116227e9282bf21822ba	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40224 264177bba341e850f74a993708a409fa2d8c8546	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	102388		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

58249 7590 10/27/2021

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

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/27/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US 342083-3260	9443

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/27/2022

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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

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

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

58249 7590 10/27/2021

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

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US 342083-3260	9443

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/27/2022

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

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

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

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

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

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

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

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US ~~342083-3260~~	9443

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

58249 7590 10/27/2021

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

DATE MAILED: 10/27/2021

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 16/821,464	Applicant(s) PERRETT et al.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (FITF) Status No

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

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

1. ☑ This communication is responsive to the Amendments, Remarks, and electronic Terminal Disclaimer filed on 09/23/21.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-2,4-14 and 22-24 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Notice of Pre-AIA or AIA Status

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

Status of Application

2. The Amendments, Remarks, and Terminal Disclaimer filed on 09/23/21 are acknowledged.

3. Claims 3 and 15-21 were previously cancelled.

4. Claims 1 and 2 were amended.

5. Claims 1-2, 4-14, and 22-24 are pending.

Information Disclosure Statement

6. The information disclosure statements (IDS) filed on 09/29/21 and 10/14/21 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements. Please see the attached copies of PTO-1449.

Reasons for Allowance

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

Claim Objections

8. In light of the amendment of claim 1, the objection to this claim is withdrawn.

Claim Rejections - 35 USC § 112

9. In light of the amendment of claim 1 to replace the recitation of "corticosteroid" with "budesonide" the rejection of claim 1 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite, is withdrawn.

Claim Rejections - 35 USC § 103

10. Applicant's arguments (Pages 4-6, filed 09/23/21) regarding the rejection of claims 1-2, 4-14, and 22-24 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Venkatesh et al. (US 2009/0169620 A1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Double Patenting Rejections

11. Applicant's arguments (Page 7, filed 09/23/21) regarding the rejection of claims 1-2, 4-14, and 22-24 on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 6, 9, 15, 22-25, 27, and 36-38 of U.S. Patent No. 10,471,071 B2; and the provisional rejection of claims 1-2, 4-14, and 22-24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 12, 14-15, and 29 of copending Application No. 17/211,119 have been fully considered and are persuasive. Therefore, these double patenting rejections have been withdrawn.

Terminal Disclaimer

12. The electronic terminal disclaimer filed on 09/23/21 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent Numbers 8,771,729; 9,486,407; and 10,632,069 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Updated Search

13. An updated prior art search did not disclose a reference that teaches the limitations of an orally dispersing tablet comprising about 0.5 mg to about 1 mg of

budesonide as recited in the instant claims. Therefore, the claimed invention is novel and unobvious over the prior art of record.

Comments

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

Conclusion

15. Claims **1-2, 4-14,** and **22-24** are allowed.

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

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 or A61K9/08 or A61K31/58 or A61K47/38 or A61K9/0053 or A61K31/56 or A61K9/0056 or A61K9/006 or A61K31/569 or A61K45/06 or A61K9/06 or A61P1/04 or A61P1/00).cpc. with keywords	07/03/2021	AS
(A61K9/0065 or A61K9/08 or A61K31/58 or A61K47/38 or A61K9/0053 or A61K31/56 or A61K9/0056 or A61K9/006 or A61K31/569 or A61K45/06 or A61K9/06 or A61P1/04 or A61P1/00).cpc. with keywords	10/22/2021	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**
(A61K31/569 same A61K2300/00).cpcc. with keywords	07/03/2021	AS

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
Reviewed IDS, prosecution history of related cases - 15816154, 17236295. EAST search - including CPC with keyword, inventor, assignee and applicant name search. SciFinder and Google/NPL searches. Please see the attached history for each search.	07/03/2021	AS
Reviewed IDS, updated EAST search - including CPC with keyword, inventor, assignee and applicant name search. IP.com /NPL search. Please see the attached history for each search.	10/22/2021	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort $4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)).clm.	10/22/2021	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	**Art Unit**
	ARADHANA SASAN	1615

CPC						
Symbol					**Type**	**Version**
A61K	/	9	/	0065	F	2013-01-01
A61K	/	9	/	0056	I	2013-01-01
A61K	/	9	/	006	I	2013-01-01
A61K	/	31	/	569	I	2013-01-01
A61K	/	45	/	06	I	2013-01-01
A61K	/	9	/	0053	I	2013-01-01
A61K	/	31	/	56	I	2013-01-01
A61K	/	9	/	08	I	2013-01-01
A61K	/	31	/	58	I	2013-01-01
A61K	/	47	/	38	I	2013-01-01
A61K	/	9	/	06	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	569	I	1	1	2013-01-01
A61K	/	2300	/	00	I	1	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	22 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20211022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	**Art Unit**
	ARADHANA SASAN	1615

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K9/00	/	9	/	00
A61K31/569	/	31	/	569
A61K45/06	/	45	/	06
A61K31/56	/	31	/	56
A61K9/08	/	9	/	08
A61K31/58	/	31	/	58
A61K47/38	/	47	/	38
A61K9/06	/	9	/	06

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCE(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 16	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	22 October 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office

Part of Paper No.: 20211022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	**Art Unit**
	ARADHANA SASAN	1615

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	22 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	4,985,418	01-15-1991	Richards	
	2.	11,026,887	06-08-2021	Meltzer, et al.	
	3.	2004/0228919 A1	11-18-2004	Houghton, et al.	
	4.	2006/0292099 A1	12-28-2006	Milburn, et al.	
	5.	2021/0205328 A1	07-08-2021	Gosselin, et al.	
	6.	2021/0244660 A1	08-12-2021	Perrett, et al.	
	7.	2021/0275438 A1	09-09-2021	Meltzer, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	8.	JP 2013-506683 A (and English Abstract)	02-28-2013	Perrett, et al.		
	9.	WO 2021/067585 A1	04-08-2021	ADARE PHARMACEUTICALS US, L.P.		

Examiner Signature		Date Considered	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

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Sheet 2 of 2

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	10.	DALEY-YATES, Peter T. "Inhaled corticosteroids: potency, dose equivalence and therapeutic index." British Journal of Clinical Pharmacology (2015); 80(3): 372-380.	
	11.	FURUTA, Glenn T., et al. "Eosinophilic esophagitis in children and adults: a systematic review and consensus recommendations for diagnosis and treatment: sponsored by the American Gastroenterological Association (AGA) Institute and North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition." Gastroenterology (2007); 133(4): 1342-1363.	
	12.	MARTIN, et al., "Pediatric Eosinophilic Esophagitis Symptom Scores (PEESS® v2.0) identify histologic and molecular correlates of the key clinical features of disease". J Allergy Clin Immunol. (2015 June); 135(6): 1519-1528.e8.	
	13.	NISHIMURA, S., et al. "Factors associated with esophageal candidiasis and its endoscopic severity in the era of antiretroviral therapy." PLoS One (2013); 8(3): e58217, 6pgs.	
	14.	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	
	15.	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	
	16.	SCHOEPFER, et al., "Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis". Gastroenterology (2014 Dec 1); 147(6): 1255-1266.	
	17.	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	
	18.	TAFT, et al., "The adult eosinophilic oesophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	
	19.	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	10/22/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Sheet 1 of 1

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Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Ellodi Pharmaceuticals, L.P.'s Written Submission in Preparation for Oral Proceedings on December 8, 2021 with new Auxiliary Requests 1-3, dated October 8, 2021, 51 pages.	
	2.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	
	3.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication - Minutes of Oral Proceeding, dated August 25, 2021, 11 pages.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	10/22/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

16821464

Report Run Date: 2021-10-22 UTC
Queries: 3
Markers: 0

Query #	Timestamp	Results	Page
1	2021-10-22 19:17 UTC	77,519	3
2	2021-10-22 19:18 UTC	13,720	4
3	2021-10-22 19:18 UTC	5299	4

Content: Patents + NPL (187)

US Patents | US Designs | US Applications | EPO Patents | EPO Applications | China Patents | China Applications | Japan Patents | Japan Applications | Korea Patents | Korea Applications | WIPO Applications | Argentina Patents | Argentina Applications | Brazil Patents | Brazil Applications | Canada Patents | Canada Applications | Chile Patents | Chile Applications | Colombia Applications | Costa Rica Applications | Cuba Patents | Cuba Applications | Dominican Republic Applications | Ecuador Patents | Ecuador Applications | El Salvador Applications | Guatemala Applications | Honduras Applications | Mexico Patents | Mexico Applications | Nicaragua Patents | Panama Applications | Peru Applications | Trinidad & Tobago Patents | Uruguay Applications | Austria Patents | Austria Applications | Belarus Patents | Belgium Patents | Belgium Applications | Bosnia & Herzegovina Patents | Bosnia & Herzegovina Applications | Bulgaria Patents | Bulgaria Applications | Croatia Patents | Croatia Applications | Czech Republic Patents | Czech Republic Applications | Czechoslovakia Patents | Czechoslovakia Applications | Denmark Patents | Denmark Applications | Estonia Patents | Estonia Applications | EUIPO Patents | Finland Patents | Finland Applications | France Patents | France Applications | Germany Patents | Germany Applications | Great Britain Patents | Great Britain Applications | Greece Patents | Greece Applications | Hungary Patents | Hungary Applications | Iceland Patents | Iceland Applications | Ireland Patents | Ireland Applications | Italy Patents | Italy Applications | Latvia Patents | Latvia Applications | Lithuania Patents | Lithuania Applications | Luxembourg Patents | Malta Patents | Monaco Patents | Montenegro Patents | Montenegro Applications | Netherlands Patents | Netherlands Applications | Norway Patents | Norway Applications | Poland Patents | Poland Applications | Portugal Patents | Portugal Applications | Republic of Moldova Patents | Republic of Moldova Applications | Romania Patents | Romania Applications | San Marino Patents | San Marino Applications | Serbia Patents | Serbia Applications | Slovakia Patents | Slovakia Applications | Slovenia Patents | Spain Patents | Spain Applications | Sweden Patents | Sweden Applications | Switzerland Patents | Switzerland Applications | Ukraine Patents | Yugoslavia/Serbia and Montenegro Patents | Yugoslavia/Serbia and Montenegro Applications | Armenia Patents | Australia Patents | Australia Applications | Cyprus Patents | Gulf Cooperation Council Patents | Hong Kong Patents | India Patents | India Applications | Indonesia Patents | Indonesia Applications | Israel Applications | Jordan Patents | Kyrgyzstan Patents | Macao Applications | Malaysia Patents | Mongolia Patents | New Zealand Patents | Philippines Patents | Philippines Applications | Saudi Arabia Patents | Singapore Patents | Singapore Applications | Taiwan Patents | Taiwan Applications | Tajikistan Patents | Tajikistan Applications | Thailand Applications | Uzbekistan Patents | Vietnam Patents | Algeria Patents | ARIPO Patents | ARIPO Applications | Egypt Patents | Kenya Patents | Malawi Patents | Morocco Patents | Morocco Applications | OAPI Patents | South Africa Patents | Tunisia Applications | Zambia Patents | Zimbabwe Patents | EAPO Patents | EAPO Applications | Georgia Patents | Georgia Applications | Kazakhstan Patents | Kazakhstan Applications | Russia Patents | Russia Applications | Turkey Patents | Turkey Applications | IEEE Xplore Publications: IEEE Periodicals | IEEE Xplore Publications: IEEE Conferences | IEEE Xplore Publications: IEEE Standards | IEEE Xplore Publications: IEEE Early Access | IEEE Xplore Publications: SMPTE Periodicals | IEEE Xplore Publications: SMPTE Conferences | IEEE Xplore Publications: SMPTE Standards | IEEE Xplore Publications: MIT Press eBooks | IEEE Xplore Publications: Wiley-IEEE eBooks | IEEE Xplore Publications: IBM Periodicals | IEEE Xplore Publications: URSI Periodicals | IEEE Xplore Publications: VDE Conferences | IEEE Xplore Publications: Periodicals from China | IP.com Prior Art Database: The IP.com Journal | IP.com Prior Art Database: Internet Society RFC | IP.com Prior Art Database: IBM TDB Archive | IP.com Prior Art Database: Legacy Journals | IP.com Prior Art Database: Software Patent Institute | OnePetro.org: Periodicals at OnePetro.org | OnePetro.org: Conferences at OnePetro.org | Other Literature: IBM Redbooks | Other Literature: PubMed Central | Other Literature: arXiv.org

1 **2021-10-22 19:17 UTC | 77,519 results from**

De-Dup: None | **Cut-off:** None | **Sort:** Relevance

Main Concept: Text
orally dispersing tablet with budesonide

Concept Modifiers: None

Filters: None

2 **2021-10-22 19:18 UTC | 13,720 results from**

De-Dup: None | **Cut-off:** None | **Sort:** Relevance

Main Concept: Same as Query 1

Concept Modifiers: None

Filters (1):
Classic Syntax limited to: topically deposited

3 **2021-10-22 19:18 UTC | 5299 results from**

De-Dup: None | **Cut-off:** None | **Sort:** Relevance

Main Concept: Same as Query 1

Concept Modifiers: None

Filters (2):
Classic Syntax limited to: topically deposited
Classic Syntax limited to: upper gastrointestinal tract

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

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[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[X] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[X] a final action under 37 C.F.R. §1.113;

[X] a notice of allowance under 37 C.F.R. §1.311; or

[X] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[X] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

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[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

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[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-162/01US	16/968,711	8/10/2020	US 2020 -0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-144/04US	17/211,119	3/4/2021	US 2021-0205328 A1	7/8/2021			Pending
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
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ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
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/ARADHANA SASAN/ 10/22/2021

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Application No.: 16/821,464 **Docket No.:** ELLO-119/06US 342083-3260

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: September 29, 2021

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

/ARADHANA SASAN/ 10/22/2021

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

VIA EFS
Commissioner for Patents
P.O. Box 1450
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ELLO-162/01US	16/968,711	8/10/2020	US 2020 - 0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
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ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

/ARADHANA SASAN/ 10/22/2021

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Application No.: 16/821,464 **Docket No.:** ELLO-119/06US 342083-3260

Remarks

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The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: October 14, 2021

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

/ARADHANA SASAN/ 10/22/2021

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S330	42	(US-20140303131-$ or US-20050009848-$ or US-20070059361-$ or US-20090123550-$ or US-20090131386-$ or US-20090169620-$ or US-20040053902-$ or US-20090123551-$ or US-20050112188-$ or US-20090149433-$ or US-20170071855-$ or US-20140187523-$ or US-20160206627-$ or US-20180153802-$ or US-20060051414-$ or US-20070111978-$ or US-20180133145-$ or US-20030099701-$ or US-20110097401-$ or US-20090191275-$ or US-20030050312-$ or US-20190008760-$ or US-20160078186-$ or US-20170183719-$ or US-20200016171-$ or US-20200214979-$).did. or (US-5403893-$ or US-4080448-$ or US-4363806-$ or US-5776433-$ or US-5135740-$ or US-9387167-$ or US-8679545-$ or US-9486407-$ or US-9849084-$ or US-10105315-$ or US-8580300-$ or US-9867780-$ or US-10176301-$ or US-10471071-$ or US-10272037-$ or US-9782347-$).did.	US-PGPUB; USPAT	OR	ON	2021/08/06 09:51
S331	1	"10632069".pn.	USPAT	OR	ON	2021/08/06 09:52
S332	7	("11026887" | "20040228919" | "20060292099" | "20210205328" | "20210244660" | "20210275438" | "4985418").PN.	US-PGPUB; USPAT	OR	ON	2021/10/22 15:11
S333	923,107	(A61K9/0065 or A61K9/08 or A61K31/58 or A61K47/38 or A61K9/0053 or A61K31/56 or A61K9/0056 or A61K9/006 or A61K31/569 or A61K45/06 or A61K9/06 or A61P1/04 or A61P1/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S334	512	(A61K31/569 same A61K2300/00).cpcc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/10/22 15:14

			DERWENT; IBM_TDB			
S335	923,107	S333 S334	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S336	21	S335 and (("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S337	4	("ELLODI").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S338	76	("EURAND").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S339	69	("APTALIS").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S340	69	("ADARE").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S341	186	((("PERRETT") near3 ("Stephen")) OR (("COHEN") near3 ("Fredric")) OR (("VENKATESH") near3 ("Gopi"))).INV,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S342	295	S337 S338 S339 S340 S341	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S343	11	S342 and (("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14

S344	5	S342 and ((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/22 15:14
S345	5	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S346	21	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S347	2	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute) same (sucralose splenda$4 mannitol osmitrol bronchitol (magnesium near2 stearate) (polyvinyl near2 pyrrolidone) polyvinylpyrrolidone PVP povidone PEG (polyethylene near2 glycol) polyethyleneglycol (poly near2 ethylene near2 glycol) (poly near2 ethyleneglycol)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/22 15:14
S348	21	(("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8	US-PGPUB; USPAT;	OR	ON	2021/10/22 15:15

		disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			

10/22/2021 3:53:47 PM
C:\Users\asasan\Documents\EAST\Workspaces\16 series\16800000\16820000\16821464.wsp

PTO/SB/08b (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Ellodi Pharmaceuticals, L.P.'s Written Submission in Preparation for Oral Proceedings on December 8, 2021 with new Auxiliary Requests 1-3, dated October 8, 2021, 51 pages.	
	2.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	
	3.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication - Minutes of Oral Proceeding, dated August 25, 2021, 11 pages.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal	
Application Number:	16821464
Filing Date:	17-Mar-2020
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/Sandra Laramore
Attorney Docket Number:	ELLO-119/06US 342083-3260

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt

EFS ID:	44029667
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	14-OCT-2021
Filing Date:	17-MAR-2020
Time Stamp:	17:24:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$260
RAM confirmation Number	E20210DH25124455
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119-06US-IDS.pdf	147448 d3f28252819b6a1e9b4be5f4b6c64f650354 6c00	no	5
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08.pdf	130772 31cb68350983dbfd65519eef328aef83215a e4e2	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	Oppn_3041476_Ellodis_Written_Submissions_10-08-2021_51_pages.pdf	5858302 0a774831375642f5654c7aea93cf25b6ae9d c0b9	no	51
Warnings:					
Information:					
4	Non Patent Literature	Oppn_2482822_EPO_Decision_revoking_EP2482822_08-25-2021_23_pgs.pdf	2777628 06ff34943480fd9b8360ada961a557c3e620 3feb	no	23
Warnings:					
Information:					
5	Non Patent Literature	Oppn_2482822_EPOs_Comm_Minutes_of_Oral_Proceedings_08-25-2021_11_pgs.pdf	912128 3be4cad3e24ae37e3367887cd98171853da 99096	no	11
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38003 a6d6acd3648c7c0a0db8f5a8b8dde3e7467 31ca4	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	9864281

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[X] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[X] a final action under 37 C.F.R. §1.113;

[X] a notice of allowance under 37 C.F.R. §1.311; or

[X] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[X] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-144/04US	17/211,119	3/4/2021	US 2021-0205328 A1	7/8/2021			Allowed
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Allowed
ELLO-162/01US	16/968,711	8/10/2020	US 2020 - 0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: October 14, 2021

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

PTO/SB/08a (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	4,985,418	01-15-1991	Richards	
	2.	11,026,887	06-08-2021	Meltzer, et al.	
	3.	2004/0228919 A1	11-18-2004	Houghton, et al.	
	4.	2006/0292099 A1	12-28-2006	Milburn, et al.	
	5.	2021/0205328 A1	07-08-2021	Gosselin, et al.	
	6.	2021/0244660 A1	08-12-2021	Perrett, et al.	
	7.	2021/0275438 A1	09-09-2021	Meltzer, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	8.	JP 2013-506683 A (and English Abstract)	02-28-2013	Perrett, et al.		
	9.	WO 2021/067585 A1	04-08-2021	ADARE PHARMACEUTICALS US, L.P.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08b (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	10.	DALEY-YATES, Peter T. "Inhaled corticosteroids: potency, dose equivalence and therapeutic index." British Journal of Clinical Pharmacology (2015); 80(3): 372-380.	
	11.	FURUTA, Glenn T., et al. "Eosinophilic esophagitis in children and adults: a systematic review and consensus recommendations for diagnosis and treatment: sponsored by the American Gastroenterological Association (AGA) Institute and North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition." Gastroenterology (2007); 133(4): 1342-1363.	
	12.	MARTIN, et al., "Pediatric Eosinophilic Esophagitis Symptom Scores (PEESS® v2.0) identify histologic and molecular correlates of the key clinical features of disease". J Allergy Clin Immunol. (2015 June); 135(6): 1519-1528.e8.	
	13.	NISHIMURA, S., et al. "Factors associated with esophageal candidiasis and its endoscopic severity in the era of antiretroviral therapy." PLoS One (2013); 8(3): e58217, 6pgs.	
	14.	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	
	15.	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	
	16.	SCHOEPFER, et al., "Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis". Gastroenterology (2014 Dec 1); 147(6): 1255-1266.	
	17.	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	
	18.	TAFT, et al., "The adult eosinophilic oesophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	
	19.	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JONATHAN COUSIN
COOLEY LLP
1299 PENNSYLVANIA AVENUE, N.W.
SUITE 700
WASHINGTON, DC 20004-2400

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 08 JAN 2021
Applicant's or agent's file reference ADAR-16702WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 20/53778	International filing date *(day/month/year)* 01 October 2020 (01.10.2020)
Applicant ADARE PHARMACEUTICALS US, L.P.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
ADAR-16702WO		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 20/53778	01 October 2020 (01.10.2020)	01 October 2019 (01.10.2019)
Applicant ADARE PHARMACEUTICALS US, L.P.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 9

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/53778

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-51, 55-102
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/53778

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61K 31/56; A61K 39/395; A61K 45/06 (2020.01)

CPC - A61K 31/56; A61K 39/395; A61K 39/3955; A61K 45/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0133145 A1 (Adare Pharmaceuticals, Inc.) 17 May 2018 (17.05.2018) entire document especially Para [0019]; Para [0232]; Para [0234]; Para [0240]; Para [0298]; Para [0486]	1-3 and 52-54
A	US 2012/0164080 A1 (Hill et al.) 28 June 2012 (28.06.2012) entire document	1-3 and 52-54
A	US 9,849,084 B2 (ADARE PHARMACEUTICALS ,INC) 26 December 2017 (26.12.2017) entire document	1-3 and 52-54
A	US 8,679,545 B2 (Dohil et al.) 25 March 2014 (25.03.2014) entire document	1-3 and 52-54
A	WO 2019/165138 A1 (ADARE DEVELOPMENT I, L.P) 29 August 2019 (29.08.2019) entire document)	1-3 and 52-54

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 November 2020	08 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: JONATHAN COUSIN
COOLEY LLP
1299 PENNSYLVANIA AVENUE, N.W.
SUITE 700
WASHINGTON, DC 20004-2400

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	08 JAN 2021
Applicant's or agent's file reference	**FOR FURTHER ACTION**
ADAR-16702WO	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 20/53778	01 October 2020 (01.10.2020)	01 October 2019 (01.10.2019)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61K 31/56; A61K 39/395; A61K 45/06 (2020.01)

CPC - A61K 31/56; A61K 39/395; A61K 39/3955; A61K 45/06

Applicant ADARE PHARMACEUTICALS US, L.P.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	30 November 2020	Lee Young PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Form PCT/ISA/237 (Box No. I) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-51, 55-102

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4-51, 55-102 are so unclear that no meaningful opinion could be formed *(specify)*:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 4-51, 55-102

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

Form PCT/ISA/237 (Box No. III) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-3 and 52-54	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-3 and 52-54	NO
Industrial applicability (IA)	Claims	1-3 and 52-54	YES
	Claims	None	NO

2. Citations and explanations:
Claims 1-3 and 52-54 lack an inventive step under PCT Article 33(3) as being obvious over US 2018/0133145 A1 to Adare Pharmaceuticals, Inc. (hereinafter "Adare").

Regarding claim 1, Adare teaches a method of treating eosinophilic esophagitis (EoE) in a patient in need thereof (Para [0232] "Primary Objectives: To evaluate the efficacy of fluticasone propionate oral disintegrating tablet (APT-1011) in adolescents and adults with eosinophilic esophagitis (EoE)") comprising orally administering to the patient about 0.5 mg to about 5 mg of fluticasone propionate (Para [0234] "This is a randomized , double - blind , placebo - controlled dose ranging study of three daily doses (1.5 mg , 3 mg , and 6 mg) of APT-1011 administered as 1.5 mg HS", where HS indicates once daily administration at bedtime), or an equipotent dose of a corticosteroid, once daily for at least 12 weeks (Para [0240] "Subjects will be treated for 12 weeks"), but does not disclose wherein during said 12 weeks: a. the patient's risk of candidiasis is less than about 10%, and b. the patient shows an improvement in at least one of the following outcomes compared to a patient that is administered the corticosteroid twice daily: i. at least one symptom score measured using a patient reported outcome symptom evaluation (PROSE) instrument after an episode of dysphagia; ii. EoE Endoscopic Reference (EREFS) score; iii. EoE Activity Index (EEsAI) avoidance, modification, and slow swallowing (AMS) score; iv. Global EoE score; v. Patient global impression of severity (PGIS); and vi. Patient global impression of change (PGIC), wherein the total daily dose for the twice daily administration and the once daily administration are the same. However, Adare discloses that candidiases will be considered an adverse event of special interest in the study (Para [0486] "Oral and esophageal candidiasis will however be considered AEs of special interest"). Furthermore, Adare discloses a separate study involving the administration of a total daily dose that is the same of once daily and twice daily administration (Para [0298] "METHODS : Subjects were randomized 1:1:1 to receive either APT-1011 1.5 mg BID [BID] (n = 8) , APT-1011 3.0 mg QD [QD] (n = 8) , or PBO (n = 8)") and that following treatment, scores in EesAI and EREFS improve (Para [0019] "after 12 weeks of daily administration of the oral corticosteroid, esophageal inflammation is reduced as measured by a reduction in eosinophil count, an increase in dysphagia-free days, a reduction in episodes of dysphagia, improvement in EREFS score, EndoFLIP documentation of improved esophageal compliance, evaluation of biomarkers, a decrease in episodes of food impaction, an improvement in EEsAI scores (patient, physician, endoscopy, pathology scores)"). It would have been obvious to one of skill in the art to identify wherein during said 12 weeks: a. the patient's risk of candidiasis is less than about 10%, and b. the patient shows an improvement in at least one of the following outcomes compared to a patient that is administered the corticosteroid twice daily: i. at least one symptom score measured using a patient reported outcome symptom evaluation (PROSE) instrument after an episode of dysphagia; ii. EoE Endoscopic Reference (EREFS) score; iii. EoE Activity Index (EEsAI) avoidance, modification, and slow swallowing (AMS) score; iv. Global EoE score; v. Patient global impression of severity (PGIS); and vi. Patient global impression of change (PGIC), wherein the total daily dose for the twice daily administration and the once daily administration are the same by routine experimentation.

Regarding claim 2, Adare teaches the method of any of the preceding claims, wherein 1.5 mg or 3.0 mg of fluticasone propionate, or an equipotent dose of a corticosteroid, is administered (Para [0234] "This is a randomized , double - blind , placebo - controlled dose ranging study of three daily doses (1.5 mg , 3 mg , and 6 mg) of APT-1011 administered as 1.5 mg HS", where HS indicates once daily administration at bedtime).

Regarding claim 3, Adare teaches the method of claim 1 or 2, wherein fluticasone propionate or the corticosteroid is administered at bedtime or at nighttime (Para [0234] "This is a randomized , double - blind , placebo - controlled dose ranging study of three daily doses (1.5 mg , 3 mg , and 6 mg) of APT-1011 administered as 1.5 mg HS", where HS indicates once daily administration at bedtime).

******** Continued on Supplemental Page ********

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Box V.2 Continued

Regarding claim 52, Adare teaches a method of treating eosinophilic esophagitis (EoE) in a patient in need thereof (Para [0232] "Primary Objectives: To evaluate the efficacy of fluticasone propionate oral disintegrating tablet (APT-1011) in adolescents and adults with eosinophilic esophagitis (EoE)") comprising orally administering to the patient about 0.5 mg to about 5 mg of fluticasone propionate (Para [0234] "This is a randomized , double - blind , placebo - controlled dose ranging study of three daily doses (1.5 mg , 3 mg , and 6 mg) of APT-1011 administered as 1.5 mg HS", where HS indicates once daily administration at bedtime), or an equipotent dose of a corticosteroid, once daily for at least 12 weeks (Para [0240] "Subjects will be treated for 12 weeks"), but does not disclose wherein during said 12 weeks: a. the patient's risk of candidiasis is less than about 10%, and b. the patient shows an improvement in at least one of the following outcomes compared to a patient that is administered the corticosteroid twice daily: i. at least one symptom score measured using a patient reported outcome symptom evaluation (PROSE) instrument after an episode of dysphagia; ii. EoE Endoscopic Reference (EREFS) score; iii. EoE Activity Index (EEsAI) avoidance, modification, and slow swallowing (AMS) score; iv. Global EoE score; v. Patient global impression of severity (PGIS); and vi. Patient global impression of change (PGIC). However, Adare discloses that candidiases will be considered an adverse event of special interest in the study (Para [0486] "Oral and esophageal candidiasis will however be considered AEs of special interest"). Furthermore, Adare discloses that following treatment, scores in EesAI and EREFS improve (Para [0019] "after 12 weeks of daily administration of the oral corticosteroid, esophageal inflammation is reduced as measured by a reduction in eosinophil count, an increase in dysphagia-free days, a reduction in episodes of dysphagia, improvement in EREFS score, EndoFLIP documentation of improved esophageal compliance, evaluation of biomarkers, a decrease in episodes of food impaction, an improvement in EEsAI scores (patient, physician, endoscopy, pathology scores)"). It would have been obvious to one of skill in the art to identify wherein during said 12 weeks: a. the patient's risk of candidiasis is less than about 10%, and b. the patient shows an improvement in at least one of the following outcomes compared to a patient that is administered the corticosteroid twice daily: i. at least one symptom score measured using a patient reported outcome symptom evaluation (PROSE) instrument after an episode of dysphagia; ii. EoE Endoscopic Reference (EREFS) score; iii. EoE Activity Index (EEsAI) avoidance, modification, and slow swallowing (AMS) score; iv. Global EoE score; v. Patient global impression of severity (PGIS); and vi. Patient global impression of change (PGIC) by routine experimentation.

Regarding claim 53, Adare teaches the method of claim 52, but does not disclose wherein the total daily dose for the twice daily administration and the once daily administration are the same. However, Adare discloses a separate study involving the administration of a total daily dose that is the same of once daily and twice daily administration (Para [0298] "METHODS : Subjects were randomized 1:1:1 to receive either APT-1011 1.5 mg BID [BID] (n = 8) , APT-1011 3.0 mg QD [QD] (n = 8) , or PBO (n = 8)"). It would have been obvious to one of skill in the art to identify wherein the total daily dose for the twice daily administration and the once daily administration are the same by routine experimentation.

Regarding claim 54, Adare teaches the method of claim 52, wherein the total daily dose for twice daily administering is more than the total daily dose for the once daily administration (Para [0234] "This is a randomized , double - blind , placebo - controlled dose ranging study of three daily doses (1.5 mg , 3 mg , and 6 mg) of APT-1011 administered as 1.5 mg HS, 1.5 mg BID, or 3.0 mg BID compared to matching placebo", where HS indicates once daily administration at bedtime and BID indicates twice daily).

Claims 1-3 and 52-54 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

Electronic Patent Application Fee Transmittal

Application Number:	16821464
Filing Date:	17-Mar-2020
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/Sandra Laramore
Attorney Docket Number:	ELLO-119/06US 342083-3260

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt

EFS ID:	43904412
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	29-SEP-2021
Filing Date:	17-MAR-2020
Time Stamp:	17:33:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$260
RAM confirmation Number	E20219SH34452439
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119-06US-IDS.pdf	147451 4665ede9cf9e5371e0887ce975185cd967f915d1	no	5
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08.pdf	196711 f4ca2e9540608537fffc609fb0d59159507099c5	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	JP2013506683A_andEnglishAbstract.pdf	21801638 e8334ed91950577bd626c6dbf2b7c149ab0d7f4b	no	30
Warnings:					
Information:					
4	Foreign Reference	WO2021067585A1.pdf	1212506 1e216ff2f58b6e67b996b781951cbbb9d8287813	no	81
Warnings:					
Information:					
5	Non Patent Literature	DALEY-YATES_2015.pdf	10183523 823a9ad543e20e6e0910245b6d0dc7d1d62df8f2	no	9
Warnings:					
Information:					
6	Non Patent Literature	FURUTA_2007.pdf	25612279 8d5bb5a2de4f4c2db819f3d15dd68fbdc20d639e	no	22
Warnings:					

Information:					
7	Non Patent Literature	MARTIN-J_Allergy_Clin_Immunol_2015.pdf	17240224 285c613ab6765a583b4bae87d4e8d2ca0c3d939c	no	22
Warnings:					
Information:					
8	Non Patent Literature	NISHIMURA_2013.pdf	6582107 c3f5e9b890a5317e6c103c8a6ba54a65d64a5032	no	6
Warnings:					
Information:					
9	Non Patent Literature	PCTUS2020053778_ISR-and-WO.pdf	1177818 803b1ae3eb7c7cdeea139cfe23cd0123903cd966	no	9
Warnings:					
Information:					
10	Non Patent Literature	RATNAPARKHI-Review_On_Fast_Dissolving_Tablet-J_Pharm_Res_2009.pdf	7853067 e52e7d0bb04337e5d172bbcdc733b933f8397bf0	no	8
Warnings:					
Information:					
11	Non Patent Literature	SCHOEPFER-Gastroenterology_2014.pdf	7608370 ece122a0887077e55d731684a573ff73f0207e15	no	33
Warnings:					
Information:					
12	Non Patent Literature	SINGH_2014.pdf	4454480 207a19ee5977d82ed45b67bf7c3ab43b7f45d2e7	no	5
Warnings:					
Information:					
13	Non Patent Literature	TAFT_Alimentary_Pharmacology_Therapeutics_2011.pdf	9329781 5e3b2476a41f2763b1c1a0013cde0e430d3c5171	no	9
Warnings:					
Information:					

14	Non Patent Literature	WECHSLER_2018.pdf	9644486 103dfe0dc96d2748f64dfc442435e53825aacbd6	no	15
Warnings:					
Information:					
15	Fee Worksheet (SB06)	fee-info.pdf	38003 e60b3c59617a49ae05f3b6c6ca82aa6f8108491d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	123082444		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[X] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[X] a final action under 37 C.F.R. §1.113;

[X] a notice of allowance under 37 C.F.R. §1.311; or

[X] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[X] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-162/01US	16/968,711	8/10/2020	US 2020 -0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-144/04US	17/211,119	3/4/2021	US 2021-0205328 A1	7/8/2021			Pending
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: September 29, 2021

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	16821464
Filing Date	17-Mar-2020
First Named Inventor	Stephen PERRETT
Attorney Docket Number	ELLO-119/06US 342083-3260
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
ELLODI PHARMACEUTICALS, L.P.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

8771729

9486407

10632069

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

○ Small Entity

○ Micro Entity

◉ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 66418

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/Jonathan M. Cousin/
Name	Jonathan M. Cousin

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	16821464
Filing Date:	17-Mar-2020
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/ZAINAB ARIYIBI
Attorney Docket Number:	ELLO-119/06US 342083-3260

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16821464

Filing Date: 17-Mar-2020

Applicant/Patent under Reexamination: PERRETT

Electronic Terminal Disclaimer filed on September 23, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	43842998
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/ZAINAB ARIYIBI
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	23-SEP-2021
Filing Date:	17-MAR-2020
Time Stamp:	13:40:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$170
RAM confirmation Number	E20219MD40480133
Deposit Account	501283
Authorized User	ZAINAB ARIYIBI

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.21 (Miscellaneous fees and charges)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	41469 2e7568fe8efb0e5d895536f648416f91d304d68a	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37804 ab236db1db9a698fb83061729e2a1a58df6be1cb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	79273		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	43842932
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/ZAINAB ARIYIBI
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	23-SEP-2021
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Time Stamp:	13:36:57
Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	ELLO11906US_RespNFOA_Signed.pdf	186454 b617fe93d4de9e08174d01f16df3e0f182458cba	no	9

Warnings:

Information:	
Total Files Size (in bytes):	186454

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	A. Sasan

For: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

AMENDMENT/RESPONSE TO OFFICE ACTION

In response to the non-final Office Action dated July 8, 2021, Applicant submits the following Amendments and/or Remarks, and respectfully requests reconsideration of the application in view thereof.

