UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/816,154	04/28/2020	10632069	ADAR-119/05US 325049-2804	4432

58249 7590 04/08/2020

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 0 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.

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

Stephen Perrett, Princeton, NJ;
Adare Pharmaceuticals US, L.P., Lawrenceville, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi Venkatesh, Vandalia, OH;

Dr. Falk Pharma Ex. 1048
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

FOR **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENTS OF REASONS FOR ALLOWANCE

In response to the Reasons for Allowance in the Notice of Allowability mailed December 18, 2019, the following comments are submitted under 37 C.F.R. 1.104(e).

While Applicant believes that the claims are allowable and patentably distinguishable over the prior art, Applicant does not acquiesce that patentability resides in each feature, exactly as expressed in the claims, nor that each and every feature is required for patentability. More specifically, Applicant does not believe it was necessary to amend "claim 44 to recite that the orally dispersing tablet disintegrates within 60 seconds" to overcome Dohil et al. Applicant submits that patentability is based on the claimed invention as a whole, and not solely on one or more particular features recited in the allowed claims.

Dated: March 17, 2020

Respectfully submitted,
COOLEY LLP

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004-2400
Tel: (202) 728-7079
Fax: (202) 842-7899

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

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

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
15816154	17-Nov-2017	Stephen Perrett	ADAR-119/05US 325049-28	4432

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	ARADHANA SASAN

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$1000	$0	$1000	18-Mar-2020	$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
Adare Pharmaceuticals US, 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**	03-17-2020
Name	Jonathan M. Cousin	**Registration Number**	66418

Electronic Patent Application Fee Transmittal

Application Number:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Carolina Pimentel
Attorney Docket Number:	ADAR-119/05US 325049-2804

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	1000	1000
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($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1000**

Electronic Acknowledgement Receipt

EFS ID:	38885640
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	17-MAR-2020
Filing Date:	17-NOV-2017
Time Stamp:	16:34:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1000
RAM confirmation Number	E20203GG34110306
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	Amendment after Notice of Allowance (Rule 312)	ADAR-119-05US_Comments_on_Examiners_Statement_of_Reasons_for_Allowance.pdf	80902 3aba805d2c1b1e314ce3141828a29d0909eda77c	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	Web85b.pdf	45837 2c3970652f7f61907803dbf19acd85cf04cb66a7	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31986 9b95093913ff4be47bbc0b1e498bad5921e64da9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	158725		

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

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

58249 7590 02/27/2020

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

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
02/27/2020	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

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
15/816,154	11/17/2017	Perrett et al.	ADAR-119/05US 325

	EXAMINER	
COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004	ARADHANA SASAN	
	ART UNIT	PAPER
	1615	20200224

DATE MAILED: _____

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

Commissioner for Patents

The Information Disclosure Statement (IDS) filed on 02/18/2020 has been considered. Please see attached copy of PTO-1449. Applicant's IDS submitted on 02/18/2020 did not change the previous determination of patentability (see Notice of Allowance mailed 12/18/2019).

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

PTO-90C (Rev.04-03)

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S308	2	("20070111978" "20030099701").PN.	US-PGPUB	OR	ON	2020/02/24 08:38
S309	4	wo-2010144865-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:39
S310	5	ep-1595533-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:40
S311	5	ep-1323417-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:40
S312	3	wo-2009064457-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:41
S313	4	ep-2214679-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:42
S314	2	wo-2009086046-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:42
S315	3	wo-2004091585-$.did.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/02/24 08:42
S316	12	"12896005" "14294660" "14311732" "15205390" "14917125" "16578568" "15680301" "16131812"	US-PGPUB	OR	ON	2020/02/24 08:44

2/24/2020 8:51:07 AM
C:\Users\asasan\Documents\EAST\Workspaces\15 series\15800000\15810000\15816154.wsp

PTO/SB/08b (07-09)
Approved for use through 11/30/2020. OMB 0651-0031
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/05US 325049-2804

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. 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.	
	2.	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.	✓

Examiner Signature	/ARADHANA SASAN/	Date Considered	02/24/2020

*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.

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

FOR **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENTS OF REASONS FOR ALLOWANCE

In response to the Reasons for Allowance in the Notice of Allowability mailed December 18, 2019, the following comments are submitted under 37 C.F.R. 1.104(e).

While Applicant believes that the claims are allowable and patentably distinguishable over the prior art, Applicant does not acquiesce that patentability resides in each feature, exactly as expressed in the claims, nor that each and every feature is required for patentability. More specifically, Applicant does not believe it was necessary to amend "claim 44 to recite that the orally dispersing tablet disintegrates within 60 seconds" to overcome Dohil et al. Applicant submits that patentability is based on the claimed invention as a whole, and not solely on one or more particular features recited in the allowed claims.

Dated: February 25, 2020

Respectfully submitted,
COOLEY LLP

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004-2400
Tel: (202) 728-7079
Fax: (202) 842-7899

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

Electronic Acknowledgement Receipt

EFS ID:	38678471
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	25-FEB-2020
Filing Date:	17-NOV-2017
Time Stamp:	12:48:56
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	Post Allowance Communication - Incoming	ADAR-119-05US_Comments_on_Examiners_Statement_of_Reasons_for_Allowance.pdf	80903 d5fb9743d8845ab192f1226c482d2046c48d2c36	no	1

Warnings:

Information:	
Total Files Size (in bytes):	80903

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

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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/08b (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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Aradhana SASAN
Attorney Docket Number	ADAR-119/05US 325049-2804

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. 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.	
	2.	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.	✓

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:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Sandra Laramore
Attorney Docket Number:	ADAR-119/05US 325049-2804

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt

EFS ID:	38619826
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	58249
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	18-FEB-2020
Filing Date:	17-NOV-2017
Time Stamp:	17:49:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$240
RAM confirmation Number	E20202HH50141018
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	ADAR-119-05US-IDS.pdf	114809 159a75289b68e69794eeb5aacefa957c143e5ba5	no	5
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119-05US-SB08.pdf	98190 ebeccеef87967354d0851dd64c03b27791b317fd	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	Oppn_2482822_Summons-to-attend-oral-proceedings_02-13-2020_13_pgs.pdf	969713 e55c61a7f60810e9d38506035ad3728216a27986	no	13
Warnings:					
Information:					
4	Non Patent Literature	Oppn_2482822_Letter-from-Opponent_01-14-2020_andEnglishtranslation_36_pages.pdf	1476692 ea3d57346b9b57dd4519e92fcbc93a1f62731138	no	36
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30551 e952a5d584570b54d813d8e761429c9e13f49852	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2689955		

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-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	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.

[] 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.

[X] 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:

[X] 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

[X] 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

[X] 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-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Pending
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	1/10/2019			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. ADAR-119/05US 325049-2804.

Dated: February 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

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
15/816,154	11/17/2017	1615	1880	ADAR-119/05US 325049-2804	14	1

CONFIRMATION NO. 4432

CORRECTED FILING RECEIPT

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

OC000000114373729

Date Mailed: 01/31/2020

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 Venkatesh, Vandalia, OH;

Applicant(s)

Adare 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 15/205,390 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: No

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: 12/01/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/816,154**

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).

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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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804

CONFIRMATION NO. 4432

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

POWER OF ATTORNEY NOTICE

OC00000014375727

Date Mailed: 01/31/2020

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/17/2020.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(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**.

/nhorne/

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
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804

CONFIRMATION NO. 4432

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

POA ACCEPTANCE LETTER

OC000000114375728

Date Mailed: 01/31/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/17/2020.

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**.

/nhorne/

Doc Code: PA..
Document Description: Power of Attorney

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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	Stephen PERRETT
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Art Unit	1615
Examiner Name	Aradhana Sasan
Attorney Docket Number	ADAR-119/05US 325049-2804

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
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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.

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.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Adare Pharmaceuticals, Inc.

Application No./Patent No.: 15/816,154 Filed/Issue Date: November 17, 2017

Titled: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Adare Pharmaceuticals US, 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, Gopi VENKATESH To: EURAND, INC.

   The document was recorded in the United States Patent and Trademark Office at
   Reel 047678, Frame 0051, 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 047720, Frame 0492, 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.

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 047720, Frame 0520, 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 047672, Frame 0450, 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 051491, Frame 0920, or for which a copy thereof is attached.

6. From: _____ To: _____

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/	January 17, 2020
Signature	Date
Jonathan M. Cousin	66,418
Printed or Typed Name	Title or Registration Number

[Page 2 of 2]

Electronic Acknowledgement Receipt

EFS ID:	38325777
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	17-JAN-2020
Filing Date:	17-NOV-2017
Time Stamp:	14:02:01
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	ADAR-119-05US_Request_to_Update_Applicant_Name.pdf	72300 c5176875a3b845fbc2285fdf2b11d6560c3c44b3	no	1

Warnings:

Information:					
2	Application Data Sheet	ADAR-119-05US_ADS_Replacement_Sheets.pdf	399286 8f045029b530a9212f2f9fbacc1e9f69b6d10d1e	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Power of Attorney	ADAR-119-05US_POAtrans_and_POAsigned.pdf	1164975 7e463a6e61d48d0fb9900423aa24f391bc455f0c	no	2
Warnings:					
Information:					
4	Assignee showing of ownership per 37 CFR 3.73	ADAR-119-05US_373c_Statement.pdf	49241 0bc2096a32b007819ed472c9b89b364240646d89	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1685802		

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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	Stephen Perrett
Art Unit	1615
Examiner Name	Aradhana Sasan
Practitioner Docket Number	ADAR-119/05US 325049-2804

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 January 17, 2020

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 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
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	142 Leabroock Lane		
Address 2			
City	Princeton	State/Province	NJ
Postal Code	08540	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	52 Bailey Drive		
Address 2			
City	Washington Crossing	State/Province	PA
Postal Code	18977	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gopi		Venkatesh	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

City	Vandalia	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	780 Waldsmith Way		
Address 2			
City	Vandalia	State/Province	OH
Postal Code	45377	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	~~91543~~ 58249		
Email Address	~~zpatdocdocketing@cooley.com~~ zIPPatentDocketingMailboxUS@cooley.com>	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	ADAR-119/05US 325049-2804	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.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
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	~~91543~~ 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	15205390	2016-07-08

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15205390	Continuation of	14311732	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)
14311732	Division of	12896005	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)
12896005	Claims benefit of provisional	61247642	2009-10-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

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 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
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 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
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, Inc.~~ 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 (11-15)
Approved for use through 04/30/2017. 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-119/05US 325049-2804
	Application Number	15/816,154
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)	2020-01-17
First Name	Jonathan M.	Last Name	Cousin	Registration Number	66418

Additional Signature may be generated within this form by selecting the Add button.

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United States Patent and Trademark Office
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www.uspto.gov

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

91543 7590 01/10/2020

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/10/2020	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

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
15/816,154	11/17/2017	Perrett et al.	ADAR-119/05US 325

		EXAMINER	
Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004		ARADHANA SASAN	
		ART UNIT	PAPER
		1615	20200106

DATE MAILED: _____

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

Commissioner for Patents

The information disclosure statement (IDS) filed on 12/17/2019 has been considered. Please see attached copy of PTO-1449. Applicant's IDS submitted on 12/17/2019 did not change the previous determination of patentability (see Notice of Allowance mailed 12/18/2019).

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.

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

PTO-90C (Rev.04-03)

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 1

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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. 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.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	01/06/2020

*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./

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NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 12/18/2019

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/18/2019

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

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

By mail, send to: Mail Stop ISSUE FEE
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By fax, send to: (571)-273-2885

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

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

91543 7590 12/18/2019

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1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

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

Certificate of Mailing or Transmission

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

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

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

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

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

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

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

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

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

1 _____
2 _____
3 _____

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

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

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

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

91543 7590 12/18/2019

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

DATE MAILED: 12/18/2019

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

   Certified copies:

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

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

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

DETAILED CORRESPONDENCE

Notice of Pre-AIA status

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

Status of Application

2. The Amendments and Remarks filed on 12/06/19 are acknowledged.

3. Claims 1-43, 45-47, 55-56 and 59 were cancelled.

4. Claims 44, 57-58, 60-63 and 65-66 were amended.

5. Claims 44, 48-54, 57-58 and 60-66 are pending.

Information Disclosure Statement

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

Reasons for Allowance

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

Claim Objection

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

Claim Rejections - 35 USC § 103

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

12/06/19) regarding the rejection of claims 44 and 48-66 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dohil et al. (US 2009/0191275 A1) have been fully considered and are persuasive. Since Dohil et al. do not teach or suggest the disintegration time of the tablet, particularly disintegration within 60 seconds in simulated saliva, as recited in instant claim 44, the rejection based on Dohil et al. is withdrawn.

Terminal Disclaimer

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

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

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

Updated Search

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

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

Comments

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

Conclusion

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

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

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

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

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	06/24/2018	AS
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	09/03/2019	AS
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	12/13/2019	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**
(A61K31/569 same A61K2300/00).cpcc. with keyword	06/24/2018	AS
(A61K31/569 same A61K2300/00).cpcc. with keyword	09/03/2019	AS
(A61K31/569 same A61K2300/00).cpcc. with keyword	12/13/2019	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.

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Search Notes		
Search Notes	**Date**	**Examiner**
Reviewed prosecution history of related cases 12896005,14311732,15205390,15680301,14294660, and 14917125. EAST search - including CPC with keyword, inventor, assignee and applicant name search. NPL search - including Google Patents and SciFinder. Please see attached history for each search.	06/24/2018	AS
Updated EAST and STIC/NPL search. Please see attached history for each search.	12/04/2018	AS
Updated EAST search. Google Patents search. Please see the attached history for each search.	09/03/2019	AS
Reviewed IDS filed on 12/06/19. Updated EAST search including CPC with keyword, inventor, assignee, applicant name, and interference search. Updated NPL - SciFinder search. Please see the attached history for each search.	12/13/2019	AS

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.	12/13/2019	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	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)	17	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	13 December 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20191213

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	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 REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	17	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	13 December 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office

Part of Paper No.: 20191213

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	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
	1		10		19		28		37		46		55	15	64
	2		11		20		29		38		47		56	16	65
	3		12		21		30		39	2	48	9	57	17	66
	4		13		22		31		40	3	49	10	58		
	5		14		23		32		41	4	50		59		
	6		15		24		33		42	5	51	11	60		
	7		16		25		34		43	6	52	12	61		
	8		17		26		35	1	44	7	53	13	62		
	9		18		27		36		45	8	54	14	63		

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	17	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	13 December 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office Part of Paper No.: 20191213

Task History

Task Began December 13, 2019 02:01 PM

Explore references by research topic: orally dispersing tablet with budesonide

Research Topic:	orally dispersing tablet with budesonide
Result Count:	4

Candidates Selected (ID 1)

3 references were found where the two concepts "orally dispersing tablet" and "budesonide" were present anywhere in the reference.