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

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

Remarks/Arguments begin on page 4 of this paper.

IN THE CLAIMS:

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

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

(i) about 0.5 mg to about 1 mg of budesonide;

(ii) ~~and~~ at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; and

(iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;

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

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

2. (Currently Amended) The orally dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity is at least one disintegrant.

3. (Cancelled)

4. (Original) The orally dispersing tablet of claim 1, comprising sucralose.

5. (Original) The orally dispersing tablet of claim 1, comprising sucralose and mannitol.

6. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, and magnesium stearate.

7. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.

8. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.

9. (Original) The orally dispersing tablet of claim 1, comprising sucralose and magnesium stearate.

10. (Original) The orally dispersing tablet of claim 1, comprising sucralose and polyvinyl pyrrolidone.

11. (Original) The orally dispersing tablet of claim 1, comprising sucralose and polyethylene glycol.

12. (Original) The orally dispersing tablet of claim 1, comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

13. (Original) The orally dispersing tablet of claim 1, comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

14. (Original) The orally dispersing tablet of claim 1, comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

15-21. (Cancelled)

22. (Original) A method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.

23. (Previously Presented) The orally dispersing tablet of claim 1, comprising about 0.5 mg of budesonide.

24. (Previously Presented) The orally dispersing tablet of claim 1, comprising about 1 mg of budesonide.

REMARKS

Upon entry to these amendments, claims 1, 2, 4-14, and 22-24 are pending in the present application. Claims 3 and 15-22 were previously cancelled, without prejudice or disclaimer. In this response, claims 1 and 2 have been amended for clarity, without prejudice or disclaimer. Support for the claim amendments can be found throughout the application as originally filed. No new matter is added.

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

Claim Objections

Claim 1 is objected to because of informalities. Claim 1 is amended to as suggested by the Examiner in the office action, page 2.

Applicant respectfully requests this objection be withdrawn.

Claim Rejections – 35 USC §112

Claim 1 is rejected under 35 U.S.C. 112 as being indefinite.

In response, has been amended to replace the recitation of "corticosteroid" with "budesonide".

For at least the foregoing reasons, Applicant submits that claim 1 is not indefinite and respectfully requests withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – 35 USC §103

Claims 1-2, 4-14 and 22-24 are rejected under 35 U.S.C. 103 as allegedly being unpatentable over U.S. Publication No. 2009/0131386 A1 to Phillips in view of U.S. Publication No. 2009/0169620 A1 to Venkatesh et al. (hereinafter "Venkatesh").

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

The pending claims are directed to an orally dispersing tablet comprising, *inter alia*, about 0.5 mg to about 1 mg of budesonide, wherein upon administration a **therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract**, and wherein the orally dispersing tablet **disintegrates within 60 seconds** in simulated saliva when tested using the USP <701> Disintegration Test.

The Office has already granted several related patents in this "family" with broader claims. See U.S. Patent Nos. 8,771,729; 9,486,407; and 10,632,069. The pending claims are consistent with the Office's Reasons for Allowance in these related patents. For example, in the Notice of Allowance for U.S. App. No. 12/896,005 (Now U.S. Patent No. 8,771,729), the Office allowed the application because the prior art does "not disclosure an orally disintegrating solid pharmaceutical composition having the limitations of **a topically administrable corticosteroid** and at least one disintegrant, wherein the **composition disintegrates within 60 seconds**." Similarly, in the Notice of Allowance for U.S. App. No. 15/816154 (Now U.S. Patent No. 10,632,069), the Office allowed the application because "Applicant Amended claim 44 to recite that the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP<701> Disintegration Test. In light of this amendment, Applicant's arguments (Pages 4-5, filed 12/06/19) regarding the rejection of claims 44 and 48-66 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1) have been fully considered and are persuasive. Since Dohil et al. do not teach or suggest the disintegration time of the tablet, particularly **disintegration within 60 seconds** in simulated saliva, as recited in instant claim 44, the rejection based on Dohil et al. is withdrawn."

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

2. The Prior Art Cited Against the Pending Claims (Phillips (US 2009/0131386 A1) and Venkatesh (US 2009/0169620)) was Previously Cited and Overcome in U.S. Patent No. 8,771,729

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

Because the pending claims recite both topical deposition/administration of a corticosteroid (budesonide) to the upper GI tract, and a disintegration rate of ≤ 60 seconds, Applicant requests withdrawal of the rejection and allowance of the claims.

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

Double Patenting

Claims 1-2, 4-14 and 22-24 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-8, 15-27, 29-31, and 35-36 of U.S. Patent No. 8,771,729 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 8,771,729, thereby obviating this rejection.

Claims 1-2, 4-14 and 22-24 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-5, 9-15, 18-19, and 35-39 of U.S. Patent No. 9,486,407 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 9,486,407, thereby obviating this rejection.

Claims 1-2, 4-14 and 22-24 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-3, 6, 9, 15, 22-25, 27 and 36-38 of U.S. Patent No. 10,471,071 B2. The Office determined that the claims in U.S. Patent No. 10,471,071 were patentably distinct from U.S. 8,771,729 and U.S. 9,486,407. This was at least because the claims in U.S. Patent No. 10,471,071 require that a corticosteroid is adsorbed to a pharmaceutically acceptable carrier, whereas no such limitation in the claims of U.S. 8,771,729 and U.S. 9,486,407. See U.S. App. No. 14/917,125 (now U.S. Patent No. 10,471,071). Final Rejection mailed January 30, 2019. Because the pending claims also do not recite a limitation regarding adsorption of budesonide on a pharmaceutically acceptable carrier, Applicant requests withdrawal of this double patenting rejection.

Claims 1-2, 4-14 and 22-24 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-17 of U.S. Patent No. 10,632,069 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 10,632,069 B2, thereby obviating this rejection.

Claims 1-2, 4-14 and 22-24 are provisionally rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over 1-2, 4-5, 12, 14-15, and 29 of co-pending Application No. 17/211,119. Applicant requests withdrawal of this rejection for at least two reasons: (1) as discussed above with respect to the double patenting rejection over U.S. Patent No. 10,471,071 (the predecessor to Application No. 17/211,119), the Office previously determined that claims similar to the pending claims are patentably distinct over claims similar to co-pending Application No. 17/211,119; and (2) the present application has an earlier effective filing date Application No. 17/211,119. MPEP 804 I.B.1.(b) states: "If a provisional nonstatutory double patenting rejection is the only rejection remaining in an application having the earliest effective U.S. filing compared to the reference application(s), the examiner should withdraw the rejection in the application having the earliest effective U.S. filing date and permit that application to issue as a patent …"

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

CONCLUSION

In view of the foregoing, Applicant respectfully submits 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 **referencing Docket No.** ELLO-119/06US 342083-3260**.**

Dated: September 23, 2021

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 58249

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US 342083-3260	9443

58249 7590 08/11/2021

COOLEY LLP
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1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/11/2021	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

Applicant-Initiated Interview Summary	**Application No.** 16/821,464	**Applicant(s)** PERRETT et al.		
	Examiner ARADHANA SASAN	**Art Unit** 1615	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

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

Date of Interview: 06 August 2021

Issues Discussed:

35 U.S.C. 103

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

☑ Attachment

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

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

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

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

Sasan, Aradhana

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

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

Hi Examiner Sasan,

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

Look forward to speaking with you.

Best regards,

Matt

Matthew Scheideman, Ph.D.
Patent Agent
Cooley LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
Direct: (202) 842-7858
Email: mscheideman@cooley.com

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

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

I. PTO Representative – Examiner Aradhana Sasan

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

III. Pending Claims:

a. Claim 1 in US 16/821,464: An orally dispersing tablet comprising: (i) about 0.5 mg to about 1 mg of budesonide; (ii) and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; (iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof; wherein upon administration a **therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract**, and wherein the orally dispersing tablet **disintegrates within 60 seconds** in simulated saliva when tested using the USP <701> Disintegration Test.

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

IV. Discussion Points:

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

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

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

ii. See also Notice of Allowance for US App. 15/816154 (Now U.S. Patent 10,632,069): "Applicant Amended claim 44 to recite that the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP<701> Disintegration Test. In light of this amendment, Applicant's arguments (Pages 4-5, filed 12/06/19) regarding the rejection of claims 44 and 48-66 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1) have been fully considered and are persuasive. Since Dohil et al. do not teach or suggest the disintegration time of the tablet, particularly disintegration within 60 seconds in simulated saliva, as recited in instant claim 44, the rejection based on Dohil et al. is withdrawn"

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

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

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

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

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

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

Doc Code: ECOMM.AUTH/ECOMM.WTDW
Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

PTO/SB/439 (11-15)

AUTHORIZATION FOR INTERNET COMMUNICATIONS IN A PATENT APPLICATION OR REQUEST TO WITHDRAW AUTHORIZATION FOR INTERNET COMMUNICATIONS		
	Application No.	16/821,464
	Filing Date	03/17/2020
	First Named Inventor	Stephen PERRETT
	Art Unit	1615
	Examiner Name	SASAN, Aradhana
	Practitioner Docket No.	ELLO-119/06US 342083-3260

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

I. To authorize permission for Internet Communications.

☑ Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned and practitioners in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03)

II. To withdraw authorization for Internet Communications.

☐ The authorization given on _____, to the USPTO to communicate with the undersigned and any practitioner in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via Internet communications such as video conferencing, instant messaging, or electronic mail is hereby withdrawn. I understand that the withdrawal is effective when approved rather than when received.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 76,605.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Matthew Scheideman/ — Signature

August 3, 2021 — Date

Matthew Scheideman — Typed or printed name

(202)842-7858 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Juristic entities must be represented by a patent practitioner (see 37 CFR 1.31, which is applicable to any paper filed on or after September 16, 2012, that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	43415815
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Matthew H. Scheideman/Carolina Pimentel
Filer Authorized By:	Matthew H. Scheideman
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	03-AUG-2021
Filing Date:	17-MAR-2020
Time Stamp:	15:28:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	ELLO-119-06US_Authorization_for_Internet_Communication.pdf	493766 4832aa39a4855eedfa5aa28ef7d8d0b7f05cdee0	no	1

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US 342083-3260	9443

58249 7590 07/08/2021

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Suite 700
Washington, DC 20004

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/08/2021	ELECTRONIC

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

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

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

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Office Action Summary	Application No. 16/821,464	Applicant(s) PERRETT et al.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (FITF) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☑ Responsive to communication(s) filed on 06/15/20.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-2,4-14 and 22-24 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-2,4-14 and 22-24 is/are rejected.

8) ☑ Claim(s) 1 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

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

Status of Application

2. The preliminary amendment filed on 06/15/20 is acknowledged.

3. Claims 3 and 15-21 were cancelled. Claim 1 was amended. New claims 23-24 were added.

4. Claims 1-2, 4-14, and 22-24 are pending and are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed on 04/10/20; 09/18/20; 11/09/20; 11/20/20; 12/10/20; 12/29/20; and 05/27/21 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. Please see attached copy of PTO-1449.

Claim Objections

6. Claim **1** is objected to because of the following informalities:

- In claim **1**, part (ii), the term "and" should be deleted and instead placed after the semi-colon.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

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

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

8. Claim **1** is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

9. Claim 1 recites the limitation "... wherein upon administration a therapeutically effective amount of **the corticosteroid** ..." in line 7 (emphasis added). The preceding portion of claim 1 specifically recites budesonide and not a corticosteroid. There is insufficient antecedent basis for this limitation in the claim.

10. Moreover, claim 1 recites both a broad limitation with a narrow limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad limitation "the corticosteroid," and the claim also recites "budesonide" which is the narrower statement of the limitation.

Claim Rejections - 35 USC § 103

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

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

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

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

12. **Claims 1-2, 4-14, and 22-24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1) in view of Venkatesh et al. (US 2009/0169620 A1)**.

The claimed invention is an orally dispersing tablet comprising: (i) about 0.5 mg to about 1 mg of budesonide, (ii) at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, and (iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof; wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the upper gastrointestinal tract, and wherein the orally dispersing

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

Phillips teaches pharmaceutical compositions for the treatment of inflammation of the gastrointestinal tract (Abstract). The composition comprises a corticosteroid such as budesonide ([0027]). The amount of corticosteroid is from about 100 µg to about 20 mg (Page 1, [0008] and Page 7, [0059]). The composition is formulated into solid dosage forms and administered locally (Page 12, [0083]). Phillips teaches that "… the corticosteroid is formulated readily using pharmaceutically acceptable excipients and/or auxiliaries well known in the art into dosages suitable for oral administration. Such excipients and auxiliaries enable the compositions … to be formulated as tablets, pills, dragees, capsules … for oral ingestion by a patient to be treated" (Page 12, [0084]). The solid dosage forms, such as tablets, dragee cores, capsules, push-fit capsules, soft capsules etc., are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach (Page 12, [0085] and Page 13, [0092]). Phillips teaches the incorporation of a disintegrant ([0010]), sweeteners such as sucralose ([0045], [0076], [0085]-[0086]), mannitol ([0032], [0034], [0045], [0074], [0076], [0085]-[0086]), lubricants such as magnesium stearate ([0088]), and excipients such as polyvinylpyrrolidone ([0045], [0046], [0087]), and polyethylene glycol ([0045], [0087]).

Phillips does not expressly teach an example or embodiment wherein the solid dosage form contains about 0.5 mg to about 1 mg of budesonide, along with sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof, or the disintegration time of within 60 seconds in simulated saliva 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 use of a corticosteroid is disclosed (Page 3, [0029] left hand column). The ODT compositions disintegrate in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising budesonide, wherein the amount of corticosteroid is from about 100 µg to about 20 mg, as taught by Phillips, prepare the composition in solid dosage forms such as tablets, dragee cores, etc., which are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth prior to reaching the stomach, and which contain disintegrants, sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, and combinations thereof, also as taught by Phillips, in view of the ODT compositions which disintegrate in about 60 seconds 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.*, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Phillips clearly teaches solid dosage forms containing budesonide ([0027]), and the dosage forms substantially dissolve or disintegrate in the mouth prior to reaching the stomach (Page 12, [0085] and Page 13, [0092]). Phillips also teaches that interaction of

the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus, is increased, in order to decrease the physiological manifestations or symptoms of gastrointestinal tract inflammation (Pages 4-5, [0036]). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing a functional orally dispersing tablet containing the corticosteroid budesonide such that the tablet dissolves or disintegrates in the mouth before reaching the stomach. Furthermore, one of ordinary skill in the art would have found it obvious to use various excipients in the tablet taught by Phillips in order to achieve the desired attributes of disintegration time in the mouth, sweetness, *etc*. One of ordinary skill in the art would have found it obvious to combine the teachings of Venkatesh *et al*. and Phillips because both these references disclose the use of corticosteroids orally administered tablet dosage forms which disperse or disintegrate rapidly, and it is obvious to combine prior art elements according to known methods to yield predictable results. Please see MPEP 2141.

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

Regarding instant claim 1, the limitations of an orally dispersing tablet would have been obvious over the composition comprising budesonide ([0027]) as taught by Phillips, wherein the composition is formulated into solid dosage forms such as tablets, dragee cores, etc., such that the dosage forms substantially dissolve or disintegrate in

the mouth and/or esophagus, prior to reaching the stomach (Page 12, [0083] - [0085] and Page 13, [0092]), in view of the ODT compositions, as taught by Venkatesh *et al.* (Page 4, [0039], Page 9, [0080] – [0082] and [0085]).

Regarding instant claims 1 and 23-24, the limitations of (i) about 0.5 mg to about 1 mg of budesonide (instant claim 1), about 0.5 mg of budesonide (instant claim 23) and about 1 mg of budesonide (instant claim 24) would have been obvious over the budesonide ([0027]) and the overlapping range of about 100 µg to about 20 mg of corticosteroid (Page 1, [0008], Page 7, [0059] and Page 10, [0069]), as taught by Phillips. According to MPEP 2144.05, "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists."

Regarding instant claims 1 and 2, the limitations of (ii) at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity (instant claim 1) and at least one disintegrant (instant claim 2) would have been obvious over the disintegrant ([0010]), as taught by Phillips.

Regarding instant claims 1 and 4-14, the limitations of (iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof would have been obvious over the sucralose ([0045], [0076], [0085]-[0086]), mannitol ([0032], [0034], [0045], [0074], [0076], [0085]-[0086]), magnesium stearate ([0088]), polyvinylpyrrolidone ([0045], [0046], [0087]), and polyethylene glycol ([0045], [0087]), as taught by Phillips. One of ordinary skill in the art would have found it obvious to combine the sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, based on the desired attributes of sweetness, disintegration time, mouth feel of the

tablet, *etc*. The recited combinations of claims 5-14 would have been obvious variants over the disclosure of Phillips.

Regarding instant claim 1, the limitation of the corticosteroid/budesonide deposited topically in the upper gastrointestinal tract would have been obvious over the local administration of the solid dosage form (Page 12, [0083]), and the compositions which contain an excipient that increases the interaction of the composition with a surface of the gastrointestinal tract, e.g., the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract, such as the esophagus (Page 4, [0036]) as taught by Phillips.

Regarding instant claim 1, the limitation of the tablet disintegration time of within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test would have been obvious over the ODT compositions which disintegrate in about 60 seconds 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 22, the limitation of treating eosinophilic esophagitis would have been obvious over the method for treating eosinophilic esophagitis ([0023], [0090], [0094] – [0099], Example 3, and claims 1, 24-25), as taught by Phillips.

Double Patenting

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

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

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

14. **Claims 1-2, 4-14, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 15-27, 29-31, and 35-36 of U.S. Patent No. 8,771,729 B2 ("the '729 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising budesonide, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration budesonide is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

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

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

15. **Claims 1-2, 4-14, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 9-15, 18-19, and 35-39 of U.S. Patent No. 9,486,407 B2 ("the '407 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising budesonide, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration budesonide is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '407 Patent recite a method of treating an inflammatory condition of the gastrointestinal tract and a topically administrable corticosteroid whereas instant claims specifically recite budesonide or a salt, solvate, or ester thereof. However, instant claim 22 recites a method for treating an inflammatory condition of the gastrointestinal tract, *i.e.*, eosinophilic esophagitis. Furthermore, claims 3 and 37 of the '407 Patent also recite budesonide. Therefore, one of ordinary skill in the art would have found it obvious to use budesonide as the corticosteroid in the orally dispersing or disintegrating tablet and successfully treat an inflammatory condition of the gastrointestinal tract based on the instant claims and arrive at the claimed method and ODT as recited in the claims of the '407 Patent.

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

16. **Claims 1-2, 4-14, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 6, 9, 15, 22-25, 27, and 36-38 of U.S. Patent No. 10,471,071 B2 ("the '071 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising budesonide, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration budesonide is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '071 Patent recite rapidly dispersing microgranules comprising a sugar alcohol, or a saccharide, or a mixture thereof and at least one disintegrant, whereas instant claims recite part (iii) which is sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof. However, since instant claims recite the transitional phrase "comprising," which is considered open language and allows the incorporation of additional components, one of ordinary skill in the art would have found it obvious to include microgranules in the orally dispersing tablet of the instant claims since these comprise the same components recited in claim 1, part (iii).

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

17. **Claims 1-2, 4-14, and 22-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 10,632,069 B2 ("the '069 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising budesonide, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration budesonide is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

One difference is that claims of the '069 Patent recite 0.5 mg to 5 mg of budesonide, whereas instant claims recite about 0.5 mg to about 1 mg of budesonide. However, one of ordinary skill in the art would have found that the overlapping range in the claims of the '069 Patent (0.5 mg to 5 mg) renders obvious the range recited in the instant claims (about 0.5 mg to about 1 mg).

Another difference is that instant claims recite part (iii) which is sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof, whereas claims of the '069 Patent do not recite these set of components. However, since claims of the '069 Patent recite the transitional phrase "comprising," which is considered open language and allows the incorporation of additional components, one of ordinary skill in the art would have found it obvious to include the components recited part (iii) of the instant claims in various combinations in the ODT of the '069 Patent.

Therefore, instant claims and claims of the '069 Patent are not patentably distinct over each other.

18. **Claims 1-2, 4-14, and 22-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 12, 14-15, and 29 of copending Application No. 17/211,119 ("the '119 Application")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally dispersing tablet comprising budesonide, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein upon administration budesonide is deposited topically in the upper gastrointestinal tract, and therefore, encompass overlapping or coextensive subject matter.

The difference is that claims of the '119 Application recite from about 0.5 mg to about 10 mg of a topically acting corticosteroid, whereas instant claims recite about 0.5 mg to about 1 mg of budesonide. However, claim 4 of the '119 Application recites budesonide. One of ordinary skill in the art would have found that the overlapping range in the claims of the '119 Application (about 0.5 mg to about 10 mg) renders obvious the range recited in the instant claims (about 0.5 mg to about 1 mg).

Another difference is that instant claims recite part (iii) which is sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof, whereas claims of the '119 Application do not recite these set of components. However, since claims of the '119 Application recite the transitional phrase "comprising," which is considered open language and allows the incorporation of additional components, one of ordinary skill in the art would have found it obvious to include the components recited part (iii) of the instant claims in various combinations in the ODT of the '119 Application.

Therefore, instant claims and claims of the '119 Application are not patentably distinct over each other.

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

Conclusion

19. No claims are allowed.

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

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

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

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

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 16/821,464	Applicant(s)/Patent Under Reexamination PERRETT et al.	
	Examiner ARADHANA SASAN	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-10632069-B2	04-2020	Perrett; Stephen	A61K9/006	1/1
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/821,464	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	Date	Examiner
(A61K9/0065 or A61K9/08 or A61K31/58 or A61K47/38 or A61K9/0053 or A61K31/56 or A61K9/0056 or A61K9/006 or A61K31/569 or A61K45/06 or A61K9/06 or A61P1/04 or A61P1/00).cpc. with keywords	07/03/2021	AS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
(A61K31/569 same A61K2300/00).cpcc. with keywords	07/03/2021	AS

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Reviewed IDS, prosecution history of related cases - 15816154, 17236295. EAST search - including CPC with keyword, inventor, assignee and applicant name search. SciFinder and Google/NPL searches. Please see the attached history for each search.	07/03/2021	AS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	JP 2013-506683 A (and English Abstract)	02-28-2013		

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Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	2.	KOUKOURAKIS, et al., "Oral Administration of Recombinant Human Granulocyte Macrophage Colony-stimulating Factor in the Management of Radiotherapy-induced Esophagitis", Clinical Cancer Research (1999 Dec); 5(12): 3970-3976.	
	3.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated February 22, 2021 enclosing Opponent's Submissions (and English translation), dated February 16, 2021, 11 pages.	
	4.	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis – Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	
	5.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Adare's Response to Opposition dated January 11, 2021, 15 pages.	
	6.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Opponent's submissions dated March 1, 2021, and English translation, 11 pages.	
	7.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Patentee in Preparation for Oral Proceedings on March 8, 2021, dated January 8, 2021, with Auxillary Requests 1-14, 52 pages.	
	8.	ROBERTSON, et al., "Oesophageal transit of small tablets", J. Pharm. Pharmacol. (1988); 40: 595-596.	
	9.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Adare's Written Submissions in Preparation for Oral Proceedings on April 23, 2021, dated February 23, 2021, 25 pages.	
	10.	German Utility Model Cancellation Proceedings DE 20201018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Statement of Grounds of Appeal dated February 26, 2021 (and English translation), and Exhibit BB17 - Current EPA register extract on D5 dated 27 November 2020, 117 pages.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	07/03/2021

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Task History

Task Began July 03, 2021 12:22 PM

Explore references by research topic: orally dispersing budesonide tablet

Research Topic:	orally dispersing budesonide tablet
Result Count:	2

Candidates Selected (ID 1)

	5945 references were found containing the concept "orally dispersing". Automatically removed 699 duplicate MEDLINE answer(s) 224 references were found containing the concept "budesonide tablet". Automatically removed 699 duplicate MEDLINE answer(s)
Answer Type:	*References*
Result Count:	*5469*

Refine by research topic (ID 2)

Research Topic:	60 seconds
From ID:	1
Answer Type:	*References*
Result Count:	*34*

1. Formulation, in vitro characterization and optimization of taste-masked orally disintegrating co-trimoxazole tablet by direct compression

By Tafere, Chernet; Yilma, Zewdu; Abrha, Solomon; Yehualaw, Adane
From PLoS One (2021), 16(3), e0246648. Language: English, Database: CAPLUS,
DOI:10.1371/journal.pone.0246648

Orally disintegrating tablet (ODT) is a dosage form that overcomes the problem of swallowing which is prevalent in about 35% of the general population. Co-trimoxazole (CTX) is given for patients with HIV for the prophylaxis of opportunistic infection (OI), commonly for pneumocystis carinii pneumonia. It was reported that CTX was assocd. with a 25-46% redn. in mortality among individuals infected with HIV in sub-Saharan Africa. Esophageal candidiasis which usually comes along with HIV/AIDS is one of AIDS defining illness affecting up to 1 in 5 of people with AIDS. This opportunistic illness is manifested by painful or difficulty of swallowing. In this respect, CTX ODT offer the advantages of both liq. dosage forms in terms of easy swallowing thereby improve patient compliance and solid dosage forms in terms of dose uniformity, stability, lower prodn., and transportation costs. The objective of this study was to formulate, characterize and optimize CTX ODT which could overcome swallowing problem and improve patient compliance. Co-trimoxazole ODTs were prepd. by direct compression technique using a semi synthetic super disintegrant (crospovidone) along with other excipients. Two taste masking techniques were employed, addn. of sweetening agent, and solid dispersion by using a pH sensitive polymer, Eudragit E-100 at different ratios (1:1, 1:2 and 1:3). Taste masking was detd. by comparing taste threshold value and in vitro drug release. Preliminary study was used to investigate the effect of crospovidone, compression force (CF) and Hydroxypropyl cellulose (HPC) on disintegration time, friability and wetting time (WT). Factorial design was used as it enables simultaneous evaluation of formulation variables and their interaction effect. From the preliminary study, the factors that were found significant were further optimized using central composite design. Design-Expert 8.0.7.1 software was employed to carry out the exptl. design. The bitterness threshold concn. of Trimethoprim was found to be 150 μg/mL and the in vitro drug release of the three batches of drug to polymer ratio (F1:1, 1:2 and 1:3) was 2.80±0.05, 2.77±0.00 and 2.63±0.00 resp. From the optimization study, the optimal concn. for the superdisintegrant was 8.60% wt./wt. and a CF of 11.25 KN which gave a rapid disintegration and WT of 13.79 and 23.19 s resp. and a friability of 0.666%. In this study, co-trimoxazole ODT was formulated successfully. Central composite design was effectively used to model and optimize friability, DT and WT. The method was found effective for estg. the effect of independent variables on the dependent variables by using polynomial equation and surface plots. Optimization of the response variables was possible by using both numerical and graphical optimization and the predicted optimal conditions were confirmed exptl. and were found to be in good agreement within 5% of the predicted responses. The results of the study showed that CTX ODT had significantly rapid disintegration, less than 1% friability and enhanced dissoln. profiles. The successful formulation of CTX ODT can solve difficulty of swallowing of conventional tablets for some group of patients which are unable to swallow solid oral dosage form.

~0 Citings

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2. Efficacy analysis of montelukast sodium combined with budesonide in treatment of cough variant asthma in children

By Fang, Cheng-chao; Yao, Hai-ming
From Zhongguo Fuyou Baojian (2017), 32(23), 5935-5937. Language: Chinese, Database: CAPLUS,
DOI:10.7620/zgfybj.j.issn.1001-4411.2017.23.47

Objective: To investigate the therapeutic effect of montelukast sodium combined with budesonide in the treatment of children with cough variant asthma. Methods: 120 Children with cough variant asthma admitted to the First People's Hospital of Yuhang District from Dec. 2015 to Dec. 2016 were selected as research objects and were randomly divided into observation group and control group, with 60 cases in each group. All children with cough variant asthma were given conventional treatments such as anti-asthma, oxygen inhalation, antispasmodic, resolving phlegm, anti-infection and cough suppressant according to their conditions. The control group received aerosol inhalation of budesonide on the basis of conventional treatment. The observation group received montelukast sodium chewable tablets on the basis of the treatment of the control group. Results: After treatment, the symptom scores of the two groups of children were significantly lower than those before treatment, and those of the observation group were significantly lower than those of the control group. The forced expiratory vol. (FEV), peak expiratory flow (PEF), and the ratio of forced expiratory vol. to forced vital capacity (FEV1%) in the two groups were significantly higher than those before treatment, and those of the observation group were higher than those of the control group, with statistically significant differences (all $P < 0.05$). The av. treatment time, symptom disappearance time, symptom remission time and recurrence rate of the children in the observation group were lower than those in the control group, with statistically significant differences (all $P < 0.05$). Conclusion: The combined treatment of budesonide and montelukast sodium in the treatment of children with cough variant asthma can significantly improve the symptoms of asthma in children and reduce the treatment time, and has a significant effect.

~0 Citings

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3. Formulation and evaluation of oro dispersible tablets based on Ondansetron Hydroxy Propyl-B-Cyclodextrin complexes

By Khan, Nadir; Shanty, Nitya; Kumar, Alok; Kumar, Robinsh; Bala, Vidhan Chand
From World Journal of Pharmaceutical Research (2020), 9(3), 1005-1024. Language: English, Database: CAPLUS, DOI:10.20959/wjpr20203-16873

Orodispersible tablets (ODTs) contg. Ondansetron (OND) Hydroxy Propyl-β-Cyclodextrin (HP-β-CD) were prepd. by direct compression. The soly. of OND was enhanced by complexation with HP-β-CD by kneading method. The complex 1:1 molar ratio exhibited highest soly. was compressed into ODT. Crospovidone was used as a Superdisintegrant in the range of 2.5 to 10% wt./wt. The disintegration time of tablets of various batches was in the range of 60 to 80 s. The in vitro release study displayed faster and complete release of drug within 30 min. The prepd. batches were compared with marketed orally disintegrating tablets. In the present study, ODT of Ondansetron contg. HP-β-CD were prepd. by direct compression using Superdisintegrant Crospovidone. 1:1 molar ratio was chosen and the complex was prepd. by kneading method. The soly. of drug was found to be 0.018±0.005mg/mL and by complexing with HP-β-CD the soly. was increased up to 2.82±0.54mg/mL. Angle of repose, bulk d., tapped d.; Carr's index and hausner ratio all were in range according to the pharmacopoeia. Disintegration time was under the limit. The In vitro release was faster as compare to the marketed formulation.

~0 Citings

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4. Formulation and evaluation of third-generation cefpodoxime proxetil as an oro-dispersible tablets for treating infections

By Kumar, S. Akshay; Gowda, D. V.; Sharadha, M.; Roohi, N. K. Famna
From International Journal of Research in Pharmaceutical Sciences (Madurai, India) (2020), 11(1), 921-932. Language: English, Database: CAPLUS, DOI:10.26452/ijrps.v11i1.1916

The main problems to humans include the infection caused in the respiratory tract and urinary tract, namely respiratory tract infection (RTI) and urinary tract infection (UTI). Cefpodoxime Proxetil drug is available in the market that has a problem with drug release profile and flows property. To overcome this problem, the compacted powder form made into a micro-ionized form for its better flow property and drug release by using a direct compression technique. The study was based on the aim to evaluate and formulate orodispersible tablets as an effective approach via orally for the treatment of RTI & UTI prepd. by direct compression technique. FTIR and DSC showed no incompatibility between drugs and excipients. The pure drug Cefpodoxime Proxetil and the excipients were blended using an octagonal blender. The Preformulation study was performed for this blend and pure drug. Further, the blend was made compressed into a tablet by direct compression technique. Two factorial design was implemented. Prepd. tablets were evaluated for drug content, hardness, thickness, uniformity in the wt., friability, disintegration test, dispersion time, in-vitro studies, release kinetics, and also stability studies. The optimized formulation A6 found to have good flow property. The evaluation results of optimized formula A6 showed 99.60% drug content, 390mg av. wt., 0.91% wt. uniformity, 3.80 kg/cm2 hardness, 0.67%, friability, 23.70s, disintegration time, 16 s dispersion time and 95.5% drug release than the other formulation batch. The current study showed that the optimized formula A6 exhibited good disintegration time, drug release, and friability than marketed product X and other batches.

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5. Buccal granule and preparation method and application thereof [Machine Translation].