Answer Type:	*References*
Result Count:	*3*

1. Pharmaceutical oral controlled release composition of budesonide [Machine Translation].

By Zhang, Wenwen; Liu, Xiaodong
From Faming Zhuanli Shenqing (2019), CN 110507627 A 20191129, Language: Chinese, Database: CAPLUS

[Machine Translation of Descriptors]. The invention relates to a pharmaceutical oral controlled release compn. of budesonide, which is characterized by comprising:a) a sustained release tablet core contg. budesonide, a pharmaceutically acceptable salt of the budesonide or a solvate of the budesonide;b) At least one amphiphilic matrix;c) At least one hydrophilic matrix;The budesonide, the pharmaceutically acceptable salt of the budesonide or the solvate of the budesonide are uniformly dispersed in the amphiphilic matrix and/or the hydrophilic matrix;And the outer part of the sustained-release tablet core is coated with a coating contg. an acid-resistant material.The compn. is simple in prepn. process and low in cost, budesonide is slowly released in small intestine and colon, and colon targeted administration and local treatment effects are achieved once a day.

~0 Citings

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2. Oral disintegrating tablet and its preparation method and method for improving the hardness and disintegration of oral disintegrating tablets and application of salts in preparing oral disintegrating tablets with high hardness and rapid disintegration

By Ma, Jun; Liu, Xiaoyan; Tang, Zhenqin; Gao, Xueqin
From Faming Zhuanli Shenqing (2018), CN 108066305 A 20180525, Language: Chinese, Database: CAPLUS

The invention discloses an oral disintegrating tablet and its prepn. method and method for improving the hardness and disintegration of oral disintegrating tablets and application of salts in prepg. oral disintegrating tablets with high hardness and rapid disintegration, and the oral disintegrating tablet has good hardness and disintegration performance. The above oral disintegrating tablet includes a tablet matrix and a plurality of coated pellets dispersed in the tablet matrix, and the coated pellets include a pellet core contg. active ingredients and at least one layer of coating covering on the surface of the pellet core.

~0 Citings

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3. Taste-masked oral formulations of influenza antivirals

By Pilgaonkar, Pratibha Sudhir; Rustomjee, Maharukh Tehmasp; Gandhi, Anilkumar Surendrakumar
From PCT Int. Appl. (2010), WO 2010143207 A1 20101216, Language: English, Database: CAPLUS

The present invention relates to taste-masked oral formulations of influenza antivirals. The taste-masked pharmaceutical formulations for oral administration comprise one or more influenza antivirals, at least one taste-masking agent and at least one pharmaceutically acceptable excipient. Further, the taste-masked influenza antiviral formulations of the present invention are provided in the form of dispersible tablets, effervescent tablets, orally disintegrating tablets, chewable tablets, bite-dispersion tablets or the like, wherein the bitter taste of influenza antivirals is masked thereby providing palatable formulations. Thus, dispersible tablets of taste-masked oseltamivir phosphate comprised (in mg/unit): taste-masked oseltamivir phosphate granules 190.92 equiv to 45 mg oseltamivir base, microcryst. cellulose 100.08, hydroxyethyl cellulose 65, crospovidone 55, hydroxypropyl cellulose 18, mannitol 25, copovidone 14, aspartame 20, vanilla flavor 5, colloidal silicon dioxide 4, magnesium stearate 3.

~4 Citings

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Task History

Task Began December 13, 2019 02:03 PM

Explore references by research topic: budesonide tablet

Research Topic:	budesonide tablet
Result Count:	2

Candidates Selected (ID 4)

11 references were found containing "budesonide tablet" as entered.

Answer Type:	*References*
Result Count:	*11*

1. Chemometrics assisted method development and validation of stability indicating liquid chromatography method for the estimation of budesonide in dosage formulation

By Rao, G. Vishnu Vardhana; Rao, V. Srinivasa; Ramakrishna, K.
From European Journal of Biomedical and Pharmaceutical Sciences (2016), 3(8), 545-553. Language: English, Database: CAPLUS

Development and validation of a novel and sensitive high performance liq. chromatog. method for the estn. of Budesonide (BDS) in tablet dosage form was established by using quality by design approach (QbD). The development activity is focused by the LC technique by UV detection using base deactivated columns.Validation procedure is intended and accomplished as per International Conference on Harmonization (ICH) guidelines. The method uses a Thermo Hypersil BDS C18, 150 x 4.6 mm, 3.0 μm column in isocratic elution with a mobile phase consisting pH 3.2 Monobasic sodium phosphate buffer, Acetonitrile and Ethanol (68:32:02 vol./vol.). All the expts. are carried out in column temp. 400C column oven temp. with UV detection at 246 nm. The eluent used for the extn. of the drug consists of pH 3.2 Monobasic sodium phosphate buffer, Acetonitrile and Methanol (50:25:25 vol./vol.). The method is validated for its specificity, linearity, accuracy, precision, Soln. stability and robustness. Design expert linear model was applied and a 2^4 full factorial design was applied to evaluate coeff., ANOVA and also establish the robustness of the method.

~0 Citings

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2. Development of a zero-order sustained-release tablet containing mesalazine and budesonide intended to treat the distal gastrointestinal tract in inflammatory bowel disease

By Gareb, Bahez; Eissens, Anko C.; Kosterink, Jos G. W.; Frijlink, Hendrik W.
From European Journal of Pharmaceutics and Biopharmaceutics (2016), 103, 32-42. Language: English, Database: CAPLUS, DOI:10.1016/j.ejpb.2016.03.018

Ulcerative colitis (UC) and Crohn's disease (CD) are diseases affecting the gastrointestinal tract. Treatment depends on the severity of the disease, site of inflammation, and patient's response. The aim of this study was to develop a zero-order sustained-release tablet contg. both the anti-inflammatory drugs mesalazine and budesonide as a new treatment option for ileo-colonic CD and UC. Tablets were attained by wet granulation with hydroxypropyl methylcellulose and direct compression. Our newly developed tablet core was coated with different ColoPulse coating thicknesses and the mesalazine and budesonide release profiles were investigated in a 600-min gastrointestinal simulation system (GISS) expt., together with com. available MMX-mesalazine and MMX-budesonide. Lag-time, release rate (k_0), completeness of release, and zero-order correlation coeff. (R^2_0) could be manipulated by varying ColoPulse coating thickness. Our newly developed combination prepn. (C[4.92]) complied with all conducted European Pharmacopoeia tests as well as an accelerated 6-mo stability test and had a lag-time of 250 min (simulated ileum targeted), a linear release profile (mesalazine $R^2_0 = 0.9002$; budesonide $R^2_0 = 0.9481$), and drug release of 100% mesalazine and 77% budesonide. Like C[4.92], MMX-mesalazine had a linear ($R^2_0 = 0.9883$) and complete release profile (96%). However, C[4.92] lag-time was longer (250 vs. 210 min), assuring simulated ileum specificity. Remarkably, MMX-budesonide lag-time was 480 min and release was only 7% with a linear character ($R^2_0 = 0.9906$). The in vitro results suggest that MMX-budesonide effectiveness may be improved if budesonide release in the aq. phase would be increased and that C[4.92] is a potential, new treatment option for ileo-colonic CD and UC.

~4 Citings

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3. Fabrication of controlled-release budesonide tablets via desktop (FDM) 3D printing

By Goyanes, Alvaro; Chang, Hanah; Sedough, Daniel; Hatton, Grace B.; Wang, Jie; Buanz, Asma; Gaisford, Simon; Basit, Abdul W.
From International Journal of Pharmaceutics (Amsterdam, Netherlands) (2015), 496(2), 414-420. Language: English, Database: CAPLUS, DOI:10.1016/j.ijpharm.2015.10.039

The aim of this work was to explore the feasibility of using fused deposition modeling (FDM) 3D printing (3DP) technol. with hot melt extrusion (HME) and fluid bed coating to fabricate modified-release budesonide dosage forms. Budesonide was successfully loaded into polyvinyl alc. filaments using HME. The filaments were engineered into capsule-shaped tablets (caplets) contg. 9 mg budesonide using a FDM 3D printer; the caplets were then overcoated with a layer of enteric polymer. The final printed formulation was tested in a dynamic dissoln. bicarbonate buffer system, and two com. budesonide products, Cortiment (Uceris) and Entocort, were also investigated for comparison. Budesonide release from the Entocort formulation was rapid in conditions of the upper small intestine while release from the Cortiment product was more delayed and very slow. In contrast, the new 3D printed caplet formulation started to release in the mid-small intestine but release then continued in a sustained manner throughout the distal intestine and colon. This work has demonstrated the potential of combining FDM 3DP with established pharmaceutical processes, including HME and film coating, to fabricate modified release oral dosage forms.

~72 Citings

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4. Colonic delivery of compression coated budesonide tablets using ethyl cellulose and eudragit rlpo polymer mixture

By Sopan, Shendge Raosaheb; Sayyad, Fahim J.
From International Journal of Pharma and Bio Sciences (2013), 4(2), 45-57. Language: English, Database: CAPLUS

Budesonide contg. Et cellulose /eudragit RLPO compression coated tablets were prepd. and there in vitro behavior tested for colonic delivery. Budesonide is an antiinflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineral corticoid activity. Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in ulcerative colitis, crohn's disease and inflammatory bowel disease. In this study, each 150 mg core tablet of budesonide was compression coated with 60% Et cellulose and 40% eudragit RLPO, 70% Et cellulose and 30% eudragit RLPO and 80% Et cellulose and 20% eudragit RLPO at a coat wt. of 200 mg, 250 mg and 300 mg resp. Drug release studies were carried out in pH 6.8 phosphate buffer IP soln. The Eudragit RLPO/Ethyl cellulose envelope was found to be a good delivery system for budesonide to be delivered to the colon.

~1 Citing

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5. Formulation and evaluation of colonic compression coated tablet of budesonide

By Jadhav, J. R.; Salunkhe, K. S.; Burute, G. D.; Chaudhari, S. R.
From Journal of Pharmacy Research (2012), 5(5), 2783-2788. Language: English, Database: CAPLUS

The aim of current study was to investigate the in-vitro performance of compress coated tablet of Budesonide. A novel colon targeted tablet formulation was developed by press coating of Budesonide with guar gum and Eudragit S-100 as barrier layer. The entire device was enteric coated so that variability in gastric emptying time can be overcome and a colon specific release can be achieved. Different ratios of polymers were selected to achieve suitable lag time for the treatment of Crohn's disease and ulcerative colitis. In-vitro release studies for prepd. tablets were carried out for 2 h in 1.2 pH phosphate buffer, 3 h in pH 6.8 phosphate buffer and 6 h in simulated colonic fluid. In vitro studies revealed that the tablet coated with guar gum and Eudragit S-100 have limited drug release in stomach and small intestinal environment and released max. amt. of drug in the colonic environment, colon specific release has been achieved from tablet of F5 formulation (0:100) which not given release in stomach and small intestine and about 98.87% drug release in the colon.

~2 Citings

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6. Improvement in Oral Chronic Graft-versus-Host Disease with the Administration of Effervescent Tablets of Topical Budesonide-An Open, Randomized, Multicenter Study

By Elad, Sharon; Zeevi, Itai; Finke, Juergen; Koldehoff, Michael; Schwerdtfeger, Rainer; Wolff, Daniel; Mohrbacher, Ralf; Levitt, Michael; Greinwald, Roland; Shapira, Michael Y.
From Biology of Blood and Marrow Transplantation (2012), 18(1), 134-140. Language: English, Database: CAPLUS, DOI:10.1016/j.bbmt.2011.06.001

Chronic graft-vs.-host disease (cGVHD) frequently involves oral tissues. Although the mucosal changes may be painful and impair oral function, there is currently no topical therapy available for oral cGVHD that has been proven to work in an evidence-based manner. The aims of this study were to (1) assess the response of patients with oral cGVHD to various doses of a new topical budesonide formulation; (2) evaluate the efficacy and safety of the new topical budesonide formulation in these patients. An open, randomized, multicenter phase II pilot study with 4 treatment arms differing in application frequency and duration was performed. Response to treatment was scored by the clinician and patient using several scales. Oral cGVHD improved in all patients, with a median redn. of 70%. Pain redn. was similar in all study arms. The rate of objective improvement (defined as ≥50%) was not significantly different among the 4 study arms. The safety profile was satisfactory. Topical budesonide mouthwash (3 mg/10 mL) improved oral cGVHD in all patients when applied for 5 or 10 min, 2 or 3 times daily. The response was similar in all treatment arms. Safety anal. supported a dosing schedule of 3 mg of budesonide 3 times a day for 10 min.

~7 Citings

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7. Ileo-cecal targeting mucoadhesive budesonide tablet

By Kshirsagar, Sanjay J.; Gupta, Sunil R.; Bhalekar, Mangesh R.; Wadekar, Sharad B.; Supe, Santosh S.
From Latin American Journal of Pharmacy (2010), 29(6), 898-905. Language: English, Database: CAPLUS

Crohn's disease occurs at any part of gastro-intestinal tract (GIT) but the most susceptible is the ileo-cecal region. For an effective treatment of this disease is essential the drug to be released at ileo-cecal region for an extended period of time. The present study is an attempt to design and develop an ileo-cecal targeting mucoadhesive drug delivery system that may be released specifically and slowly in ileo-cecal region without being released in the upper GIT for an extended period of time (12 h). Budesonide mucoadhesive tablets are coated with Eudragit S100, which is a polymer that specifically dissolves at and above pH 6.8. The in vitro drug release by changing pH method was done and in vivo study using X-ray radiog. was carried out to ascertain the position of tablets in GIT after specific time intervals. The in vitro performance of the tablet with 10 % wt./wt. coating level showed that the tablet did not disintegrate till 16 h with const. drug release. An in vivo study also reveals that the tablet lasted till 16 h in the ileo-cecal region.