By Zhang, Zhiqiang; Cai, Ya; Jin, Suo; Chen, Ke; Jie, Guoliang; Yang, Jinhua; Wu, Xuejin; Ge, Liang; Qi, Dengfeng; Wang, Linlin
From Faming Zhuanli Shenqing (2019), CN 110419664 A 20191108, Language: Chinese, Database: CAPLUS

[Machine Translation of Descriptors]. The invention provides buccal granule and prepn. method and application thereof, and belongs to the tech. field of buccal granule processing.According to the prepn. method, auxiliary materials such as starch, rhizoma polygonati and the like are not required to be added, and only sorbitol and a plant ext. aq. soln. are adopted to carry out boiling atomization coating granulation.The buccal granules obtained by the invention have very strong soly., and can be completely melted by only 2s after 60 DEG C water dissoln. test.During human body testing, the product is directly poured onto the oral tongue tip, and the product requires only 2-3 s to fully dissolve and disperse.The active substances in the buccal granules are kept relatively intact, and the health effect is obvious.

~0 Citings

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6. Antioxidant activity and photostability assessment of trans-resveratrol acrylate microspheres

By Pignatello, Rosario; Pecora, Tiziana M. G.; Cutuli, Giuseppa G.; Catalfo, Alfio; De Guidi, Guido; Ruozi, Barbara; Tosi, Giovanni; Cianciolo, Simona; Musumeci, Teresa
From Pharmaceutical Development and Technology (2019), 24(2), 222-234. Language: English, Database: CAPLUS, DOI:10.1080/10837450.2018.1455697

Trans-resveratrol (RSV) was microencapsulated in Eudragit RS100 and RL100 resin blends. Lyophilized microspheres were characterized in the solid state for their micromeritic properties and drug loading. FT-IR, PXRD, and DSC analyzes suggested that RSV formed an intimate microcryst. dispersion within the polymer network, also confirmed by SEM anal. This produced a reduced degrdn. of RSV after storage at 40°C, compared to the neat drug, and a protection of the drug from UV light-induced trans-cis isomerization (60% intact drug was found after 60 s irradn. at 350 nm, compared to 37% for the pure drug). Soly. and in vitro dissoln. studies indicated that microencapsulation did not improve the dissoln. pattern of RSV in simulated gastric and intestinal aq. fluids. Evaluation of the in vitro antioxidant activity showed that, compared to the neat drug in aq. soln., RSV loaded in the microspheres retained for a longer time, up to 22 days of incubation, the initial ORAC capacity. The present study thus demonstrated that Eudragit Retard resins can be used to easily produce micro-sized solid dispersions with RSV, for potential oral administration, contributing to ameliorate the physico-chem. stability and antioxidant activity of this compd.

~6 Citings

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7. Fluoxertine hydrochloride dispersible tablet and preparation method thereof

By Wang, Xiaoquan; Jia, Yongtao; Chen, Chang; Yin, Qiyue; Yang, Jianmin
From Faming Zhuanli Shenqing (2017), CN 107334742 A 20171110, Language: Chinese, Database: CAPLUS

The dispersible tablet is prepd. by fluoxetine hydrochloride 20-25%, low-substituted hydroxypropyl cellulose 3-10%, microcryst. cellulose 30-50%, sodium stearyl fumarate 0.2-2%, silicon dioxide 1.5-5% and mannitol 20-45%. The dispersible tablet is prepd. by (1) batching all the raw materials resp., swelling low-substituted hydroxypropyl cellulose in 0.3-0.4 fold water at 50-60°C, mixing uniformly under stirring to obtain adhesive, (2) feeding fluoxetine hydrochloride, microcryst. cellulose, silicon dioxide and mannitol in a high efficiency wet granulator, mixing at120-150 rpm for 120-180 s under stirring, adding low-substituted hydroxypropyl cellulose, mixing at120-150 rpm for 120-180 s under stirring, performing oscillation granulation through a 20-30 mesh stainless steel oscillation granulator, (3) oven drying at 60°C for 2-4 h to moisture content <2%, and (4) adding silicon dioxide and sodium stearyl fumarate in that order, mixing uniformly at 10-20 rpm for 10-20 min, tabletting. The dispersible tablet has glaze surface, which hardness is 30-50 N. The method has simple technol. operation, and good repeatability, and good compressibility of all raw and supplementary materials, which are suitable for large-scale prodn. technique. When the obtained fluoxetine hydrochloride dispersible tablet is dissolved in water, its dissoln. rate reaches more than 95%, and active ingredient fluoxetine hydrochloride is evenly distributed in pharmaceutical prepn., its disintegration rate in water is rapid, the fineness of the particles being distributed in disintegrated material is suitable, so the dispersible tablet meets the requirement of Chinese Pharmacopoeia.

~0 Citings

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8. Silkworm pupa protein and peptide oral liquid, and preparation method thereof

By Liu, Shiqiang; Sun, Zhizheng; Liu, Jianwen; Wang, Jing
From Faming Zhuanli Shenqing (2017), CN 106666755 A 20170517, Language: Chinese, Database: CAPLUS

The title oral liq. is prepd. by: (1) selecting silkworm pupa, soaking for 3-4 h, washing, and crushing; (2) adding 0.5-1.0% sodium hydroxide soln., stirring at 75-85°C for 3-5 h to obtain silkworm pupa protein ext.; (3) cooling to <50°C, and centrifuging; (4) cooling to <30°C, and degreasing; (5) adjusting pH to 4.0-4.2 with 10% sulfuric acid or hydrochloric acid, pptg. for 10 h, centrifuging ppt., washing for 2-3 times with pH 4.0-4.2 purified water, and centrifuging to obtain desalting silkworm pupa sepd. protein; (6) dispersing in purified water to prep. soln. with 15-25% solid concn., adjusting pH to 9.0-9.5 with sodium hydroxide soln., adding trypsin at 50-55°C, stirring for 40-60 min, adding papain, and performing enzymolysis at 50-55°C for 2-3 h; (7) adding 3-5% activated carbon, heating to 85-95°C, holding for 10-15 min, filtering, and decolorizing; (8) adjusting pH to 5.5-6.0 with sodium hydroxide soln., and vacuum drying to obtain silkworm pupa protein and peptide powder; (9) mixing the silkworm pupa protein and peptide powder, xylitol, citric acid, aspartame, potassium sorbate, hawthorn flavone powder and distd. water, and filtering with diatomite; (10) instant high temp. sterilizing at 95-100°C for 30-35 s, ageing for 36-48 h, filtering, and instant high temp. sterilizing at 95-100°C for 15-20 s; (11) bottling and sealing. The present invention has reasonable technique, simple and feasible operation, low prodn. cost and good mouthfeel, and can improve added value and utilization rate of silkworm pupa.

~0 Citings

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9. Development of Extended-Release Oral Flexible Tablet (ER-OFT) Formulation for Pediatric and Geriatric Compliance: an Age-Appropriate Formulation

By Chandrasekaran, Prabagaran; Kandasamy, Ruckmani
From AAPS PharmSciTech (2017), 18(7), 2394-2409. Language: English, Database: CAPLUS, DOI:10.1208/s12249-017-0715-3

Development of age-appropriate formulation suitable for pediatric and geriatric patients involves various challenges. The objective of this research was to develop extended-release oral flexible tablet (ER-OFT) formulation using carbamazepine (CBZ) as model drug for pediatric and geriatric compliance. ER-microparticles of carbamazepine, a BCS class 2, and narrow therapeutic index (NTI) drug, were prepd. using Et cellulose as matrixing polymer and hypromellose as hydrophilic pore former. Microparticles were prepd. using high-shear granulator fitted with an atomizing spray system. Granulation of carbamazepine and Et cellulose (EC-FP) with ethanolic binder soln. resulted in ER-microparticles with extended-release >16 h. Release kinetics of ER microparticles showed Higuchi model by drug diffusion and erosion. Korsemeyer-peppas release exponent "n" value 0.42 suggested Fickian diffusion. ER-OFT was prepd. by blending of ER-microparticles with water-insol. compressible aid and disintegrating agent. ER-OFT was characterized for performance characteristics and elemental impurities. As the polymer content in formulation was <10%, the size of ER-OFT was smaller compared to marketed ER-formulations. ER-OFT showed in vitro disintegration time of <30 s as per USP and dispersion time of ~60 to 180 s in 5 to 10 mL of water. Drug release profiles of ER-microparticles and ER-OFT were comparable as f2 values were >50. In vitro dissoln. of ER-OFT was comparable to the marketed ER formulation in the pH range of GIT. ER-OFT can be orally swallowed, orally disintegrating, and used as dispersible tablets. Compared to non-disintegrating type ER-formulations, ER-OFT would provide uniform drug release in GIT with low within-subject variability an essential criterion for NTI drug.

~3 Citings

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10. (S)-ibuprofen dry suspension specific for infant influenza and preparation method thereof

By Zou, Qing; Pan, Shanqing
From Faming Zhuanli Shenqing (2015), CN 104771365 A 20150715, Language: Chinese, Database: CAPLUS

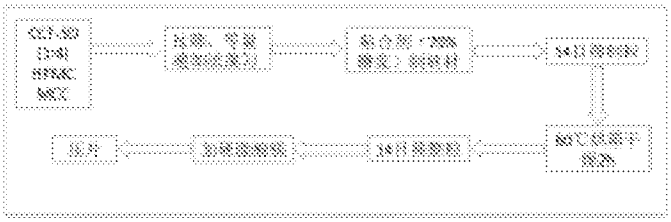
The invention discloses a kind of (S)-ibuprofen dry suspension and prepn. method. The (S)-ibuprofen dry suspension contains the following compns. in wt. parts: (S)-ibuprofen 2.5-8, suspending agent 1-3, filler 80-100, corrective 0.1-5, preservative 0.01-1.5, pH adjusting agent 0.1-10, wetting agent 1-10, essence 0.1-1, and pigment 0-0.1. Its prepn. method is that mix each component, granulate, and subpackage. (S)-ibuprofen dry suspension provided by the invention is researched for treating children colds; it can be stored in solid state, and can be orally taken in the form of suspension, which brings convenience to transportation, and overcomes the shortcoming that traditional tablet, capsule, and dispersible tablet are not suitable for children to take. Meanwhile, dry suspension of the present invention is packaged by dose; it can be brewed temporarily according to child age, and it overcomes the shortcoming that the poured dosage is not accurate because medicine dispersion is uneven during taking suspension.

~0 Citings

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11. An oral crocetin sustained release preparation and its preparation method

By Xu, Ximing; Zhong, Hui; Zhu, Yuan; Yu, Jiangnan; Li, Qiang
From Faming Zhuanli Shenqing (2014), CN 104042583 A 20140917, Language: Chinese, Database: CAPLUS



An oral crocetin sustained release prepn. is provided, wherein the oral crocetin sustained release prepn. mainly comprises following components by mass part: crocetin 1 part; polyvidone-K30 2-20 part, hypromellose 4000cPa.s 0.22-2.2 part; hypromellose 15000cPa.s 0-2.2 part; microcryst. cellulose 1.8-3.4 part. The invention combines the solid dispersion technique with slowly released hydrophilic gel framework technique to prep. a sustained release prepn. of insol. drug of crocetin according to the double releasing medicine principle of quickly releasing firstly and slowly releasing lately, so that it can obviously improve the soly. of crocetin, and realize the purpose of rapid onset firstly and steady and slow release lately of the oral crocetin sustained release prepn. Sustained release tablet has const. release rate in simulated in-vivo medium, and the in vitro drug release is in compliance with the Higuchi kinetic equation, wherein the 24-h cumulative drug releasing amt. is up to about 40 percent, and has obvious slow-release characteristics. The invention discloses its prepn. method. The prepn. method comprises (1) dissolving crocetin and polyvidone-K30 in anhyd. ethanol, evapg. to dryness, placing in refrigerator of -20°C for 2 h, placing in vacuum drying oven of 50°C for 12 h, pulverizing, sieving through 80 mesh screen to obtain solid dispersion; (2) mixing the solid dispersion with hypromellose 4000cPa.s, hypromellose 15000cPa.s and microcryst. cellulose, prepg. soft material with 70% syrup, granulating with 14 mesh screen to obtain wet granule, drying in oven at 60°C for 1 h, finishing with 14 mesh screen, tabletting to obtain oral crocetin sustained release tablet.

~0 Citings

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12. Oral care compositions comprising monohydric or polyhydric alcohols

By Parker, Andrew Philip
From PCT Int. Appl. (2014), WO 2014117904 A2 20140807, Language: English, Database: CAPLUS

The invention provides oral care compn. suitable for delivering a temporary whitening effect to the surface of teeth, the compn. comprising: (a) a liq. continuous phase comprising water or monohydric or polyhydric alc. or a mixt. thereof; (b) a particulate tooth surface whitening agent which is dispersed in the continuous phase; (c) a deposition aid for the particulate tooth surface whitening agent; (d) from 0.1 to 5% by wt. (based on the total wt. of the oral care compn.) of one or more surfactants; characterized in that, of the total surfactants (d) present in the compn., at least 50% by wt. is selected from nonionic surfactants, amphoteric or zwitterionic surfactants, calcium-tolerant anionic surfactants and mixts. thereof. A mouthwash contained water 83.155, sorbitol (70%) 12.00, trisodium phosphate 0.60, PEG40 hydrogenated castor oil 2.50, GANTREZ S-97 0.50, sodium lauryl sulfate 0.34, phenoxyethanol 0.30, benzyl alc. 0.30, Blue Covarine W6795 (C.1.74160) 0.005, and flavor 0.30%.

~1 Citing

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13. Controlled release and taste masking oral pharmaceutical composition containing budesonide

By Villa, Roberto; Pedrani, Massimo; Ajani, Mauro; Fossati, Lorenzo
From U.S. Pat. Appl. Publ. (2012), US 20120021052 A1 20120126, Language: English, Database: CAPLUS

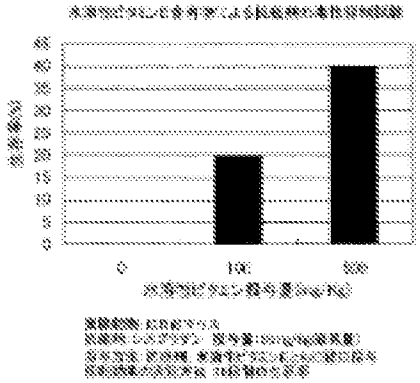
Controlled release and taste masking compns. contg. one or more active principles inglobated in a three-component matrix structure, i.e. a structure formed by successive amphiphilic, lipophilic or inert matrixes and finally inglobated or dispersed in hydrophilic matrixes. The use of a plurality of systems for the control of the dissoln. of the active ingredient modulates the dissoln. rate of the active ingredient in aq. and/or biol. fluids, thereby controlling the release kinetics in the gastrointestinal tract. For example, a tablet was formulated from budesonide 9, stearic acid 10, lecithin 10, microcryst. cellulose 156, hydroxypropyl cellulose 60, lactose monohydrate 50, silicon dioxide 2, and magnesium stearate 3 mg, and coated with a coating compn. contg. Eudragit L100 14, Eudragit S100 12, talc 7.9, titanium dioxide 4.5, triethylcitrate 1.6, and alc. q.s. to give a controlled-release tablet of the present invention.

~1 Citing

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14. Cancer therapy-induced adverse reaction inhibitors containing dispersion or powder of fat-soluble vitamin E-carbohydrate complex

By Miwa, Shoji; Okamura, Katsumasa; Kagitani, Tsutomu
From Jpn. Kokai Tokkyo Koho (2012), JP 2012001479 A 20120105, Language: Japanese, Database: CAPLUS



The inhibitors, which inhibit adverse reactions due to chemotherapy or radiotherapy for cancer, contain water-sol. vitamin E-contg. prepns. which are manufd. by mixing (a) a dispersion contg. fat-sol. vitamin E, fat/oil, and a lipophilic emulsifier and (b) a dispersion contg. a carbohydrate, H_2O, and a hydrophilic emulsifier or powder prepd. from the mixed dispersion. Thus, 2.5 g Ryoto Sugar Ester S 170 was dispersed in 100 g Panacet 800 (medium-chain triglyceride) under stirring at 10-30° for 30 min, further heated to 50°, and mixed with 100 g fat-sol. vitamin E. The vitamin E dispersion was gradually added to a sep. prepd. aq. dispersion contg. H_2O 500, Ryoto Sugar Ester S 1570 2.5, and dextrin 60 g and stirred at room temp. for 30 min to give a fat-sol vitamin E-contg. dispersion. Oral administration of the dispersion to mice just before or 30 min after irradn. with LD of radiation (7.5 Gy) significantly prolonged lifespan.

~0 Citings

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15. Controlled release and taste masking oral pharmaceutical composition

By Villa, Roberto; Pedrani, Massimo; Ajani, Mauro; Fossati, Lorenzo
From U.S. (2011), US 8029823 B2 20111004, Language: English, Database: CAPLUS

Controlled release and taste masking compns. contg. one or more active principles inglobated in a three-component matrix structure, i.e., a structure formed by successive amphiphilic, lipophilic or inert matrixes and finally inglobated or dispersed in hydrophilic matrixes. The use of a plurality of systems for the control of the dissoln. of the active ingredient modulates the dissoln. rate of the active ingredient in aq. and/or biol. fluids, thereby controlling the release kinetics in the gastrointestinal tract. Thus, coated tablets comprised (in mg/tablet): budesonide 9.0, stearic acid 10.0, lecithin 10.0, microcryst. cellulose 156.0, hydroxypropyl cellulose 60.0, lactose monohydrate 50.0, silicon dioxide 2.0, magnesium stearate 3.0; Coating materials: Eudragit L100 14.0, Eudragit S100 12.0, talc 7.9, titanium dioxide 4.5, tri-Et citrate 1.6, alc. q.s.

~1 Citing

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16. Manufacture of orally rapidly disintegrating tablets without using special apparatus and orally rapidly disintegrating tablets manufactured by the method

By Tanaka, Nobukazu; Koizumi, Haruka; Machimura, Hitoshi
From Jpn. Kokai Tokkyo Koho (2011), JP 2011026311 A 20110210, Language: Japanese, Database: CAPLUS

Title tablets are manufd. by (1) pressure molding active ingredients with particles manufd. by granulating sugars, inorg. powders, and disintegration agents in the presence of water, then (2) heating the resulting moldings at 30-90° for 1-72 h substantially without humidification. Thus, mannitol 40, xylitol 30, Mg aluminate metasilicate 5, hydroxypropyl Me cellulose 2, crospovidone 5, and acetaminophen 45 parts were dispersed in water, granulated using spray dryer, mixed with cellulose 8.5, crospovidone 4, sucralose 1.5, K acesulfam 0.5, citric acid 2, and Mg stearate 0.5 wt. part, press molded, and air dried at 60° for 16 h in a sealed condition to show oral disintegration time 28.8 s, vs. 42.6 s, before the air drying.

~2 Citings

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17. Orally disintegrating tablet: rapid disintegration, sweet taste, and target release profile

By Kumaresan, C.
From Pharmaceutical Reviews (2008), 6(5), No pp. given. Language: English, Database: CAPLUS

A review. Orally Disintegrating Tablet (ODT) is a solid unit dosage form contg. drugs that disintegrates rapidly and dissolves in the mouth without taking water within 60 s or less. Drug absorption through local oral-mucosal and through pre and post gastric parts of G.I.T. ODTs are also called as Oro-disperse, mouth dissolving, rapidly disintegrating, fast melt, quick dissolve and freeze dried wafers.

~6 Citings

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18. Development and Evaluation of antipyretic paediatric formulation

By Shanbhag, Pradnya Palekar; Bhalerao, S. S.
From International Journal of PharmTech Research (2009), 1(4), 1373-1375. Language: English, Database: CAPLUS

Paracetamol (PCT), an analgesic and antipyretic drug commonly used and safe for children, was chosen as the model drug candidate to obtain a dosage form with improved palatability, enhanced bioavailability, attractive paediatric elegance and cost effectiveness. The present work was carried out to design and develop oral effervescent granules of Paracetamol, to be dispersed and then given with effervescence for children of age group 6-12 years. To increase the drug soly., formulations were prepd. with solid dispersion technique using PEG 6000. All formulations showed excellent flow properties and satisfactory organoleptic characteristics with in vitro effervescence time of 2-3 min and in vitro drug release more than 50% during 60 s of effervescence.

~1 Citing

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19. Oral dispersable tablet

By Laich, Tobias; Steenpass, Thomas
From PCT Int. Appl. (2009), WO 2009071219 A2 20090611, Language: English, Database: CAPLUS

The present invention is directed to an oral disintegratable tablet which exhibits oral disintegratability of not more than 60 s. The tablet for oral administration, comprises an effective amt. of at least one active agent, an amt. of at least 50% (wt./wt.) of a water insol. parts, a surfactant and a disintegrant, such that said tablet is orally disintegretable or dispersable.

~8 Citings

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20. Modified pulse release oral dosage forms of tacrolimus of improved bioavailability

By Jain, Rajesh; Singh, Amarjit; Singh, Sarabjit; Puthli, Shivanand
From Eur. Pat. Appl. (2008), EP 1974722 A2 20081001, Language: English, Database: CAPLUS

The present invention provides a modified release dosage form of tacrolimus that releases two or more amt. of tacrolimus upon oral administration, the first amt. of tacrolimus releases from the immediate release dosage unit substantially immediately within 0-2 h followed by a time interval ranging from about 1-10 h during which substantially no amt. of tacrolimus is released from the dosage form, after which a second amt. of tacrolimus is released wherein said second amt. is released from the delayed release dosage unit either immediately e.g. within 0-2 h or over a period of time ranging from about 2-12 h from its initial release from the delayed release dosage unit. The dosage form may further comprise addnl. amt. of tacrolimus to provide addnl. pulse of tacrolimus. The dosage forms of tacrolimus exhibit improved bioavailability and reduced flux or fluctuation over existing compn. of tacrolimus. A method of prepg. the dosage forms is also described. Thus, tacrolimus formulation based on mixt. of hydrophilic surfactant and lipophilic surfactant comprised (in mg): Immediate release dosage unit: tacrolimus 1.60, iso-Pr alc. 26.14, vitamin E TPGS 24.13, glycerol monooleate 9.05, non-pareil seeds q.s.; Delayed release dosage unit: tacrolimus 3.40, iso-Pr alc. 5.56, vitamin E TPGS 51.27, glycerol monooleate 19.24; Enteric coating: methacrylic acid copolymer 11.69, tri-Et citrate 2.98; Immediate release dosage unit: acetone 60.78, iso-Pr alc. 52.06, purified water 10.63, talc 6.44.

~4 Citings

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21. Liquid toothpaste of attapulgite and green tea, its production method and application

By Yuan, Changbing; Jia, Jian; Xu, Shengying; Xu, Qinghua
From Faming Zhuanli Shenqing (2008), CN 101249055 A 20080827, Language: Chinese, Database: CAPLUS

The liq. toothpaste is produced by steam deactivating enzymes of fresh green tea at 100-110°C for 6-60 s, pulverizing the raw materials at 500-800 rpm in a low-speed stirring mill, pulping at 2500-3000 rpm, grinding at 2900 rpm to grain size < 0.015 mm in a multi-purpose colloid mill, stirring at 4000-11,000 rpm for 5-30 min in an ultrahigh-speed stirring mill, vacuum degassing, and bulking. The liq. toothpaste is composed (by wt.%) of pasty attapulgite clay 5-30, fresh green tea 2-15, fresh Jasminum sambac flower 1-8, fresh Michelia alba flower 0.5-5, Na dodecyl sulfate 0.2-2.5, K sorbate 0.05-0.5, borneol 0.05-0.5, and deionized water 55-85. The pasty attapulgite clay contg. 15-35% attapulgite clay and 65-85% water is prepd. by stirring attapulgite clay raw ore, pressing to schistous matters, naturally drying, immersing with water, impacting with an air pump, discharging water, sieving to remove impurities, immersing with water, impacting with the air pump, and discharging water. The liq. toothpaste has the advantages of low viscosity, good dispersivity and rheol., stable chem. structure, normal flavor and color, and may be used for prepg. liq. toothpaste of attapulgite and green tea and liq. toothpaste of Chinese herbal medicines etc. to remove off-flavor of oral cavity.

~0 Citings

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22. Method and apparatus for determining disintegration time limit of orally disintegrating tablets

By Wang, Zhi; Wang, Liqiang
From Faming Zhuanli Shenqing (2007), CN 101042394 A 20070926, Language: Chinese, Database: CAPLUS

The title method comprises the steps of: (1) placing 6 pieces of orally disintegrating tablets in 6 detn. apparatuses filled with 1.0-3.0 mL water (37 ±> 0.5), (2) starting timing as soon as the orally disintegrating tablets contact water, and stopping timing when the frames of the orally disintegrating tablets are completely dispersed, and (3) gently shaking the disintegrated particles, and passing them through the 10-40 mesh screen in the detn. apparatuses. In step 2, the disintegration time limit less than 60 s is qualified. In step 3, only if all the disintegrated particles can pass through the screens, the disintegration particle sizes are qualified.

~0 Citings

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23. New solid oral formulations of amodiaquine

By Wang, Xianzhu; Mu, Caihua; Zhang, Tao
From Faming Zhuanli Shenqing (2007), CN 100998594 A 20070718, Language: Chinese, Database: CAPLUS

The pharmaceutical compn., which disintegrates and disperses in mouth or in vitro, contains effective amt. of amodiaquine or amodiaquine hydrochloride dihydrate or pharmaceutically acceptable salt, and pharmaceutical acceptable adjuvant. The pH of amodiaquine suspension in 10 mL water is ≥5. The above adjuvant is basic compd. selected from sodium carbonate, sodium hydrogen carbonate, trisodium citrate, disodium citrate, disodium hydrogen phosphate, sodium phosphate, disodium maleate, disodium succinate, sodium acetate, sodium lactate, sodium malate, sodium gluconate, basic amino acid and acrylic resin IV. The pharmaceutical compn. can be prepd. into chewable tablet, dispersing tablet, granule, buccal tablet, dry suspension, orally disintegrating tablet, granule, oral gel, chewable gel, etc. The oral disintegrating tablet is composed of amodiaquine 15-40, filler 50-80, disintegrating agent 3-6, sweetening agent 0.05-2, lubricant 1-3% and a suitable amt. of binder, wherein filler is microcryst. cellulose, glucose, lactose, mannitol, sorbitol, xylitol, etc; disintegrating agent is low-substituted hydroxypropylmethyl cellulose, crosslinked sodium CM-cellulose, crosslinked povidone, sodium carboxymethyl starch; sweetening agent is saccharin sodium, aspartame, stevioside, etc; flavoring agent is mint essence, butter essence, etc; lubricant is magnesium stearate, calcium stearate, stearic acid, talcum powder, micropowder silica gels. The inventive product has advantages of good taste, no bitter taste and disintegration time limit of ≤60 s.

~0 Citings

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24. Orally-dispersible multilayer tablet

By Oury, Pascal; Lamoureux, Gael; Herry, Catherine; Prevost, Yann
From U.S. Pat. Appl. Publ. (2007), US 20070036861 A1 20070215, Language: English, Database: CAPLUS

The present invention relates to a multilayer orodispersible tablet and to the process for prepg. it. Thus, , a bilayer orodispersible tablet contg. paracetamol 500 mg and caffeine 65 mg was prepd. by compression of the first powder mixt. (layer A) contg. coated paracetamol 46.9%, mannitol M300 21.5%, mannitol 60 21.5%, Kollidon CL 6.9%, Sucralose 1.0%, rootbeer mint flavor 1.0%, biscuit vanilla flavor 0.2% and magnesium stearate 1.0% and the sec. mixt. (layer B) contg. coated caffeine 42.3%, mannitol M360 23.2%, mannitol 60 23.2%, Kollidone CL 7.4%, sucralose 1.1%, rootbeer mint flavor 1.1%, biscuit vanilla flavor 0.2%, green color 0.5% and magnesium stearate 1.0%. Tablets disintegrated in the mouth within 20 s.

~2 Citings

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25. Taste-masked pharmaceutical compositions

By Venkatesh, Gopi M.
From U.S. Pat. Appl. Publ. (2006), US 20060078614 A1 20060413, Language: English, Database: CAPLUS

There is provided a method for prepg. an orally disintegrating tablet (ODT) compn. comprising microparticles of one or more taste-masked active pharmaceutical ingredient(s), rapidly-dispersing microgranules, and other optional, pharmaceutically acceptable excipients wherein the ODT disintegrates on contact with saliva in the buccal cavity in about 60 s forming a smooth, easy-to-swallow suspension. Furthermore, the microparticles (crystals, granules, beads or pellets contg. the active) applied with a taste-masking membrane comprising a combination of water-insol. and gastro-sol. polymers release not less than about 60% of the dose is in the stomach in about 30 min, thus maximizing the probability of achieving bioequivalence to the ref. immediate-release product having rapid onset of action (short T_{max}). A process for prepg. such compns. for oral administration using conventional fluid-bed equipment and rotary tablet press is also disclosed. For example, drug-layered cetirizine dihydrochloride beads (drug load: 8.4%) were prepd. by coating sugar spheres with an aq. soln. of cetirizine dihydrochloride and polyvinylpyrrolidone to obtain pellets and seal coating the pellets with Opadry Clear. The beads were then coated with Et cellulose/Eudragit E100 with Myvacet 9-45/talc to give taste-masked beads. The taste-masked beads coated at 20% released 13% drug in 5 min using the USP App. 2. Taste-masked beads at 20% coating, rapidly-dispersing microgranules, crospovidone, flavor, and Aspartame would be blended and compressed into orally disintegrating tablets contg. 10 mg of cetirizine dihydrochloride.

~6 Citings

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26. Emulsions containing hardly water-soluble drugs for oral administration

By Yoshinari, Tomohiro
From PCT Int. Appl. (2005), WO 2005089714 A1 20050929, Language: Japanese, Database: CAPLUS

It is intended to provide a medicinal compn. having a high biol. availability and a process for producing the same which comprises dispersing a drug component in two or more surfactants (for example, surfactants belonging to the same series such as a long-chain fatty acid glyceride having a long-chain polyoxyethylene in its hydrophilic group with a medium-chain fatty acid glyceride having a short-chain polyoxyethylene in its hydrophilic group), adding a small amt. of water thereto to give a semisolid or liq. medicinal compn. in the form of a microemulsion, and producing an oral prepn. such as capsules by using the same so as to form and sustain a stable microemulsion contg. the drug component (in particular, a hardly water-sol. drug component) in the digestive tract. For example, (S)-(-)-8-[4-(2-butoxyethoxy)phenyl]-1-isobutyl-N-[4-[[(1-propyl-1H-imidazol-5-yl)methyl]sulfinyl]phenyl]-1,2,3,4-tetrahydro-1-benzazocine-5-carboxamide methanesulfonic acid salt 1 g, ethoxylated hydrogenated castor oil 3.4 g, ethoxylated caprylic/capric glyceride 3.4g, and medium-chain triglyceride 1.6 g were mixed and heated at 60° to give a dispersion. Distd. water 0.5 g was added to the dispersion to give a clear compn., which was filled into capsules.

~0 Citings

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27. Liquid jelly-type oral pharmaceutical compositions

By Suekuni, Hiroshi; Konishi, Yasuhiro; Isomi, Yukio; Narita, Yoshihiko
From Jpn. Kokai Tokkyo Koho (2005), JP 2005187362 A 20050714, Language: Japanese, Database: CAPLUS

The invention relates to a liq. jelly-type oral pharmaceutical compn. suitable for administration to elderly patients, wherein the compn. contains an active component with an aq. dispersing agent, a thickening agent and/or gelling agent, and the compn. has low viscosity and high fluidity with a viscosity at 20° of 5-150 mPa s. For example, a liq. jelly compn. was prepd. from acetaminophen 900, anhyd. caffeine 75, dl-Me ephedrine hydrochloride 60, dextromethorphan hydrobromide 48, chlorpheniramine maleate 7.5, agar 330, xanthan gum 70, calcium lactate 300, citric acid 100, erythritol 900, sucrose 26,000 mg, and water q.s. to 90 mL.

~1 Citing

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28. Tablet quickly disintegrating in oral cavity

By Tanaka, Nobukazu; Nagai, Yoshiro; Fukami, Tadashi; Hosokawa, Terumasa
From PCT Int. Appl. (2005), WO 2005037254 A1 20050428, Language: Japanese, Database: CAPLUS

It is intended to provide a tablet quickly disintegrating in the oral cavity which shows a short disintegration period and has a sufficient hardness, compared with quickly integrating tablets in the prior art. The above object is achieved by a compn. wherein a disintegrating agent and an inorg. filler are uniformly dispersed in complex grains made of mannitol and another saccharide at a specific ratio and a tablet quickly disintegrating in the oral cavity which is produced by directly compressing the compn. For example, a tablet comprising mannitol 252, lactose 28, Mg aluminate metasilicate 28, cryst. cellulose 60, and low-substituted hydroxypropyl cellulose 32 parts, was disintegrated in 19 s in an oral cavity.

~9 Citings

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29. Effect of levobupivacaine on the oral mucosal blood flow in rats

By Minato, Takao; Nagoh, Tetsuya; Sano, Kimito; Kanri, Tomio
From Nippon Shika Masui Gakkai Zasshi (2004), 32(5), 609-613. Language: English, Database: CAPLUS

In this study, the authors examd. the influences of levobupivacaine on rat oral mucosal blood flow using the radioisotope (^{201}Tl) clearance method. Sixteen Wistar rats weighing an av. 605.0±78.9 g (400-710 g) were used. Thiopental sodium, 0.05 mg/g, was i.p. administered to the rats. Then, a mixt. of 0.15 mL of 0.75% levobupivacaine (L group, 8 animals) or physiol. saline (control group, 8 animals) and 0.05 mL of ^{201}Tl 3.7 MBq was injected into the rat oral mucosa. Immediately after this injection, ^{201}Tl imaging was conducted using a scintillation camera. Later, a region of interest (ROI) measuring about 11 mm in diam. was set, and based on the no. of counts in 120 frames (60 s per frame for 2 h), a clearance curve was prepd. Clearance curves were drawn on the basis of the 2^{201}Tl count. The time const. (TC) and half life ($T_{1/2}$) during elimination phase I and elimination phase II were calcd. and compared by exponential function curve approxn. using the non-linear least squares method with an exponentially fitted curve. For statistical anal., one-way anal. of variance and t-test were applied. $P<0.05$ was considered to denote a significant difference. The following results were obtained. The phase the author showed a TC=1471±326 for group L and 879±256 for the control, the difference being significant. The phase II revealed the following: TC=7864±1260 for group L and 6849±1017, for the control, the difference again being significant. The phase the author showed the following: $T_{1/2}$=1018±226 for group L and 609±178 for the control. The difference was significant. The phase II showed $T_{1/2}$=5450±873 for group L and 4746±705 for the control group, with a significant difference. Inhibition of the dispersion of ^{201}Tl suggested that levobupivacaine reduced blood flow in the oral mucosa. The results of this study clearly show that 0.75% levobupivacaine administered to the oral mucosa exerts a vasoconstrictive action. This is a new finding regarding the pharmacol. properties of levobupivacaine.