~0 Citings

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8. Colon delivery of budesonide: evaluation of chitosan-chondroitin sulfate interpolymer complex

By Kaur, Gurpreet; Rana, Vikas; Jain, Subheet; Tiwary, Ashok K.
From AAPS PharmSciTech (2010), 11(1), 36-45. Language: English, Database: CAPLUS, DOI:10.1208/s12249-009-9353-8

The present study was aimed at formulating tablets comprising of coating susceptible to microbial enzyme degrdn. for releasing budesonide in the colon. Tablets prepd. by using Avicel pH 102 as diluent and Eudragit L100-55 as binder were coated to a wt. gain of 10% wt./wt. employing aq. mixts. contg. chitosan (CH) and chondroitin sulfate (CS). The interpolymer complex between CH and CS was characterized using Fourier transform IR (FTIR) and differential scanning calorimetry (DSC) studies. The tablets were evaluated for release of budesonide through in vitro in vivo studies. Formation of bonds between $-COO^-$ and $-OSO_3^-$ groups of CS and $-NH_3^+$ groups of CH was evident in the FTIR spectra of these interpolymer complexed (IPC) films. The DSC thermograms of these films revealed one endothermic transition between 190°C and 205°C, suggesting the formation of new bonds in the IPC. The pH sensitive swelling exhibited by these films was obsd. to be a function of CH concn. Tablets coated with aq. mixts. contg. 40:60 or 50:50 ratio of CH/CS totally prevented the release of budesonide in pH 1.2 buffer. The peaks (FTIR) and endothermic transitions (DSC) characteristic of interpolymer complexation were obsd. to remain unaffected after sequential exposure of the films to pH 1.2 and pH 7.4 buffer IP. This proved the versatility of these IPC films for colon delivery, C_{max} of 1,168.99 and 1,174.2 ng/mL, resp., at 12 and 8 h post-oral dosing of tablets coated with 40:60 or 50:50 ratio of CH/CS was obsd. in rats. The aq. CH/CS (40:60) coating could provide a facile method for delivering budesonide to the colon.

~29 Citings

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9. Evaluation on colon-targeting characteristics of budesonide colonic localization tablet in rat

By Liu, Hui; Pan, Weisan
From Zhongguo Yaoxue Zazhi (Beijing, China) (2008), 43(23), 1804-1807. Language: Chinese, Database: CAPLUS

Colon-targeting effects of budesonide colonic localization tablet were evaluated by comparing budesonide concn. in gastrointestinal tissue after oral administration of different budesonide prepns. The different tissue fluids were sampled, and the HPLC method was used to det. the budesonide concn. in stomach, small intestine, large intestine tissue after budesonide localization tablet, budesonide tablet and budesonide suspension were administrated in rats, resp. With oral administration of budesonide localization tablets, the peak concn. of budesonide [c_{max} = (7.17 ± 2.32) $\mu g/g^{-1}$] in large intestine tissue was reached at the 6 h, and it was significantly higher than that of suspension group (1.37 ± 0.82) $\mu g/g^{-1}$ and common tablet group (0.47 ± 0.18) $\mu g/g^{-1}$. By investigating the effects of different oral prepns. on the gastrointestinal tissue distribution of budesonide in rats at the same time, budesonide was found only in the large intestine tissue, but no drug was distributed in the stomach and the small intestine tissue with oral administration of budesonide localization tablet. The budesonide colonic localization tablet has conspicuous colon-targeting property.

~0 Citings

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10. Estimation and characterisation of budesonide tablets impurities

By Ferraboschi, Patrizia; Bertacche, Vittorio; Maccone, Isabella; Pini, Elena; Ragonesi, Laura; Venturini, Alessio; Stradi, Riccardo
From Journal of Pharmaceutical and Biomedical Analysis (2008), 47(3), 636-640. Language: English, Database: CAPLUS, DOI:10.1016/j.jpba.2008.01.050

Budesonide is the 16α,17α-acetal of 16α-hydroxyprednisolone with n-butyraldehyde, endowed with anti-inflammatory activity. In a sample of budesonide tablets, kept for 3 years at 25 °C and 60% RH unknown impurities, not reported in European Pharmacopoeia, were present. Their identification was achieved by means of chem. and spectroscopic methods.

~4 Citings

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11. A process for the preparation of a drug delivery system

By Shareef, Mohd Ajmal; Ahmad, Farhan Jalees; Ahuja, Alka; Khar, Roop K.
From Indian Pat. Appl. (2006), IN 2004DE00736 A 20060602, Language: English, Database: CAPLUS

This invention relates to a novel delivery system for targeting drugs to the colon. The system is a tablet comprising: (1)an outer enteric coating (2) an inner semi-permeable polymer membrane contg. a plasticizer and (3)a central core comprising swelling excipients and an active ingredient. The drug releases the drug consistently in the colon by a time-dependent diffusion mechanism. This delivery system is particularly suitable for delivering drugs to the colon.

~0 Citings

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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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	8,679,545	03-25-2014	Dohil, et al.	
	2.	9,782,347	10-10-2017	Dohil, et al.	
	3.	10,272,037	04-30-2019	Dohil, et al.	
	4.	10,471,071	11-12-2019	Gosselin, et al.	
	5.	2009/0181099	07-16-2009	Dohil, et al.	
	6.	2014/0187523	07-03-2014	Dohil, et al.	
	7.	2018/0071211	03-15-2018	Dohil, et al.	
	8.	2019/0201333	07-04-2019	Dohil, 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]
	9.	DE 202010018594 U1 (and English Abstract)	02-16-2018	ADARE PHARMACEUTICALS INC.	(corresponds to US 2011/081411, cited in IDS filed 12/20/2017)	✓
	10.	EP 2214679 B1	03-27-2019	Meritage Pharma, Inc.		
	11.	WO 2010/021636 A1	02-25-2010	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		
	12.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		
	13.	WO 2019/165138 A1	08-29-2019	ADARE DEVELOPMENT I, 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.

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

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	14.	[Author Unknown] Jorveza® package leaflet, Jorveza 1mg orodispersible tablets, Mat-No: 1147370 (Losan Pharma), Date Code Falk: GB-IE/03.18, 2 pages. 2018	
	15.	BREUER, et al., "Glossary of Terms Related to Pharmaceutics (IUPAC Recommendations 2009)" Pure Appl. Chem. (2009); 81 (5): 971-999.	
	16.	European Application No. EP 19189185.2, Extended European Search Report dated August 29, 2019, 9 pages.	
	17.	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.	
	18.	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.	✓
	19.	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.	✓

Examiner Signature	/ARADHANA SASAN/	Date Considered	12/13/2019

*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.

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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
S279	8	("10272037" | "10471071" | "20090181099" | "20140187523" | "20180071211" | "20190201333" | "8679545" | "9782347").PN.	US-PGPUB; USPAT	OR	ON	2019/12/13 12:14
S280	4	("10272037" | "10471071" | "20090181099" | "20140187523" | "20180071211" | "20190201333" | "8679545" | "9782347").PN.	US-PGPUB	OR	ON	2019/12/13 12:25
S281	4	("10272037" | "10471071" | "20090181099" | "20140187523" | "20180071211" | "20190201333" | "8679545" | "9782347").PN.	USPAT	OR	ON	2019/12/13 12:25
S282	1	S279 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT	OR	ON	2019/12/13 12:29
S283	0	S279 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount)).CLM.	US-PGPUB; USPAT	OR	ON	2019/12/13 12:29
S284	12257	("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 12:39
S286	12253	("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount) same (time period second minute))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 12:39
S287	79	((("ODT") ((oral$2 mouth buccal$2) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4	US-PGPUB; USPAT; USOCR;	OR	ON	2019/12/13 12:43

		compact$4 pill lozenge dragee))) same (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4))	FPRS; EPO; JPO; DERWENT; IBM_TDB			
S288	79	((("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))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 12:43
S289	13	((("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	2019/12/13 13:53
S290	13	((("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	2019/12/13 13:54
S291	3	((("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	2019/12/13 14:00
S292	720291	(A61K31/569 OR A61K2300/00 OR A61K31/56 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/0065 OR A61K9/06 OR A61K9/08).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 14:04
S293	248	(A61K31/569 same A61K2300/00).cpcc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 14:04
S294	720291	S292 S293	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 14:04

S295	3	S294 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; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/12/13 14:05
S296	13	S294 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	2019/12/13 14:05
S297	15	((Stephen) near2 (PERRETT)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S298	19	((Fredric) near2 (COHEN)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S299	137	((Gopi) near2 (VENKATESH)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S300	157	(APTALIS ADARE EURAND).AS.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S301	74	(APTALIS ADARE EURAND).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S302	4	((Stephen) near2 (PERRETT)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S303	2	((Fredric) near2 (COHEN)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S304	19	((Gopi) near2 (VENKATESH)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S305	246	S297 S298 S299 S300 S301 S302 S303 S304	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/13 14:05
S306	3	S305 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	2019/12/13 14:21

12/ 13/ 2019 2:26:28 PM

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Sheet 1 of 1

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First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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. 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.	

Examiner Signature		Date Considered	

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Electronic Patent Application Fee Transmittal

Application Number:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Sandra Laramore
Attorney Docket Number:	ADAR-119/05US 325049-2804

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt

EFS ID:	38052039
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	17-DEC-2019
Filing Date:	17-NOV-2017
Time Stamp:	13:03:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$240
RAM confirmation Number	E2019BGD04161709
Deposit Account	
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Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119-05US-SB08.pdf	96785 b80ccc1e0667a47b55cd64902aa2a205942d73a9	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	Response-filed-12-16-2019.pdf	11790586 4479859498 07ca84635d7aa5b90fdbb8886d8f15	no	16
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30551 6be17287715d84ab86ad17a75ce6e74d0d92f014	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	12006255		

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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

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Docket No.: ADAR-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	Examiner:	SASAN, Aradhana

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 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 $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

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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 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.

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).

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. ADAR-119/05US 325049-2804.

Dated: December 17, 2019

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 91543

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

91543 7590 12/09/2019

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/09/2019	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

Applicant-Initiated Interview Summary	**Application No.** 15/816,154	**Applicant(s)** Perrett et al.	
	Examiner ARADHANA SASAN	**Art Unit** 1615	**AIA (FITF) Status** No

All participants (applicant, applicants representative, PTO personnel):

(1) ARADHANA SASAN. (3) _____.

(2) JONATHAN M. COUSIN. (4) _____.

Date of Interview: 04 December 2019.

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

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

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

Claim(s) discussed: 44.

Identification of prior art discussed: Dohil et al. (US 2009/0191275 A1) and US Patent 10,105,315 (the '315 Patent).

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

Mr. Cousin proposed adding a limitation regarding the disintegration time of 60 seconds into the claims since this was critical to the invention. The Examiner agreed that adding this limitation would better define the claimed orally dispersing tablet, and also that the Dohil et al. reference did not disclose the disintegration time.
There was a brief discussion regarding the double patenting rejection over the '315 Patent. Mr. Cousin explained that step a. in the method claim of the '315 Patent was specific to administering the oral corticosteroid while the patient was lying down, and that this is not an obvious variant. The Examiner agreed that even though the patient populations in both instant claims and claims of the '315 Patent overlapped, the step of requiring a patient to lie down before administering the drug would not be obvious.
Mr. Cousin agreed that terminal disclaimers over the related patents would be filed to overcome the other two double patenting rejections (over US Patents 8,771,729 and 9,486,407).
An updated search and further consideration will be required once amendments and arguments are filed..

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

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

☐ Attachment

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Summary of Record of Interview Requirements

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

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

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

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

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	8,679,545	03-25-2014	Dohil, et al.	
	2.	9,782,347	10-10-2017	Dohil, et al.	
	3.	10,272,037	04-30-2019	Dohil, et al.	
	4.	10,471,071	11-12-2019	Gosselin, et al.	
	5.	2009/0181099	07-16-2009	Dohil, et al.	
	6.	2014/0187523	07-03-2014	Dohil, et al.	
	7.	2018/0071211	03-15-2018	Dohil, et al.	
	8.	2019/0201333	07-04-2019	Dohil, 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]
	9.	DE 202010018594 U1 (and English Abstract)	02-16-2018	ADARE PHARMACEUTICALS INC.	(corresponds to US 2011/081411, cited in IDS filed 12/20/2017)	✓
	10.	EP 2214679 B1	03-27-2019	Meritage Pharma, Inc.		
	11.	WO 2010/021636 A1	02-25-2010	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		
	12.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		
	13.	WO 2019/165138 A1	08-29-2019	ADARE DEVELOPMENT I, 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.**

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

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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Substitute for form 1449A/PTO

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(Use as many sheets as necessary)

Sheet 2 of 2

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First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	14.	[Author Unknown] Jorveza® package leaflet, Jorveza 1mg orodispersible tablets, Mat-No: 1147370 (Losan Pharma), Date Code Falk: GB-IE/03.18, 2 pages.	
	15.	BREUER, et al., "Glossary of Terms Related to Pharmaceutics (IUPAC Recommendations 2009)" Pure Appl. Chem. (2009); 81 (5): 971-999.	
	16.	European Application No. EP 19189185.2, Extended European Search Report dated August 29, 2019, 9 pages.	
	17.	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.	
	18.	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.	✓
	19.	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.	✓

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.

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Docket No.: ADAR-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	Examiner:	SASAN, Aradhana

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 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:

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

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

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[X] 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):

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[] 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.

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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.

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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).

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. ADAR-119/05US 325049-2804.