~0 Citings

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30. Solid dispersions comprising a hygroscopic and/or deliquescent drug

By Trivedi, Jay S.; Gokhale, Rajeev D.
From PCT Int. Appl. (2004), WO 2004060353 A1 20040722, Language: English, Database: CAPLUS

A pharmaceutical compn. comprises a solid dispersion having a carrier medium that contains (a) a matrix-forming agent selected from hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl Me cellulose, hydroxypropyl Me cellulose phthalate, polyvinylpyrrolidone, polyethylene glycol, polyglycolized glycerides, cyclodextrins and Carbomes, and (b) a filler, and having a hygroscopic and/or deliquescent drug dispersed or dissolved in the carrier medium. The compn. is acceptably non-hygroscopic. Thus, a solid dispersion contained S-[2-[(1-iminoethyl)amino]ethyl]-2-methyl-L-cysteine-2HCl 25.53, Carbowax-8000 75.15, and AvicelPH-101 25.60 mg.

~5 Citings

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31. Fast dispersing dosage forms essentially free of mammalian gelatin

By Murray, Owen James; Green, Richard; Kearney, Patrick; Grother, Leon Paul
From U.S. (2003), US 6509040 B1 20030121, Language: English, Database: CAPLUS

A fast dispersing solid dosage form designed to release an active ingredient rapidly in the oral cavity comprises a modified starch at concns. 20-90% by wt. The solid dosage form has a disintegration/dispersion time of 1-60 s, is mech. and chem. stable, and is able to deliver higher concns. of an active ingredient than the heretofore utilized gelatin-based fast dispersing solid dosage form. A novel feature of the solid dosage forms resides in the fact that the compn. is essentially free or absolutely free of mammalian gelatin. Further, the solid dosage forms are obtainable by removing a solvent, such as water, from a mixt. comprising an active ingredient, a modified starch and a matrix-forming agent via freeze drying. A formulation contg. Avebe MD20 (an enzymically modified starch) 10%, mannitol 3%, and water 87% was prepd.

~10 Citings

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32. Fast dispersing dosage forms free of gelatin containing modified starch

By Grother, Leon Paul; Murray, Owen James; Green, Richard; Kearney, Patrick
From PCT Int. Appl. (2000), WO 2000044351 A1 20000803, Language: English, Database: CAPLUS

The present invention relates to fast dispersing solid dosage forms that preferably dissolve in the oral cavity within 60, more preferably within 30, most preferably within 10 s. A novel feature of the solid dosage forms according to the invention reside in the fact that the compn. is essentially free or absolutely free of mammalian gelatin. It has been discovered that the use of certain modified starches at concns. from 20 to 90 % by wt. of the solid dosage form preps. dosage forms that are mech. and chem. stable and are able to deliver higher concns. of an active ingredient than the heretofore utilized gelatin based fast dispersing solid dosage forms. Further, the solid dosage forms according to the invention are obtainable by removing a solvent, such as water, from a mixt. comprising an active ingredient, a modified starch and a matrix forming agent via freeze drying. A formulation was prepd. contg. Amylogum CLS (a starch ester).

~7 Citings

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33. Aqueous alcoholic dispersions of pH sensitive polymers and plasticizing agents and a solid medicinal oral dosage form containing an enteric coating prepared by using them

By Chopra, Sham K.
From Eur. Pat. Appl. (1983), EP 72021 A2 19830216, Language: English, Database: CAPLUS

An enteric coating for solid drugs is prepd. from a suspension of fine particles which contain a plasticizer and a pH-sensitive acid-resistant polymer in an aq. alc. medium contg. no org. solvents. Thus, a tablet coating compn. was prepd. contg. cellulose acetate phthalate [9004-38-0] 60, tri-Et citrate [77-93-0] 25, alc. 60 g, concd. NH_4OH 4.25 mL and H_2O, q.s. 400 g; tablets coated with this compn. developed a rupture in the coating >60 min in simulated gastric fluid and in 12 min in simulated intestinal fluid.

~9 Citings

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34. Design, Formulation, and Physicochemical Evaluation of Montelukast Orally Disintegrating Tablet

By Aslani Abolfazl; Beigi Maryam
From International journal of preventive medicine (2016), 7120, Language: English, Database: MEDLINE

BACKGROUND: Orally disintegrating tablets (ODTs) are a modern form of tablets that when placed in the oral cavity, disperses rapidly. These tablets have advantages, particularly good applications for children and old patients who have a complication in chewing or swallowing solid dosage forms. The aim of this study was to design, formulate, and evaluate the physicochemical properties of 5 mg montelukast ODTs for the prevention of asthma and seasonal allergies. METHODS: Formulations were prepared with different amounts of super disintegrating agents and effervescent bases as disintegrant agents. Flowability and compressibility of mixed powders were evaluated. The prepared formulations were tested for hardness, thickness, friability, weight variation, drug content, wetting time, disintegration time, dissolution study, and moisture uptake studies. RESULTS: The compressibility index and angle of repose were in the range of 15.87%-23.43% and 32.93-34.65, respectively. Hardness, thickness, friability, wetting time, and content uniformity of formulations were in the range of 33.7-37.1 N, 3.00-3.81 mm, 0.27%-0.43%, 31-50 s and 96.28%-99.90%, respectively. Disintegration time of the tablets prepared with super disintegrating agents, effervescent bases, and combination of two were in the range of 30-50, more than 60 and 20-36 s, respectively. CONCLUSIONS: Mixture of powders and tablets passed all the specified tests. The results showed formulations prepared by super disintegrating agents and super disintegrating agents with effervescent bases had shorter disintegration time compared to formulations with effervescent bases alone.

~2 Citings

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S308	12	"12896005"	US-PGPUB; USPAT	OR	ON	2021/07/03 11:39
S309	1	"16821464"	US-PGPUB; USPAT	OR	ON	2021/07/03 11:40
S310	0	("20130506683").PN.	US-PGPUB; USPAT	OR	ON	2021/07/03 12:10
S311	2	("20200368147" | "20200381097").PN.	US-PGPUB; USPAT	OR	ON	2021/07/03 12:10
S312	6	("10632069" | "20070020330" | "20100034894" | "20110123460" | "6171617" | "6596311").PN.	US-PGPUB; USPAT	OR	ON	2021/07/03 12:10
S313	71	("10105315" | "10176301" | "10272037" | "10471071" | "20010014340" | "20030050312" | "20030054036" | "20030099701" | "20030215500" | "20040009212" | "20040053902" | "20040106663" | "20040265375" | "20050009848" | "20050112188" | "20050232988" | "20060051414" | "20070059361" | "20070111978" | "20090074862" | "20090123550" | "20090123551" | "20090131386" | "20090149433" | "20090155360" | "20090169620" | "20090181099" | "20090191275" | "20100215753" | "20100216754" | "20110081411" | "20110097401" | "20140187523" | "20140287051" | "20140303131" | "20150231156" | "20160078186" | "20160206627" | "20160213681" | "20170071855" | "20170183719" | "20180071211" | "20180133145" | "20180153802" | "20190008760" | "20190201333" | "20200016171" | "3705172" | "3929768" | "4080448" | "4335121" | "4363806" | "4472393" | "5135740" | "5278175" | "5403893" | "5446070" | "5482934" | "5776433" | "6316027" | "6596298" | "6740332" | "7033606" | "8580300" | "8679545" | "8771729" | "9387167" | "9486407" | "9782347" | "9849084" | "9867780").PN.	US-PGPUB; USPAT	OR	ON	2021/07/03 12:10

S314	891,854	(A61K9/0065 or A61K9/08 or A61K31/58 or A61K47/38 or A61K9/0053 or A61K31/56 or A61K9/0056 or A61K9/006 or A61K31/569 or A61K45/06 or A61K9/06 or A61P1/04 or A61P1/00).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:12
S315	491	(A61K31/569 same A61K2300/00).cpcc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:12
S316	891,854	S314 S315	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:16
S317	20	S316 and (("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:16
S318	1	((("ELLODI") near3 ("PHARMACEUTICALS") near3 ("L.P"))).AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:17
S319	1	("ELLODI").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:17
S320	76	("EURAND").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:18
S321	69	("APTALIS").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:18
S322	67	("ADARE").AS,AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:18
S323	180	((("PERRETT") near3 ("Stephen")) OR (("COHEN") near3 ("Fredric")) OR	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:18

		(("VENKATESH") near3 ("Gopi"))).INV,AANM.				
S324	287	S319 S320 S321 S322 S323	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:18
S325	10	S324 and (("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:19
S326	5	S324 and ((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/03 12:19
S327	5	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:19
S328	20	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/03 12:19
S329	2	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2021/07/03 12:21

		lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) same (mg milligram quantity weight wt "wt." "%" amount) same (time period second minute) same (sucralose splenda$4 mannitol osmitrol bronchitol (magnesium near2 stearate) (polyvinyl near2 pyrrolidone) polyvinylpyrrolidone PVP povidone PEG (polyethylene near2 glycol) polyethyleneglycol (poly near2 ethylene near2 glycol) (poly near2 ethyleneglycol)))	JPO; DERWENT; IBM_TDB			

7/3/2021 12:43:01 PM
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Web Search History

date, time	web site	search string
7/3/2021 12:21:30 PM	Google Scholar	corticosteroid dispersing tablet orally dispersing sucralose disintegrant
7/3/2021 12:21:30 PM	Google Patents	Keyword Group 1 [corticosteroid] Keyword Group 2 [dispersing tablet] Keyword Group 3 [orally dispersing] Keyword Group 4 [sucralose] Keyword Group 5 [disintegrant] Before Priority Date: priority:20091001
7/3/2021 12:21:35 PM	Google Scholar	corticosteroid dispersing tablet orally dispersing sucralose disintegrant budesonide
7/3/2021 12:21:35 PM	Google Patents	Keyword Group 1 [corticosteroid] Keyword Group 2 [dispersing tablet] Keyword Group 3 [orally dispersing] Keyword Group 4 [sucralose] Keyword Group 5 [disintegrant] Keyword Group 6 [budesonide] Before Priority Date: priority:20091001

date, time	web site	search string
7/3/2021 12:21:50 PM	Google Scholar	corticosteroid dispersing tablet orally dispersing sucralose disintegrant budesonide 60 seconds
7/3/2021 12:21:50 PM	Google Patents	Keyword Group 1 [corticosteroid] Keyword Group 2 [dispersing tablet] Keyword Group 3 [orally dispersing] Keyword Group 4 [sucralose] Keyword Group 5 [disintegrant] Keyword Group 6 [budesonide] Keyword Group 7 [60 seconds] Before Priority Date: priority:20091001

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 29, 2020 advising of and enclosing Notice of Opposition filed by Dr. Falk Pharma GmbH on July 22, 2020, 82 pages.	
	2.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Opposition and Statement of Grounds of Opposition (with English translation of Statement of Grounds of Opposition), and Consolidated List of references relied upon, filed July 22, 2020, 513 pages.	✓
	3.	MORETON, R. Christian, "Disintegrants in Tableting". In book: Pharmaceutical Dosage Forms: Tablets, Vol. 2, Herausgeber Augsburger & Hoag, CRC Press, Taylor and Francis Group (2008); Ch. 6, pgs. 217-249	
	4.	WEBB, Paul A., "Surface Area, Porosity, and Related Physical Characteristics". In book: Pharmaceutical Dosage Forms: Tablets, 3rd Edition, Vol. 3, CRC Press, Taylor and Francis Group, Boca Raton, London, New York (2008); Chapter 11, pgs. 277-302.	
	5.	Dolo-Dobendan®, 1.4 mg/10 mg lozenges package insert, Reference ID 3030657, Revised: January 2015, with English translation, 7 pages.	✓
	6.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk dated February 10, 2020, 6 pages, in German and English.	✓
	7.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Writ as filed, dated February 11, 2020, and English translation, 5 pages.	✓
	8.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 12, 2020, and English translation, 5 pages.	✓
	9.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 13, 2020, and English translation, 5 pages.	✓
	10.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Auxiliary Request I-IV (marked-up) dated and as filed July 1, 2020, and English translation, 17 pages.	✓

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	11.	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB4 - Letter from Lederer & Keller dated September 27, 2018 regarding European Patent No. 2211896, and Machine English translation, 28 pages.	✓
	12.	Supplementary European Search Report in European Patent Application No. EP 20192973.4, dated November 18, 2020, 5 pages.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	07/03/2021

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Sheet 1 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6,171,617	01-09-2001	Gruber	
	2.	6,596,311	07-22-2003	Dobetti	
	3.	10,632,069	04-28-2020	Perrett, et al.	
	4.	2007/0020330	01-25-2007	Dang, et al.	
	5.	2010/0034894	02-11-2010	Szymczak, et al.	
	6.	2011/0123460	05-26-2011	Wilhelm, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	7.	EP 1 310 243 A1	05-14-2003	ASTRAZENECA AB		
	8.	EP 3354276 B1	01-01-2020	Meritage Pharma, Inc.		
	9.	JP 2011-503073 A (and English Abstract, corresponds to WO 2009/064457 A2)	01-27-2011			✓

Examiner Signature		Date Considered	

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Sheet 2 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	10.	JORVEZA (budesonide) Update by the Committee for Medicinal Products for Human Use (CHMP), Summary of opinion1 (post authorisation) dated March 26, 2020, European Medicines Agency, 1 page.	
	11.	KRISHNA, et al., "Treatment of Eosinophilic Esophagitis Is Oral Viscous Budesonide Superior to Swallowed Fluticasone Spray?" Gastroenterol Hepatol (2011 Jan); 7(1): 55-59.	
	12.	Langdon, BA and Mullamey, (2006) Handbook of Pharmaceutical Excipients. (eds.) Rowe, R.C., Sheskey, PJ and Owen, S.C., London: Pharmaceutical Press and American Pharmacists Association (extract - pages 53-55 and 742-743), 14 pages.	
	13.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated June 22, 2020, 1 page..	
	14.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated May 8, 2020, 1 page.	
	15.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Statement of Grounds of Opposition filed on April 28, 2020, and English translation, 38 pages.	✓
	16.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Falk's Communication to the EPO re oral proceedings, dated August 12, 2020, 3 pages.	
	17.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Adare's Communication to the EPO re oral proceedings, dated August 11, 2020, 4 pages.	
	18.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication re oral proceedings, dated August 5, 2020, 1 page.	
	19.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Written Submission from Adare (Proprietor) dated July 17, 2020, 126 pages.	
	20.	Declaration of Stephen Perrett, MBA, Ph.D. dated July 16, 2020, 6 pages.	
	21.	PELLE, et al., "Using defined daily doses to study the use of antibacterials in UK hospitals". Hosp Pharm (2006); 13: 133-136.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Sheet 3 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	22.	LEE, Geoffrey, Professor, Report of Professor Geoffrey Lee, Ph.D. on measurement of disintegration time of "Jorveza® 1 mg orodispersible tablet" dated November 15, 2019, 16 pages.	
	23.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's consolidated list of cited opposition documents, July 18, 2020, 1 page.	
	24.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 13, 2020, 3 pages.	
	25.	LIACOURAS, et al., "Primary Eosinophilic Esophagitis in Children: Successful Treatment with Oral Corticosteroids". Journal of Pediatric Gastroenterology & Nutrition (1998); 26(4): 380-385.	
	26.	FURUTA, Glenn T., "Eosinophils in the Esophagus: Acid is Not the Only Cause". Journal of Pediatric Gastroenterology & Nutrition (April 1998); 26(4): 468-471.	
	27.	KATDARE and CHAUBAL (eds)., Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Systems, Herausg. CRC Press, Taylor & Francis Group, Boca Raton, USA, 2006; dart: Excipients for Oral Liquid Formulations, S. 155-180, 28 pages.	
	28.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Opponent's response to Summons dated July 17, 2020, and English translation, 15 pages.	✓
	29.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare - Letter to EPO re Oral Proceedings dated July 17, 2020, 5 pages.	
	30.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication re Oral Proceedings dated July 13, 2020, 3 pages.	
	31.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to Attend Oral Hearing and Preliminary Opinion in opposition dated February 13, 2020, 15 pages.	
	32.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated September 26, 2019, transmitting Adare's submission filed September 20, 2019, 88 pages.	
	33.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, D18 - Dr F's novelty table 2020, 2 pages.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

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	34.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication - communication of notice of opposition dated May 13, 2019, 1 page.	
	35.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Notice of Opposition dated March 1, 2019, and English translation, 23 pages.	✓
	36.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Submission filed by Adare Development I, L.P., on September 20, 2019, 91 pages.	
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	43.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated July 24, 2020 regarding oral proceedings, 6 pages.	
	44.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication re Summons to Attend Oral Proceedings and Preliminary Opinion, dated July 2, 2020, and English translation, 18 pages.	✓

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Sheet 5 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

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	45.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated March 25, 2020 transmitting communication from Dr. Falk Pharma GmbH dated March 20, 2020, and English translation, 34 pages.	✓
	46.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, Consolidated List of Cited Opposition Documents, 1 page.	
	47.	Auszug von European Pharmacopeia 6.0 (English language) <2.9.8>; 23 July 2007, 2 pages.	
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	54.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Pleadings as filed, dated December 16, 2019, and English translation, 66 pages.	✓
	55.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk - rejoinder dated January 30, 2020 (and English translation), 38 pages.	✓
	56.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Response to Rejoinder as filed, dated February 6, 2020 (and English translation), 36 pages.	✓

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Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

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	57.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk - statement of defense, filed October 7, 2019 (and English translation), 14 pages.	✓
	58.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, submission by Dr. Falk Pharma GmbH dated May 24, 2020 (and English translation), 16 pages.	✓
	59.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Submission of Dr. Falk - response to Adare and summons, dated July 8, 2020 (and English translation), 11 pages.	✓
	60.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Dr. Falk and Summons dated July 2, 2020, and English translation, 18 pages.	✓
	61.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, submission/Response by Dr. Falk Pharma GmbH dated April 8, 2020 (and English translation), 18 pages.	✓
	62.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Communication from Adare to German Patent Office, Auxiliary Requests 1 and 2 (clean, marked-up and English translations) as filed April 6, 2020, 23 pages.	✓
	63.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Official Communication - Interlocutory Notice dated January 22, 2020 (and English translation), 12 pages.	✓
	64.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Submission of Dr. Falk - Pleadings dated September 13, 2019 (and English translation), 27 pages.	✓
	65.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Adare - Further Submission as filed dated July 12, 2019, and English translation, 56 pages.	✓
	66.	ACEVES, et al., "Topical viscous budesonide suspension for treatment of eosinophilic esophagitis". The Journal of Allergy and Clinical Immunology (2005 Sep 1); Volume 116, Issue 3, pp. 705-706. Epub 2005 Jul 1.	
	67.	ACEVES, et al., "Oral viscous budesonide: a potential new therapy for eosinophilic esophagitis in children". Am J Gastroenterol. (2007 Oct); 102(10): 1-9. Epub 2007 Jun 20.	

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Sheet 7 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

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	68.	THORBURN and FERGUSON, "Topical corticosteroids and lesions of the oral mucosa". Advanced Drug Delivery Reviews, Volume 13, Issues 1–2, January–February 1994, Pages 135-149.	
	69.	PONCHEL, Gilles, "Formulation of oral mucosal drug delivery systems for the systemic delivery of bioactive materials". Advanced Drug Delivery Reviews, Volume 13, Issues 1–2, January–February 1994, Pages 75-87.	
	70.	Exhibit BB2 - Handbook of Pharmaceutical Excipients (2009); Sixth Edition, ISBN 978 1 58212 135 2, (eds.) ROWE, et al., Cover Page, Print/Copyright and Preface Pages, 4 pages.	
	71.	Wikipedia, "Retard", https://de.wikipedia.org/wiki/Retard, June 13, 2019, and Google machine translation, 7 pages.	✓
	72.	EPO Communication dated April 25, 2019 in connection with Application No. EP 08848597.4, 13 pages.	
	73.	Budesonid, https://www.chemie.de/lexikon/Budesonid.html, and English version, 3 pages.	✓
	74.	New World Encyclopedia, "Gastrointestinal tract", https://www.newworldencyclopedia.org/entry/Gastrointestinal_tract, July 8, 2019, 6 pages.	
	75.	New World Encyclopedia, "Gastrointestinal tract", https://web.archive.org/web/20090917122455/https://www.newworldencyclopedia.or..., July 8, 2019, 7 pages.	
	76.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk - Rejoinder dated September 13, 2019 (English translation), 8 pages.	✓
	77.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk -statement of defense, dated May 24, 2019 (and English translation), 16 pages.	✓

Examiner Signature	/ARADHANA SASAN/	Date Considered	07/03/2021

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	1.	DE 60202794 T2	05-18-2006	ETHYPHARM SA		
	2.	KR 10-2012-0104975 (and English Abstract)	09-24-2012	APTALIS PHARMATECH INC.	(corresponds to US 2011-0081411)	✓
	3.	WO 2003/039520 A1 (with English Abstract)	05-18-2003	ETHYPHARM		✓

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Sheet 2 of 2

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

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	4.	ALEXANDER, et al., "Review. Therapeutic Options for Eosinophilic Esophagitis". Gastroenterology & Hepatology (2011 Jan. 1); 7(1): 59-61.	
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	8.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Opponent in response to the Summons to attend Oral Proceedings, dated and filed December 8, 2020, and English translation, 37 pages.	✓
	9.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Consolidated List of References dated and filed December 8, 2020, 1 page.	
	10.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Further Written Submissions dated and filed December 8, 2020, and English translation, 30 pages.	
	11.	REMEDIOS, et al., "Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate". Gastrointestinal Endoscopy (2006); 63(1): 3-12.	✓
	12.	SCHAEFER, et al., "Comparison of Oral Prednisone and Topical Fluticasone in the Treatment of Eosinophilic Esophagitis: A Randomized Trial in Children". Clinical Gastroenterology and Hepatology (2008); 6: 165-173.	
	13.	WEN, Hong, (ed. SWARBICK, James) "Adsorption at Solid Surfaces: Pharmaceutical Applications". Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1 (2007); pgs. 34-38, 7 pages.	
	14.	Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Decision (and English translation) dated October 26, 2020, pronounced in the oral hearing of 21 July 2020, 45 pages.	✓

Examiner Signature	/ARADHANA SASAN/	Date Considered	07/03/2021

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Bibliographic Data

Application No: 16/821,464

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /ARADHANA SASAN/ Examiner's Signature | Initials

Title: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/17/2020	424	1615	ELLO-119/06US 342083-3260
RULE			

APPLICANTS

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Fredric Jay Cohen, Washington Crossing, PA, UNITED STATES

Gopi M. Venkatesh, Vandalia, OH, UNITED STATES

CONTINUING DATA

This application is a CON of 15816154 11/17/2017 PAT 10632069

15816154 is a CON of 15205390 07/08/2016 PAT 9849084

15205390 is a CON of 14311732 06/23/2014 PAT 9387167

14311732 is a DIV of 12896005 10/01/2010 PAT 8771729

12896005 has PRO of 61247642 10/01/2009

FOREIGN APPLICATIONS

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03/30/2020

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UNITED STATES

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ATTN: IP Docketing Department

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Suite 700

Washington, DC 20004

UNITED STATES

FILING FEE RECEIVED

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Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	1.	CA 2704946 A1	05-22-2019	MERITAGE PHARMA, INC.		
	2.	CA 2776164 A1	04-07-2011	APTALIS PHARMATECH, INC.		

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NON PATENT LITERATURE DOCUMENTS

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	3.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Adare's Response to the Grounds of Opposition, filed November 2, 2020, 78 pages.	
	4.	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	✓
	5.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, Patentee, Dr. Falk's Written Submissions, Auxiliary Request I and Test Report Jorveza® 1 mg (dated August 18, 2020, produced by Patentee, Dr. Falk Pharma), filed September 10, 2020, and English translation, 22 pages.	✓
	6.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Adare's Written Submissions in Preparation for Oral Proceedings, Auxiliary Requests 1-7 (clean and marked-up), including supporting evidence, as filed July 17, 2020, 126 pages.	
	7.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Adare's Response dated April 6, 2020 to Interlocutory Decision, and English translation, 29 ages.	✓
	8.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Pleadings as filed dated October 17, 2019, and English translation, 25 pages.	✓
	9.	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB1 "Breakdown of Features", and English translation, 2 pages.	✓
	10.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Replica dated July 19, 2019, and English translation, 25 pages.	✓
	11.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Complaint dated July 3, 2019, and English translation, 34 pages.	✓
	12.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, submission by Dr. Falk Pharma GmbH dated May 24, 2020, and English translation, 16 pages.	✓

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Sheet 1 of 2

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2020/0368147	11-26-2020	Meltzer, et al.	
	2.	2020/0381097	12-03-2020	Meltzer, et al.	

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	3.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication in connection with Summons to attend oral proceedings, dated November 20, 2020, 12 pages.	

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Sheet 1 of 12

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	3,705,172	12-05-1972	Buchel, et al.	
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	58.	2012/0282335	11-08-2012	Venkatesh, et al.	
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document — Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
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	75.	CL 3827-2008	12-21-2007	EURAND, INC.		
	76.	DE 202010018594 U1 (and English Abstract)	02-16-2018	ADARE PHARMACEUTICALS INC.		
	77.	DE 2323215 A1	11-29-1973	AP Bofors		
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	93.	JP 2003-509359 A	03-11-2003	GLAXO GROUP LTD		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

FOREIGN PATENT DOCUMENTS

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	100.	WO 1998/047535 A1	10-29-1998	WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED		
	101.	WO 2000/064450 A1	11-02-2000	LEO PHARM PROD LTD.		
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	111.	WO 2007/074472 A2	07-05-2007	JUBILANT ORGANOSYS LIMITED		
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	113.	WO 2009/064457 A2	05-22-2009	MERITAGE PHARMA, INC.		

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Sheet 6 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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Sheet 7 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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	162.	McGINITY, J. W., et al. "Dissolution and uniformity properties of ordered mixes of micronized griseofulvin and a directly compressible excipient." Drug Development and Industrial Pharmacy, 11(4): 891-900 (1985).	
	163.	Merck Index, "Budesonide," 14th Edition, p. 240 (2006)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 10 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	164.	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006)	
	165.	Merck Index, "Clotrimazole," 14th Edition, p. 407 (2006)	
	166.	Merck Index, "Mometasone Furoate," 14th Edition, pp. 1077-1078 (2006)	
	167.	Merck Index, "Voriconazole," 14th Edition, p. 1728 (2006)	
	168.	MIEHLKE, et al., "A randomised, double-blind trial comparing budesonide formulations and dosages for short-term treatment of eosinophilic oesophagitis", Gut (2016); 65: 390-399.	
	169.	Novopulmon E Novolizer®, Instructions for the medical use of the medicament, [Instrukciya po medicinskomu primeneniyu preparata Novopulmon E Novolizer (international nonproprietary name: budesonide), registracionniy nomer N LS-002405-231211, 23.12.2011], MEDA Manufacturing, GmbH Registration No. LS-002405, Date of Registration December 23, 2011 (with English summary of relevant portions), 9 pages.	
	170.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding of notice of opposition, 1 page.	
	171.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated November 5, 2019, enclosing Opponent's Further Written Submissions dated/filed on October 29, 2019 (and English translation) including consolidated list of prior art, 29 pages.	
	172.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Submission filed by Adare Development I, L.P., on September 20, 2019, 29 pages.	
	173.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Patentee, Adare Development I, L.P.'s Response dated December 16, 2019 in response to further submissions filed by Dr. Falk Pharma GmbH on 10/29/2019, 16 pages.	
	174.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, "Summons to attend oral proceedings pursuant to Rule 115(1) EPC", dated February 13, 2020, 13 pages.	

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Sheet 11 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	175.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, "Letter from Opponent" dated January 14, 2020 (and English translation of letter), 36 pages.	
	176.	Patent Complaint filed with Regional Court Mannheim, Germany, re Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, dated July 3, 2019, with English translation, 107 pages.	
	177.	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	
	178.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	
	179.	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	
	180.	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	
	181.	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	
	182.	PCT Application No. PCT/US2014/052073, Written Opinion of the International Searching Authority dated November 20, 2014.	
	183.	PCT Application No. PCT/US2014/054203, International Preliminary Report on Patentability dated March 8, 2016.	
	184.	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	
	185.	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	
	186.	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	
	187.	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 12 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	188.	Taiwanese Application No. TW 099133628, Search Report (English translation) dated November 16, 2014, 9 pages.	
	189.	Taiwanese Application No. TW 104107443, Search Report (English translation) dated May 29, 2015, 1 page.	
	190.	TAKAKU, Fumimaro, et al. Manual of Therapeutic Agents 2007, Published 2007, p. 617-619 (and English translation/summary of pertinent paragraphs), 5 pages.	
	191.	TEITELBAUM et al. "Eosinophilic esophagitis in children: immunopathological analysis and response to fluticasone propionate." Gastroenterology (2002), 122(5): 1216-1225.	
	192.	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	
	193.	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	
	194.	YALKOWSKY and BOLTON. "Particle size and content uniformity." Pharmaceutical Research, 7(9): 962-966 (1990).	

Examiner Signature	/ARADHANA SASAN/	Date Considered	07/03/2021

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Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	JP 2013-506683 A (and English Abstract)	02-28-2013		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

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	2.	KOUKOURAKIS, et al., "Oral Administration of Recombinant Human Granulocyte Macrophage Colony-stimulating Factor in the Management of Radiotherapy-induced Esophagitis", Clinical Cancer Research (1999 Dec); 5(12): 3970-3976.	
	3.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated February 22, 2021 enclosing Opponent's Submissions (and English translation), dated February 16, 2021, 11 pages.	
	4.	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis – Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	
	5.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Adare's Response to Opposition dated January 11, 2021, 15 pages.	
	6.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Opponent's submissions dated March 1, 2021, and English translation, 11 pages.	
	7.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Patentee in Preparation for Oral Proceedings on March 8, 2021, dated January 8, 2021, with Auxillary Requests 1-14, 52 pages.	
	8.	ROBERTSON, et al., "Oesophageal transit of small tablets", J. Pharm. Pharmacol. (1988); 40: 595-596.	
	9.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Adare's Written Submissions in Preparation for Oral Proceedings on April 23, 2021, dated February 23, 2021, 25 pages.	
	10.	German Utility Model Cancellation Proceedings DE 20201018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Statement of Grounds of Appeal dated February 26, 2021 (and English translation), and Exhibit BB17 - Current EPA register extract on D5 dated 27 November 2020, 117 pages.	

Examiner Signature		Date Considered	

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Electronic Acknowledgement Receipt

EFS ID:	42836942
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	27-MAY-2021
Filing Date:	17-MAR-2020
Time Stamp:	17:23:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119-06US-IDS.pdf	145480 6f64457320bd6141fd45f32c2b0eef67aaef29c9	no	5

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3	Foreign Reference	JP2013506683A_andEnglishAbstract.pdf	21801638 e8334ed91950577bd626c6dbf2b7c149ab0d7f4b	no	30
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4	Non Patent Literature	KOUKOURAKIS-Clin_Can_Res_1999.pdf	9529043 71353679ed9d709acf5a4b5ad037f26907eebcaa	no	8
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Information:					
7	Non Patent Literature	Oppn_3041476_Adares_Response_to_Opposition_01-11-2021_15_pgs.pdf	8422254 3805a825685a301c1f33da7edf0a7d8e0da776ae	no	15
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Information:					
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Warnings:					
Information:					

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Information:					
10	Non Patent Literature	ROBERTSON-J_Pharm_Pharmacol_1988.pdf	820000 8db2f4c64dd92506e99e5395106969ae201909bd	no	2
Warnings:					
Information:					
11	Non Patent Literature	Oppn_2886108_Adares_Written_Submissions_02-23-2021_25_pgs.pdf	15366445 d3fe5e587e2c54b1f9920220460740a7e8d256d3	no	25
Warnings:					
Information:					
12	Non Patent Literature	UM_cancellation_proceedings_2021-02-26-Statement-of-grounds-of-appeal_1OF2_PGS_1-60.pdf	10768643 487147efce2dee7297b99133336e4f795988f67b	no	60
Warnings:					
Information:					
13	Non Patent Literature	UM_cancellation_proceedings_2021-02-26-Statement-of-grounds-of-appeal_2OF2_PGS_61-117.pdf	23851991 2489c8190f038a8766a608bc2c386b49e993b8f4	no	57
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

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[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following pending U.S. application(s) and issued US patent(s) having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-119/07US	17/236,295	4/21/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending
ELLO-144/04US	17/211,119	3/24/2021					Pending
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	1/10/2019	11,026,887	6/8/2021	Registered
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-150/06US	17/306,458	5/3/2021					Pending
ELLO-162/01US	16/968,711	2/21/2019	US 2020-0381097 A1	12/3/2020			Pending

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: May 27, 2021

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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

Tel: (202) 842-7800
Fax: (202) 842-7899

By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Matthew Scheideman
Reg. No. 76,605

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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/821,464	03/17/2020	1615	1920	ELLO-119/06US 342083-3260	22	1

CONFIRMATION NO. 9443

CORRECTED FILING RECEIPT

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

OC000000125039015

Date Mailed: 04/22/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Stephen PERRETT, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi M. Venkatesh, Vandalia, OH;

Applicant(s)

ELLODI PHARMACEUTICALS, L.P., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 58249

Domestic Priority data as claimed by applicant

This application is a CON of 15/816,154 11/17/2017 PAT 10632069
which is a CON of 15/205,390 07/08/2016 PAT 9849084
which is a CON of 14/311,732 06/23/2014 PAT 9387167
which is a DIV of 12/896,005 10/01/2010 PAT 8771729
which claims benefit of 61/247,642 10/01/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/30/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/821,464**
Projected Publication Date: Not Applicable
Non-Publication Request: No
Early Publication Request: No
Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/821,464	03/17/2020	Stephen PERRETT	ELLO-119/06US 342083-3260

CONFIRMATION NO. 9443

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

POA ACCEPTANCE LETTER

OC000000125038980

Date Mailed: 04/22/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/19/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

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

/cnguyen/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/821,464	03/17/2020	1615	1920	ELLO-119/06US 342083-3260	22	1

CONFIRMATION NO. 9443

CORRECTED FILING RECEIPT

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

OC000000124974203

Date Mailed: 04/20/2021

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Stephen PERRETT, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi M. Venkatesh, Vandalia, OH;

Applicant(s)

Adare Pharmaceuticals US, L.P., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 58249

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which is a CON of 15/205,390 07/08/2016 PAT 9849084
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which claims benefit of 61/247,642 10/01/2009

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Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/30/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/821,464**
Projected Publication Date: Not Applicable
Non-Publication Request: No
Early Publication Request: No
Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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SelectUSA

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technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Art Unit	1615
Examiner Name	Aradhana Sasan
Attorney Docket Number	ELLO-119/06US 342083-3260

SIGNATURE of Applicant or Patent Practitioner

Signature	/Jonathan M. Cousin/	Date (Optional)	
Name	Jonathan M. Cousin	Registration Number	66,418
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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: 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.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 58249

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

ELLODI PHARMACEUTICALS, L.P.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Troy Hamilton	Date (Optional)	3/14/2021
Name	Troy Hamilton		
Title	CEO		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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: 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.

Electronic Acknowledgement Receipt

EFS ID:	42484670
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	19-APR-2021
Filing Date:	17-MAR-2020
Time Stamp:	14:19:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Req to correct/update/change appl name until pay issue fee	ELLO-119-06US_Request_to_Change_Applicant_Name.pdf	132315 67bc509a206304a20b8daa4c98f14bba7f99bbc5	no	1

Warnings:

Information:					
2	Application Data Sheet	ELLO-119-06US_ADS_Replacement_Sheets.pdf	9531424 bd0784671657db54d8b91f979259f9984a588487	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Assignee showing of ownership per 37 CFR 3.73	ELLO-119-06US_373c_Statement.pdf	85247 ecad2b32ca49ab08ae30815c73be5ae62dc76d4a	no	3
Warnings:					
Information:					
4	Assignee showing of ownership per 37 CFR 3.73	ELLO-119-06US_Name_Change_Aptalis-to-Adare.pdf	251889 59f46f8446b6ab2eb552e02e5b13d51868fc1f7d	no	2
Warnings:					
Information:					
5	Assignee showing of ownership per 37 CFR 3.73	ELLO-119-06US_Name_Change_AdareUSIP-to-Ellodi.pdf	435880 6c50d7afa45a772d1e75083c0957867ebe3be9b5	no	3
Warnings:					
Information:					
6	Power of Attorney	ELLO-119-06US_POAtransmittal_and_POAsigned.pdf	397866 984c6834aa5ad50dd7c75f89805f41cf3d069b8c	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	10834621	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: R46C.REQ
Document Description: Request under 37 CFR 1.46(c) to correct, update or change the applicant.

PTO/AIA/41 (04-15)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST TO CORRECT OR UPDATE THE NAME OF THE APPLICANT UNDER 37 CFR 1.46(c)(1), OR CHANGE THE APPLICANT UNDER 37 CFR 1.46(c)(2)
(FOR USE ONLY IN APPLICATIONS FILED ON OR AFTER SEPTEMBER 16, 2012)

Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana Sasan
Practitioner Docket Number	ELLO-119/06US 342083-3260

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

Applicant hereby **requests that the name of the applicant be corrected or updated under 37 CFR 1.46(c)(1), or that the applicant be changed under 37 CFR 1.46(c)(2),** in the above-identified application. **Requests under 37 CFR 1.46(c)(1) or (c)(2) cannot be submitted after payment of the issue fee or if the application has been patented.**

Please check the applicable box(es) below.

☐ 1. This request is to **correct or update the name of the applicant (under 37 CFR 1.46(c)(1))** and includes:

☐ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). A Corrected Web-based ADS may be used.

Note: Requests under 37 CFR 1.46(c)(1) may be filed to correct typographical errors in the name of the § 1.46 applicant, or for updating the name of the § 1.46 applicant (*i.e.*, where there is no change in the applicant itself but just in the applicant's name). See the Manual of Patent Examining Procedure (MPEP) section 605.01.

☒ 2. This request is to **change the applicant (under 37 CFR 1.46(c)(2))** and includes:

☒ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) that identifies the changes with proper markings (underlining for insertions and strikethrough for deletions). A Corrected Web-based ADS may be used.

☒ A Statement Under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent). See MPEP 325.

I am the

☐ applicant* ☒ attorney or agent of record Registration number 66,418 ☐ attorney or agent acting under 37 CFR 1.34 Registration number _____

Signature /Jonathan M. Cousin/
Typed or printed name Jonathan M. Cousin
Date April 19, 2021

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☒ ** Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.36. 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: 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.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

ELLO-119/06US 342083-3260

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US-325049-3260~~
	Application Number	16/821,464

Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Stephen		PERRETT	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Princeton	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.
Address 2	1200 Lenox Drive, Suite 100

City	Lawrenceville	State/Province	NJ
Postal Code	08648	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Fredric	Jay	COHEN	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Washington Crossing	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.
Address 2	1200 Lenox Drive, Suite 100

City	Lawrenceville	State/Province	NJ
Postal Code	08648	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gopi	M.	VENKATESH	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

REPLACEMENT SHEET

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US-326049-3260~~
	Application Number	16/821,464 ELLO-119/06US 342083-3260

Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

City	Vandalia	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.		
Address 2	1200 Lenox Drive, Suite 100		
City	Lawrenceville	**State/Province**	NJ
Postal Code	08648	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	58249		
Email Address	zIPPatentDocketingMailboxUS@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	~~ADAR-119/06US-326049-3260~~	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional ELLO-119/06US 342083-3260		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US 325648-3260~~
	Application Number	16/821,464 ELLO-119/06US 342083-3260
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(●) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	58249		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15/816154	2017-11-17

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/816154	Continuation of	15/205390	2016-07-08	9849084	2017-12-26

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/205390	Continuation of	14/311732	2014-06-23	9387167	2016-07-12

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/311732	Division of	12/896005	2010-10-01	8771729	2014-07-08

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
12/896005	Claims benefit of provisional	61/247642	2009-10-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US 326040-3260~~
	Application Number	16/821,464 ~~ELLO-119/06US 342083-3260~~
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US 325048-3260~~
	Application Number	16/821,464 ELLO-119/06US 342083-3260
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☒ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAR-119/06US 325840-3260~~
	Application Number	16/821,464 ELLO-119/06US 342083-3260
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	

If the Applicant is an Organization check here. ☒

Organization Name	~~Adare Pharmaceuticals US, L.P.~~ ELLODI PHARMACEUTICALS, L.P.

Mailing Address Information For Applicant:

Address 1	1200 Lenox Drive, Suite 100		
Address 2			
City	Lawrenceville	**State/Province**	NJ
Country	US	Postal Code	08648
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~ADAP-119/06US 342083-3260~~
	Application Number	16/821,464 ELLO-119/06US 342083-3260
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		State/Province	
Country[i]		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Jonathan M. Cousin/			Date (YYYY-MM-DD)	2021-04-19
First Name	Jonathan	Last Name	Cousin	Registration Number	66,418

Additional Signature may be generated within this form by selecting the Add button.

PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Adare Pharmaceuticals US, L.P.

Application No./Patent No.: 16/821,464 Filed/Issue Date: March 17, 2020

Titled: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Ellodi Pharmaceuticals, L.P., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Stephen Perrett, Frederic Jay Cohen and Gopi Venkatesh To: Eurand, Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 052141, Frame 0668, or for which a copy thereof is attached.

2. From: Eurand, Inc. To: APTALIS PHARMATECH, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel 052184, Frame 0573, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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: 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.

PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

3. From: APTALIS PHARMATECH, INC. To: ADARE PHARMACEUTICALS, INC.

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: ADARE PHARMACEUTICALS, INC. To: ADARE DEVELOPMENT I, L.P.

The document was recorded in the United States Patent and Trademark Office at

Reel 052141, Frame 0708, or for which a copy thereof is attached.

5. From: ADARE DEVELOPMENT I, L.P. To: ADARE PHARMACEUTICALS US, L.P.

The document was recorded in the United States Patent and Trademark Office at

Reel 052184, Frame 0586, or for which a copy thereof is attached.

6. From: ADARE PHARMACEUTICALS US, L.P. To: ELLODI PHARMACEUTICALS, L.P.

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Jonathan M. Cousin/	April 19, 2021
Signature	Date
Jonathan M. Cousin	66,418
Printed or Typed Name	Title or Registration 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.



BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Filed in the office of	Document Number
Barbara K. Cegavske	20150196822-06
Secretary of State	Filing Date and Time
State of Nevada	04/29/2015 2:44 PM
	Entity Number
	C3818-1980

Certificate of Amendment

(PURSUANT TO NRS 78.385 AND 78.390)

USE BLACK INK ONLY - DO NOT HIGHLIGHT

ABOVE SPACE IS FOR OFFICE USE ONLY

Certificate of Amendment to Articles of Incorporation
For Nevada Profit Corporations
(Pursuant to NRS 78.385 and 78.390 - After Issuance of Stock)

1. Name of corporation:

APTALIS PHARMATECH, INC.

2. The articles have been amended as follows: (provide article numbers, if available)

Article I: The name of the Corporation is Adare Pharmaceuticals, Inc.

3. The vote by which the stockholders holding shares in the corporation entitling them to exercise at least a majority of the voting power, or such greater proportion of the voting power as may be required in the case of a vote by classes or series, or as may be required by the provisions of the articles of incorporation* have voted in favor of the amendment is: 100%

4. Effective date and time of filing: (optional) Date: Time:

(must not be later than 90 days after the certificate is filed)

5. Signature: (required)

X

Signature of Officer John Fraher, Director

*If any proposed amendment would alter or change any preference or any relative or other right given to any class or series of outstanding shares, then the amendment must be approved by the vote, in addition to the affirmative vote otherwise required, of the holders of shares representing a majority of the voting power of each class or series affected by the amendment regardless to limitations or restrictions on the voting power thereof.

IMPORTANT: Failure to include any of the above information and submit with the proper fees may cause this filing to be rejected.

This form must be accompanied by appropriate fees.

Nevada Secretary of State Amend Profit-After
Revised: 1-5-15

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

ADARE PHARMACEUTICALS, INC.

Nevada Business Identification # NV19801006556

Expiration Date: July 31, 2015

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.

Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on April 30, 2015

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

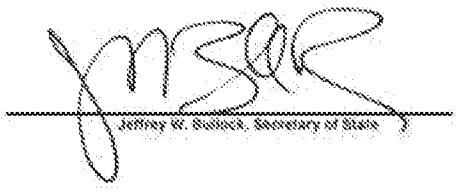
You may verify this license at www.nvsos.gov under the Nevada Business Search.

License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which by law cannot be waived.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "ADARE PHARMACEUTICALS US, L.P.", CHANGING ITS NAME FROM "ADARE PHARMACEUTICALS US, L.P." TO "ELLODI PHARMACEUTICALS, L.P.", FILED IN THIS OFFICE ON THE THIRTIETH DAY OF SEPTEMBER, A.D. 2020, AT 4:44 O`CLOCK P.M.





7103186 8100
SR# 20207572899

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State of Delaware
Secretary of State
Division of Corporations
Delivered 04:44 PM 09/30/2020
FILED 04:44 PM 09/30/2020
SR 20207572899 - File Number 7103186

STATE OF DELAWARE

AMENDMENT TO THE CERTIFICATE OF

LIMITED PARTNERSHIP

OF

ADARE PHARMACEUTICALS US, L.P.

Dated as of September 30, 2020

The undersigned, desiring to amend the Certificate of Limited Partnership pursuant to Section 17-202 of the Revised Uniform Limited Partnership Act of the State of Delaware, does hereby certify as follows:

FIRST: The name of the limited partnership is Adare Pharmaceuticals US, L.P.

SECOND: Article I of the Certificate of Limited Partnership shall be amended as follows:

"I. The name of the limited partnership is Ellodi Pharmaceuticals, L.P."

[*Remainder of this page intentionally left blank*]

IN WITNESS WHEREOF, the undersigned has executed this Certificate on the date first set forth above.

ADARE PHARMACEUTICALS US, L.P.
By: Adare Development I Genpar, LLC
its general partner

Troy Hamilton
Name: Troy Hamilton
Title: President

[*Signature Page to Amendment to the Certificate of Limited Partnership of Adare Pharmaceuticals US, L.P.*]

PTO/SB/08a (07-09)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	1.	DE 60202794 T2	05-18-2006	ETHYPHARM SA		
	2.	KR 10-2012-0104975 (and English Abstract)	09-24-2012	APTALIS PHARMATECH INC.	(corresponds to US 2011-0081411)	✓
	3.	WO 2003/039520 A1 (with English Abstract)	05-18-2003	ETHYPHARM		✓

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	4.	ALEXANDER, et al., "Review. Therapeutic Options for Eosinophilic Esophagitis". Gastroenterology & Hepatology (2011 Jan. 1); 7(1): 59-61.	
	5.	BEVERIDGE, et al., "Novel Therapeutic Approaches to Eosinophilic Esophagitis". Gastroenterology & Hematology (2020 Jun); 16(6): 294-301.	
	6.	DELLON, et al., "Efficacy of Budesonide vs Fluticasone for Initial Treatment of Eosinophilic Esophagitis in a Randomized Controlled Trial". Gastroenterology (2019); 157: 65-73.	
	7.	FURUTA, et al., "Review article: the pathogenesis and management of eosinophilic oesophagitis". Alimentary Pharmacology & Therapeutics (2006); 24: 172-182.	
	8.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Opponent in response to the Summons to attend Oral Proceedings, dated and filed December 8, 2020, and English translation, 37 pages.	✓
	9.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Consolidated List of References dated and filed December 8, 2020, 1 page.	
	10.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Further Written Submissions dated and filed December 8, 2020, and English translation, 30 pages.	
	11.	REMEDIOS, et al., "Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate". Gastrointestinal Endoscopy (2006); 63(1): 3-12.	✓
	12.	SCHAEFER, et al., "Comparison of Oral Prednisone and Topical Fluticasone in the Treatment of Eosinophilic Esophagitis: A Randomized Trial in Children". Clinical Gastroenterology and Hepatology (2008); 6: 165-173.	
	13.	WEN, Hong, (ed. SWARBICK, James) "Adsorption at Solid Surfaces: Pharmaceutical Applications". Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1 (2007); pgs. 34-38, 7 pages.	
	14.	Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Decision (and English translation) dated October 26, 2020, pronounced in the oral hearing of 21 July 2020, 45 pages.	✓

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	41504342
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	29-DEC-2020
Filing Date:	17-MAR-2020
Time Stamp:	18:16:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	DE60202794T2.pdf	1170637 14823ea64f4038cebe963295e8f55ce3f1bb6b36	no	17

Warnings:

Information:					
2	Foreign Reference	KR1020120104975_andEnglish Abstract.pdf	13734547 96f3e14b5bce71ba8408fbdea0508ed4e5f05253	no	20
Warnings:					
Information:					
3	Foreign Reference	WO2003039520A1.pdf	443008 eae83741e7ee4ef50adac0ccb5af7a857a2798fe	no	20
Warnings:					
Information:					
4	Non Patent Literature	ALEXANDER_2011.pdf	2530087 d88b107d32991901fe1f745f4f02a144e1e990e2	no	4
Warnings:					
Information:					
5	Non Patent Literature	BEVERIDGE_2020.pdf	8023082 a059137f2f026e582a742e5a6bd2baa9d3f82b76	no	8
Warnings:					
Information:					
6	Non Patent Literature	DELLON_2009.pdf	12450768 1fcbacbd7dbbc6707da38641f16afdf8021a52b9	no	14
Warnings:					
Information:					
7	Non Patent Literature	Oppn_3086782_Consolidated_List_of_Refs_12-8-2020_1_page.pdf	589890 45d70304436bd3de0642e8c7a8d87586ab4b277e	no	1
Warnings:					
Information:					
8	Non Patent Literature	Oppn_3086782_Opponent_Further_Written_Subm_andEngtrans_12-8-2020_30_pgs.pdf	16600126 21bac962f9220478cda6e1b7d874b3166f7aef84	no	30
Warnings:					
Information:					

9	Non Patent Literature	WEN_Adsorption-of-solid-surfaces_2007_7_pgs.pdf	4797695 62077da2b6856de61a4e1b3266d42e3bb6d07d03	no	7
Warnings:					
Information:					
10	Non Patent Literature	Oppn_2482822_Opponent_Written_Submissions_12-8-2020_andEngtrans_37_pgs.pdf	19975634 d951ba5dda08d979007cbfcce374346028771f78	no	37
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11	Non Patent Literature	FURUTA_2006.pdf	11909070 11346cfb1c23ba6c0640245b4bc47a69dc3d0bd5	no	10
Warnings:					
Information:					
12	Non Patent Literature	REMEDIOS_2006.pdf	10821626 71635cbaf5acbd52417934b0889bc1b35efa6f58	no	10
Warnings:					
Information:					
13	Non Patent Literature	SCHAEFER_2006.pdf	9905576 35361cb39cb00ad94e6ed1b977a28957a44df38c	no	9
Warnings:					
Information:					
14	Non Patent Literature	Patent_complaint_proceedings_2020-10-26_Decison_andEnglishtrans_45_pgs.pdf	23797567 5f8ffc4de8f724c7312e7501422a9b14e1f9527d	no	45
Warnings:					
Information:					
15	Transmittal Letter	ELLO-119-06US-IDS.pdf	150473 2799fda152333a07bc16ff5ae1b84bef937d81fb	no	5
Warnings:					
Information:					

16	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08.pdf	185430 011394db0dc6022e54844bc622ab3cb77bbd11df	no	2

Warnings:	
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Total Files Size (in bytes):	137085216

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

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[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending
ELLO-162/01US	16/968,711	8/10/2020	US 2020 - 0381097 A1	12/3/2020			Pending

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: December 29, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
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By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

PTO/SB/08a (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2020/0368147	11-26-2020	Meltzer, et al.	
	2.	2020/0381097	12-03-2020	Meltzer, et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
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Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	3.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication in connection with Summons to attend oral proceedings, dated November 20, 2020, 12 pages.	

Examiner Signature		Date Considered	

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Electronic Acknowledgement Receipt

EFS ID:	41346308
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Matthew H. Scheideman/Sandra Laramore
Filer Authorized By:	Matthew H. Scheideman
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	10-DEC-2020
Filing Date:	17-MAR-2020
Time Stamp:	15:36:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119-06US-IDS-2020-12-10.pdf	150524 344411ab15e4f03f4756555f8cb3949d4da1280e	no	5

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08-2020-12-10.pdf	162510 8af6e94a8c0d84f6176e9ef0c74fc94dfddf59d7	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	Oppn_2482822_EP_Comm_Summons-to-attend-oral-proceedings_11-20-2020_12_pgs.pdf	7883068 081a9a57874cb7896ad4230f6e840e09446d6a90	no	12
Warnings:					
Information:					
		Total Files Size (in bytes):	8196102		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

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UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

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Dated: December 10, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

By: /Matthew Scheideman/
Matthew Scheideman
Reg. No. 76,605
Jonathan M. Cousin
Reg. No. 66,418

PTO/SB/08b (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 29, 2020 advising of and enclosing Notice of Opposition filed by Dr. Falk Pharma GmbH on July 22, 2020, 82 pages.	
	2.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Opposition and Statement of Grounds of Opposition (with English translation of Statement of Grounds of Opposition), and Consolidated List of references relied upon, filed July 22, 2020, 513 pages.	✓
	3.	MORETON, R. Christian, "Disintegrants in Tableting". In book: Pharmaceutical Dosage Forms: Tablets, Vol. 2, Herausgeber Augsburger & Hoag, CRC Press, Taylor and Francis Group (2008); Ch. 6, pgs. 217-249	
	4.	WEBB, Paul A., "Surface Area, Porosity, and Related Physical Characteristics". In book: Pharmaceutical Dosage Forms: Tablets, 3rd Edition, Vol. 3, CRC Press, Taylor and Francis Group, Boca Raton, London, New York (2008); Chapter 11, pgs. 277-302.	
	5.	Dolo-Dobendan®, 1.4 mg/10 mg lozenges package insert, Reference ID 3030657, Revised: January 2015, with English translation, 7 pages.	✓
	6.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk dated February 10, 2020, 6 pages, in German and English.	✓
	7.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Writ as filed, dated February 11, 2020, and English translation, 5 pages.	✓
	8.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 12, 2020, and English translation, 5 pages.	✓
	9.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 13, 2020, and English translation, 5 pages.	✓
	10.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Auxiliary Request I-IV (marked-up) dated and as filed July 1, 2020, and English translation, 17 pages.	✓

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/08b (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	11.	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB4 - Letter from Lederer & Keller dated September 27, 2018 regarding European Patent No. 2211896, and Machine English translation, 28 pages.	✓
	12.	Supplementary European Search Report in European Patent Application No. EP 20192973.4, dated November 18, 2020, 5 pages.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019			Pending
ELLO-150/05US	16/992,671	8/13/2020					Pending
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: November 20, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

Electronic Acknowledgement Receipt

EFS ID:	41171016
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	20-NOV-2020
Filing Date:	17-MAR-2020
Time Stamp:	14:36:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Oppn_3041476_EPO_Comm_07-29-2020_withNoticeofOpposition_82_pgs.pdf	15522985 c1bc663561570a84d9a23b02223a00854f853ccd	no	82

Warnings:

Information:					
2	Non Patent Literature	MORTEON-Pharmaceutical_Dosage_Forms_pgs_217-249_2008_33_pgs.pdf	8119318 278b88a593c5c45bfffd9e4344fa2f1fb36996fd	no	33
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Information:					
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Warnings:					
Information:					
4	Non Patent Literature	Patent_complaint_proceedings_2020-02-10_Submission_of_Dr_Falk_German-and-English_6_pgs.pdf	430562 1d30c85bcdbb9c7a91b234a857cdf811c1d547bd	no	6
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Information:					
5	Non Patent Literature	Patent_complaint_proceedings_2020-02-11_Writ_as_filed_andEnglishtranslation_5_pgs.pdf	1445649 f2d9ac8a6cd7b5d67ad322d5b9045ee8ee7a1422	no	5
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Information:					
6	Non Patent Literature	Patent_complaint_proceedings_2020-02-12_Writ_as_filed_andEnglishtranslation_5_pgs.pdf	310906 e3cb4966e4958383ecc7f732e76ea37dfb30605f	no	5
Warnings:					
Information:					
7	Non Patent Literature	Patent_complaint_proceedings_2020-02-13_Writ_as_filed_andEnglishtranslation_5_pgs.pdf	317110 0706f2dd6948f1bc6a49cb0aec8313c770faa3c9	no	3
Warnings:					
Information:					
8	Non Patent Literature	UM_cancellation_proceedings-2020-07-01_Auxiliary_request_I-IV_andEnglishtranslation_17_pgs.pdf	354065 9ae9b4676daa563d64831c9272ce4db70d601ddb	no	17
Warnings:					
Information:					

9	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exh_BB4_Ltr_fr_Lederer_09-27-2018_andMachEngtrans_28_pgs.pdf	836409 084e8a7d90554b86c5f76a70cdaaef80459fe555	no	28
Warnings:					
Information:					
10	Non Patent Literature	Oppn_3041476_Notice-of-Opposition_and_Statementof-Grounds_07-22-2020_513_pt_1_160-pgs.pdf	22471170 def9b4f704ddd38fbe2841c748c1084c9c264ee8	no	160
Warnings:					
Information:					
11	Non Patent Literature	Oppn_3041476_Notice-of-Opposition_and_Statementof-Grounds_07-22-2020_513_pt_2_126-pgs.pdf	20845795 c98a9a85585c15f774a0aedf494567ae0946a98f	no	126
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Information:					
12	Non Patent Literature	Oppn_3041476_Notice-of-Opposition_and_Statementof-Grounds_07-22-2020_513_pt_3_134-pgs.pdf	16886957 44ae0a1758a201d81fc16649c2b37c770fbe1ba5	no	134
Warnings:					
Information:					
13	Non Patent Literature	Oppn_3041476_Notice-of-Opposition_and_Statementof-Grounds_07-22-2020_513_pt_4_93-pgs.pdf	16579418 8d7d2ec6b825762b247593f452e999893a1ff637	no	93
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Information:					
14	Non Patent Literature	WEBB-Pharmaceutical_Dosage_Forms_pgs_277-302_2008_26_pgs.pdf	6273173 45f32ea5812871face6140f0cc091df225c4175d	no	26
Warnings:					
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15	Non Patent Literature	EP20192973_SESR.pdf	335031 750069bfd191d2f580d9cef8a79faeac3e3dc087	no	5
Warnings:					
Information:					

16	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08.pdf	113420 59374ea8d428884ff779fed53db52040e0711610	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
17	Transmittal Letter	ELLO-119-06US-IDS.pdf	115319 af981f5f91a1c0f48ac02a4981c79ff4140ec4cb	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	113898959		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	1.	CA 2704946 A1	05-22-2019	MERITAGE PHARMA, INC.		
	2.	CA 2776164 A1	04-07-2011	APTALIS PHARMATECH, INC.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08b (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ELLO-119/06US 342083-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	3.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Adare's Response to the Grounds of Opposition, filed November 2, 2020, 78 pages.	
	4.	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	✓
	5.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, Patentee, Dr. Falk's Written Submissions, Auxiliary Request I and Test Report Jorveza® 1 mg (dated August 18, 2020, produced by Patentee, Dr. Falk Pharma), filed September 10, 2020, and English translation, 22 pages.	✓
	6.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Adare's Written Submissions in Preparation for Oral Proceedings, Auxiliary Requests 1-7 (clean and marked-up), including supporting evidence, as filed July 17, 2020, 126 pages.	
	7.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Adare's Response dated April 6, 2020 to Interlocutory Decision, and English translation, 29 ages.	✓
	8.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Pleadings as filed dated October 17, 2019, and English translation, 25 pages.	✓
	9.	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB1 "Breakdown of Features", and English translation, 2 pages.	✓
	10.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Replica dated July 19, 2019, and English translation, 25 pages.	✓
	11.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Complaint dated July 3, 2019, and English translation, 34 pages.	✓
	12.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, submission by Dr. Falk Pharma GmbH dated May 24, 2020, and English translation, 16 pages.	✓

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Docket No.: ELLO-119/06US 342083-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019			Pending
ELLO-150/05US	16/992,671	8/13/2020					Pending
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/06US 342083-3260.

Dated: November 9, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

Electronic Acknowledgement Receipt

EFS ID:	41068341
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/06US 342083-3260
Receipt Date:	09-NOV-2020
Filing Date:	17-MAR-2020
Time Stamp:	18:19:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	CA2704946A1.pdf	3345114 957a5b90ccff68848d50765fc92cee5a9766a8ab	no	50

Warnings:

Information:					
2	Foreign Reference	CA2776164A1.pdf	2126501 dc1e11281de8a1f46ff4ba7c0cf2f1e8e9fb01e9	no	36
Warnings:					
Information:					
3	Non Patent Literature	Oppn_3403654_Adare-s_Response_to_Grounds_of_Opposition_11-2-2020_78_pages.pdf	9698321 8fe339b318364af163e48fba67fcb23c42451eb4	no	78
Warnings:					
Information:					
4	Non Patent Literature	Oppn_2482822_EPO_Comm_07-23-2020_with_Submission-from-Adare_dtd_07-17-2020_126_pgs.pdf	20165432 58a613cfe5fa03cb6b61686d0e38bb6f0db239ac	no	126
Warnings:					
Information:					
5	Non Patent Literature	Oppn_3086782_Dr_Falk_Written_Subm_Auxiliary_Req_I_Jorveza_test_09-10-2020_andEngtrans_22_pgs.pdf	1624437 94a2e4e3def6b959e52dc122cece05d2f2bd7f32	no	22
Warnings:					
Information:					
6	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exhibit_BB1_and Englishtranslation_2_pgs.pdf	156520 1858cd4a3120f42782594 0082be07cc956b62914	no	2
Warnings:					
Information:					
7	Non Patent Literature	UM_Complaint_Proceedings-Patent-Complaint-07-03-2019_andEnglishtrans_34pgs.pdf	2829111 d518f1d1b6d20e7134b0011d2ea8ae7b7a9525e6	no	34
Warnings:					
Information:					
8	Non Patent Literature	NUROFEN_Package_insert_Feb_2018_andEnglishversion_2_pgs.pdf	664419 48577de5bc11b3d60b9272c99b9e04c769768657	no	2
Warnings:					
Information:					

9	Non Patent Literature	UM_cancellation_proceedings_2019-10-17_Response_to_pleadings_asfiled_andEnglishtrans_25_pgs.pdf	2834386 6b61bd5b3de0fdf59d65cda2acadd35796d7557e	no	25
Warnings:					
Information:					
10	Non Patent Literature	UM_cancellation_proceedings_2020-04-06_Adare_Resp_to_Interlocutory_Dec_andEnglishtrans_29_pgs.pdf	3306050 4282b79099a256f2fb5d282e6ca4788237946bc3	no	29
Warnings:					
Information:					
11	Non Patent Literature	UM_complaint_proceedings_2019-07-19_Replica_as_filed_andEnglishtrans_25_pgs.pdf	2751527 8e072074954ca189cc86d05310a26d8829d6ff99	no	25
Warnings:					
Information:					
12	Non Patent Literature	UM_complaint_proceedings_2019-05-24_Submission_of_Dr_Falk_andEnglishtranslation_16_pgs.pdf	8396682 afea07161a3dd45bf5cdf8f7d5c7d21b1ff5ae4e	no	16
Warnings:					
Information:					
13	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119-06US-SB08.pdf	128715 fcffc3ddefc9037ccb11d5d164a24c485fd9e81f	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
14	Transmittal Letter	ELLO-119-06US-IDS.pdf	115314 ce874bb2f1bb9caca20c51a971b150e60599c865	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	58142529		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference ADAR16201WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2019/019040	International filing date *(day/month/year)* 21 February 2019 (21.02.2019)	Priority date *(day/month/year)* 21 February 2018 (21.02.2018)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ADARE PHARMACEUTICALS US, L.P.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 27 August 2020 (27.08.2020)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Agnès Wittmann-Regis e-mail: pct.team6@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
C/O COOLEY LLP
1299 PENNSYLVANIA AVENUE, NW
SUITE 700
WASHINGTON, DC 20004-2400

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	25 JUN 2019
Applicant's or agent's file reference	**FOR FURTHER ACTION**
ADAR16201WO	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 19/19040	21 February 2019 (21.02.2019)	21 February 2018 (21.02.2018)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61P 1/00, C07K 16/28, G16H 10/00, G16H 10/60 (2019.01)
CPC - A61P 1/00, C07K 16/244, G16H 10/20

Applicant ADARE PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	03 June 2019	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 19/19040

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 19/19040

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-25, 29-33, 37-57, 92A

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 9-25, 29-33, 37-57, 92A are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 9-25, 29-33, 37-57, 92A are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 9-25, 29-33, 37-57, 92A

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 19/19040

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: claims 1-8, 26-28, 34-36, 91, drawn to a method of managing eosinophilic esophagitis (EoE) in a patient in need thereof, comprising comparing the results obtained from patient-reported outcome (PRO) questionnaires before and after the treatment of dysphagia.

Group II: claims 58-90, 92B, drawn to a system or a method of treating EoE in a patient in need thereof, comprising using a PRO questionnaire to obtain a transformed daily score and administering a therapeutic agent based on the score.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features

Group I includes the special technical feature of a method of managing EoE in a patient comprising measuring esophageal eosinophils in the patient; and comparing the results obtained from PRO questionnaires before and after therapeutic treatment, not required by Group II.

Group II includes the special technical feature of evaluating the score obtained from transformed PRO questionnaire results against a treatment range and administering a therapeutic agent when the score falls within the treatment range, not required by Group I.

Common Technical Features

The inventions of Groups I and II share the technical feature of a method of evaluating EoE in a patient comprising providing a PRO questionnaire.

However, these shared technical features do not represent a contribution over prior art in view of US 2016/0078186 A1 to Meritage Pharma Inc. (hereinafter 'MPI').

MPI teaches (instant claim 1) a method of managing eosinophilic esophagitis (EoE) in a patient in need thereof (abstract, a daily patient questionnaire, the questionnaire.; para [0006], the patient has dysphagia associated with eosinophilic esophagitis.; [0171], To demonstrate that an oral budesonide solution (OBS) induces, over a 12-week course of therapy:...a symptom response as measured by the Dysphagia Symptom Questionnaire (DSQ).), comprising:
(i) prior to treatment with a therapeutic agent (para [0174], Patients were given a placebo for a 4-week period to establish a Baseline for the co-primary endpoint determinations.),
(a) providing, via a digital processing device (abstract, computer-based systems, software, and methods of using the same including a daily patient questionnaire.), a patient-reported outcome (PRO) questionnaire (Title, A PATIENT-REPORTED OUTCOME MEASURE OF DYSPHAGIA PATIENTS WITH EOSINOPHILIC ESOPHAGITIS.)
(b) recording each episode of dysphagia, at the time the episode occurs (para [0189], A paper-based 4-question DSQ (see FIG. 21) was converted into an electronic format for hand-held devices.; Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat."), for a period of at least about two weeks using the PRO questionnaire (para [0174], a Final Treatment Period Evaluation at week 16.); and
--------continued in Supplemental Box--------

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-8, 26-28, 34-36, 91

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 19/19040

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-8, 26-28, 34-36, 91	YES
	Claims	7-8, 91	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-8, 26-28, 34-36, 91	NO
Industrial applicability (IA)	Claims	1-8, 26-28, 34-36, 91	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-6, 26-28, 34-36 lack novelty under PCT Article 33(2) as being anticipated by US 2016/0078186 A1 to Meritage Pharma Inc. (hereinafter 'MPI').