Dated: December 6, 2019

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 91543

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

Tel: (202) 842-7800
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Electronic Patent Application Fee Transmittal

Application Number:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Sandra Laramore
Attorney Docket Number:	ADAR-119/05US 325049-2804

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt

EFS ID:	37951013
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	06-DEC-2019
Filing Date:	17-NOV-2017
Time Stamp:	16:10:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$240
RAM confirmation Number	E2019B6G10449228
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		ADAR-119-05US_Amendment_and_Response_to_NFOA_dated_09_09_19.pdf	190139 8cf8db4b5f7de1205e175a1d742a4b7cc3c22ae4	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	3	
	Applicant Arguments/Remarks Made in an Amendment		4	6	
Warnings:					
Information:					
2	Foreign Reference	DE202010018594U1_andEnglishAbstract.pdf	2030488 fe6d126037d33704b98a6402462101fbd767bdd5	no	21
Warnings:					
Information:					
3	Foreign Reference	EP2214679B1.pdf	4824876 1720ef438c35ea53fa0ced7a4d177a928eb60737	no	64
Warnings:					
Information:					
4	Foreign Reference	WO2010021636A1.pdf	4064611 59a8d616ed032ecbc0aadcfa32ff6a79e009ecab	no	66
Warnings:					
Information:					
5	Foreign Reference	WO2018035393A1.pdf	17095440 a043730f95736469c55e5517ae11c41aeed48d78	no	192

Warnings:					
Information:					
6	Foreign Reference	WO2019165138A1.pdf	6000272 0f2489ccb11ebbdfdf2833f51621d64bc011807c	no	113
Warnings:					
Information:					
7	Non Patent Literature	Author-Unknown_Jorveza_package_leaflet_1mg-datecode-03-18__2-pages.pdf	76661 4d17c5c3f8ef28fc60064e64c98ab92248deafc6	no	2
Warnings:					
Information:					
8	Non Patent Literature	BREUER_2009.pdf	7658134 7fa5bd62896b82fd59ef6ced5322d774c44cfc04	no	29
Warnings:					
Information:					
9	Non Patent Literature	EP19189185_EESR.pdf	384175 bb355afffa0dcd1e5b66fa8cf027e2fcc12205a4	no	9
Warnings:					
Information:					
10	Non Patent Literature	Oppn_2482822_Submission_filed_09-20-2019_29_pgs.pdf	3335826 801f8c2c30ee68249930c6426722d5ae17411589	no	29
Warnings:					
Information:					
11	Non Patent Literature	Oppn_2482822_EP_Comm_and_Further_Written_Submissions_filed_10-29-2019_29_pgs.pdf	6073165 b7d8a100dcf1e2c72db08ca79d08a63408baf1be	no	29
Warnings:					
Information:					
12	Non Patent Literature	Patent-Complaint_July_3_2019_107Pages.pdf	21260153 1a3f347bf886066e5c1023846d7e112c34c7c097	no	107
Warnings:					
Information:					

13	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119-05US-SB08.pdf	123638 efb1cc7aea1bd60f755ff69a8dab5b46d681a62d	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
14	Transmittal Letter	ADAR-119-05US-IDS.pdf	87348 3521c21b18a55bd27aa8081bbf21839525811111	no	4
Warnings:					
Information:					
15	Fee Worksheet (SB06)	fee-info.pdf	30552 5a6ab28d48611ff2cf930445c1f88f5d5ee1737c	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	73235478	

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

AMENDMENT UNDER 37 C.F.R. § 1.111

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

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

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

AMENDMENT TO THE CLAIMS:

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

1.-43. (Cancelled)

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

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

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

45-47. (Cancelled)

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

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

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

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

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

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

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

55. (Cancelled)

56. (Cancelled)

57. (Currently Amended) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of budesonide ~~or fluticasone propionate~~.

58. (Currently Amended) The orally dispersing tablet of claim 44, comprising about 1 mg of budesonide.

59. (Cancelled)

60. (Currently Amended) The orally dispersing tablet of claim 51, comprising about 1 mg of budesonide.

61. (Currently Amended) The orally dispersing tablet of claim 52, comprising about 1 mg of budesonide.

62. (Currently Amended) The orally dispersing tablet of claim 53, comprising about 1 mg of budesonide.

63. (Currently Amended) The orally dispersing tablet of claim 54, comprising about 1 mg of budesonide.

64. (Previously Presented) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof an orally dispersing tablet according to claim 44.

65. (Currently Amended) The method of claim [[65]]64, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus.

66. (Currently Amended) The method of claim [[65]]64, wherein said inflammatory condition of the gastrointestinal tract is eosinophilic esophagitis.

REMARKS

I. Status of Claims

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

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

II. Summary of Examiner Interview

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

III. Claim Objections

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

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

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

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

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

V. Double Patenting Rejections

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

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

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

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

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

CONCLUSION

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

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

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

Respectfully submitted,
COOLEY LLP

Dated: December 6, 2019

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004
Tel: (202) 728-7126
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	15816154
Filing Date	17-Nov-2017
First Named Inventor	Stephen Perrett
Attorney Docket Number	ADAR-119/05US 325049-2804
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
Adare Pharmaceuticals, Inc.	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

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:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Carolina Pimentel
Attorney Docket Number:	ADAR-119/05US 325049-2804

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	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

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

Application No.: 15816154

Filing Date: 17-Nov-2017

Applicant/Patent under Reexamination: Perrett

Electronic Terminal Disclaimer filed on December 6, 2019

☒ 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:	37950927
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	06-DEC-2019
Filing Date:	17-NOV-2017
Time Stamp:	16:11:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$160
RAM confirmation Number	E2019B6G11449263
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	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33433 abb493c5a52afd6228f5583667bb8045e77bbf86	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30417 6ac9a1a5677f28ad69692046f54ec431a41de31d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	63850		

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New Applications Under 35 U.S.C. 111

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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/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 15/816,154	Filing Date 11/17/2017	☐ 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 $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ 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	12/06/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 17	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".	/APRIL L. WALKER/
*** 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.

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.	15/816,154
	Filing Date	November 17, 2017
	First Named Inventor	Stephen PERRETT
	Art Unit	1615
	Examiner Name	Aradhana Sasan
	Practitioner Docket No.	ADAR-119/05US 325049-2804

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 66,418.

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

/Jonathan M. Cousin/ — Signature

December 3, 2019 — Date

Jonathan M. Cousin — Typed or printed name

202-728-7126 — 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:	37917171
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	ADAR-119-05US_Authorization_for_Internet_Communications.pdf	626235 b7e5126756c5c2c22e153d6a3b9051be9f47bfef	no	1

Warnings:

Information:	
Total Files Size (in bytes):	626235

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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.
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804	4432

91543 7590 09/09/2019

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
09/09/2019	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

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

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

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 06/10/19.

☐ 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) 44 and 48-66 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) 44 and 48-66 is/are rejected.

8) ☑ Claim(s) 65 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED *CORRESPONDENCE*

Notice of Pre-AIA or AIA status

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

Status of Application

2. The remarks, amendments, and Request for Continued Examination filed on 06/10/19 are acknowledged.

3. Claims 1-43 and 45-47 were cancelled. Claim 44 was amended. New claims 48-66 were added.

4. Claims 44 and 48-66 are included in the prosecution.

Continued Examination under 37 CFR 1.114

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

Information Disclosure Statement

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

Response to Amendments/Arguments

Claim Objections

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

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

Rejection of claims under 35 USC § 112, second paragraph

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

Rejection of claims under 35 USC § 102(b)

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

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

Claim Objections

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

Claim Rejections - 35 USC § 103

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response to Arguments

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

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

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

Applicant argues that "… at the time of Applicant's invention, liquid dosage forms, such as those exemplified in Dohil and in the evidence of record[5], were the standard of care for treating inflammation of the upper GI tract, because such liquid dosage forms ensured that a therapeutically effective amount of the corticosteroid "reach[ed] the targeted and/ or inflamed portion of the gastrointestinal tract ..."[6] Applicant argues that there is no motivation to formulate a corticosteroid in Dohil's "lozenge or other similar tablet" to treat inflammation of the upper GI tract, or a reasonable basis to believe that such a composition would successfully deposit a "therapeutically effective amount" of corticosteroid on the upper GI tract, as required by the present claims.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Double Patenting

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response to Arguments

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

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

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

Conclusion

13. No claims are allowed.

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

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

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

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

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/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	06/24/2018	AS
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	09/03/2019	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**
(A61K31/569 same A61K2300/00).cpcc. with keyword	06/24/2018	AS
(A61K31/569 same A61K2300/00).cpcc. with keyword	09/03/2019	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 prosecution history of related cases 12896005,14311732,15205390,15680301,14294660, and 14917125. EAST search - including CPC with keyword, inventor, assignee and applicant name search. NPL search - including Google Patents and SciFinder. Please see attached history for each search.	06/24/2018	AS
Updated EAST and STIC/NPL search. Please see attached history for each search.	12/04/2018	AS
Updated EAST search. Google Patents search. Please see the attached history for each search.	09/03/2019	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

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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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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	8,580,300	11-12-2013	Wilhelm, et al.	
	2.	9,867,780	01-16-2016	Greinwald, et al.	
	3.	10,176,301	01-08-2019	Hill, et al.	
	4.	2016/0078186	03-17-2016	Hill, et al.	
	5.	2017/0183719	06-29-2017	Rothenberg, 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]
	6.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	7.	LI, Xiaowei, et al., "Advances in Injectable Thermosensitive Polymers". Polymer Bulletin, No. 3, pages 109-115, June 30, 2015 (with English Abstract), 7 pages.	
	8.	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	
	9.	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	
	10.	[Author Unknown] Jorveza® summary of product characteristics (downloaded from the European Medicines Agency at www.ema.europa.eu/en/medicines/human/EPAR/jorveza#product-informationsection); accessed 8/1/2019, 9 pages.	
	11.	[Author Unknown] Jorveza® package leaflet (downloaded from the European Medicines Agency at www.ema.europa.eu/en/medicines/human/EPAR/jorveza#product-informationsection); accessed 8/1/2019, 8 pages.	
	12.	[Author Unknown] Povidone (polyvinylpyrrolidone (PVP)) compound summary (downloaded from Wikipedia at https://en.wikipedia.org/wiki/Polyvinylpyrrolidone); accessed 7/31/2019, 5 pages.	
	13.	[Author Unknown] Definition of slow-release (downloaded from Merriam-Webster online at https://www.merriam-webster.com/medical/slow-release); accessed 7/31/2019, 1 page.	
	14.	[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.	
	15.	[Author Unknown] Solubility of budesonide (downloaded from https://pubchem.ncbi.nlm.nih.gov/compound/Budesonide#section=Solubility&fullscreen=true); accessed 8/1/2019, 1 page.	
	16.	BONNET, et al., "Formulation of a 3-months Stability Oral Viscous Budesonide Gel and Development of an Indicating Stability HPLC Method", Pharm Technol Hosp Pharm (2018); 3(2): 91-99.	
	17.	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.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	09/03/2019

*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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Patents (corticosteroid) (tablet) (orally dispersing) (budesonide) (fluticasone) (Sign in

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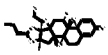
Methods for treating gastrointestinal disorders

WO EP US CA · US20110092401A1 · Elaine Phillips · Meritage Pharma, Inc.
Priority 2009-06-12 · Filed 2010-06-11 · Published 2011-04-28
In some embodiments, the **corticosteroid** is **budesonide**. In another embodiment, the **corticosteroid** is an ester of **fluticasone**, e.g., **fluticasone** ... , nanoparticles, a **tablet**, an effervescent **tablet**, a melting **tablet**, a disintegrating **tablet**, a dissolving wafer, an **orally disintegrating tablet**, a ...



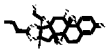
Compositions for the treatment of gastrointestinal inflammation

WO EP US JP KR AU CA CY DK ES GB HR HU IE LT MX NZ PL PT RU SI ZA · PT2211896T · Hill Malcolm · Meritage Pharma Inc
Priority 2007-11-13 · Filed 2008-11-12 · Published 2018-03-21
In certain embodiments, the **corticosteroids** used in the present invention include **topical** steroids including, for example, **budesonide** or **fluticasone** ... The **tablet** or other similar dosage form (eg, a **tablet**, capsule or other solid) will dissolve in the mouth or **esophagus** to produce a solution which ...



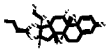
Compositions for the treatment of gastrointestinal inflammation

US · US20090123390A1 · Malcolm Hill · Meritage Pharma, Inc.
Priority 2007-11-13 · Filed 2008-11-12 · Published 2009-05-14
In certain embodiments, the **corticosteroids** used in the present invention include **topical** steroids including, for example, **budesonide** or **fluticasone** ... The lozenge or other similar dosage form (e.g., a **tablet**, capsule, or other solid), would dissolve in the mouth or **esophagus** to produce a solution ...



Topical corticosteroids for the treatment of inflammatory diseases of the ...

US · US20190201333A1 · Ranjan Dohil · The Regents Of The University Of California
Priority 2005-11-12 · Filed 2019-03-11 · Published 2019-07-04
... e.g., a **topical corticosteroid**, such as, for example, **budesonide**) and a coating agent (e.g., a mucoadhesive agent) in the form of a dissolving **tablet**. ... ** Prior therapy was with elimination diet (ELIM), **topical fluticasone** propionate and/or proton pump inhibitors (PPI). + Site of **esophageal** ...



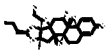
Compositions for the treatment of inflammation of the gastrointestinal tract

US · US20180325892A1 · Malcolm Hill · Meritage Pharma, Inc.
Priority 2007-11-13 · Filed 2018-07-26 · Published 2018-11-15
... **corticosteroid** is provided in the form of a **tablet**, a capsule, or, for example a gel capsule, designed for slow release and delivery to the **esophagus** ... claim 56 , wherein the **topical corticosteroid** is **budesonide**. 58 . The method of claim 56 , wherein the **topical corticosteroid** is **fluticasone** propionate.



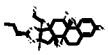
Corticosteroid compositions

US · US20150231156A1 · Elaine Phillips · Meritage Pharma, Inc.
Priority 2007-11-13 · Filed 2015-05-01 · Published 2015-08-20
... secondary to caustic/irritant ingestion, persistent/recurrent **esophageal** strictures of any cause and including caustic/irritant ingestion, pill- ... In certain embodiments, the **corticosteroids** used in the present invention include **topical** steroids including, for example, **budesonide** or **fluticasone** ...



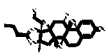
Corticosteroids for the treatment of inflammatory diseases of the ...

WO EP CA · CA2734763C · Ranjan Dohil · Ranjan Dohil
Priority 2008-08-20 · Filed 2008-11-12 · Granted 2016-06-28 · Published 2016-06-28
... compositions comprising a **corticosteroid**, for example a **topical corticosteroid**, such as, for example, **Budesonide**, in the form of a dissolving **tablet**, ... He was subsequently treated with omeprazole (Prilosec) 10 mg twice daily and **fluticasone** (Flovent) 220 ug twice daily as **topical esophageal** therapy ...



Viscous budesonide for the treatment of inflammatory diseases of the ...

US · US20130296288A1 · Ranjan Dohil · The Regents Of The University Of California
Priority 2005-11-12 · Filed 2013-07-08 · Published 2013-11-07
... compositions comprising a **corticosteroid**, for example a **topical corticosteroid**, such as, for example, **Budesonide**, in the form of a dissolving **tablet**, ... **Prior therapy was with elimination diet (ELIM), **topical fluticasone** propionate and/or proton pump inhibitors (PPI). + Site of **esophageal** ...



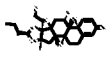
Corticosteroid compositions

CN · CN101938988B · 艾莱利普斯 · 梅里蒂奇制药公司
Priority 2007-11-13 · Filed 2008-11-12 · Granted 2014-03-05 · Published 2014-03-05
8. The stabilized pharmaceutical composition as claimed in claim 7, wherein the **topically** active **corticosteroid** is **budesonide**, **fluticasone**, ... with the surface of the **esophagus**, and i. media. 37. The oral composition as claimed in claim 36, wherein said composition is formulated as a **tablet**.

Viscous budesonide for the treatment of inflammatory diseases of the ...

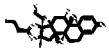
US · US9877924B2 · Ranjan Dohil · The Regents Of The University Of California

Priority 2005-11-12 • Filed 2012-11-30 • Granted 2015-03-10 • Published 2015-03-10
... compositions comprising a **corticosteroid**, for example a **topical corticosteroid**, such as, for example, **budesonide**, in the form of a dissolving **tablet**, ... **Prior therapy was with elimination diet (ELIM), **topical fluticasone** propionate and/or proton pump inhibitors (PPI). + Site of **esophageal** ...



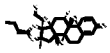
Use of antivirals against inflammatory bowel diseases

WO US • US20050038468A1 • Victor Brami • Ion Pharmaceuticals Switzerland Ltd.
Priority 2003-07-10 • Filed 2003-07-10 • Published 2005-01-13
... inactive **corticosteroids**. 7 . The method of claim 6 , wherein the **corticosteroids** are selected from the group consisting of **budesonide**, **fluticasone** and ... , wherein said medicament is formulated for intravenous administration, parenteral administration, oral administration, inhalation, **topical** ...



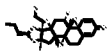
Method for treating inflammatory diseases of the digestive tract

WO US • WO2008031013A1 • Louis Anthony Tartaglia • Gene Logic Inc.
Priority 2006-09-08 • Filed 2007-09-07 • Published 2008-03-13
... agent comprises a **corticosteroid** selected from the group consisting of beclomethazone, beclomethazone dipropionate, **budesonide**, **fluticasone**, ... e.g., prednisone, prednisolone, **budesonide**, dexamethasone), or **topically** (enema, suppository or foam preparations). [0031] Intravenous **corticosteroids** ...



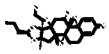
Method for reducing or alleviating inflammation in the digestive tract

WO EP US CN JP AT AU CA DK ES IL • WO2008031014A1 • Louis Anthony Tartaglia • Ore Pharmaceuticals Inc.
Priority 2006-09-08 • Filed 2007-09-07 • Published 2008-03-13
... agent comprises a **corticosteroid** selected from the group consisting of beclomethazone, beclomethazone dipropionate, **budesonide**, **fluticasone**, ... e.g., prednisone, prednisolone, **budesonide**, dexamethasone), or **topically** (enema, suppository or foam preparations). [0031] Intravenous **corticosteroids** ...



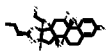
A method of providing a **steroid**-sparing benefit with a cyclooxygenase-2 ...

WO EP US JP BR CA MX • EP1611096A2 • Karen Seibert • Pharmacia Corporation
Priority 2003-03-28 • Filed 2004-03-16 • Published 2006-01-04
... group consisting of hydrocortisone, mometasone, **fluticasone**, fluocinolone acetonide, fluocinolone, flurandrenolone acetonide, ciclesonide, **budesonide** ... , by administering to the subject the Cox-2 inhibitor and **corticosteroid** together in one therapeutic dosage form, such as in a single capsule, **tablet**, ...



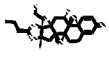
Gastrointestinal delivery systems

US • US20090123557A1 • Elaine Phillips • Meritage Pharma, Inc.
Priority 2007-11-13 • Filed 2008-11-12 • Published 2009-05-14
... mg, or about 0.5 mg, or about 1.4 mg, or about 2 mg of **corticosteroid** (e.g., **budesonide**). In certain embodiments, the therapeutic agent is **topically** ... secondary to caustic/irritant ingestion, persistent/recurrent **esophageal** strictures of any cause and including caustic/irritant ingestion, **pill**- ...



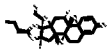
Method for reducing or alleviating inflammation in the digestive tract

• IN2009CN01882A • Louis Anthony Tartaglia • Ore Pharmaceuticals Inc
Priority 2006-09-08 • Filed 2009-04-03 • Published 2009-08-21
[0177] Nonlimiting examples of **corticosteroids** include beclomethazone, beclomethazone dipropionate, **budesonide**, dexamethasone, **fluticasone**, ... e.g., prednisone, prednisolone, **budesonide**, dexamethasone), or **topically** (enema, suppository or foam preparations). [0031] Intravenous **corticosteroids** ...



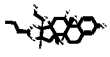
Topically active steroids for use in radiation and chemotherapeutics injury

WO EP US CN JP KR AU CA DK HK IL NZ SG • US20100183749A1 • Robert N. Brey • Brey Robert N
Priority 2008-12-08 • Filed 2009-12-08 • Published 2010-07-22
... budesonide, 22R budesonide, beclomethasone-17-monopropionate, clobetasol propionate, diflorasone diacetate, flunisolide, flurandrenolide, **fluticasone** ... dipropionate (BDP). Along with **budesonide** and similar **topically** acting **corticosteroid** drugs (TACs), BDP is a potent, locally-acting **corticosteroid**.



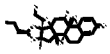
Quinazoline derivatives as metabolically inert antifolate compounds

WO EP US JP AU CA • CA2579096C • Michael J. Roberts • Chelsea Therapeutics, Inc.
Priority 2004-09-08 • Filed 2005-09-08 • Granted 2012-11-13 • Published 2012-11-13
... -M, flunisolide), Azmacort (triamcinolone acetonide), Beclovet (Vanceril, beclomethasone dipropionate), Flovent (**fluticasone**), Pulmicort (**budesonide**), ... **Topical** treatments: **corticosteroids** (cortisone), calcipotriene (a synthetic form of vitamin D3); coal tar; anthralin; **topical** retinoids (e.g. ...



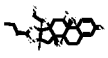
Alkylthio pyrimidines as crth2 antagonists

WO EP US CN JP KR AR AT AU BR CA CY DK ES HK IL MX NZ PT RU SI TW ZA • PT2205569E • Tai Wai Ly • Actimis Pharmaceuticals Inc
Priority 2007-09-25 • Filed 2008-09-24 • Published 2012-05-25
... , prednisone, prenisolone, triamcinolone, dexamethasone, **fluticasone**, flunisolide and hydrocortisone, and **corticosteroid** analogues such as **budesonide**; ... of any of the diseases according to claim 11, characterized in that the compound is prepared to be administered orally, parenterally or **topically**.



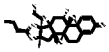
2-S-benzyl substituted pyrimidines as CRTH2 antagonists

WO EP US CN JP KR AR AU BR CA IL MX NZ RU TW ZA • US8314116B2 • Tai Wei Ly • Actimis Pharmaceuticals, Inc.
Priority 2007-09-25 • Filed 2008-09-24 • Granted 2012-11-20 • Published 2012-11-20
... , prednisone, prenisolone, triamcinolone, dexamethasone, **fluticasone**, flunisolide and hydrocortisone, and **corticosteroid** analogs such as **budesonide**; ... induced asthma. 35. The method of claim 33 , wherein the compound is administered orally, parenterally or **topically**. 36. The method of claim 33 ,



Quinazoline derivatives as metabolically inert antifolate compounds

AU • AU2011226557A1 • Simon Peddar • Chelsea Therapeutics, Inc.
Priority 2004-09-08 • Filed 2011-06-03 • Published 2011-06-23
...), **budesonide** (Pulmicort, Rhinocort), dexamethasone sodium phosphate (Decadron phosphate), flunisolide (Aerobid, Bronalide, Nasalide), **fluticasone** ... in combination or alternation with agents used to treat psoriasis including, but not limited to the following: **Topical** treatments: **corticosteroids** (...



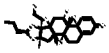
Methods for treating diseases and conditions with inverse agonists and for ...

WO EP US JP AU CA IL • EP1684764A2 • Richard A. Bond • Inverseon, Inc.
Priority 2003-10-09 • Filed 2004-10-08 • Published 2006-08-02
... dry powder inhalers have been introduced (e.g. Diskhaler® , Turbuhaler®). Potential problems associated with dry powder inhalers include **esophageal** ... **Topically** active **corticosteroid** drugs used for the treatment of patients with asthma include beclomethasone, betamethasone valerate, **budesonide**, ...



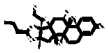
Corticosteroid beta-agonist compounds for use in therapy

WO • WO2010132748A1 • William R. Baker • Gilead Sciences, Inc.
Priority 2009-05-15 • Filed 2010-05-14 • Published 2010-11-18
Formulations for **topical** administration in the mouth, for example buccally or sublingually, include lozenges, comprising the active ingredient in a ... invention and a **corticosteroid** selected from ciclesonide, desisobutyryl- ciclesonide, **budesonide** mometasone, **fluticasone** propionate, and **fluticasone** ...



Corticosteroid linked beta-agonist compounds for use in therapy

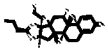
WO • WO2010128958A1 • William R. Baker • Gilead Sciences, Inc.
Priority 2009-04-29 • Filed 2010-04-28 • Published 2010-11-04
Spray compositions for **topical** delivery to the endobronchial space or lung by inhalation may for example be formulated as aqueous solutions or ... amount of a compound of the invention and a **corticosteroid** selected from ciclesonide, desisobutyryl- ciclesonide, **budesonide** mometasone, **fluticasone** ...



Methods for Treating Diseases and Conditions with Inverse Agonists and for ...

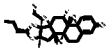


US • US20070276024A1 • Richard Bond • Inverseon , Inc.
Priority 2003-10-09 • Filed 2004-10-08 • Published 2007-11-29
... dry powder inhalers have been introduced (e.g. Diskhaler® , Turbuhaler®). Potential problems associated with dry powder inhalers include **esophageal** ... in another alternative, the additional agent is a **steroid**. The **steroid** can be beclomethasone, **budesonide**, ciclesonide, flunisolide, **fluticasone**, ...



Synthesis of resorcylic acid lactones useful as therapeutic agents

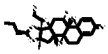
WO EP US CN JP KR AU BR CA ES IL MX RU • CA2755876A1 • Nicolas Winssinger • Universite De Strasbourg
Priority 2008-01-15 • Filed 2009-01-15 • Published 2009-07-23
... -M, flunisolide), Azmacort (triamcinolone acetonide), Beclovet (Vanceril, beclomethasone dipropionate), Flovent (**fluticasone**), Pulmicort (**budesonide**), ... method of claim 27, wherein the cancer is a solid tumor, blood borne tumor, breast, ovary, cervix, prostate, testis, genitourinary tract, **esophagus**, ...



Modulators of CRTH2, COX-2 and FAAH



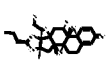
WO EP US JP • US20050234030A1 • Wilmin Bartolini • Wilmin Bartolini
Priority 2004-04-20 • Filed 2005-01-03 • Published 2005-10-20
Certain substituted indoles that are modulators of one or more or of CRTH2, COX-2 AND FAAH are described. The compounds are useful for treatment of pain and/or inflammation as well as other disorders.



Method of treating airway diseases with beta-adrenergic inverse agonists



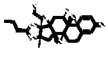
US • US20060194882A1 • Richard Bond • Bond Richard A
Priority 2004-10-08 • Filed 2005-10-07 • Published 2006-08-31
... dry powder inhalers have been introduced (e.g. Diskhaler®, Turbuhaler®). Potential problems associated with dry powder inhalers include **esophageal** ... **Topically** active **corticosteroid** drugs used for the treatment of patients with asthma include beclomethasone, betamethasone valerate, **budesonide**, ...



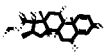
Pyrimidine derivatives used as pi-3 kinase inhibitors



WO EP US CN JP KR AR AT AU BR CA CR CY DE DK EA EC ES GE GT HK HN HR IL JO MA ME MY NO NZ PE PT RS SI SM SV TN TW UA ZA • EP2261222A1 • Matthew Burger • Novartis AG
Priority 2006-01-20 • Filed 2007-01-22 • Published 2010-12-15
Such anti-inflammatory drugs include steroids, in particular glucocorticosteroids such as **budesonide**, beclamethasone, **fluticasone**, ciclesonide or ... uterine corpus; uterine cervix; ovary; multiple myeloma; **esophagus**; acute myelogenous leukemia; chronic myelogenous leukemia; lymphocytic leukemia;



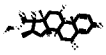
Novel Compositions and Methods for Binding and Inhibiting 5-HT4 Receptor



WO EP US • US20100035858A1 • Stephen Roth • Immune Control, Inc.
Priority 2008-07-18 • Filed 2009-07-16 • Published 2010-02-11
... as well as in the central nervous system. In the periphery it is found in the gastrointestinal tract, for example in the **esophagus** (Moummi et al., ... nasal spray: Beconase™/Vancenase™), **budesonide** (Rhinocort™/Pulmicort™, AstraZeneca), flunisolide (AeroBid™/Nasaline™/Nasarel™), **fluticasone** ...

Methods of treating epithelial lesions





US • US20060168671A1 • Daniel Podolsky • Podolsky Daniel K
Priority 2002-10-31 • Filed 2006-01-18 • Published 2006-08-24
19 . The method of claim 12 , wherein said **steroid** is triamcinolone, hydrocortisone, **fluticasone**, **budesonide**, or beclomethasone. 20 . The method of ... The invention further features methods of preventing or treating an eye disorder, e.g., dry eye, by **topically** administering to the eye a composition ...

Substituted acylanilides and methods of use thereof





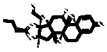
WO EP US CN JP KR AR AU BR CA CY DK EA ES HU IL MX PL PT • US8846756B2 • James T. Dalton • University Of Tennessee Research Foundation
Priority 2006-08-24 • Filed 2013-04-23 • Granted 2014-09-30 • Published 2014-09-30
wherein said composition is administered as a **tablet**, a capsule, a **pill**, a granule, a pellet, a powder, a solution, a suspension, a dispersion, an ... in one embodiment, the agent treating inflammation is 5-amino-salicylate, **corticosteroid**, metronidazole, ciprofloxacin, infliximab, **budesonide**, or ...