Regarding claim 1, MPI teaches a method of managing eosinophilic esophagitis (EoE) in a patient in need thereof (abstract, a daily patient questionnaire, the questionnaire.; para [0006], the patient has dysphagia associated with eosinophilic esophagitis.; [0171], To demonstrate that an oral budesonide solution (OBS) induces, over a 12-week course of therapy:...a symptom response as measured by the Dysphagia Symptom Questionnaire (DSQ).), comprising:
(i) prior to treatment with a therapeutic agent (para [0174], Patients were given a placebo for a 4-week period to establish a Baseline for the co-primary endpoint determinations.),
(a) providing, via a digital processing device (abstract, computer-based systems, software, and methods of using the same including a daily patient questionnaire.), a patient-reported outcome (PRO) questionnaire (Title, A PATIENT-REPORTED OUTCOME MEASURE OF DYSPHAGIA PATIENTS WITH EOSINOPHILIC ESOPHAGITIS.)
(b) recording each episode of dysphagia, at the time the episode occurs (para [0189], A paper-based 4-question DSQ (see FIG. 21) was converted into an electronic format for hand-held devices.; Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat."), for a period of at least about two weeks using the PRO questionnaire (para [0174], a Final Treatment Period Evaluation at week 16.); and
(c) measuring esophageal eosinophils in the patient (para [0176], 93 randomized EoE subjects 11-40 years old with >15/HPF at two levels of the esophagus and persistent dysphagia after 4 week blinded placebo Baseline period.); then
(ii) treating the patient with a therapeutically effective amount of a therapeutic agent for at least two weeks (para [0174], Patients were then divided into 2 groups, one receiving OBS treatment and the other continued placebo for a 12-week period.); and
(iii) recording, using the PRO questionnaire, each episode of dysphagia, at the time each episode occurs, while the patient is being treated (para [0174], a Final Treatment Period Evaluation at week 16.; abstract, a daily patient questionnaire.),
wherein dysphagia over a two week period of time while the patient is being treated is reduced compared to the dysphagia prior to treatment (para [0194], The proportion of subjects who were overall responders, which is defined as a reduction in the DSQ Score of >30% from Baseline to the Final Treatment Period Evaluation and a peak eosinophil count of <6/HPF across all available esophageal levels at the Final Treatment Period Evaluation (week 16), is shown in FIG. 24.).

Regarding claim 2, MPI teaches the method of claim 1, wherein recording in step (i)(b) comprises recording one or more of: incidence of an episode of dysphagia (Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat.").

Regarding claim 3, MPI teaches the method of claim 1, wherein recording in step (iii) comprises recording one or more of: incidence of an episode of dysphagia (Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat.").

Regarding claim 4, MPI teaches the method of claim 1 or 2, wherein the therapeutic agent is a corticosteroid (para [0174], Patients were then divided into 2 groups, one receiving OBS (Oral Budesonide Solution) treatment and the other continued placebo for a 12-week period.).

Regarding claim 5, MPI teaches the method of claim 4, wherein the corticosteroid is budesonide (para [0174], Patients were then divided into 2 groups, one receiving OBS (Oral Budesonide Solution) treatment and the other continued placebo for a 12-week period.).

Regarding claim 6, MPI teaches the method of claim 4, wherein the PPI is omeprazole, lansoprazole, dexlansoprazole, esomeprazole, pantoprazole, or rabeprazole (para [0101], the therapy comprises orally administering to the patient an effective amount of a proton pump inhibitor (PPI), e.g., omeprazole, lansoprazole, dexlansoprazole, esomeprazole, pantoprazole, or rabeprozol.).

--------continued in Supplemental Box--------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 19/19040

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. IV. Lack of unity of invention

(c) measuring esophageal eosinophils in the patient (para [0176], 93 randomized EoE subjects 11-40 years old with >15/HPF at two levels of the esophagus and persistent dysphagia after 4 week blinded placebo Baseline period.); then
(ii) treating the patient with a therapeutically effective amount of a therapeutic agent for at least two weeks (para [0174], Patients were then divided into 2 groups, one receiving OBS treatment and the other continued placebo for a 12-week period.); and
(iii) recording, using the PRO questionnaire, each episode of dysphagia, at the time each episode occurs, while the patient is being treated (para [0174], a Final Treatment Period Evaluation at week 16.; abstract, a daily patient questionnaire.),
wherein dysphagia over a two week period of time while the patient is being treated is reduced compared to the dysphagia prior to treatment (para [0194], The proportion of subjects who were overall responders, which is defined as a reduction in the DSQ Score of >30% from Baseline to the Final Treatment Period Evaluation and a peak eosinophil count of <6/HPF across all available esophageal levels at the Final Treatment Period Evaluation (week 16), is shown in FIG. 24.).

As said technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Groups I and II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Note, There are two claims have the same claim number (Claim 92). The first claim 92 is labeled as 92A and the second claim 92 is labeled as 92B.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US 19/19040

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V2. Citations and explanation

Regarding claim 26, MPI teaches a method of managing eosinophilic esophagitis (EoE) in a patient in need thereof (abstract, a daily patient questionnaire, the questionnaire.; para [0006], the patient has dysphagia associated with eosinophilic esophagitis.; [0171], To demonstrate that an oral budesonide solution (OBS) induces, over a 12-week course of therapy:...a symptom response as measured by the Dysphagia Symptom Questionnaire (DSQ).), comprising:
(i) prior to treatment with a therapeutic agent, recording a number of episodes of dysphagia for a period of two weeks using a patient reported outcome (PRO) questionnaire (para [0174], Patients were given a placebo for a 4-week period to establish a Baseline for the co-primary endpoint determinations.); then
(ii) treating the patient with a therapeutically effective amount of a therapeutic agent for at least two weeks (para [0174], Patients were then divided into 2 groups, one receiving OBS treatment and the other continued placebo for a 12-week period.);
(iii) recording each episode of dysphagia, at the time the episode occurs, while the patient is being treated using the PRO questionnaire (para [0174], a Final Treatment Period Evaluation at week 16.; abstract, a daily patient questionnaire.); and
(iv) measuring esophageal eosinophils in the patient (para [0176], 93 randomized EoE subjects 11-40 years old with >15/HPF at two levels of the esophagus and persistent dysphagia after 4 week blinded placebo Baseline period.);
wherein the number of episodes of dysphagia over any two week period of time while the patient is being treated is reduced compared to the number of episodes of dysphagia prior to treatment (para [0194], The proportion of subjects who were overall responders, which is defined as a reduction in the DSQ Score of >30% from Baseline to the Final Treatment Period Evaluation and a peak eosinophil count of <6/HPF across all available esophageal levels at the Final Treatment Period Evaluation (week 16), is shown in FIG. 24.).

Regarding claim 27, MPI teaches the method of claim 26, wherein recording in step (i) comprises recording one or more of: incidence of an episode of dysphagia (Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat.").

Regarding claim 28, MPI teaches the method of claim 26, wherein recording in step (iii) comprises recording one or more of: incidence of an episode of dysphagia (Fig. 21, Q2 "Since you work up this morning, has food gone down slowly or been stuck in your throat.").

Regarding claim 34, MPI teaches the method of claim 26, wherein the esophageal eosinophils are measured by obtaining a biopsy (para [0181], Modified Intent-to-Treat (MITT) analysis set includes all randomized subjects who received at least one dose of double blind study drug and have both an evaluable post-baseline biopsy in the Treatment Period.).

Regarding claim 35, MPI teaches the method of claim 34, wherein the biopsy is an endoscopy (para [0192], Table 8, Baseline Total Endoscopy Score.).

Regarding claim 36, MPI teaches the method of claim 35, wherein the patient is a histological non-responder (para [0197], Table 9, OBS (2mg bid) (N=49) [Line 2, Histologic responders.... 19(38.8)]; [Line 10-11, Symptom responders - % reduction in DSQ score; > 30% reduction in DSQ score [n(%)] 34(69.4)]. Note, the above data suggest the histologic non-responders comprise 15 subjects.).

Claim 91 lacks an inventive step under PCT Article 33(3) as being obvious over MPI.

Regarding claim 91, MPI teaches the method of claims 2, 3, 27, or 28, further comprising one or more of: scoring the at least one severity question from 0 to 1 (para [0087], A second question is for determining whether the patient had difficulty swallowing solid food 820. An answer option indicating that the patient did not have difficulty swallowing solid food is assigned the numeric element 0 (e.g., Q2=0) 825. An answer option indicating that the patient did have difficulty swallowing solid food is assigned the numeric element 1 (e.g., Q2=1).). MPI does not specifically teach scoring question from 0 to 10, however, it would have been obvious to one of ordinary skill in the art to have applied a scoring system comprising 0 to 10, to measure the degree of the severity in said subject.

Claims 7-8 lack an inventive step under PCT Article 33(3) as being obvious over MPI, in view of US 2017/0183719 A1 to Children's Hospital Medical Center (hereinafter 'CHMC').

Regarding claims 7-8, MPI teaches the method of any one of claim 4, but does not specifically teach wherein the antibody is an IL-5 antibody, mepolizumab. CHMC teaches a method of treating of eosinophilic esophagitis with IL-5 specific antibody, mepolizumab (para [0125], In some embodiments, EoE can be treated through the inhibition of eosinophil survival, such as through IL-5 and/or IL-5Ra blockade....for example, IL-5-specific antibodies, such as mepolizumab.). It would have been obvious to one of ordinary skill in the art to have applied mepolizumab of CHMC to treat the eosinophilic esophagitis of MPI.

Claims 1-8, 26-28, 34-36, 91 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

Electronic Acknowledgement Receipt

EFS ID:	40583834
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/06US 325049-3260
Receipt Date:	18-SEP-2020
Filing Date:	17-MAR-2020
Time Stamp:	19:21:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP1310243A1.pdf	289052 ea99faf1e0d979e3781bd58b30a1c47368d96dcf	no	7

Warnings:

Information:					
2	Foreign Reference	EP3354276B1.pdf	3099462 324d07ceb2c7ee3bdd31de079ca54f8c257b0e7a	no	39
Warnings:					
Information:					
3	Non Patent Literature	JORVEZA-update_CHMP-03-26-2020_1pg.pdf	107910 62a552aa4eab1b321c6568e5018f7d924f5e24fe	no	1
Warnings:					
Information:					
4	Non Patent Literature	KRISHNA-Gastro_Hepa_2011.pdf	92084 5694f5fc472070bb55e852b4965aa78f8798ed43	no	5
Warnings:					
Information:					
5	Non Patent Literature	LANGDON-and-MULLAMEY_eds_ROWE_Handbook_2006.pdf	4507692 d3eb08f9891c6cd5299bd17762c55ba9ef48acb8	no	14
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Information:					
6	Non Patent Literature	Oppn_3403654_EPO_Comm_Notice_of_Opposition_06-22-2020_1_pg.pdf	34743 401f69472f7220cefb85e2695507a6ab19eb41d4	no	1
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Information:					
7	Non Patent Literature	Oppn_3403654_EPO_Comm_noticeofopposition_05-08-2020_1_pgs.pdf	43718 4d9da7abbe041ed4ec0010684be99536de65d9f0	no	1
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Information:					
8	Non Patent Literature	Oppn_3403654_Notice-of-Opposition_filed_04-28-2020_andEnglishtranslation_38_pgs.pdf	1555532 5203b7aa62db7bfa0006a7446ed6e90cfe283a67	no	38
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9	Non Patent Literature	Oppn_2482822_Falk_comm-to-EPO_oral_proceedings_08-12-2020_3_pgs.pdf	289471 1e8582a143051f467fdec9901324ea4043cbb2e3	no	3
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Information:					
10	Non Patent Literature	Oppn_2482822_Adares_Comm_08-11-2020_4_pgs.pdf	2128479 40b5069d2c017ff1f491e7daa2c6a39dc09ff9f3	no	4
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Information:					
11	Non Patent Literature	Oppn_2482822_EPO_Comm_07-23-2020_with_Submission-from-Adare_dtd_07-17-2020_126_pgs.pdf	20165432 58a613cfe5fa03cb6b61686d0e38bb6f0db239ac	no	126
Warnings:					
Information:					
12	Non Patent Literature	Declaration-of-Stephen-Perrett_07-16-2020_6_pages.pdf	3389180 f79e46acca226726cad337b157094ac6ff16a4fb	no	6
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Information:					
13	Non Patent Literature	PELLE-Hosp_Pharm_2006.pdf	3229593 b117a9b85c4b86f0b7aacfb588d01134787ee6df	no	4
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14	Non Patent Literature	LEE-Test_Report_11-15-2019_16_pgs.pdf	2582030 6fe5b6f60522c72f2f3c136908a701668f1f3862	no	16
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15	Non Patent Literature	Oppn_2482822_EPO_Comm_Consolidated-list-ofcited-oppositions-docs_07-18-2020_1_pg.pdf	42998 99ad4510b842dacef41cc4d8556f9c1af7952809	no	2
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16	Non Patent Literature	Oppn_2482822_EPO_Comm_re_Oral_proceedings_07-13-2020_3_pgs.pdf	106797 a1edd87f7f36c619727e7690c7c10242b9bd735e	no	3
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17	Non Patent Literature	Oppn_2482822_EPO_comm-to-EPO_oral_proceedings_08-05-2020_1_page.pdf	41224 43915b1cdfbdecddf37d9fcddd623c41a527b128	no	1
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18	Non Patent Literature	LIACOURAS_1998.pdf	402326 4acadb97e651eb5ba678b48384ea40cda863045f	no	7
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19	Non Patent Literature	FURUTA_1998.pdf	94013 3cfa085906a948000a9c2e0015d4a0addab6327f	no	5
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20	Non Patent Literature	KATDARE-and-CHAUBAL_2006_28_pgs.pdf	1913791 0cb05363fb921d6c8f88303d1ddb02554578e2ad	no	28
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21	Non Patent Literature	Oppn_2482822_Opponents_response_to_Summons_07-17-2020-andEnglish_translation_15_pgs.pdf	9119884 b3cdf53562d28f9ae10cb80f5bc98e7c44819c54	no	15
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22	Non Patent Literature	Oppn_2482822_Adare_Ltr_toEPO_re_Oral_Proceedings_07-17-2020_5_pgs.pdf	1276547 4628db938148eb3e9f861f8ce2b68ac6ec5150fa	no	5
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23	Non Patent Literature	Oppn_2482822_EPO_Comm_07-13-2020_3_pgs.pdf	106797 9b1e39e8796b9767ab2682fcb2b8af19f04fa788	no	3
Warnings:					
Information:					
24	Non Patent Literature	Oppn_2482822_Summons-to-attend-oral-proceedings-and_Preliminary_Opinion_02-13-2020_15pgs.pdf	19488896 45a4713949ef72557acdf9da935091a24cbab470	no	15
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25	Non Patent Literature	Oppn_2482822_EPO_Comm_09-26-2019_88_pg.pdf	8555072 62ee66d2afdc19bcbc71da030ad75241a07706ad	no	88
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26	Non Patent Literature	Dr_Fs_novelty_table_2_pgs.pdf	228329 1d2c29eaba1764f20c27a2cc22b2b4c99086f182	no	2
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27	Non Patent Literature	Oppn_2482822_Submission_filed_09-20-2019_91_pgs.pdf	8626181 a2397f101c1ce2caed0d4dc623d3d670a221e4d9	no	91
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28	Non Patent Literature	Oppn_2482822_EPO_Comm_re_notice-of-opposition_05-13-2019_1_pg.pdf	27471 aa45ec7e362f7b6560d58524ea07676d8cb08f11	no	1
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29	Non Patent Literature	Oppn_2482822_Notice-of-opposition_03-01-2019_andEnglishtranslation_23_pgs.pdf	768528 888db3a0c09bc4b25a39b3dba804e23f232da860	no	23
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30	Non Patent Literature	Oppn_3086782_EPO_Comm_re_oral_proceedings_07-22-2020_3pgs.pdf	136895 c1fb4367a9c665cb21754d1f3f65770b7412320c	no	6
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31	Non Patent Literature	Oppn_3086782_EPO_Comm_Patentee_resp-to-oppn_11-8-2020_22_pgs.pdf	911993 1fd79f2c7bd005cabc540943123b7c71175651cb	no	22
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32	Non Patent Literature	Oppn_3086782_EPO_Comm_07-2-2019_transmitting_Notice-of-Opposition_filed_06-26-2019_43_pgs.pdf	9230108 3c046631cbe979b041eef9ce361f105943b8984b	no	43
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33	Non Patent Literature	PCTUS2019019040_IPRP.pdf	445187 7c43b00a7a25a9b2997c3bbcbdf88d01a99513ab	no	8
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Information:					
34	Non Patent Literature	HAHM-and-AUGSBURGER_Orally_Disintegrating_2008_21_pages.pdf	22716527 c5e0ac5efc06251df6dead60b7891a352770ad6c	no	21
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35	Non Patent Literature	Oppn_2886108_EPO_Comm_re_oral_proceedings_07-24-2020_6_pgs.pdf	3376025 069f5f55ef134f2850e04bc7125550c960135cfd	no	6
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36	Non Patent Literature	Oppn_2886108_Response_fr_Falk_03-20-2020_andEnglishtranslation_34_pgs.pdf	18962867 bd739ee7e05ff951997ccaf8ea1bd0de53630a6a	no	34
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37	Non Patent Literature	Oppn_2886108_11-06-2019_Consolidated_list_of_cited_opposition_docs.pdf	38662 2e48d0ea1bbb64ed9092ce1231e34753476740fc	no	1
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Information:					
38	Non Patent Literature	Auszug-von-European-Pharmacopeia-6_0_English_language_07-23-2007_2_pgs.pdf	212062 2248be104c3b926b816124ad9fdad6ce41265aee	no	2
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39	Non Patent Literature	Auszug-von-European-Pharmacopeia-8_0_German_language_07-15-2013_1_pg.pdf	127344 774e9296717f5dfc4ee493602c2dcd7e550ff364	no	1
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40	Non Patent Literature	Auszug-von-US-Pharmacopeia-35-1217_05-01-2012_3_pages.pdf	352252 4aa8ab31302a7201f32ede7120923e01edd22006	no	3
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41	Non Patent Literature	Dr_Schleuniqer_Key-Factors_Pharmatron_2011_5_pages.pdf	1421267 530f71be1f89c3eb3db35cc951a137c728b5de10	no	5
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Information:					
42	Non Patent Literature	Author_Unknown_WHT_3ME_brochure_Version_date-unknown_13_pgs.pdf	8046901 ea6402e5a1ffed2224b32a8cc6fb94b09cbb0544	no	13
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43	Non Patent Literature	DOHIL-Gastroenterol_2010.pdf	1841434 9725d1f6ee051c1ee07d8ba3c2d4ad6625765f33	no	13
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Information:					

44	Non Patent Literature	TAYEBI-and-MORTAZAVI_Iran_J_Pharm_Res_2011.pdf	1553135 2c2dd5d551a08baf5e21ae9d3c30c2b6556 58b51	no	12
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45	Non Patent Literature	Patent_Complaint_Proceedings-Submission-of-Dr-Falk-statement-of-defense_10-07-2019_14pgs.pdf	935512 670d028cfce4dd9574c41fecc7dfccfa95947 1d9	no	14
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46	Non Patent Literature	UM_complaint_proceedings_2019-05-24_Submission_of_Dr_Falk_andEnglishtranslation_16_pgs.pdf	8396682 afea07161a3dd45bf5cdf8f7d5c7d21b1ff5a e4e	no	16
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47	Non Patent Literature	UM_cancellation_proceedings_2020-07-08_Submission-of-Dr-Falk_andEnglishtranslation_11_pgs.pdf	14040001 4180081e8313a52f2b76b752b789227a529 ac7d7	no	11
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48	Non Patent Literature	UM_cancellation_proceedings_2020-07-02_Response_to_Dr_Falk_and_summons_andEnglishtrans_18_pgs.pdf	9160413 de039c392f74a311a315be3d6d245b424c3 ed346	no	18
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49	Non Patent Literature	UM_Cancellation_Proceedings-SubmissionResponse-to_Prel_Opin_by-Falk_04-08-2020_andEngtrans_18pgs.pdf	9703649 233c56a339c63a7e95171cd9d7e1b418ca1 35194	no	18
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50	Non Patent Literature	UM_cancellation_proceedings_2020-04-06AuxiliaryRequests_1and2_andEnglishtranslations_23pgs.pdf	11326366 f02fffee211b18a77e80fc69a4efaca4bb7a7 351	no	23
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51	Non Patent Literature	UM_cancellation_proceedings_2020-01-22_Official_Comm_interlocutory_notice_andEngtrans_12_pgs.pdf	7677121 e944016b4983755a43f17979fa5ec1b0be241044	no	12
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52	Non Patent Literature	UM_cancellation_proceedings_2019-09-13_Subm_of_Dr_Falk_pleadings_andEngtrans_27_pgs.pdf	23611635 5c7e4cb8728a5afc76b27fa0ea4dddea8bbef147	no	27
Warnings:					
Information:					
53	Foreign Reference	JP2011503073A_andEnglishAbstract_corr_to_WO2009064457A2.pdf	12976388 152c3e3e68c06a392bd7673f80b71c444672cc06	no	89
Warnings:					
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54	Non Patent Literature	Oppn_2886108_EPO_Comm_Preliminary_Opinion-andEnglishtranslation_07-02-2020_18_pgs.pdf	2478545 c1374fd69773538a1b8391a466ce746aacc4db3c	no	18
Warnings:					
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55	Non Patent Literature	Oppn_3086782_EPO_Comm_to_Adare_oral_proceedings_03-02-2020_14_pgs.pdf	2210225 ebb169e4f6244fdaeab3a596f3c25838c6d01c68	no	14
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56	Non Patent Literature	Patent_complaint_proceedings_2019-12-16_Pleadings_as_filed_andEnglishtranslation_66_pgs.pdf	8028207 199cc8928a2ff9ce2ca259b0986e081905160a70	no	66
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57	Non Patent Literature	Patent_complaint_proceedings_2020-01-30_Submission_of_Dr_Falk-rejoinder_andEngtrans_38_pgs.pdf	4408837 fd57ec26fe6c6bcd9d52aa24533b0a05ca098402	no	38
Warnings:					
Information:					

58	Non Patent Literature	Patent_complaint_proceedings_2020-02-06_Resp_to_rejoinder_as_filed_andEngtrans_36_pgs.pdf	4466409 6eed793e68f2358494dd764bf07135fc12b97133	no	36
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			Total Files Size (in bytes):	281105881	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6,171,617	01-09-2001	Gruber	
	2.	6,596,311	07-22-2003	Dobetti	
	3.	10,632,069	04-28-2020	Perrett, et al.	
	4.	2007/0020330	01-25-2007	Dang, et al.	
	5.	2010/0034894	02-11-2010	Szymczak, et al.	
	6.	2011/0123460	05-26-2011	Wilhelm, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	7.	EP 1 310 243 A1	05-14-2003	ASTRAZENECA AB		
	8.	EP 3354276 B1	01-01-2020	Meritage Pharma, Inc.		
	9.	JP 2011-503073 A (and English Abstract, corresponds to WO 2009/064457 A2)	01-27-2011			✓

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Sheet 2 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

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	10.	JORVEZA (budesonide) Update by the Committee for Medicinal Products for Human Use (CHMP), Summary of opinion1 (post authorisation) dated March 26, 2020, European Medicines Agency, 1 page.	
	11.	KRISHNA, et al., "Treatment of Eosinophilic Esophagitis Is Oral Viscous Budesonide Superior to Swallowed Fluticasone Spray?" Gastroenterol Hepatol (2011 Jan); 7(1): 55-59.	
	12.	Langdon, BA and Mullamey, (2006) Handbook of Pharmaceutical Excipients. (eds.) Rowe, R.C., Sheskey, PJ and Owen, S.C., London: Pharmaceutical Press and American Pharmacists Association (extract - pages 53-55 and 742-743), 14 pages.	
	13.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated June 22, 2020, 1 page..	
	14.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated May 8, 2020, 1 page.	
	15.	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Statement of Grounds of Opposition filed on April 28, 2020, and English translation, 38 pages.	✓
	16.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Falk's Communication to the EPO re oral proceedings, dated August 12, 2020, 3 pages.	
	17.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Adare's Communication to the EPO re oral proceedings, dated August 11, 2020, 4 pages.	
	18.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication re oral proceedings, dated August 5, 2020, 1 page.	
	19.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Written Submission from Adare (Proprietor) dated July 17, 2020, 126 pages.	
	20.	Declaration of Stephen Perrett, MBA, Ph.D. dated July 16, 2020, 6 pages.	
	21.	PELLE, et al., "Using defined daily doses to study the use of antibacterials in UK hospitals". Hosp Pharm (2006); 13: 133-136.	

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Sheet 3 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	22.	LEE, Geoffrey, Professor, Report of Professor Geoffrey Lee, Ph.D. on measurement of disintegration time of "Jorveza® 1 mg orodispersible tablet" dated November 15, 2019, 16 pages.	
	23.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's consolidated list of cited opposition documents, July 18, 2020, 1 page.	
	24.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 13, 2020, 3 pages.	
	25.	LIACOURAS, et al., "Primary Eosinophilic Esophagitis in Children: Successful Treatment with Oral Corticosteroids". Journal of Pediatric Gastroenterology & Nutrition (1998); 26(4): 380-385.	
	26.	FURUTA, Glenn T., "Eosinophils in the Esophagus: Acid is Not the Only Cause". Journal of Pediatric Gastroenterology & Nutrition (April 1998); 26(4): 468-471.	
	27.	KATDARE and CHAUBAL (eds)., Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Systems, Herausg. CRC Press, Taylor & Francis Group, Boca Raton, USA, 2006; dart: Excipients for Oral Liquid Formulations, S. 155-180, 28 pages.	
	28.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Opponent's response to Summons dated July 17, 2020, and English translation, 15 pages.	✓
	29.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare - Letter to EPO re Oral Proceedings dated July 17, 2020, 5 pages.	
	30.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication re Oral Proceedings dated July 13, 2020, 3 pages.	
	31.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to Attend Oral Hearing and Preliminary Opinion in opposition dated February 13, 2020, 15 pages.	
	32.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated September 26, 2019, transmitting Adare's submission filed September 20, 2019, 88 pages.	
	33.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, D18 - Dr F's novelty table 2020, 2 pages.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	34.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication - communication of notice of opposition dated May 13, 2019, 1 page.	
	35.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Notice of Opposition dated March 1, 2019, and English translation, 23 pages.	✓
	36.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Submission filed by Adare Development I, L.P., on September 20, 2019, 91 pages.	
	37.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 22, 2020 regarding date of oral proceedings, 3 pages.	
	38.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication to Adare regarding oral proceedings dated March 2, 2020, and English translation, 14 pages.	✓
	39.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated November 19, 2019, with Patentee's response to Opposition dated November 8, 2019, and English translation, 22 pages.	✓
	40.	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 2, 2019, transmitting Notice of Opposition filed June 26, 2019, 43 pages.	
	41.	PCT Application No. PCT/US2019/019040, International Preliminary Report on Patentability, dated August 27, 2020, 8 pages.	
	42.	HAHM and AUGSBURGER, Orally Disintegrating Tablets and Related Tablet Formulations, Pharmaceutical Dosage Forms: Tablets, Third Edition, Ch. 9, Volume 2, Herausgeber: (eds) Larry L. Augsburger, Stephen W. Hoag, CRC Press (2008), 21 pages.	
	43.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated July 24, 2020 regarding oral proceedings, 6 pages.	
	44.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication re Summons to Attend Oral Proceedings and Preliminary Opinion, dated July 2, 2020, and English translation, 18 pages.	✓

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

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	45.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated March 25, 2020 transmitting communication from Dr. Falk Pharma GmbH dated March 20, 2020, and English translation, 34 pages.	✓
	46.	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, Consolidated List of Cited Opposition Documents, 1 page.	
	47.	Auszug von European Pharmacopeia 6.0 (English language) <2.9.8>; 23 July 2007, 2 pages.	
	48.	Auszug von European Pharmacopeia 8.0 (German language) <2.9.8>; 15 July 2013, 1 page.	
	49.	Auszug von US Pharmacopeia 35 <1217>; 1 May 2012, 3 pages.	
	50.	Dr. Schleuniqer, "Key factors influencing measured tablet hardness"; Pharmatron; 2011, 5 pages.	
	51.	Author Unknown, WHT 3ME brochure Version 2.0; "Fully Automated 4 in 1 Tablet Testing Instrument' Pharma Test; publication date unknown	
	52.	DOHIL, et al., "Oral Viscous Budesonide Is Effective in Children With Eosinophilic Esophagitis in a Randomized, Placebo-Controlled Trial". Gastroenterol. (2010 August); 139(2): 418-429.	
	53.	TAYEBI and MORTAZAVI, "Formulation and Evaluation of a Novel Matrix-Type Orally Disintegrating Ibuprofen Tablet". Iran J Pharm Res. (2011 Summer); 10(3): 469-479.	
	54.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Pleadings as filed, dated December 16, 2019, and English translation, 66 pages.	✓
	55.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk - rejoinder dated January 30, 2020 (and English translation), 38 pages.	✓
	56.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Response to Rejoinder as filed, dated February 6, 2020 (and English translation), 36 pages.	✓

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Sheet 6 of 8

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

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	57.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk - statement of defense, filed October 7, 2019 (and English translation), 14 pages.	✓
	58.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, submission by Dr. Falk Pharma GmbH dated May 24, 2020 (and English translation), 16 pages.	✓
	59.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Submission of Dr. Falk - response to Adare and summons, dated July 8, 2020 (and English translation), 11 pages.	✓
	60.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Dr. Falk and Summons dated July 2, 2020, and English translation, 18 pages.	✓
	61.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, submission/Response by Dr. Falk Pharma GmbH dated April 8, 2020 (and English translation), 18 pages.	✓
	62.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Communication from Adare to German Patent Office, Auxiliary Requests 1 and 2 (clean, marked-up and English translations) as filed April 6, 2020, 23 pages.	✓
	63.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Official Communication - Interlocutory Notice dated January 22, 2020 (and English translation), 12 pages.	✓
	64.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Submission of Dr. Falk - Pleadings dated September 13, 2019 (and English translation), 27 pages.	✓
	65.	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Adare - Further Submission as filed dated July 12, 2019, and English translation, 56 pages.	✓
	66.	ACEVES, et al., "Topical viscous budesonide suspension for treatment of eosinophilic esophagitis". The Journal of Allergy and Clinical Immunology (2005 Sep 1); Volume 116, Issue 3, pp. 705-706. Epub 2005 Jul 1.	
	67.	ACEVES, et al., "Oral viscous budesonide: a potential new therapy for eosinophilic esophagitis in children". Am J Gastroenterol. (2007 Oct); 102(10): 1-9. Epub 2007 Jun 20.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 7 of 8

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	68.	THORBURN and FERGUSON, "Topical corticosteroids and lesions of the oral mucosa". Advanced Drug Delivery Reviews, Volume 13, Issues 1–2, January–February 1994, Pages 135-149.	
	69.	PONCHEL, Gilles, "Formulation of oral mucosal drug delivery systems for the systemic delivery of bioactive materials". Advanced Drug Delivery Reviews, Volume 13, Issues 1–2, January–February 1994, Pages 75-87.	
	70.	Exhibit BB2 - Handbook of Pharmaceutical Excipients (2009); Sixth Edition, ISBN 978 1 58212 135 2, (eds.) ROWE, et al., Cover Page, Print/Copyright and Preface Pages, 4 pages.	
	71.	Wikipedia, "Retard", https://de.wikipedia.org/wiki/Retard, June 13, 2019, and Google machine translation, 7 pages.	✓
	72.	EPO Communication dated April 25, 2019 in connection with Application No. EP 08848597.4, 13 pages.	
	73.	Budesonid, https://www.chemie.de/lexikon/Budesonid.html, and English version, 3 pages.	✓
	74.	New World Encyclopedia, "Gastrointestinal tract", https://www.newworldencyclopedia.org/entry/Gastrointestinal_tract, July 8, 2019, 6 pages.	
	75.	New World Encyclopedia, "Gastrointestinal tract", https://web.archive.org/web/20090917122455/https://www.newworldencyclopedia.or..., July 8, 2019, 7 pages.	
	76.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk - Rejoinder dated September 13, 2019 (English translation), 8 pages.	✓
	77.	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk -statement of defense, dated May 24, 2019 (and English translation), 16 pages.	✓

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Docket No.: ADAR-119/06US 325049-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Aradhana SASAN

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form used in lieu of PTO/SB/08 is enclosed.

[] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

[X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $240.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $120.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $60.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $240.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $120.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $60.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ADAR-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ADAR-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ADAR-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ADAR-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ADAR-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ADAR-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ADAR-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ADAR-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019			Pending
ADAR-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: September 18, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

Electronic Acknowledgement Receipt

EFS ID:	40586933
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/06US 325049-3260
Receipt Date:	18-SEP-2020
Filing Date:	17-MAR-2020
Time Stamp:	19:17:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	ACEVES_2005.pdf	56597 cee8887acb1c75472c84e752f9c815fcd70f3f2a	no	2

Warnings:

Information:					
2	Non Patent Literature	ACEVES_2007.pdf	225874 d71b78fd25397f120dbbddf49680a836408069a2	no	9
Warnings:					
Information:					
3	Non Patent Literature	THORBURN-and-FERGUSON_1994.pdf	17630383 888a73852e5b93b0905303275e209a36c1704d28	no	15
Warnings:					
Information:					
4	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exhibit_BB3_Wikipedia-Retard_andGoogletranslation_7_pgs.pdf	3732619 86bfcb74cdb868627f2c2d664b82ef019abb1e9e	no	7
Warnings:					
Information:					
5	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exhibit_BB5_EPO_Comm_04-25-2019_13_pgs.pdf	722123 b7bec07466b45c4a3c3457b9e53548a64df8dd0c	no	13
Warnings:					
Information:					
6	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exhibit_BB6_Budesonid_andEnglishversion_3_pgs.pdf	1366334 fd8d9aa8c5b54f41dd2bc965cb00131d0846e968	no	3
Warnings:					
Information:					
7	Non Patent Literature	New_World_Encyclopedia_Gastrointestinal_tract_6_pgs.pdf	254759 4bce9495ed6605406851408861 9f0e658924aff1	no	6
Warnings:					
Information:					
8	Non Patent Literature	New_World_Encyclopedia_Gastrointestinal_tract_7_pgs.pdf	306574 2ece7331c5bde66f62ff0566831c7db765680a56	no	7
Warnings:					
Information:					

9	Non Patent Literature	UM_complaint_proceedings_2019-09-13_Submission_of_Dr_Falk_Rejoinder_Englishtranslation_8_pgs.pdf	143898 f63ae727202553c1875d78aa49c8e8f193297dec	no	8
Warnings:					
Information:					
10	Non Patent Literature	UM_complaint_proceedings_2019-05-24_Submission_of_Dr_Falk_andEnglishtranslation_16_pgs.pdf	8396682 afea07161a3dd45bf5cdf8f7d5c7d21b1ff5ae4e	no	16
Warnings:					
Information:					
11	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Further_submission_as_filed_andEnglishtranslation_56_pgs.pdf	6531597 b0338b7455ecd19a02b2c10c838a2fb0b1c04435	no	56
Warnings:					
Information:					
12	Non Patent Literature	UM_cancellation_proceedings_2019-07-12_Exhibit_BB2_Handbook-of-Pharm-Excipients_2009_4_pgs.pdf	622045 a10dfb59de5503f6a11c78304347720 62bd3aed7	no	4
Warnings:					
Information:					
13	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119-06US-SB08.pdf	191684 99aa42691a433ddc4b2fcf08c1d97cfcd5f84844	no	7
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
14	Transmittal Letter	ADAR-119-06US-IDS.pdf	114166 80b958f46f3a9797387a4b9fc1472659376c5568	no	5
Warnings:					
Information:					
15	Non Patent Literature	PONCHEL-Adv_Drug_Del_Rev_1994.pdf	862361 14b680a9d7414944fb532e850d3f8c2998f601d4	no	13
Warnings:					
Information:					
		Total Files Size (in bytes):	41157696		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/821,464	03/17/2020	Stephen PERRETT	ADAR-119/06US 325049-3260

CONFIRMATION NO. 9443

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

PUBLICATION NOTICE



Title:ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Publication No.US-2020-0214979-A1
Publication Date:07/09/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/821,464	Filing Date 03/17/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/15/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/KAREN L VESTAL/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: 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.