Drug metabolism and pharmacokinetics



Google Scholar • www.researchgate.net • Benedetti M • Drug metabolism reviews
Published 2009
... Formulation Route of application Location **Tablet** Oral Stomach, intestine Sublingual Tongue Buccal Oral cavity ... 6. Conjunctiva: a. bulbar con- junctiva; b. palpebral conjunctiva ... example, the absolute bioavailability of an intra- nasal drug (eg, intranasal **corticosteroids**) is defined ...

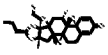
Heterocyclic cytokine inhibitors



WO • WO2007075883A2 • Erik Boman • Kemia, Inc.
Priority 2005-12-22 • Filed 2006-12-20 • Published 2007-07-05
[0088] In Crohn's disease, the following groups of drugs combined with the cytokine inhibitor may be effective: steroids such as **budesonide**, 5-ASA ... [00176] In yet other embodiments, the cytokine inhibitor is administered orally or **topically**. In some embodiments, ingredient A is a **corticosteroid** ...

Adenine derivative as pi3k inhibitor





WO EP US CN JP KR AU BR CA CY DK ES HK HR IL IN MX NZ PH PT RU SG SI SM UA ZA • EP2918589B1 • Pingda Ren • Incyte Corp.
Priority 2009-07-15 • Filed 2010-07-15 • Granted 2016-11-02 • Published 2016-11-02
... , e.g. methapyrilene; anti-inflammatories, e.g. beclomethasone, flunisolide, **budesonide**, tipredane, triamcinolone acetonide or **fluticasone**; ... , bladder, gastric, stomach, pancreatic, bladder, breast, cervical, head, neck, renal, kidney, liver, ovarian, prostate, colorectal, **esophageal**, ...

Substituted acylanilides and methods of use thereof





WO EP US CN JP KR AR AU BR CA CY DK EA ES HU IL LT MX PL PT • US20080076828A1 • James Dalton • Dalton James T
Priority 2006-07-12 • Filed 2007-07-12 • Published 2008-03-27
Further, in another embodiment, the pharmaceutical compositions are administered **topically** to body surfaces, and are thus formulated in a form ... In one embodiment, the agent treating inflammation is 5-amino-salicylate, **corticosteroid**, metronidazole, ciprofloxacin, infliximab, **budesonide**, or ...

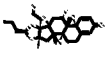
... term treatment of graft-versus-host disease using **topical** active **corticosteroids**



US • US20100184782A1 • George McDonald • Mcdonald George
Priority 2000-09-15 • Filed 2009-11-18 • Published 2010-07-22
... budesonide, 22R **budesonide**, beclomethasone-17-monopropionate, clobetasol propionate, diflorasone diacetate, flunisolide, flurandrenolide, **fluticasone** ... The method includes orally administering to the patient a therapeutically effective amount of a **topically** active **corticosteroids**, such as ...

Immunostimulatory G,U-containing oligoribonucleotides





WO EP US JP AU CA ES HK IL NZ RU • EP2368431A1 • Greyson B. Lipford • Coley Pharmaceutical GmbH
Priority 2002-04-04 • Filed 2003-04-04 • Published 2011-09-28
); and 1-(2-methylpropyl)-1 H- imidazo[4,5-c]quinoline-4-amine (imiquimod or R-837 or S-26308). Imiquimod is currently used in the **topical** treatment of ... The steroids include, but are not limited to, beclomethasone, **fluticasone**, triamcinolone, **budesonide**, **corticosteroids** and **budesonide**. **Corticosteroids** ...

Agonists of guanylate cyclase useful for the treatment of gastrointestinal, ...

WO EP US JP AU CA ES • AU2009270833B2 • Kunwar Shailubhai • Synergy Pharmaceuticals Inc.
Priority 2008-07-16 • Filed 2009-07-16 • Granted 2015-02-19 • Published 2015-02-19

... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ... Dosage forms include preparations for inhalation or injection, solutions, suspensions, emulsions, **tablets**, capsules, **topical** salves and lotions, 20 ...

Agonists of guanylate cyclase useful for the treatment of gastrointestinal ...



WO EP US CN JP AU CA DK EA ES HK IL MX · EP2522356B1 · Kunwar Shailubhai · Synergy Pharmaceuticals Inc.

Priority 2007-06-04 · Filed 2008-06-04 · Granted 2015-10-28 · Published 2015-10-28

... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ... The pharmaceutical composition of claim 2, wherein the unit dose form is selected from the group consisting of a **tablet**, a capsule, a solution and ...

Compounds and methods useful for treating asthma and allergic inflammation

WO EP US JP AU CA ES MX · CA2688521BC · Matthew Brown · Amgen Inc.

Priority 2007-05-02 · Filed 2008-05-01 · Granted 2014-02-11 · Published 2014-02-11

[00195] The pharmaceutical compositions containing the active ingredient may be in a form suitable for oral use, for example, as **tablets**, troches, ... , prednisone, prenisolone, triamcinolone, dexamethasone, **fluticasone**, flunisolide and hydrocortisone, and **corticosteroid** analogs such as **budesonide**;

Agonists of guanylate cyclase useful for the treatment of gastrointestinal ...

WO EP US JP AU CA ES HK · EP2810952A2 · Kunwar Shailubhai · Synergy Pharmaceuticals Inc.

Priority 2008-06-04 · Filed 2009-06-04 · Published 2014-12-10

... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ... The pharmaceutical composition of claim 2, wherein the unit dose form is selected from the group consisting of a **tablet**, a capsule, a solution or ...

Agonists of Guanylate Cyclase Useful for the Treatment of Gastrointestinal ...

WO EP US JP AU CA ES HK · US20100063306A1 · Kunwar Shailubhai · Synergy Pharmaceuticals, Inc.

Priority 2008-06-04 · Filed 2009-06-04 · Published 2010-03-18

... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ... Dosage forms include preparations for inhalation or injection, solutions, suspensions, emulsions, **tablets**, capsules, **topical** salves and lotions, ...

Method and compositions for the treatment of gastrointestinal disorders



WO EP US CA · US20060094668A1 · Mark Currie · Currie Mark G

Priority 2003-06-13 · Filed 2005-02-08 · Published 2006-05-04

The agents can be administered, e.g., by intravenous injection, intramuscular injection, subcutaneous injection, intraperitoneal injection, **topical**, ... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ...

Asthma and allergic inflammation modulators

WO EP US CN JP KR AU BR CA EA ES IS MX NO NZ PL ZA · EP1585511B1 · Zice Fu · Amgen Inc.

Priority 2002-12-20 · Filed 2003-12-19 · Granted 2013-01-23 · Published 2013-01-23

... and urticaria. The compound for use according to claim 18 or claim 20, wherein said compound is to be administered orally, parenterally or **topically**. ... , prednisone, prenisolone, triamcinolone, dexamethasone, **fluticasone**, flunisolide and hydrocortisone, and **corticosteroid** analogs such as **budesonide**;

Substituted Acylanilides and Methods of Use Thereof

AU · AU2015264893B2 · James Dalton · University Of Tennessee Research Foundation

Priority 2006-07-12 · Filed 2015-12-03 · Granted 2017-06-29 · Published 2017-06-29

... as betamethasone dipropionate, clobetasol, diflorasone, amcinonide, desoximetasone, fluocinonide, aclometasone, desonide triamcinolone, **fluticasone**, ... In one embodiment, the agent treating inflammation is 5-amino-salicylate, **corticosteroid**, metronidazole, ciprofloxacin, infliximab, **budesonide**, or ...

Substituted acylanilides and methods of use thereof



US · US20180071242A1 · James T. Dalton · University Of Tennessee Research Foundation

Priority 2006-07-12 · Filed 2017-09-12 · Published 2018-03-15

In one embodiment, the agent treating inflammation is 5-amino-salicylate, **corticosteroid**, metronidazole, ciprofloxacin, infliximab, **budesonide**, or ... Further, in another embodiment, the pharmaceutical compositions are administered **topically** to body surfaces, and are thus formulated in a form ...

Methods and compositions for the treatment of gastrointestinal disorders

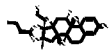
WO EP US CN JP KR AU BR CA IL MX NO NZ SG · AU2005222387B2 · Mark G. Currie · Ironwood Pharmaceuticals, Inc.

Priority 2004-03-09 · Filed 2005-03-08 · Granted 2010-12-02 · Published 2010-12-02

... beclomethasone, beclomethasone dipropionate, betamethasone, **budesonide**, bunedoside, butixocort, dexamethasone, flunisolide, fluocortin, **fluticasone**, ... (3) #2-agonist-**corticosteroid** combinations [e.g., salmeterol-**fluticasone** (ADVAIR@), formoterol-budesonid (SYMBICORT@)]; (4) leukotriene D4 receptor ...

Bisamide cytokine inhibitors

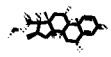
WO - WO2007056016A2 - Nancy G.L. Delaet - Kemia, Inc.
Priority 2005-11-02 • Filed 2006-11-01 • Published 2007-05-18



... , betamethasone, halobetasol (ulobetasol), methylprednisolone, prednisolone, clobetasone, deflazacort, fluocinolone acetonide, **fluticasone**, ... [0078] In Crohn's disease, the following groups of drugs combined with the cytokine inhibitor may be effective: steroids such as **budesonide**, 5-ASA ...

Compositions and methods using proton pump inhibitors

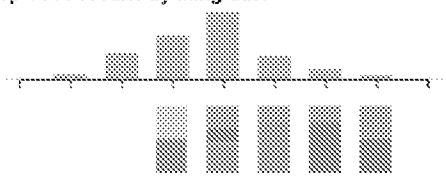
WO US AU TW - WO2003097011A1 - Jay Barth - Eisai Co., Ltd.
Priority 2002-05-17 • Filed 2003-05-16 • Published 2003-11-27



... , betamethasone, **budesonide**, clobetasol, clotrimazole/betamethasone, desonide, diflorasone, fluocinolone, fluocinolone, flurandrenolide, **fluticasone**, ... method of claim 12, wherein the ulcer is a peptic ulcer, a bleeding peptic ulcer, a stress ulcer, a stomal ulcer, a refractory ulcer, an **esophageal** ...

Next > About 401 results

Top 1000 results by filing date



Relative count of top 5 values

Assignees	Inventors	CPCs
Intellikine, LLC		4.1%
济南康泉医药科技有限公司		4.1%
孔庆忠		4.1%
University Of Tennessee Research Foundation		3.5%
Heritage Pharma, Inc.		3.5%

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	2003/0050312	03-13-2003	Hjorth, et al.	
	2.	2007/0111978	05-17-2007	Dohil, et al.	
	3.	2019/0008760	01-10-2019	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]
	4.	EP 1323417 A1	07-02-2003	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
	5.	EP 2211896 B1	01-03-2018	MERITAGE PHARMA, 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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	6.	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.	
	7.	Copy of certified copy of Priority Document US 61/186,777 filed June 12, 2009, 104 pages.	
	8.	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, 10 pages.	✓
	9.	International Preliminary Report on Patentability for International Application No. PCT/US2017/047474, dated February 19, 2019, 8 pages.	
	10.	KHAN and ORENSTEIN, "Eosinophilic Gastroenteritis: Epidemiology, Diagnosis and Management." Paediatr Drugs. (2002); 4(9): 563-570.	
	11.	Opposition to European Patent No. 2482822, filed by Dr. Falk Pharma GmbH on March 1, 2019, Notice of Opposition and Statement of Grounds of Opposition dated March 1, 2019, 13 pages.	
	12.	Opposition to European Patent No. 2482822, filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding notice of opposition, 1 page.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	09/03/2019

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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
S252	3	("20030050312" | "20070111978" | "20190008760").PN.	US-PGPUB; USPAT	OR	ON	2019/09/03 11:55
S253	5	("10176301" | "20160078186" | "20170183719" | "8580300" | "9867780").PN.	US-PGPUB; USPAT	OR	ON	2019/09/03 12:03
S254	52	(US-20140303131-$ or US-20050009848-$ or US-20070059361-$ or US-20090123550-$ or US-20090131386-$ or US-20090169620-$ or US-20140287051-$ or US-20110081411-$ 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-20060134199-$ or US-20110097401-$ or US-20090191275-$ or US-20030050312-$ or US-20190008760-$ or US-20160078186-$).did. or (US-20170183719-$).did. or (US-8771729-$ or US-5000956-$ or US-5049387-$ or US-5077054-$ or US-5776432-$ or US-5863910-$ or US-5980867-$ 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-8407766-$ or US-10105315-$ or US-8580300-$ or US-9867780-$ or US-10176301-$).did. or (KR-20120057841-$).did. or (US-20110027331-$ or WO-0059565-$ or GB-2409160-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	ON	2019/09/03 12:08
S255	35	S254 and (budesonide horacort$4 pulmicort$4 rhinocort$4 entocort$4 symbicort$4 fluticasone cutivate$4 flixonase$4 flixotide$4 flonase$4 flovent$4 fluticasonum$4 fluticaps$4 fluticasona$4)	US-PGPUB; USPAT; FPRS; DERWENT	OR	ON	2019/09/03 12:11
S256	28	S254 and (budesonide horacort$4 pulmicort$4 rhinocort$4 entocort$4 symbicort$4 fluticasone cutivate$4 flixonase$4 flixotide$4 flonase$4 flovent$4 fluticasonum$4 fluticaps$4 fluticasona$4) same (mg milligram)	US-PGPUB; USPAT; FPRS; DERWENT	OR	ON	2019/09/03 12:12
S257	20	S254 and ((budesonide horacort$4 pulmicort$4 rhinocort$4 entocort$4	US-PGPUB; USPAT;	OR	ON	2019/09/03 12:13

		symbicort$4 fluticasone cutivate$4 flixonase$4 flixotide$4 flonase$4 flovent$4 fluticasonum$4 fluticaps$4 fluticasona$4) same (mg milligram)) and ("ODT" ((oral$2 mouth buccal$2) near3 (dispers$8 disintegra$4 dissol$4 break$4) near3 (tablet$4 compress$4 compact$4 pill lozenge dragee)))	FPRS; DERWENT			
S258	146	((budesonide horacort$4 pulmicort$4 rhinocort$4 entocort$4 symbicort$4 fluticasone cutivate$4 flixonase$4 flixotide$4 flonase$4 flovent$4 fluticasonum$4 fluticaps$4 fluticasona$4) same (mg milligram)) and ("ODT" ((oral$2 mouth buccal$2) near3 (dispers$8 disintegra$4 dissol$4 break$4) near3 (tablet$4 compress$4 compact$4 pill lozenge dragee)))	US-PGPUB; USPAT; FPRS; DERWENT	OR	ON	2019/09/03 12:44
S259	146	((budesonide horacort$4 pulmicort$4 rhinocort$4 entocort$4 symbicort$4 fluticasone cutivate$4 flixonase$4 flixotide$4 flonase$4 flovent$4 fluticasonum$4 fluticaps$4 fluticasona$4) same (mg milligram)) and ("ODT" ((oral$2 mouth buccal$2) near3 (dispers$8 disintegra$4 dissol$4 break$4) near3 (tablet$4 compress$4 compact$4 pill lozenge dragee)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 12:44
S260	76	((("ODT") ((oral$2 mouth buccal$2) 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))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:23
S261	15	((Stephen) near2 (PERRETT)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S262	19	((Fredric) near2 (COHEN)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S263	131	((Gopi) near2 (VENKATESH)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S264	153	(APTALIS ADARE EURAND).AS.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S265	68	(APTALIS ADARE EURAND).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S266	4	((Stephen) near2 (PERRETT)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S267	2	((Fredric) near2 (COHEN)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S268	19	((Gopi) near2 (VENKATESH)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S269	240	S261 S262 S263 S264 S265 S266 S267	US-PGPUB;	OR	ON	2019/09/03