Docket No.: ADAR-119/06US 325049-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Not Yet Assigned

For: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, please amend the above-captioned application as follows:

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

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

IN THE CLAIMS:

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

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

(i) about 0.5 mg to about 1 mg of budesonide;

(ii) and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity;

(iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;

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

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

2. (Original) The orally dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

3. (Cancelled)

4. (Original) The orally dispersing tablet of claim 1, comprising sucralose.

5. (Original) The orally dispersing tablet of claim 1, comprising sucralose and mannitol.

6. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, and magnesium stearate.

7. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.

8. (Original) The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.

9. (Original) The orally dispersing tablet of claim 1, comprising sucralose and magnesium stearate.

10. (Original) The orally dispersing tablet of claim 1, comprising sucralose and polyvinyl pyrrolidone.

11. (Original) The orally dispersing tablet of claim 1, comprising sucralose and polyethylene glycol.

12. (Original) The orally dispersing tablet of claim 1, comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

13. (Original) The orally dispersing tablet of claim 1, comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

14. (Original) The orally dispersing tablet of claim 1, comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

15-21. (Cancelled)

22. (Original) A method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.

23. (New) The orally dispersing tablet of claim 1, comprising about 0.5 mg of budesonide.

24. (New) The orally dispersing tablet of claim 1, comprising about 1 mg of budesonide.

REMARKS

After entry of the present amendments, claim 1, 2, 4-14 and 22-24 are pending. Claim 1 has been amended to further define the subject matter recited by the claim. Claims 23 and 24 have been added. Claims 3 and 15-21 have been cancelled. These amendments are supported by the application as originally-filed and do not introduce any new matter. Entry and consideration of the foregoing amendments is respectfully requested.

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.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1283, under Order No. ADAR-119/06US 325049-3260 from which the undersigned is authorized to draw.

Dated: June 15, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
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Electronic signature: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

Electronic Acknowledgement Receipt

EFS ID:	39713822
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/06US 325049-3260
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Time Stamp:	09:42:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ADAR-119-06US_Preliminary_Amendment.pdf	133145 4516a3990300f92650367f5102d404498aa62a10	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	133145	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	3,705,172	12-05-1972	Buchel, et al.	
	2.	3,929,768	12-30-1975	Brattsand, et al.	
	3.	4,080,448	03-21-1978	Mirsky	
	4.	4,335,121	06-15-1982	Phillipps, et al.	
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	12.	5,776,433	07-07-1998	Tzou, et al.	
	13.	6,316,027	11-13-2001	Johnson, et al.	
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	16.	7,033,606	04-25-2006	Besse, et al.	
	17.	8,580,300	11-12-2013	Wilhelm, et al.	
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	28.	10,471,071	11-12-2019	Gosselin, et al.	

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Sheet 2 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

U. S. PATENT DOCUMENTS

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	29.	2001/0006625	07-05-2001	Bohn et al.	
	30.	2001/0014340	08-16-2001	Ohta, et al.	
	31.	2003/0050312	03-13-2003	Hjorth, et al.	
	32.	2003/0054036	03-20-2003	Liggins, et al.	
	33.	2003/0099701	05-29-2003	Takaishi, et al.	
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	35.	2004/0053902	03-18-2004	Smith, Steven C.	
	36.	2004/0009212	01-15-2004	Tsai, Tsui-min	
	37.	2004/0106663	06-03-2004	Talley, et al.	
	38.	2004/0265375	12-30-2004	Platteeuw, et al.	
	39.	2005/0009848	01-13-2005	Brantl	
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	41.	2005/0232988	10-20-2005	Venkatesh, et al.	
	42.	2006/0051414	03-09-2006	Ramalho, et al.	
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	45.	2009/0074862	03-19-2009	Schioppi, et al.	
	46.	2009/0123550	05-14-2009	Phillips, et al.	
	47.	2009/0123551	05-14-2009	Phillips, et al.	
	48.	2009/0131386	05-21-2009	Phillips	
	49.	2009/0149433	06-11-2009	Phillips	
	50.	2009/0155360	06-18-2009	Venkatesh, et al.	
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	52.	2009/0181099	07-16-2009	Dohil, et al.	
	53.	2009/0191275	07-30-2009	Dohil, et al.	
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	57.	2011/0097401	04-28-2011	Phillips, et al.	

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Sheet 3 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	58.	2012/0282335	11-08-2012	Venkatesh, et al.	
	59.	2014/0287051	09-25-2014	Perrett, et al.	
	60.	2014/0187523	07-03-2014	Dohil, et al.	
	61.	2014/0303131	10-09-2014	Perrett, et al.	
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	64.	2016/0206627	07-21-2016	Gosselin, et al.	
	65.	2016/0213681	07-28-2016	Phillips, et al.	
	66.	2018/0133145	05-17-2018	Meltzer, et al.	
	67.	2017/0071855	03-16-2017	Perrett, et al.	
	68.	2017/0183719	06-29-2017	Rothenberg, et al.	
	69.	2018/0153802	06-07-2018	Perrett, et al.	
	70.	2018/0071211	03-15-2018	Dohil, et al.	
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	73.	2020/0016171	01-16-2020	Gosselin, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	74.	CA 2430481 A1	06-13-2002	SAMYANG CORPORATION		
	75.	CL 3827-2008	12-21-2007	EURAND, INC.		
	76.	DE 202010018594 U1 (and English Abstract)	02-16-2018	ADARE PHARMACEUTICALS INC.		
	77.	DE 2323215 A1	11-29-1973	AP Bofors		
	78.	DE 4129535 A1 (and English Abstract)	03-12-1992	Especialidades Latinas Medicamentos Universales S.A.		
	79.	EP 0057401 A1	08-11-1982	Schering Corporation		
	80.	EP 0440372 A1	08-07-1991	Pfizer Limited et al.		
	81.	EP 1323417 A1	07-02-2003	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
	82.	EP 1595533 A1	11-16-2005	NIPPON SHINKAYU CO LTD.		
	83.	EP 2211896 B1	01-03-2018	Meritage Pharma, Inc.		
	84.	EP 2214679 B1	03-27-2019	Meritage Pharma, Inc.		
	85.	JP 2003-261439 A (English Abstract)	09-16-2003	ASAHI KASEI CORP		
	86.	JP 2006-516616 A	07-06-2006			
	87.	JP 2006-77018 A (and English Abstract)	03-26-2006	KYOWA HAKKO KOGYO CO. LTD.		
	88.	JP H11-511162 A (English Abstract)	09-28-1999			
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Sheet 5 of 12

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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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	95.	JP 2009-519793 (English Abstract)	05-21-2009			
	96.	JP 2009-521523 A (English Abstract)	06-04-2009	JUBILANT ORGANOSYS LIMITED		
	97.	JP S56-138200 A	10-28-1981	GLAXO GROUP LTD		
	98.	KR 2006-0123160 A (and English Abstract)	12-01-2006	ALZA CORP.		
	99.	WO 1997/006786 A1	02-27-1997	R.P. SCHERER LIMITED		
	100.	WO 1998/047535 A1	10-29-1998	WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED		
	101.	WO 2000/064450 A1	11-02-2000	LEO PHARM PROD LTD.		
	102.	WO 2003/093344 A1	11-13-2003	JANSSEN PHARMACEUTICAL N.V.		
	103.	WO 2001/019342 A2	03-22-2001	GLAXO GROUP LIMITED		
	104.	WO 2004/064810 A1 (with English Abstract)	08-05-2004	NIPPON SHINYAKU CO., LTD.		
	105.	WO 2002/092057 A1 (with English Abstract)	11-21-2002	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
	106.	WO 2004/067004 A1	08-12-2004	OREXO AB		
	107.	WO 2004/069225 A1	08-19-2004	ELAN PHARMA INTERNATIONAL LTD.		
	108.	WO 2004/091585 A1	10-28-2004	SYNTHON B.V.		
	109.	WO 2005/087194 A1	09-22-2005	SCHERING AKTIENGESELLSCHAFT		
	110.	WO 2007/071179 A1 (with English Abstract)	06-28-2007	QUANTUM HI-TECH (BEIJING) RESEARCH INSTITUTE		
	111.	WO 2007/074472 A2	07-05-2007	JUBILANT ORGANOSYS LIMITED		
	112.	WO 2008/098634 A1	08-21-2008	POLICHEM S.A.		
	113.	WO 2009/064457 A2	05-22-2009	MERITAGE PHARMA, INC.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] "Number[4] "Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	114.	WO 2009/064458 A2	05-22-2009	MERITAGE PHARMA, INC.		
	115.	WO 2009/064819 A2	05-22-2009	MERITAGE PHARMA, INC.		
	116.	WO 2009/086046 A1	07-09-2009	EURAND, INC.		
	117.	WO 2009/098595 A2	08-13-2009	FOAMIX LTD.		
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	119.	WO 2010/144865 A2	12-16-2010	MERITAGE PHARMA, INC.		
	120.	WO 2011/041509 A1	04-07-2011	EURAND, INC.		
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	122.	WO 2015/035114 A1	03-12-2015	APTALIS PHARMATECH, INC.		
	123.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		
	124.	WO 2019/165138 A1	08-29-2019	ADARE DEVELOPMENT I, L.P.		
	125.	ZA 6805392	06-04-1969	Farbenfabriken Bayer AG		

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Sheet 7 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	126.	[Author Unknown] Definition of sustained-release (downloaded from Merriam-Webster online at https://www.merriam-webster.com/dictionary/sustainedrelease#medicalDictionary); accessed 7/31/2019, 1 page.	
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	130.	[Author Unknown] Solubility of budesonide (downloaded from https://pubchem.ncbi.nlm.nih.gov/compound/Budesonide#section=Solubility&fullscreen=true); information available as of 15 October 2015, accessed 8/1/2019, 1 page.	
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	136.	BREUER, et al., "Glossary of Terms Related to Pharmaceutics (IUPAC Recommendations 2009)" Pure Appl. Chem. (2009); 81 (5): 971-999.	
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Sheet 8 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	138.	BUCKTON, G., "Water sorption and near IR spectroscopy to study the differences between microcrystalline cellulose and silicified microcrystalline cellulose before and after wet granulation." International Journal of Pharmaceutics (1999 Apr); 181 (1): 41-47.	
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Sheet 9 of 12

Complete if Known	
Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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	151.	Forum of the National Formulary of Japan, compilation, Drugs in Japan, 2009 edition, published 2008, p. 2161-2165 (and English translation/summary of pertinent paragraphs), 8 pages.	
	152.	Georgia Application No. AP 2010012674, Search Report (with English translation) dated November 28, 2013, 11 pages.	
	153.	German Cancellation Action filed by Dr. Falk Pharma GmbH on March 1, 2019 with the German Patent Office, in connection with DE Patent No. 202010018594 U1 in the name of Adare Pharmaceuticals, Inc., and English translation, 21 pages.	
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Sheet 10 of 12

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Application Number	16/821,464
Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
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	164.	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006)	
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	170.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding of notice of opposition, 1 page.	
	171.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated November 5, 2019, enclosing Opponent's Further Written Submissions dated/filed on October 29, 2019 (and English translation) including consolidated list of prior art, 29 pages.	
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	173.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Patentee, Adare Development I, L.P.'s Response dated December 16, 2019 in response to further submissions filed by Dr. Falk Pharma GmbH on 10/29/2019, 16 pages.	
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Sheet 11 of 12

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Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/06US 325049-3260

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	176.	Patent Complaint filed with Regional Court Mannheim, Germany, re Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, dated July 3, 2019, with English translation, 107 pages.	
	177.	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	
	178.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	
	179.	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	
	180.	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	
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	184.	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	
	185.	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	
	186.	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	
	187.	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	

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Sheet 12 of 12

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Filing Date	March 17, 2020
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
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	192.	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	
	193.	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	
	194.	YALKOWSKY and BOLTON. "Particle size and content uniformity." Pharmaceutical Research, 7(9): 962-966 (1990).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	39119950
Application Number:	16821464
International Application Number:	
Confirmation Number:	9443
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/06US 325049-3260
Receipt Date:	10-APR-2020
Filing Date:	17-MAR-2020
Time Stamp:	09:26:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ADAR-119-06US-IDS.pdf	151084 bd8c8d45799bb435ebcc32fcbce0c8d3c448feed	no	5

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119-06US-SB08.pdf	291253 c1f45a3ef64cdba837cd659d916f666469cf0996	no	12
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2004091585A1.pdf	858701 80f31412f50d00d446a4caa1a0ca498e1217cb46	no	39
Warnings:					
Information:					
4	Foreign Reference	WO2009086046A1.pdf	1745374 93bfc507ac482548ced0d626532d84e2176384a9	no	52
Warnings:					
Information:					
5	Non Patent Literature	EP19207287_EESR.pdf	7330025 c091dee6fb76308e75cb4abd404f0dba19f93a9d	no	9
Warnings:					
Information:					
6	Non Patent Literature	EP17842162_EESR.pdf	6516823 9ff299eb9d3d0df8d0200578df2f0f4daee4ae6c	no	8
Warnings:					
Information:					
			Total Files Size (in bytes):	16893260	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ADAR-119/06US 325049-3260
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	9443
Application No.:	16/821,464	Group Art Unit:	1615
Filed:	March 17, 2020	Examiner:	Not Yet Assigned

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[X] Pursuant to 37 C.F.R. §1.98, copies of each non-US patent documents, **Cite Nos. 108, 116, 148 and 149** cited in the attached Form used in lieu of PTO/SB/08 **are** enclosed.

[X] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08, except for the Cite Nos. listed above, are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in **prior Applications Serial No(s). 15/816,154, 15/205,390 (U.S. Patent No. 9,849,084), 14/311,732 (U.S. Patent No. 9,387,167) and 12/896,005 (U.S. Patent No. 8,771,729)** to which the above-identified application claims priority under 35 U.S.C. §120.

[] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application Serial No. _____.

[X] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[X] before the mailing date of a first office action on the merits; or

[] before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:

[] a final action under 37 C.F.R. §1.113;

[] a notice of allowance under 37 C.F.R. §1.311; or

[] an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $240.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $120.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $60.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $240.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $120.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $60.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

[] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

[] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Applicant(s) also wish to make the examiner aware of the following U.S. application(s) and issued US patent(s) either having the same assignee or a common inventor with the above-identified application:

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ADAR-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ADAR-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ADAR-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ADAR-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ADAR-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ADAR-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ADAR-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019			Pending
ADAR-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending
ADAR-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018			Allowed

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: April 10, 2020

Respectfully submitted,
COOLEY LLP

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

Tel: (202) 842-7800
Fax: (202) 842-7899

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

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
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/821,464	03/17/2020	1615	1920	ADAR-119/06US 325049-3260	22	1

CONFIRMATION NO. 9443

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

FILING RECEIPT

OC000000113809558

Date Mailed: 04/01/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Stephen PERRETT, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi M. Venkatesh, Vandalia, OH;

Applicant(s)

Adale Pharmaceuticals US, L.P., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 58249

Domestic Priority data as claimed by applicant

This application is a CON of 15/816,154 11/17/2017
which is a CON of 15/205,390 07/08/2016 PAT 9849084
which is a CON of 14/311,732 06/23/2014 PAT 9387167
which is a DIV of 12/896,005 10/01/2010 PAT 8771729
which claims benefit of 61/247,642 10/01/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/30/2020
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/821,464**
Projected Publication Date: 07/09/2020
Non-Publication Request: No
Early Publication Request: No
Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/821,464

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2			OR	x 100 =	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1920

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

PTO/AIA/15 (10-17)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	ADAR-119/06US 325049-3260
First Named Inventor	Stephen PERRETT
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Priority Mail Express® Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [ ] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✓] **Specification** [*Total Pages* 28] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [ ] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* ____]
6. **Inventor's Oath or Declaration** [*Total Pages* 3] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [✓] A copy from a prior application (37 CFR 1.63(d))
7. [✓] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✓] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [ ] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [ ] **Other:** _____

*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

[✓] The address associated with Customer Number: 58249 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Jonathan M. Cousin/	Date	March 17, 2020
Name (Print/Type)	Jonathan M. Cousin	Registration No. (Attorney/Agent)	66,418

This collection of information is required by 37 CFR 1.53(b). 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: 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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	

Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Stephen		PERRETT	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Princeton	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.		
Address 2	1200 Lenox Drive, Suite 100		
City	Lawrenceville	State/Province	NJ
Postal Code	08648	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Fredric	Jay	COHEN	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Washington Crossing	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.		
Address 2	1200 Lenox Drive, Suite 100		
City	Lawrenceville	State/Province	NJ
Postal Code	08648	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gopi	M.	VENKATESH	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

City	Vandalia	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o ADARE PHARMACEUTICALS US, L.P.		
Address 2	1200 Lenox Drive, Suite 100		
City	Lawrenceville	**State/Province**	NJ
Postal Code	08648	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	58249		
Email Address	zIPPatentDocketingMailboxUS@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	ADAR-119/06US 325049-3260	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(●) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	58249		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15/816154	2017-11-17

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/816154	Continuation of	15/205390	2016-07-08	9849084	2017-12-26

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/205390	Continuation of	14/311732	2014-06-23	9387167	2016-07-12

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/311732	Division of	12/896005	2010-10-01	8771729	2014-07-08

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
12/896005	Claims benefit of provisional	61/247642	2009-10-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☒ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	

If the Applicant is an Organization check here. ☒

Organization Name	Adare Pharmaceuticals US, L.P.

Mailing Address Information For Applicant:

Address 1	1200 Lenox Drive, Suite 100		
Address 2			
City	Lawrenceville	**State/Province**	NJ
Country	US	Postal Code	08648
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Jonathan M. Cousin/			Date (YYYY-MM-DD)	2020-03-17
First Name	Jonathan	Last Name	Cousin	Registration Number	66,418

Additional Signature may be generated within this form by selecting the Add button.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/06US 325049-3260
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 the Freedom of Information Act requires disclosure of these records.

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 CooperationTreaty.

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 inspections 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.

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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.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	TBD (Continuation of 15/816,154, filed November 17, 2017)
Filing Date	Concurrent Herewith
First Named Inventor	Stephen PERRETT
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	ADAR-119/06US 325049-3260

SIGNATURE of Applicant or Patent Practitioner

Signature	/Jonathan M. Cousin/	Date (Optional)	
Name	Jonathan M. Cousin	Registration Number	66,418
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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: 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.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 58249

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Adare Pharmaceuticals US, L.P.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/Peter Richardson/	Date (Optional)	January 9, 2020
Name	Peter Richardson		
Title	President		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14/311,732

filed on June 23, 2014.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Stephen PERRETT Date (Optional): 10 May 2016

Signature: 

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LEGAL NAME OF INVENTOR

Inventor: Fredric Jay COHEN Date (Optional): 11 May 2016

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: Gopi VENKATESH Date (Optional): Aug 20, 2014

Signature: G. M Venkatesh

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ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation application of U.S. Patent Application No. 15/816,154, filed November 17, 2017, which is a continuation of U.S. Patent Application No. 15/205,390, filed July 8, 2016, now U.S. Patent No. 9,849,084, issued December 26, 2017, which is a continuation application of 14/311,732, filed June 23, 2014, now U.S. Patent 9,387,167, issued July 12, 2016, which is a divisional application of U.S. Patent Application No. 12/896,005, filed October 1, 2010, now U.S. Patent No. 8,771,729, issued July 8, 2014, and claims the benefit of priority to U.S. Provisional Application No. 61/247,642, filed October 1, 2009, the disclosures of each of which are herein incorporated by reference in its entirety for all purposes.

TECHNICAL FIELD OF THE INVENTIONS

[0002] This invention relates to orally administered corticosteroid compositions, useful for the treatment of conditions associated with inflammation of the gastrointestinal tract.

BACKGROUND OF THE INVENTION

[0003] There are currently no approved topically administered anti-inflammatory medications for the treatment of conditions associated with inflammation of the upper portion of the gastrointestinal tract. One such condition, eosinophilic esophagitis (EE), is an inflammatory condition of the esophagus. It is characterized histologically by a proliferation of eosinophils. The disease is painful, leads to difficulty swallowing and predisposes patients to food impaction and other complications.

[0004] Experimental and "off-label" treatments for EE include directing steroid medications formulated and approved for inhalation to the back of the throat such that they are not appreciably inhaled, and instructing the patient to rinse their mouth immediately after administration and not to swallow food or water for two hours after administration. Rinsing is recommended because residual drug in the mouth and throat can lead to candiasis infection, and swallowing is contraindicated because it may wash drug away from the esophagus. Aqueous corticosteroid preparations intended for oral inhalation through nebulization are also mixed with sugars to produce a thickened and sweetened liquid for administration.

[0005] Off-label treatments for EE also include administration of corticosteroid tablets containing steroids such as prednisolone. However, systemic administration of corticosteroids is associated with a number of known and undesirable side-effects. For example, oral prednisolone can produce generalized suppression of immune function, and in children, particularly troubling side-effects from long term systemic exposure include growth retardation, which may lead to a reduction in adult height.

[0006] There is therefore a need in the art for orally administered corticosteroid formulations which provide topical (rather than systemic) treatment of inflammation of the gastrointestinal tract, particularly inflammation of the upper gastrointestinal tract, such as EE.

SUMMARY OF THE INVENTION

[0007] 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.

[0008] In another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, and a pharmaceutically acceptable substantially non-aqueous liquid.

[0009] In another embodiment, the present invention is directed to a method for treating an inflammatory condition of the gastrointestinal tract. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

[0010] In yet another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, a pharmaceutically acceptable aqueous or substantially non-aqueous liquid, and a pharmaceutically acceptable phase change agent dissolved or suspended in the liquid, wherein after administration to a patient, the composition undergoes a change in physical properties upon contact with the gastrointestinal tract of the patient.

[0011] In yet another embodiment, the present invention is direction to a composition in solid or liquid form additionally comprising cyclodextrins.

[0012] The compositions of the present invention are useful for various conditions including the treatment of inflammatory conditions of the gastrointestinal tract. Accordingly, the present invention also provides a method for treating inflammatory conditions of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0013] All documents (e.g., patents, patent publication, journal articles, etc.) cited in the present application are incorporated by reference in their entirety for all purposes.

[0014] The term "drug", "active" or "active pharmaceutical ingredient" as used herein includes a pharmaceutically acceptable and therapeutically effective compound (e.g., corticosteroid), pharmaceutically acceptable salts, stereoisomers and mixtures of stereoisomers, solvates (including hydrates), and/or esters thereof (e.g., of corticosteroid).

[0015] The terms "orally disintegrating tablet", "orally dispersing tablet", or "ODT" refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing. The rate of oral disintegration can vary, but is significantly faster than the rate of oral disintegration of conventional solid dosage forms or chewable solid dosage forms (i.e., tablets or capsules) which are intended to be swallowed immediately after administration. ODT compositions of the present invention can contain pharmaceutically acceptable ingredients which swell, dissolve or otherwise facilitating the disintegration or dissolution of the ODT composition. Such ingredients can include pharmaceutical a disintegrant, a sugar alcohol, a saccharide, or a mixture thereof, a water-soluble binder, a meltable solid (e.g., a wax), which can release the corticosteroid upon entering the stomach, etc.

[0016] The term "about", as used herein to refer to a numerical quantity, includes "exactly". For example, "about 60 seconds" includes 60 seconds, exactly, as well as values close to 60 seconds (e.g., 50 seconds, 55 seconds, 59 seconds, 61 seconds, 65 seconds, 70 seconds, etc.). When the term "about" is used in reference to a range of values, the term "about" refers to both the minimum and maximum value of the range (e.g., "about 1-50 μm" means "about 1 μm to about 50 μm").

[0017] The term "adhesive agent", as used herein refers to agents which promote adhesion of the corticosteroid to biological surfaces, and includes, but is not limited to bio-adhesive agents. Adhesive agents can include compounds which adhere to the oropharyngeal mucosa, as well as

compounds which increase the residence time of the compositions of the present invention on the oropharyngeal mucosa of a patient.

[0018] The term "intimately associated", as used herein to describe the spatial relationship between two or more components of a composition refers to components that are intimately mixed, such as for example in mixtures, coatings and matrices.

[0019] The term "having no significant systemic glucocorticoid or mineralocorticoid activity", as used herein refers to corticosteroid compositions which do not provide a generalized effect in the body through absorption into the circulation, but do provide local effects through topical contact with a diseased tissue. Corticosteroids which have high systemic glucocorticoid potencies when administered orally include e.g., hydrocortisone, prednisone, prednisolone, methylprednisolone, dexamethasone, betamethasone, etc.) or mineralocorticoid potencies (e.g., alsosterone). These corticosteroids may be suitable for use in the compositions of the present invention if they are used at a sufficiently low dose, or are otherwise formulated such that they do not have significant systemic glucocorticoid or mineralcorticoid activity. Exemplary corticosteroids suitable for use in the compositions of the present invention include, but are not limited to budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone and tixocortol.

[0020] The term "bio-gelling polymer" as used herein refers to a polymer forms a gel under GI tract physiological conditions, for example, upon contact with physiological fluids or at physiological temperature.

[0021] The term "substantially non-aqueous liquid" refers to liquids which are completely anhydrous, or include only small amounts of water (e.g. less than about 10% water, for example less than about 9%, less than about 8%, less than about 7%, less than about 6%, less than about 5%, less than about 4%, less than about 3%, less than about 2%, or less than about 1% water).

[0022] The term "phase change agent" refers to an agent which, upon dissolution or suspension in the substantially non-aqueous liquids of the present invention, causes the liquid pharmaceutical compositions of the present invention to undergo a change in physical properties after administration to a patient. For example such changes in physical properties include precipitation of the dissolved or suspended components of the composition (e.g. the corticosteroid, optional excipients, and the phase change agent); gelation of the composition (e.g., formation of a hydrogel of the phase change agent and optionally excipients, wherein the hydrogel comprises at least a portion of the corticosteroid); or an increase in viscosity of the composition. These changes in

physical properties have the effect of increasing or enhancing contact of the corticosteroid to the mucosa of the gastrointestinal tract of the patient.

[0023] Unless indicated otherwise, all percentages and ratios are calculated by weight. Unless indicated otherwise, all percentages and ratios are calculated based on the total composition.

[0024] The solid and liquid pharmaceutical compositions of the present invention are suitable for topical administration of a corticosteroid to the gastrointestinal tract, for example the upper gastrointestinal tract such as the esophagus. Topical 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. Such side-effects are reduced still further with the use of corticosteroids which do not have significant systemic glucocorticoid or mineralocorticoid activity because of their reduced systemic exposure.

[0025] The pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract, for example inflammatory conditions of the upper gastrointestinal tract such as the esophagus. Thus, the present invention includes treating inflammatory conditions of the gastrointestinal tract by administering to a patient in need thereof a solid or liquid pharmaceutical composition of the present invention. Inflammatory conditions of the gastrointestinal tract which may be treated according to the present invention include inflammation of the esophagus, inflammation of the glottis, inflammation of the epiglottis, inflammation of the tonsils, inflammation of the oropharynx, eosinophilic esophagitis, gastroesophageal reflux disease (GERD), non-erosive reflux disease (NERD), erosive esophagitis, Barrett's esophagus, eosinophilic gastroenteritis, hypereosinophilic syndrome, corrosive (caustic) chemical esophagitis, radiation-induced esophagitis, chemotherapy-induced esophagitis, transient drug-induced esophagitis (also known as medication esophagitis), persistent drug-induced esophagitis, Crohn's disease of the esophagus, scleroderma, and scleroderma sine scleroderma, systemic lupus erythematosus, systemic vasculitides, leukocytoclastic vasculitis, polyarteritis nodosa, Churg-Strauss syndrome, rheumatoid vasculitis, and pseudomembranous esophagitis.

[0026] In other embodiments, the pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract such as an autoimmune disease, Behcet's syndrome, Kawasaki disease, X-linked lymphoproliferative syndrome; an infectious viral disease caused by one or more of the following viruses: Adenoviridae, Coronaviridae, Coxsackie virus, Herpes simplex, HIV, Influenza (Type A), Lassa virus, Epstein-

Barr virus, Parainfluenza, or Respiratory syncytial virus; an infectious bacterial disease caused by one or more of the following bacteria: Arcanobacterium hemolyticum, Chlamydia (Chlamydophila), Corynebacterium, Francisella tularensis, Group A, C, G Streptococcus, S. pneumoniae, S. pyogenes, Haemophilus influenza type B, Mycoplasma pneumonia, Neisseria gonorrhea, Multiple (e.g. peritonsillar cellulitis/abscess); an infectious fungal disease caused by Candida (e.g. Candida albicans) or Histoplasma (e.g. H capsulatum); inflammation caused by injury or an irritant selected from the group consisting of an airway foreign body, chloroacetophenone, chlorobenzylidene malononitrile, chronic smoke exposure, morpholine, sulfuryl fluoride, and scalded throat; lepidopterism, Seasonal allergic pharyngitis, and Stevens-Johnson syndrome; or periodic fever; etc.

[0027] In one embodiment, the present invention includes a method for treating inflammation of the esophagus comprising administering to a patient in need thereof a pharmaceutical composition of the present invention. In one such embodiment, the present invention includes a method for treating eosinophilic esophagitis comprising administering to a patient in need thereof a pharmaceutical composition of the present invention.

[0028] In another embodiment, the present invention includes a method for treating gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis comprising administering to an individual in need thereof a pharmaceutical composition of the present invention.

[0029] In another embodiment, the present invention includes a method for treating a food allergy with an identified allergen, e.g., “atopic IBS”, and “atopic bowel”.

[0030] 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.

[0031] Solid pharmaceutical compositions of the present invention can include, for example, an ODT (as described herein), a wafer, a film, or other solid dosage form which disintegrates or dissolves rapidly in the mouth to form a solution or dispersion of a corticosteroid, which can readily be swallowed.

[0032] In another embodiment, the present invention provides a liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable solvent, wherein the liquid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity. In one such embodiment the composition also includes a pharmaceutically acceptable bio-gelling polymer dissolved in the solvent, and the composition increases in viscosity upon contact with the gastrointestinal tract of an individual. In other embodiments, the liquid compositions of the present invention comprise a corticosteroid complex with a cyclodextrin, typically suspended or dissolved in a liquid carrier. The liquid compositions of the present invention may be in the form of a solution or a suspension. Liquid pharmaceutical compositions according to the present invention are compositions which are liquids at standard temperature and pressure conditions.

[0033] Suitable pharmaceutically acceptable liquids which may be used in the liquid pharmaceutical compositions of the present invention include, for example, alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone (NMP), 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. In one embodiment, the liquid is selected from the group of alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, glycerol and combinations thereof. In one such embodiment, the liquid is selected from the group of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof. In other embodiments, the liquid pharmaceutical

compositions of the present invention can comprise aqueous suspensions or solutions of a corticosteroid.

[0034] In one embodiment the bio-gelling polymer is a thermosensitive polymer. Suitable thermosensitive polymers include polyacrylamides, such as poly(N-isopropylacrylamide), as well as poly(ether-ester) copolymers, such as poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol). Such thermosensitive polymers can precipitate or cause an increase in viscosity of the liquid compositions of the present invention upon administration to a patient, and subsequent warming in the gastrointestinal tract. Thus, the compositions of the invention precipitate on or have a longer residence time on the gastrointestinal mucosa the patient, thereby increasing the topical contact of the corticosteroid on the gastrointestinal mucosa. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0035] In another embodiment, the compositions of the present invention include a bioadhesive agent, which is a lipid or a mixture of lipids. Such lipids or lipid mixtures may undergo a phase transition on contact with wetted biological surfaces to form an adhesive film. Examples of such lipids include mixtures of so-called membrane and non-membrane lipids which will typically form lamellar and non-lamellar structures, such as hexagonal or cubic phases, respectively. Examples of such lipids are glycerphospholipids such as phosphatidyl choline, and diacyl glycerols such as glycerol dioleate. Such self-organizing structures demonstrate superior spreading and adhesion to biological surfaces and have the advantage or being pharmaceutically acceptable materials. Advantageously the active agent, e.g. a corticosteroid may be dissolved in the lipid component.

[0036] Suitable non-aqueous solvents which may be included in the liquid pharmaceutical compositions of the present invention include pharmaceutically acceptable non-aqueous solvents in which the particular bio-gelling polymer is soluble. For example, the solvent may be an alcohol (e.g., ethanol), N-methyl-pyrrolidone (NMP), glycerol, propylene glycol, liquid polyethylene glycol, diethylene glycol monoethyl ether and mixtures thereof. In certain embodiments the solvent is water-miscible and the bio-gelling polymer is water-insoluble, so that upon administration the solvent mixes rapidly with the water from the digestive tract of the patient, causing the bio-gelling polymer and corticosteroid to precipitate on the gastrointestinal mucosa of the patient. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0037] Other bio-gelling polymers which may be included within the liquid pharmaceutical compositions of the present invention include cellulose derivatives (e.g., esters and/or ethers, crosslinked cellulose esters and/or ethers) cellulose esters, methacrylic acid and methacrylate polymers, 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, and copolymers, terpolymers and mixtures thereof. Bio-gelling polymers swell, and/or form hydrogels upon contact with moisture in the gastrointestinal tract, thereby adhering or increasing the viscosity of the compositions of the present invention on the mucosa of the gastrointestinal tract. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0038] In certain embodiments, the liquid pharmaceutical compositions of the present invention increase in viscosity upon contact with the gastrointestinal tract of an individual. In one embodiment, the increase in viscosity is at least 50% (relative to the viscosity prior to administration). In another such embodiment, the increase in viscosity is at least 100%. In yet another such embodiment, the increase in viscosity is at least 200%. The viscosity of the compositions before contact with the gastrointestinal tract of an individual may be measured using a viscometer. The change in viscosity of the compositions upon contact with the gastrointestinal tract of an individual may be determined by measuring the viscosity of the composition under simulated physiological conditions. For example, the viscosity of a given composition may be measured in simulated saliva.

[0039] Suitable corticosteroids which may be included in the pharmaceutical compositions of the present invention include budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, tixocortol and salts, solvates, and esters thereof. In a particular embodiment, the compositions of the present invention comprise fluticasone. In other embodiments, the compositions of the present invention comprise budesonide. Corticosteroids which typically have systemic glucocorticoid or mineralocorticoid activity when administered orally can also be used in the compositions of the present invention, if the composition is modified to reduce or suppress systemic uptake of the corticosteroid.

[0040] The amount of corticosteroid present in the pharmaceutical compositions of the present invention will depend upon the particular corticosteroid utilized. In general, however, the amount will be selected so as to maximize the therapeutic benefit from topical administration while minimizing systemic absorption. In the case of solid pharmaceutical compositions of the present invention, the amount of corticosteroid in the composition typically is less than or equal to 20 mg. In one embodiment the amount of corticosteroid in the pharmaceutical composition is between about 0.01 mg and about 20 mg. In another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 1 mg and about 15 mg. In still another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 10 mg. In yet another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 5 mg. In still other embodiments, the amount of corticosteroid is about 0.01 mg, about 0.02 mg, about 0.03 mg, about 0.04 mg, about 0.05 mg, about 0.06 mg, about 0.07 mg, about 0.08 mg, about 0.09 mg, about 0.1 mg, about 0.2 mg, about 0.3 mg, about 0.4 mg, about 0.5 mg, about 1 mg, about 2 mg, about 3 mg, about 4 mg, about 5 mg, about 6 mg, about 7 mg, about 8 mg, about 9 mg, about 10 mg, about 11 mg, about 12 mg, about 13 mg, about 14 mg, about 15 mg, about 16 mg, about 17 mg, about 18 mg, about 90 mg, or about 20 mg, inclusive of all ranges and subranges therebetween.

[0041] Typical amounts of corticosteroid in the solid pharmaceutical compositions of the present invention include about 0.25 mg, about 0.5 mg, about 1 mg, about 1.5 mg, about 2 mg, about 2.5 mg, about 3 mg, about 3.5 mg, about 4 mg, about 4.5 mg and about 5 mg. In the case of liquid pharmaceutical compositions of the present invention, the concentration of corticosteroid in the composition typically is such that an amount of corticosteroid consistent with the amounts described above (i.e., 0.01 mg to 20 mg) may be conveniently administered to an individual. For example, the concentration of corticosteroid may be such that a single pump from a spray pump device delivers about 0.05 mg, or any other therapeutically effective pre-selected amount, of corticosteroid to the oral cavity of an individual. In a particular embodiment, the compositions of the present invention comprise about 0.25 mg of fluticasone.

[0042] Upon administration of a solid pharmaceutical composition of the present invention to an individual, the composition disintegrates in the patient's oral cavity. In one embodiment, the composition of the present invention is in the form of an ODT. An ODT comprises drug containing particles (e.g., a corticosteroid as described herein optionally coated or combined with an adhesive

agent as described herein), combined with rapidly dispersing microgranules. Rapidly dispersing microgranules can be prepared as described in US 2005/0232988 or US 20010014340 by granulating a disintegrant having an average particle size of not more than about 30 μm with a sugar alcohol and/or saccharide having an average particle size of not more than about 30 μm. The granulation can be carried out, for example, in a high shear granulator with approximately 20-25% water as the granulating fluid, and if needed wet milled and dried to produce rapidly dispersing microgranules having an average particle size of not more than about 300 μm (e.g., about 175-300 μm).

[0043] The ratio of the disintegrant to the sugar alcohol, saccharide, or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01, for example about 90/10, about 91/9, about 92/8, about 93/7, about 94/6, about 95/5, about 96/4, about 97/3, about 98/2, about 99/1, inclusive of all values, ranges, and subranges therebetween.

[0044] The ratio of the rapidly dispersing microgranules to drug-containing particles ranges from about 5/1 to about 1/1, including about 5/1, 4/1, 3/1, 2/1, 1/1, inclusive of all values, ranges, and subranges therebetween.

[0045] The corticosteroid containing particles of the ODT dosage form should also have a small enough particle size such that after disintegration of the ODT in the oral cavity of the patient, a smooth, easy-to-swallow suspension results. In most embodiments in which the pharmaceutical compositions of the present invention is provided as an ODT dosage form, the average particle size of the taste-masked non-opioid analgesic/opioid analgesic drug-containing microparticles is not more than about 400 μm, or in some embodiments not more than about 300 μm.

[0046] The ODT dosage form as described herein may also include pharmaceutically acceptable excipients typically used in disintegrating tablet formulations such as microcrystalline cellulose and spray dried mannitol (compressible diluents), croscarmellose sodium or crospovidone (super disintegrant), coloring agents, and optionally magnesium stearate or sodium stearyl fumarate (lubricant intragranularly mixed or used externally to lubricate die and punch surfaces).

[0047] Tablet dosage forms, including ODT dosage forms, comprising the pharmaceutical composition of the present invention have a low friability, e.g., less than about 1%, (e.g., less than about 0.9%, less than about 0.8%, less than about 0.7%, less than about 0.6%, less than about 0.5%, less than about 0.4%, less than about 0.3%, etc., inclusive of all ranges and subranges

therebetween) in order to have sufficient durability to withstand handling, shipping, and/or packaging in push-through blister packaging.

[0048] A non-limiting list of suitable disintegrants for the rapidly dispersing microgranules includes crospovidone (cross-linked PVP), sodium starch glycolate, cross-linked sodium carboxymethylcellulose, calcium silicate, and low substituted hydroxypropyl cellulose. The amount of disintegrant in the ODT is typically in the range of about 1% to about 10% by weight.

[0049] A non-limiting list of suitable sugar alcohols includes mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol and combinations thereof. A non-limiting list of suitable saccharides includes lactose, sucrose, maltose, and combinations thereof. The amount of sugar alcohol and/or saccharide in the ODT ranges from about 30% to about 70% by weight.

[0050] Pharmaceutically acceptable excipients include fillers, diluents, glidants, disintegrants, binders and lubricants. Other pharmaceutically acceptable excipients include acidifying agents, alkalizing agents, preservatives, antioxidants, buffering agents, chelating agents, coloring agents, complexing agents, emulsifying and/or solubilizing agents, flavors, perfumes, humectants, sweetening agents and wetting agents.

[0051] Examples of suitable fillers, diluents and/or binders include lactose (e.g. spray-dried lactose, α-lactose, β-lactose, TABLETOSE®, various grades of PHARMATOSE®, MICROTOSE® or FAST-FLO®), microcrystalline cellulose (various grades of AVICEL®, CEOLUS®, ELCEMA®, VIVACEL®, MING TAI® or SOLKA-FLOC®), hydroxypropylcellulose, L-hydroxypropylcellulose (low substituted), low molecular weight hydroxypropyl methylcellulose (HPMC) (e.g. Methocel E, F and K from Dow Chemical, Metolose SH from Shin-Etsu, Ltd), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylhydroxyethylcellulose and other cellulose derivatives, sucrose, agarose, sorbitol, mannitol, dextrins, maltodextrins, starches or modified starches (including potato starch, maize starch and rice starch), calcium phosphate (e.g. basic calcium phosphate, calcium hydrogen phosphate, dicalcium phosphate hydrate), calcium sulfate, calcium carbonate, sodium alginate and collagen.

[0052] Examples of suitable diluents include e.g. calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrans, dextrin, dextrose, fructose, kaolin, lactose, mannitol, sorbitol, starch, pregelatinized starch, sucrose and sugar.

[0053] Examples of suitable disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrillin potassium, sodium starch glycolate, starch, pregelatinized starch, and carboxymethyl starch (e.g. PRIMOGEL® and EXPLOTAB®).

[0054] Specific examples of glidants and lubricants include stearic acid, magnesium stearate, calcium stearate or other metallic stearates, talc, waxes and glycerides, light mineral oil, PEG, glyceryl behenate, colloidal silica, hydrogenated vegetable oils, corn starch, sodium stearyl fumarate, polyethylene glycols, alkyl sulfates, sodium benzoate and sodium acetate.

[0055] Other excipients include e.g. flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and agents for modified release.

[0056] Other functional excipients such as cyclodextrins may be used, for example as taste-masking agents (e.g., by means of their complexation with the corticosteroid). Cyclodextrins may also be used as a carrier and/or a dispersant to facilitate delivery and distribution of the corticosteroid at the intended site of therapeutic activity.

[0057] Compositions of the present invention in the form of an ODT disintegrate into corticosteroid containing particles while sugar alcohol/saccharide-containing granules included within the composition rapidly dissolve, thereby forming a smooth suspension that can be readily swallowed.

[0058] Other corticosteroid-containing orally disintegrating or orally dissolving dosage forms such as wafers or films can also be used. For example, wafers can include dried or lyophilized compositions such as orally disintegrating or dissolving dosage forms prepared using ZYDIS® lyophilization technology (e.g., as described in U.S. Patent No. 6,316,027), containing a corticosteroid as the active pharmaceutical ingredient. Film dosage forms can include edible films such as those described in US 6,596,298 or US 6,740,332, containing a corticosteroid as the active pharmaceutical ingredient.

[0059] The rate of disintegration of the compositions of the present invention in the oral cavity of an individual can be on the order of about 60 seconds or less, about 50 seconds or less, about 40 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

[0060] The rate of disintegration of the solid pharmaceutical compositions of the present invention can be measured using various in vitro test methods, for example the USP <701> Disintegration Test. When using the USP <701> Disintegration Test, the rate of disintegration of the compositions of the present invention typically is about 60 seconds or less, about 45 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

[0061] In other embodiments, the solid pharmaceutical compositions of the present invention can have any rate of disintegration or dissolution in the oral cavity of a patient which provides a therapeutically effective amount of corticosteroid to the inflamed tissues of the gastrointestinal tract. For example, in some embodiments, solid pharmaceutical compositions according to the present invention include compositions that provide about 0.5 mg to about 20 mg of the corticosteroid to the inflamed tissues of the gastrointestinal tract after oral administration.

[0062] 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 gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

[0063] In certain embodiments of the solid pharmaceutical compositions of the present invention, the corticosteroid and the adhesive agent are intimately associated. In one such embodiment the solid pharmaceutical composition comprises corticosteroid surrounded or encapsulated by the adhesive agent. In another such embodiment the solid pharmaceutical composition comprises corticosteroid disposed on the surface of the adhesive agent. In still other embodiments, the solid pharmaceutical composition comprises corticosteroid mixed or granulated with the adhesive agent.

[0064] Topical administration of a corticosteroid to the oral cavity of individuals has been associated with candidiasis infection. Consequently, in one embodiment pharmaceutical compositions of the present invention include an antifungal agent. Suitable antifungal agents

include, but are not limited to mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and other "uncategorized" antifungals recognized in the art that do not fall within any of the above categories (e.g., tolnaflate and ciclopirox). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abafungin, amorolfine, anidulafungin, bifonazole, butenafine, butoconazole, candicin, caspofungin, ciclopirox, clotrimazole, econazole, fenticonazole, filipin, fluconazole, flucytosine, griseofulvin, isavuconizole, isoconazole, itraconazole, ketoconazole, micafungin, miconazole, miconazole nitrate, naftifine, natamycin, nystatin, oxiconazole, posaconazole, pramiconazole, ravuconazole, rimocidin, setaconizole, sulconazole, terbafine, terconazole, tioconazole, tolnaftate, undecylenic acid, and voriconazole.

[0065] 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 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.

[0066] In one embodiment, the solid pharmaceutical compositions of the present invention comprise corticosteroid-containing granules. The corticosteroid-containing granules may be granules comprising corticosteroid crystals and a film-forming binder, e.g., prepared by granulation. The corticosteroid crystals can have an average particle size ranging from about 1-300 μm, for example about 1-50 μm, about 1-100 μm, about 1-150 μm, about 1-200 μm, about 1-250 μm, about 50-100 μm, about 50-150 μm, about 50-200 μm, about 50-250 μm, about 50-300 μm, about 100-150 μm, about 100-200 μm, about 150-200 μm, about 150-250 μm, about 150-300 μm, about 200-250 μm, about 200-300 μm, or about 250-300 μm.

[0067] In another embodiment, the corticosteroid may be in the form of crystals. Such crystals may have an average size in the sub-micron range (e.g., average particle size of about < 1 μm), or may be nanoparticles (e.g., average particle size in the range of about 1-100 nm).

[0068] In yet another embodiment, the corticosteroid may be present in amorphous form, for example in association with a stabilizing agent which limits drug recrystallization, e.g., polyvinylpyrrolidone (PVP) (including homo- and copolymers of polyvinylpyrrolidone and homopolymers or copolymers of N-vinylpyrrolidone); crospovidone; gums; cellulose derivatives (including hydroxypropyl methylcellulose (HPMC), hydroxypropyl methylcellulose phthalate, hydroxypropyl cellulose, ethyl cellulose, hydroxyethylcellulose, sodium carboxymethyl cellulose, calcium carboxymethyl cellulose, sodium carboxymethyl cellulose, and others); dextran; acacia; homo- and copolymers of vinyllactam, and mixtures thereof, cyclodextrins; gelatins; hypromellose phthalate; sugars; polyhydric alcohols; polyethylene glycol (PEG); polyethylene oxides; polyoxyethylene derivatives; polyvinyl alcohol; propylene glycol derivatives and the like, sodium lauryl sulphate, TWEEN® surfactants, EUDRAGIT® polymers; and combinations thereof.

[0069] The film-forming binder may comprise any suitable binder used in granulation. Non-limiting examples of suitable film-forming binders include water-soluble, alcohol-soluble or acetone/water soluble binders, e.g. polyvinylpyrrolidone (PVP), corn starch, polyethylene oxide, polyethylene glycol, hydroxypropyl methylcellulose (HPMC), methylcellulose, or hydroxypropylcellulose (HPC). The amount of film-forming binder in the corticosteroid-containing granules can range from about 0.5% to about 10%, including about 0.5%-1%, about 0.5%-2%, about 0.5%-5%, about 0.5%-7%, about 1%-2%, about 1%-5%, about 1%-7%, about 1%-10%, about 2%-5%, about 2%-7%, about 2%-10%, about 5%-7%, about 5%-10%, and about 7%-10%.

[0070] The corticosteroid-containing granules of the present invention may also include other pharmaceutically acceptable ingredients, for example, fillers or diluents. Non-limiting examples of other pharmaceutically acceptable ingredients for the corticosteroid-containing granules include, for example, mannitol, lactose, microcrystalline cellulose, potassium sulfate, calcium phosphate, modified starch, and mixtures thereof. The amount of other pharmaceutically acceptable ingredients (e.g. fillers or diluents) in the corticosteroid-containing granules can range from about 5%-80%, including about 5%-70%, about 5%-60%, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, about 5%-15%, about 5%-10%, about 10%-70%, about 10%-60%, about 10%-50%, about 10%-40%, about 10%-30%, about 10%-20%, about 10%-15%, about 20%-70%, about 20%-60%, about 20%-50%, about 20%-40%, about 20%-30%, about 20%-25%, about 30%-70%, about 30%-60%, about 30%-50%, about 30%-40%, about 30%-35%, about 40%-70%, about 40%-60%, about 40%-50%, about 40%-45%, about 50%-70%, about 50%-60%, about 50%-55%, about 60%-70%, or about 60%-65%.

[0071] In another embodiment, the corticosteroid-containing granules of the present invention can be in the form of corticosteroid-layered beads. Corticosteroid-layered beads comprise a core, e.g. a pharmaceutically acceptable sugar bead, coated with a corticosteroid layer. Such corticosteroid-layered beads can be prepared, for example, by dissolving or suspending corticosteroid in a polymeric binder solution, which is then sprayed or coated onto inert particles (e.g., sugar spheres or cellulose spheres (CELPHERE®)). Suitable polymeric binders include any of those disclosed herein, for example starches, modified celluloses (e.g., hydroxypropylcellulose, carboxymethylcellulose sodium), alginic acid, polyvinyl pyrrolidone (povidone), and mixtures thereof. The amount of corticosteroid in the corticosteroid layer, and the thickness of the corticosteroid layer can be modified to provide a therapeutically effective dose of corticosteroid. The corticosteroid-containing layer comprises about 90%-99% corticosteroid, and about 1% to about 10% binder.

[0072] The corticosteroid-containing granules of the present invention can be prepared by any suitable method. For example, the corticosteroid-containing granules can be prepared by granulation of corticosteroid crystals, one or more disintegrants, and one or more fillers (e.g., sugar alcohol, saccharide and/or microcrystalline cellulose) in a high shear granulator or a fluid-bed granulator using a solution of one or more polymeric binders, and dried in fluid bed equipment or on trays in a conventional oven to produce the corticosteroid-containing granules.

[0073] The solid pharmaceutical compositions of the present invention may include rapidly dispersing granules comprising a disintegrant and a sugar alcohol and/or a saccharide. The disintegrant-containing granules can include disintegrants or so-called super-disintegrants, e.g. crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethyl cellulose, low substituted hydroxypropylcellulose, and mixtures thereof. The amount of disintegrant in the rapidly dispersing granules can range from about 1%-10%, or about 5%-10% of the total weight of the rapidly dispersing granules, including all ranges and subranges therebetween.

[0074] Sugar alcohols are hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group. Non-limiting examples of suitable sugar alcohols for the rapidly dispersing granules of the pharmaceutical compositions of the present invention include e.g. arabitol, isomalt, erythritol, glycerol, lactitol, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof. The term "saccharide" is synonymous with the term "sugars" includes monosaccharides such as glucose, fructose, the lactose, and ribose; and disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose. In one embodiment, non-limiting examples of suitable saccharides for use in the compositions of the present invention include e.g. lactose, sucrose, maltose, and mixtures thereof. In another embodiment, the rapidly dispersing granules comprise at least one disintegrant in combination with a sugar alcohol. In another embodiment, the rapidly dispersing granules comprise at least one disintegrant in combination with a saccharide. In yet another embodiment, the disintegrant-containing granules comprise at least one disintegrant in combination with a sugar alcohol and a saccharide. The amount of sugar alcohol and/or saccharide in the rapidly dispersing granules ranges from about 99%-90%, or about 95%-90% of the total weight of the disintegrant-containing granules, including all ranges and subranges therebetween. In one embodiment, the average particle size of a sugar alcohol and/or saccharide is 30 μm or less, for example about 1-30 μm, about 5-30 μm, about 5-25 μm, about 5-20 μm, about 5-15 μm, about 5-10 μm, about 10-30 μm, about 10-25 μm, about 10-20 μm, about 10-15 μm, about 15-30 μm, about 15-25 μm, about 15-20 μm, about 20-30 μm, about 20-25 μm, or about 25-30 μm.

[0075] The corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) of the solid pharmaceutical compositions of the present invention can also be coated with a taste-masking layer to improve the palatability of the composition. The corticosteroid-containing

particles can be taste-masked by coating the corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) with a water-insoluble polymer. Non-limiting examples of suitable water-insoluble polymers for the taste-masking layer include ethylcellulose, polyvinyl acetate (PVA), cellulose acetate (CA), cellulose acetate butyrate (CAB), methacrylate copolymers, such as those available under the tradename "EUDRAGIT" (e.g., type RL, RS, and NE30D), and combinations thereof.

[0076] In one embodiment, the water-insoluble polymer is ethylcellulose having a viscosity of about 90-110 cps when tested in an Ubbelohde viscometer as a 5 weight % 80:20 toluene/ethanol solution at 25°C.

[0077] In one embodiment, the solid pharmaceutical compositions of the present invention comprise about 25-35% of corticosteroid crystals, microencapsulated with a taste-masking layer comprising a water-insoluble polymer (e.g., ethylcellulose); about 60-70% of rapidly-dispersing granules (e.g., comprising crospovidone and mannitol); about 5% of additional disintegrant (e.g., crospovidone); about 1% of one or more flavors, and about 0.5%-1% of a sweetener (e.g., sucralose).

[0078] The method of producing drug-layered beads in one embodiment of the invention comprises dissolving or suspending corticosteroid in a polymeric binder solution and layering onto inert particles (50-100 mesh or 150-300 μm in diameter) such as sugar spheres or cellulose spheres (e.g., CELPHERE® CP-203) using a fluid-bed coater equipped with a bottom-spray Wurster insert. These corticosteroid-coated beads can then be taste-masked by fluid-bed coating or by solvent coacervation as described herein.

[0079] In another embodiment, the compositions of the present invention can comprise corticosteroid particles (e.g., crystals), coated with a taste-masking layer. The taste-masking layer (as described herein) can be applied to the corticosteroid particles by any suitable method, for example coacervation or fluidized bed coating methods. Alternatively, the compositions of the present invention can comprise a corticosteroid complexed with a cyclodextrin.

[0080] In one embodiment, the method of preparing the compositions of the present invention includes a taste-masking step. The taste-masked corticosteroid-containing particles of the compositions of the present invention (e.g., corticosteroid crystals, corticosteroid-containing microgranules or drug-layered beads) of the present invention can be prepared by various methods, including solvent coacervation with a water-insoluble polymer such as ethylcellulose. The water-

insoluble polymer (e.g., ethylcellulose), a phase-inducer (e.g., polyethylene), and corticosteroid are loaded into a coacervation tank containing cyclohexane. The mixture in the tank is heated to about 80°C to dissolve the ethylcellulose, and then slowly cooled under controlled conditions thereby causing phase-induced microencapsulation of corticosteroid particles by the ethylcellulose. Microencapsulation or coacervation refers to the process of applying a membrane by phase separation for imparting taste-masking (or sustained release) properties. Upon reaching ambient temperature, the suspension of microencapsulated corticosteroid particles are filtered, washed with fresh cyclohexane and dried to reduce residual solvent levels within acceptable limits (e.g., <4,000 ppm), in one embodiment less than 1,000 ppm. The coating weight of the microencapsulated corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. Examples of such a coacervation process are disclosed in U.S. Pat. Nos. 5,252,337, 5,639,475, 6,139,865 and 6,495,160.

[0081] Alternatively, the coacervation solution can comprise a mixture of the water-insoluble polymer (e.g., ethylcellulose) and a water-insoluble or gastrosoluble pore-former (e.g., calcium carbonate). The ratio of water-insoluble polymer to pore-former can range from about 50/50 to 95/05, including about 55/45, about 60/40, about 65/35, about 70/30, about 75/25, about 80/20, about 85/15, and about 90/10, including all ranges and subranges therebetween. The coating weight of the microencapsulated corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. In one embodiment, the coacervation step comprises suspending the drug-containing particles in a solution of water-insoluble ethylcellulose at 80°C in the coacervation tank. During the cooling cycle, the micronized pore-former is introduced into the tank at a temperature of about 58°C, while constantly stirring the suspension to uniformly distribute the pore-former in the microcapsule-membrane, at the forming/hardening phase. Examples of such a coacervation process are disclosed in U.S. Patent Publication No. US 2006/0105038.

[0082] In one embodiment, the solid pharmaceutical composition of the present invention is in the form of an orally disintegrating tablet (ODT). In one such embodiment 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. The drug particles may comprise, for example, corticosteroid crystals with or without a coating,

corticosteroid-layered beads or granulates of corticosteroid with one more additional components. In certain embodiments the ODT is in the form of a wafer or film (for example those described in US 6,534,549, US 7,125,564, etc.).

[0083] In one embodiment of the present invention the solid composition comprises a lyophilized matrix, wherein the lyophilized matrix comprises corticosteroid and an excipient. Suitable excipients include mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

[0084] The amount of corticosteroid-containing granules in the solid compositions of the present invention can range from about 5% to about 50%, including about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, and about 50%, inclusive of all values, ranges, and sub-ranges therebetween. In one embodiment, the composition of the present invention is an ODT comprising about 30% by weight of corticosteroid-containing granules.

[0085] One embodiment of a method for producing pleasant tasting corticosteroid ODT formulations of the present invention, comprising corticosteroid microparticles with a mean particle size of about 100-400 μm, comprises (i) preparing drug-containing cores having corticosteroid crystals with a desired mean particle size, e.g., as microgranules, corticosteroid particles (e.g., crystals), or as drug-layered beads, (ii) preparing granules comprising a disintegrant, a sugar alcohol and/or a saccharide, and (iii) compressing a blend comprising the corticosteroid microparticles and the disintegrant granules, optionally with pharmaceutically acceptable flavorant(s), sweetener(s), other disintegrant(s), colorant(s) and/or compression aides such as microcrystalline cellulose in sufficient quantities into the ODT form using a tablet press, such as a rotary tablet press equipped with an external lubrication system to lubricate the punches and dies prior to compression. These ODT tablets rapidly disintegrate upon exposure to the saliva in the mouth into a smooth, easy-to-swallow suspension with no gritty aftertaste.

[0086] In another embodiment, the method for preparing ODT formulations of the present invention comprising corticosteroid microparticles with a mean particle size of about 100-400 μm can also include a unit process for taste-masking the corticosteroid-containing particles (e.g., corticosteroid crystals, corticosteroid-containing granules or drug-layered beads) by coacervation or fluid bed coating prior to blending and compression into ODT tablets. For example, corticosteroid crystalline material with an average particle size range of about 1-200 μm, more

particularly about 50-150 μm can be coated with a taste-masking layer by either fluid-bed coating or solvent coacervation in accordance with other aspects of the invention. Corticosteroid crystalline material with a mean particle size of about 5-50 μm can also be taste-masked by solvent coacervation as described herein.

[0087] In another embodiment, the compositions of the present invention can be orally disintegrating tablets prepared by mixing corticosteroid microgranules or taste-masked corticosteroid microparticles, one or more flavoring agents, a sweetener, rapidly-dispersing microgranules, microcrystalline cellulose, and an additional disintegrant, and compressing this mixture into orally disintegrating tablets. The orally disintegrating tablets formed thereby rapidly disintegrate on contact with saliva in the buccal cavity, and have a pleasant taste (good creamy mouth feel) and provide rapid, substantially-complete release of the dose in the stomach.

[0088] In yet another embodiment, the compositions of the present invention may be orally disintegrating tablets formed by compressing a composition comprising corticosteroid-containing particles, rapidly-dispersing granules, and optionally flavoring agents, sweeteners, and other pharmaceutically acceptable excipients in a tablet press equipped with an externally lubricating system to pre-lubricate dies and punches, thereby providing a tablet formulation otherwise free of lubricant. The orally disintegrating tablets thus produced typically exhibit sufficient hardness and sufficiently low friability to be suitable for packaging in HDPE bottles and push-through film backed or peel-off paper backed blister packs using conventional equipment for storage, transportation and commercial distribution.

[0089] In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: (a) preparing corticosteroid-containing microgranules by granulating crystalline corticosteroid material having an average particle size of about 5-50 μm and one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and mixtures thereof, with a polymeric binder in a high-shear granulator or a fluid-bed coater; (b) granulating one or more sugar alcohols and/or saccharides, each having an average particle diameter of not more than about 30 μm, with a disintegrant such as crospovidone, using water or an alcohol-water mixture in a conventional granulator, and drying the granulate in fluid-bed equipment or a conventional oven to produce rapidly-dispersing microgranules with an average particle size of not more than about 400 μm, as described in U.S. Patent Publication No. US 20050232988; filed Apr. 19, 2004; (c) blending the corticosteroid microgranules of step (a) with

one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and the rapidly-dispersing microgranules of step (b); and (d) compressing the blend of step (c) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

[0090] In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: a) preparing a drug-containing core particle (e.g., corticosteroid crystals, drug-layered beads, or corticosteroid-containing microgranules) by granulating the drug and optionally one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and mixtures thereof with a polymeric binder in a high-shear granulator or a fluid-bed coater, or drug-layering on an inert particle (60-100 mesh sugar sphere or cellulose sphere, e.g., CELPHERE® CP-203) from a solution/suspension comprising a polymeric binder and the drug in a fluid-bed coater and optionally applying a seal-coat (e.g., OPADRY® Clear); b) taste-masking core particles by microencapsulation, e.g. by solvent coacervation or fluid-bed coating with a water-insoluble polymer such as ethylcellulose, or with a mixture of a water-insoluble functional polymer and a water-soluble/gastrosoluble pore-former (e.g., ethylcellulose and sodium chloride or calcium carbonate at a ratio ranging from about 50/50 to 95/5) to produce pleasant-tasting microparticles with a desired particle size distribution (e.g., an average particle size of not more than about 400 μm, or an average particle size of not more than about 300 μm); c) granulating one or more sugar alcohols and/or saccharides, each of which has an average particle diameter of not more than about 30 μm, with a disintegrant such as crospovidone, as disclosed herein; d) blending the taste-masked microparticles of step (b) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and rapidly-dispersing microgranules of step (c); and e) compressing the blend of step (d) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

EXAMPLE 1

[0091] Fluticasone Propionate Microgranules A: Mannitol 25 (91.2% w/w) and Crospovidone XL-10 (4.8% w/w) at a ratio of 95/5 are co-milled individually by passing the mixture through a COMIL® milling apparatus, equipped with 0.225'' spacers, at a speed of about 1400-1500 rpm. The mannitol, crospovidone, and fluticasone propionate (4% w/w) crystalline material are blended for about 3-5 minutes to mix the ingredients. A Glatt GPCG-3 fluid-bed apparatus equipped with

a top spray granulation chamber and a granulation bowl is charged with the pre-blend of mannitol, crospovidone, and fluticasone propionate (batch size: 1500 g) and granulated by spraying purified water (nozzle: 1.2 mm tip) at an atomization pressure of about 1.25 bar and at a spray rate of 30-50 mL/min and an outlet temperature of >70°C and at a product temperature of >33°C. The wet mass is dried until the moisture level (the percent loss on drying) is less than about 1%.

[0092] Tableting: A Hata production tablet press equipped with a vacuum transfer system, tablet de-duster, a metal detector, and a Matsui Ex-lube system were set up according to standard operating procedures. Magnesium stearate was used as a processing aid, i.e., to externally lubricate the punch and die surfaces and was therefore present in only trace amounts on the tablets. The weight range for the tablets was typically ±5% of the target tablet weight. The Ex-lube system was started to ensure that the lubricant was spraying properly when the tablet press was running. The tableting parameters, such as fill depth (mm), pre-compression position (mm or kN) and main compression position (mm or kN) were adjusted on the press in order to produce 4 mg tablets that meet the exemplary specifications listed below:

TABLE:

Tablet Parameters		
Parameter	Target	Range
Weight (mg)	100	95-105
Thickness (mm)	2.4	2.0-2.8
Hardness (N)	28	8-48
Friability	NMT 0.6%	1.0%
Weight 10 tablets (g)	1.0g	0.96-1.04

[0093] Following the successful set-up, the press was run in `Automatic Mode` until completion. During the run, tablets were sampled periodically to ensure that the tablets produced would meet the specifications listed above.

[0094] The tablets are tested in the USP <701> Disintegration test and disintegrate in about 60 seconds or less.

EXAMPLE 2

[0095] A liquid is prepared by mixing 89.8% of 95% ethanol, by weight 5% ethylcellulose, 0.2% by weight oleic acid and 5% fluticasone propionate. Upon dabbing on to a mucosal surface a film is formed which adheres readily to skin or mucosal tissues.

[0096] An ethyl alcohol based gel is prepared by mixing the following components: 67% by weight of 95% ethyl alcohol; 8% by weight ethylcellulose; 2% by weight hydroxypropylcellulose; 2% by weight polyacrylic acid; 14% by weight menthol; 5% by weight water USP; and 2% by weight fluticasone propionate. A smooth, slightly opaque and sticky gel is formed.

[0097] The film, resulting from the application of this gel to a mucosal surface adheres to the surface and requires mechanical effort for its removal.

[0098] It will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without departing from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

WHAT IS CLAIMED IS:

1. An orally dispersing tablet comprising:

(i) about 1 mg of budesonide;

(ii) and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity;

(iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;

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

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

2. The orally dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

3. The orally dispersing tablet of claim 2, 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.

4. The orally dispersing tablet of claim 1, comprising sucralose.

5. The orally dispersing tablet of claim 1, comprising sucralose and mannitol.

6. The orally dispersing tablet of claim 1, comprising sucralose, mannitol, and magnesium stearate.

7. The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.

8. The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.

9. The orally dispersing tablet of claim 1, comprising sucralose and magnesium stearate.

10. The orally dispersing tablet of claim 1, comprising sucralose and polyvinyl pyrrolidone.

11. The orally dispersing tablet of claim 1, comprising sucralose and polyethylene glycol.

12. The orally dispersing tablet of claim 1, comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

13. The orally dispersing tablet of claim 1, comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

14. The orally dispersing tablet of claim 1, comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

15. The orally dispersing tablet of claim 4, comprising a disintegrant.

16. The orally dispersing tablet of claim 5, comprising a disintegrant.

17. The orally dispersing tablet of claim 6, comprising a disintegrant.

18. The orally dispersing tablet of claim 7, comprising a disintegrant.

19. The orally dispersing tablet of claim 8, comprising a disintegrant.

20. The orally dispersing tablet of claim 9, comprising a disintegrant.

21. The orally dispersing tablet of claim 10, comprising a disintegrant.

22. A method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.

ABSTRACT

The present invention is directed to orally administered corticosteroid compositions. The present invention also provides a method for treating a condition associated with inflammation of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/Carolina Pimentel
Attorney Docket Number:	ADAR-119/06US 325049-3260

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	2	100	200
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1920**

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First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
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1	Transmittal of New Application	ADAR-119-06US_New_Utility_Transmittal_for_Continuation.pdf	197300 7e0e98e996eaed7ecb17b2eaf00e34d914599280	no	1
Warnings:					
Information:					
2	Application Data Sheet	ADAR-119-06US_Application_Data_Sheet.pdf	123445 1b3f257e8b86ddc848a6e84ec34094d213752958	no	9
Warnings:					
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3	Power of Attorney	ADAR-119-06US_POAtransmittal_POAsigned.pdf	1584960 4c1322b18681921f90ec04abb6a17db18b3cb2af	no	2
Warnings:					
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4	Oath or Declaration filed	ADAR-119-06US_Inventors_Oaths_executed_parent.pdf	3071796 6e6cb9e96a0bd50fc6921d383ed43bcf116cbe56	no	3
Warnings:					
Information:					
5		ADAR-119-06US_Specification_Continuation.pdf	197644 099c3d17ce88803b6e301a2d9fd01a017158a541	yes	28

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	25
Claims	26	27

	Abstract		28	28	
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	36740 591bf7c9b71e08902ec4486d55cf21e0df6c8eb7	no	2
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National Stage of an International Application under 35 U.S.C. 371

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