		S268	USPAT; USOCR			14:23
S270	4	S269 and ((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S271	4	S269 and ((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR	OR	ON	2019/09/03 14:23
S272	643631	(A61K31/569 OR A61K2300/00 OR A61K31/56 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/0065 OR A61K9/06 OR A61K9/08).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24
S273	396	(A61K31/569 same A61K2300/00).cpcc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24
S274	643631	S272 S273	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24
S275	0	S274 and ((oral$2 mouth buccal$2) near3 (dispers$8 disintegra$4 dissol$4 break$4) near3 (tablet$4 compress$4 compact$4 pill lozenge dragee) near3 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near3 (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24
S276	7	S274 and ((oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) near10 (tablet$4 compress$4 compact$4 pill lozenge dragee) near20 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near25 (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24
S277	733	S274 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) near10 (tablet$4 compress$4 compact$4 pill	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2019/09/03 14:24

		lozenge dragee) near20 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near25 (mg milligram quantity weight wt "wt." amount))	EPO; JPO; DERWENT; IBM_TDB			
S278	733	S274 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/03 14:24

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	8,580,300	11-12-2013	Wilhelm, et al.	
	2.	9,867,780	01-16-2016	Greinwald, et al.	
	3.	10,176,301	01-08-2019	Hill, et al.	
	4.	2016/0078186	03-17-2016	Hill, et al.	
	5.	2017/0183719	06-29-2017	Rothenberg, 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]
	6.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		

Examiner Signature		Date Considered	

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	7.	LI, Xiaowei, et al., "Advances in Injectable Thermosensitive Polymers". Polymer Bulletin, No. 3, pages 109-115, June 30, 2015 (with English Abstract), 7 pages.	
	8.	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	
	9.	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	
	10.	[Author Unknown] Jorveza® summary of product characteristics (downloaded from the European Medicines Agency at www.ema.europa.eu/en/medicines/human/EPAR/jorveza#product-informationsection); accessed 8/1/2019, 9 pages.	
	11.	[Author Unknown] Jorveza® package leaflet (downloaded from the European Medicines Agency at www.ema.europa.eu/en/medicines/human/EPAR/jorveza#product-informationsection); accessed 8/1/2019, 8 pages.	
	12.	[Author Unknown] Povidone (polyvinylpyrrolidone (PVP)) compound summary (downloaded from Wikipedia at https://en.wikipedia.org/wiki/Polyvinylpyrrolidone); accessed 7/31/2019, 5 pages.	
	13.	[Author Unknown] Definition of slow-release (downloaded from Merriam-Webster online at https://www.merriam-webster.com/medical/slow-release); accessed 7/31/2019, 1 page.	
	14.	[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.	
	15.	[Author Unknown] Solubility of budesonide (downloaded from https://pubchem.ncbi.nlm.nih.gov/compound/Budesonide#section=Solubility&fullscreen=true); accessed 8/1/2019, 1 page.	
	16.	BONNET, et al., "Formulation of a 3-months Stability Oral Viscous Budesonide Gel and Development of an Indicating Stability HPLC Method", Pharm Technol Hosp Pharm (2018); 3(2): 91-99.	
	17.	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.	

Examiner Signature		Date Considered	

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Docket No.: ADAR-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	Examiner:	SASAN, Aradhana

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 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;

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

[X] 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 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.

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).

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. ADAR-119/05US 325049-2804.

Dated: August 7, 2019

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 91543

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

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Fax: (202) 842-7899

Electronic Acknowledgement Receipt

EFS ID:	36810284
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	07-AUG-2019
Filing Date:	17-NOV-2017
Time Stamp:	15:07:44
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	WO2018035393A1.pdf	17095440 a043730f95736469c55e5517ae11c41aeed48d78	no	192

Warnings:

Information:					
2	Non Patent Literature	LI_Polymer_Bulletin_2015_withEnglishAbstract_7_pgs.pdf	1168104 75bfc0677a59131ea83681277a8df3908c8cb8b3	no	7
Warnings:					
Information:					
3	Non Patent Literature	PCTUS2019019040_Inv-to-pay-add-fees.pdf	140451 fdb1ff72664d52a9b82261e1249f97abf3ee6e5b	no	2
Warnings:					
Information:					
4	Non Patent Literature	PCTUS2019019040_ISR-and-WO.pdf	710244 6bc931ce5f8c84471c67d736e6cb014453785628	no	12
Warnings:					
Information:					
5	Non Patent Literature	Author-Unknown_Jorveza_summary_product_characteristics_8-1-2019_9_pgs.pdf	195487 b59172fc7c547e53c5fc79e7f9f7822433f48da1	no	9
Warnings:					
Information:					
6	Non Patent Literature	Author-Unknown_Jorveza_package_label_8-1-2019_8_pgs.pdf	208453 a540d1490b5d403aaad86c80b6e746cb71b30bbf	no	8
Warnings:					
Information:					
7	Non Patent Literature	Author-Unknown_Povidone_Wikipedia_7-31-2019_5_pgs.pdf	240389 05cdbd5ed146e04f228b85f8cd8a664d4c4a44da	no	5
Warnings:					
Information:					
8	Non Patent Literature	Author-Unknown_slow_release_Merriam-Webster_7-31-2019_1_pg.pdf	143629 945e81e23453f934ee436486dd6e8d6ab2f5e9d9	no	1
Warnings:					
Information:					

9	Non Patent Literature	Author-Unknown_sustained-release_Merriam-Webster_7-31-2019_1_pg.pdf	134450 94c62a0cbc035ba8b43377df69c8dba59203e542	no	1
Warnings:					
Information:					
10	Non Patent Literature	Author-Unknown_solubility_of_budesonide_pubchem_8-1-2019_1_pg.pdf	53919 5bff44c83916f35fb021e6c698a3bba80468c9a4	no	1
Warnings:					
Information:					
11	Non Patent Literature	BONNET-Pharm_Technol_Hosp_Pharm_2018.pdf	799186 e402c73068f5d8f4575e49837520c94d82c0564d	no	9
Warnings:					
Information:					
12	Non Patent Literature	MIEHLKE-Gut_2016.pdf	869357 f52f6f3fd3ce4686426e0f1404c9d6f6c94bb2c2	no	10
Warnings:					
Information:					
13	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119_05US_SB08.pdf	127614 93047bff3b3a7ae7d812136245776b9c83d07e8e	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
14	Transmittal Letter	ADAR-119_05US_IDS.pdf	87229 c43f7d69ec2fa3b7e8dea9d1f04bda632cec10a5	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	21973952		

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

From the INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
C/O COOLEY LLP
1299 PENNSYLVANIA AVENUE, NW
SUITE 700
WASHINGTON, DC 20004-2400

PCT

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

(PCT Article 17(3)(a) and Rules 40.1 and 40.2(e))

	Date of mailing *(day/month/year)* 25 APR 2019
Applicant's or agent's file reference ADAR16201WO	**PAYMENT DUE** within **ONE MONTH** from the above date of mailing
International application No. PCT/US 19/19040	International filing date *(day/month/year)* 21 February 2019 (21.02.2019)
Applicant ADARE PHARMACEUTICALS, INC.	

1. This International Searching Authority

(i) considers that there are 2 *(number of)* inventions claimed in the international application covered by the claims indicated below/on an extra sheet:
-----see extra sheet-----

(ii) therefore considers that **the international application does not comply with the requirement of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated below/on an extra sheet:
-----see extra sheet-----

(iii) ☐ has carried out a partial international search (see Annex) ☒ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
1-8, 26-28, 34-36, 91

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, additional fees in the amount indicated below:

$2080	x 1	= $2080 (See Item 2 of annex)
Fee per additional invention	number of additional inventions	total amount of additional fees/currency

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fees may be made under protest**, that is, a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fees is excessive, where applicable, subject to the payment of a protest fee.

Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of _____ *(amount/currency)*

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. ☒ Claim(s) Nos. 9-25, 29-33, 37-57, 92A have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

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 W. Young PCT Helpdesk: 571-272-4300

Form PCT/ISA/206 (April 2005)

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

International application No.
PCT/US 19/19040

Item 2 (continued). For International Applications filed on or after 01 January 2014, Applicant is reminded that the search fee per additional invention indicated in item 2 is the undiscounted fee per additional invention. An Applicant may pay the search fee per additional invention fee reduced by 50% (small entity assertion) or 75% (micro entity certification), as appropriate. See 37 CFR 1.27 and 1.29.

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
(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.

Item 4 (continued):
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).

Form PCT/ISA/206 (extra sheet) (April 2005)

From the INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
C/O COOLEY LLP
1299 PENNSYLVANIA AVENUE, NW
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)* 25 JUN 2019
Applicant's or agent's file reference ADAR16201WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 19/19040	International filing date *(day/month/year)* 21 February 2019 (21.02.2019)
Applicant ADARE PHARMACEUTICALS, INC.	

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 of WIPO preferably through ePCT or on paper to, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *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 W. Young Telephone No. PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2014)

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ADAR16201WO	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 19/19040	International filing date *(day/month/year)* 21 February 2019 (21.02.2019)	(Earliest) Priority Date *(day/month/year)* 21 February 2018 (21.02.2018)
Applicant ADARE PHARMACEUTICALS, INC.		

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 4 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. _____

☐ 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) (January 2015)

International application No.
PCT/US 19/19040

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.: 9-25, 29-33, 37-57, 92A
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:

- see extra sheet for Box No. III Observations where unity of invention is lacking -

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.:
1-8, 26-28, 34-36, 91

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.

International application No.
PCT/US 19/19040

A. CLASSIFICATION OF SUBJECT MATTER
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

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 -- Y	US 2016/0078186 A1 (MERITAGE PHARMA INC.) 17 March 2016 (17.03.2016) title, abstract, para [0006], [0087], [0101], [0171], [0174], [0176], [0181], [0189], [0192], [0194], [0197], Fig. 21, 24, Table 8-9	1-6, 26-28, 34-36, 91 ---- 7-8
Y	US 2017/0183719 A1 (CHILDREN'S HOSPITAL MEDICAL CENTER) 29 June 2017 (20.06.2017) para [0125]	7-8

☐ 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
"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
03 June 2019	25 JUN 2019

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

International application No.
PCT/US 19/19040

Continuation of:
Box No. III. Observations where unity of invention is lacking

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
(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.

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 ADAR16201WO	**FOR FURTHER ACTION** 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.

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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	2003/0050312	03-13-2003	Hjorth, et al.	
	2.	2007/0111978	05-17-2007	Dohil, et al.	
	3.	2019/0008760	01-10-2019	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]
	4.	EP 1323417 A1	07-02-2003	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
	5.	EP 2211896 B1	01-03-2018	MERITAGE PHARMA, 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.

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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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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	6.	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.	
	7.	Copy of certified copy of Priority Document US 61/186,777 filed June 12, 2009, 104 pages.	
	8.	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, 10 pages.	✓
	9.	International Preliminary Report on Patentability for International Application No. PCT/US2017/047474, dated February 19, 2019, 8 pages.	
	10.	KHAN and ORENSTEIN, "Eosinophilic Gastroenteritis: Epidemiology, Diagnosis and Management." Paediatr Drugs. (2002); 4(9): 563-570.	
	11.	Opposition to European Patent No. 2482822, filed by Dr. Falk Pharma GmbH on March 1, 2019, Notice of Opposition and Statement of Grounds of Opposition dated March 1, 2019, 13 pages.	
	12.	Opposition to European Patent No. 2482822, filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding notice of opposition, 1 page.	

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.

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

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

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☒ Other Petition for Three-Month Extension of Time + fee

MISCELLANEOUS

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

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 501283

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

X Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

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

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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.

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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 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

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

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

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

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

AMENDMENT TO THE CLAIMS:

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

1.-43. (Cancelled)

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

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

45-47. (Cancelled)

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

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

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

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

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

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

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

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

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

57. (New) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of budesonide or fluticasone propionate.

58. (New) The orally dispersing tablet of claim 44, comprising 1 mg of budesonide.

59. (New) The orally dispersing tablet of claim 44, comprising from about 1 mg to about 3 mg of fluticasone propionate.

60. (New) The orally dispersing tablet of claim 51, comprising 1 mg of budesonide.

61. (New) The orally dispersing tablet of claim 52, comprising 1 mg of budesonide.

62. (New) The orally dispersing tablet of claim 53, comprising 1 mg of budesonide.

63. (New) The orally dispersing tablet of claim 54, comprising 1 mg of budesonide.

64. (New) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof an orally dispersing tablet according to claim 44.

65. (New) The method of claim 65, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus.

66. (New) The method of claim 65, wherein said inflammatory condition of the gastrointestinal tract is eosinophilic esophagitis.

REMARKS

I. Status of Claims

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

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

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

II. Claim Objections

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

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

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

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

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

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

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

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

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

Applicant respectfully requests withdrawal of the present rejection.

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

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

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

[1] Arkley, 455 F.2d at 588.

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

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

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

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

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

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[2] Because claims directed to a lyophilized composition were deleted, *Rawas-Qalaji* will not be addressed in the present response.
[3] Applicant's specification, page 4, lines 9-21
[4] U.S. Pub. 2007/0111978, paragraph [0007].
[5] *See also* U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; U.S. Pub. 2009/0131386; U.S. Pub. 2007/0111978; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225.
[6] U.S. Pub. 2009/0131386, paragraph [0060]
[7] NFOA, page 4.
[8] FOA, page 7.

clinical data showing that such dosage forms actually deposit a "therapeutically effective amount" of corticosteroid on the upper GI tract, as required by the present claims. Rather, *Dohil* is directed to liquid dosage forms containing, for example, surfactants[9] that promote efficient dispersion of a corticosteroid in a liquid composition, buffering agents[10] that maintain the pH of a liquid composition, and viscosity enhancing agents[11] that provide a liquid composition with a high viscosity.[12] In fact, out of the 177 paragraphs in *Dohil*, only 10 paragraphs mention a solid dosage form. The other 167 paragraphs are directed primarily to liquid dosage forms and the viscosity of such dosage forms. Importantly, *Dohil* teaches that the liquid dosage form exemplified in Examples 1 and 2 administers "an effective dose to reduce the inflammation of the esophagus."[13]

1. No Motivation to Select a Solid Dosage Form

As discussed above, at the time of the present invention, liquid dosage forms[14] were the standard of care[15] because such dosage forms were well-known to deliver "an effective dose to reduce the inflammation of the esophagus."[16] There is no teaching or suggestion in *Dohil* that liquid dosage forms were ineffective, and no problems identified in *Dohil* that solid dosage forms could address but liquid dosage forms could not. Indeed, the evidence of record establishes the opposite – that liquid dosage forms were efficacious.[17] As such, the skilled artisan would have no motivation to modify the standard of care and select a solid dosage form from *Dohil*.

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

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[9] *Dohil*, paragraph [0087]
[10] *Dohil*, paragraph [0081]
[11] *See*, *Dohil*, paragraph [0021]
[12] *See*, *Dohil*, paragraphs [0073] and [0097]-[0101]
[13] *Dohil*, paragraph [0034]
[14] *See Dohil,* Examples 1-5
[15] *See also* U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017)
[16] *Dohil*, paragraph [0034]
[17] See, e.g., Dohil, Examples 1-5.
[18] *Dohil*, Examples 1-5

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

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

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

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

[19] See paragraph [0057] "In specific embodiments, a volume sufficient to coat the esophagus is a volume that provides a bolus when orally administered to an individual.
[20] See, e.g., Applicant's specification, paragraph [00105]; Teitelbaum, et al. Gastroenterology, 2002; 122:1216-1225, disclosed in the IDS submitted on December 20, 2017
[21] *Dohil*, paragraph [0034]

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

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

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

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

V. Double Patenting Rejections

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted,
COOLEY LLP

Dated: June 10, 2019

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

Electronic Patent Application Fee Transmittal

Application Number:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Carolina Pimentel
Attorney Docket Number:	ADAR-119/05US 325049-2804

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($)
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1300	1300
		Total in USD ($)		**2700**

Electronic Acknowledgement Receipt

EFS ID:	36247689
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	10-JUN-2019
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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	ADAR-119_05US_IDS.pdf	87535 2e8fea9e63999f66d08051f353eb7ac91d09fb27	no	4
Warnings:					
Information:					
2	Foreign Reference	EP1323417A1.pdf	3302234 cce787f2ff000a25bd9b62b1658011fd0f656283	no	26
Warnings:					
Information:					
3	Foreign Reference	EP2211896B1.pdf	15824949 9d1e3fe82a1576896d8f8e53e493fc832116f627	no	41
Warnings:					
Information:					
4	Non Patent Literature	BUCKTON_Int_J_Pharmaceutics_1999.pdf	112829 cfb75ef4b574d143557ecec3de9e006c9ab37057	no	7
Warnings:					
Information:					
5	Non Patent Literature	Copy_of_Certified_copy_of_priority_doc_US61186777_104_pgs.pdf	7271836 b07b014f4a7b10ec6eec9ffb3e400dc18ee87caf	no	104
Warnings:					
Information:					
6	Non Patent Literature	German_Cancellation_action_DE202010018594_Mar_1_2019_andEnglishtranslation_21_pgs.pdf	1238419 d35ce4de8c3824a07d6a7f57f7e73464538cabd0	no	21
Warnings:					
Information:					

7	Non Patent Literature	IPRP_PCTUS2017047474.pdf	419489 74acca91c38c206c33dbc5af20f3a234125acc95	no	8
Warnings:					
Information:					
8	Non Patent Literature	KHAN-and-ORENSTEIN_Pediatr_Drugs_2002.pdf	144854 d498dac5d69e96075cfd17da938144374f468767	no	8
Warnings:					
Information:					
9	Non Patent Literature	Oppn_2482822_Notice-of-Oppn_and_Statement-of-Grounds_dtd_Mar_1_2019_13_pgs.pdf	13457721 12725c0f3a9e2eae79fbe888580b9798a02531dd	no	13
Warnings:					
Information:					
10	Non Patent Literature	Oppn_2482822_EPO_Comm_Mar_8_2019_advising_of_Oppn_1_pg.pdf	908699 2dd2f348866d8aa02ba9ae3d2ec8493c82eef0ca	no	1
Warnings:					
Information:					
11	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119_05US_SB08.pdf	127689 5544763f004c4c85e7b1a4ef193097278485dd96	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
12	Request for Continued Examination (RCE)	ADAR-119-05US_Request_for_Continued_Examination.pdf	1350048 57221bbf3db87da5ce06bfc47cb181a5f5b30d84	no	3
Warnings:					
Information:					
13		ADAR-119-05US_Response_to_FOA.pdf	212837 9319d6f7e3a895d9ede806d0e790516b2390d147	yes	10
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	

	Response After Final Action		1	1	
	Claims		2	3	
	Applicant Arguments/Remarks Made in an Amendment		4	10	
Warnings:					
Information:					
14	Fee Worksheet (SB06)	fee-info.pdf	32396 a4fb5334ef2f5d869efb810c829148f20af0045f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	44491535		

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-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	Examiner:	SASAN, Aradhana

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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 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;

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

[X] 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 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.

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).

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. ADAR-119/05US 325049-2804.

Dated: June 10, 2019

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 91543

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

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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 ADAR-15003WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2017/047474	International filing date *(day/month/year)* 18 August 2017 (18.08.2017)	Priority date *(day/month/year)* 18 August 2016 (18.08.2016)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ADARE PHARMACEUTICALS, INC.		

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 19 February 2019 (19.02.2019)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Athina Nickitas-Etienne e-mail: pct.team4@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
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)* 26 DEC 2017

Applicant's or agent's file reference
ADAR-15003WO

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 17/47474	18 August 2017 (18.08.2017)	18 August 2016 (18.08.2016)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61K 31/56; A61K 9/20 (2017.01)
CPC - A61K 31/56; A61K 9/20; A61K 9/2054

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	28 November 2017	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 17/47474

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 17/47474

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. 43

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. see below are so unclear that no meaningful opinion could be formed *(specify)*:

Claim 43 is unsearchable because it is a dependent claim and is 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. 43

☐ 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) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 17/47474

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.

Group I: Claims 1-21 and 40-42 directed to a method of treating eosinophilic esophagitis (EoE) in a patient in need thereof, comprising administering an oral corticosteroid in an induction phase and a maintenance phase, wherein the induction phase results in an improvement in Peak eosinophilic counts in at least one esophageal biopsy and the treating results in no worsening of patient mean weekly scores in a patient-reported outcome assessment which includes the assessment of dysphagia-free days.

Group II: Claims 22-39 directed to a method of treating EoE in a patient in need thereof, comprising administrating an oral corticosteroid in an induction phase and a maintenance phase, wherein the induction phase does not result in a substantial improvement in Peak eosinophilic counts in at least one esophageal biopsy, and treatment is continued resulting in an improvement in Peak eosinophilic counts in at least one esophageal biopsy, and the treatment results in no-worsening of patient mean weekly scores in a patient-reported outcome assessment which includes the assessment of dysphagia-free days.

Group III: Claims 44-68, directed to a method of topically treating eosinophilic esophagitis (EoE) in patient in need thereof with an oral corticosteroid, comprising: administering the oral corticosteroid while the patient is lying down or immediately prior to the patient lying down, wherein a therapeutically effective amount of the oral corticosteroid contacts the esophagus, thereby topically treating EoE.

The group of inventions listed above 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 technical feature of a method of treating EoE wherein the induction phase results in an improvement in Peak eosinophilic counts in at least one esophageal biopsy, not required by Groups II-III.

Group II includes the technical feature of a method of treating EoE, wherein the induction phase does not result in a substantial improvement in Peak eosinophilic counts in at least one esophageal biopsy, not required by Groups I and III.

Group III includes the technical feature of a method of topically treating eosinophilic esophagitis (EoE) in patient in need thereof with an oral corticosteroid, not required by Groups I and II.

---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. 1-21 and 40-42

Form PCT/ISA/237 (Box No. IV) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 17/47474

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	9-10, 13, 16	YES
	Claims	1-8, 11-12, 14-15, 17-21, 40-42	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-21, 40-42	NO
Industrial applicability (IA)	Claims	1-21, 40-42	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-8, 11-12, 14-15, 17-21 and 40-42 lack novelty under PCT Article 33(2) as being anticipated by US 2012/0164080 A1 to Hill et al. (hereinafter 'Hill').

Regarding claim 1, Hill teaches a method of treating eosinophilic esophagitis (EoE) in a patient in need thereof comprising administering an oral corticosteroid (para [0063]-[0065]) in an induction phase and a maintenance phase (para [0065]-[0067], induction dose; maintenance dose), wherein the induction phase results in an improvement in Peak eosinophilic counts in at least one esophageal biopsy (para [0064], biopsy score; para [0067]-[0068], decreasing the dose if the clinical score during treatment is lower than the total clinical score prior to treatment (e.g., with a maintenance dose); para [0069], scoring of an induction dose therapy is monitored using a biopsy) and the treating results in no worsening of patient mean weekly scores in a patient-reported outcome assessment which includes the assessment of dysphagia-free days (para [0031]-[0035], clinical symptom score; determining if the individual exhibits a symptom in any one or more of the following conditions category or categories: 1) heartburn; 2) abdominal pain; 3) nocturnal awakening with symptoms; 4) nausea, regurgitation or vomiting; 5) anorexia or early satiety; or 6) dysphagia; para [0040]-[0041], reduction of score).

Regarding claim 2, Hill teaches the method of claim 1, wherein the induction phase comprises administration for at least about 6 weeks (para [0071], administered an induction dose (e.g. for a period of time, such as three months).

Regarding claim 3, Hill teaches the method of claim 1, wherein the induction phase comprises administration for at least about 8 weeks (para [0071], administered an induction dose (e.g. for a period of time, such as three months).

Regarding claim 4, Hill teaches the method of claim 1, wherein the induction phase comprises administration for at least about 10 weeks (para [0071], administered an induction dose (e.g. for a period of time, such as three months).

Regarding claim 5, Hill teaches the method of claim 1, wherein the induction phase comprises administration for at least about 12 weeks (para [0071], administered an induction dose (e.g. for a period of time, such as three months).

Regarding claim 6, Hill teaches the method of any one of claims 2 to 5, wherein the administration is at least twice daily (para [0128]-[0129]).

Regarding claim 7, Hill teaches the method of claim 1, wherein the corticosteroid is in an orally dissolving dosage form (para [0077]-[0078], orally dissolving tablet or lozenge).

Regarding claim 8, Hill teaches the method of claim 7, wherein the corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, cidesonide, mometasone, beclomethasone, tixocortol and salts, esters, and mixtures thereof (para [0072]).

Regarding claim 11, Hill teaches the method of claim 1, wherein the patient does not relapse with active symptoms of EoE (para [0071], [0189], demonstrated significant histological response and remission).

Regarding claim 12, Hill teaches the method of claim 1, wherein the induction phase results in a histological response in which Peak eosinophil counts per HPF are reduced to 6 or less (para [0143], [0173]-[0175], Table 4A, Peak Eos <= 6/HPF).

Regarding claim 14, Hill teaches the method of claim 1, wherein the maintenance dose is less than the induction dose (para [0063]-[0067], decreasing the dose if the clinical score during treatment is lower than the total clinical score prior to treatment (e.g., with a maintenance dose)).

Regarding claim 15, Hill teaches the method of claim 1, wherein the maintenance dose is higher than the induction dose (para [0063]-[0066], [0069], increasing the dose if the clinical score during treatment is equal to or higher than the clinical score prior to treatment).

----------Continued in Supplemental Box-----

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 17/47474

Supplemental Box

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

Regarding claim 17, Hill teaches the method of claim 7, wherein the oral dissolving dosage form is a tablet or wafer (para [0078]).

Regarding claim 18, Hill teaches the method of claim 1, wherein the induction and maintenance doses are between about 1.5 mg and about 3 mg (para [0156], first daily amount is about 3-4 mg; para [0161], second daily amount s about 1-2 mg).

Regarding claim 19, Hill teaches the method of claim 18, wherein the dose is administered twice daily (para [0128]-[0129]).

Regarding claim 20, Hill teaches the method of claim 17, wherein the corticosteroid is deposited topically in the upper gastrointestinal tract (para [0070], orally administering; para [0072], topically active corticosteroid).

Regarding claim 21, Hill teaches the method of claim 1, wherein the patient exhibits substantial improvement in esophageal function and morphology (para [0189], significant histological response and remission; para [0190]-[0192]), including lessening of esophageal furrows, lessening of esophageal focal narrowing, increased esophageal diameter, increased esophageal compliance, increased esophageal body distensibility, increased ease swallowing, reduced edema, improved vascularity, reduction of rings, decrease or absence of exudate, and/or absence of stricture (para [0195]-[0197], Endoscopic findings with respect to ...2) furrowing with thickened mucosa,... 4) concentric rings or strictures; para [0199]-[0200], clinical symptom score; Fig 1; Fig 2; Fig 7; Fig 10).

Regarding claim 40, Hill teaches the method of claim 1, wherein the oral corticosteroid is administered before breakfast (para [0130], fasted state) and/or at bedtime (para [0130], about 30 minutes prior to bed).

Regarding claim 41, Hill teaches the method of claim 1, wherein the treatment results in no significant systemic glucocorticoid or mineralocorticoid effect (para [0131], to reduce side effects; para [0142], the individual's morning cortisol levels during administration of the corticosteroid are in a normal range; Fig 4).

Regarding claim 42, Hill teaches the method of claim 1, wherein Peak eosinophil counts are measured by esophageal biopsy during the maintenance phase (para [0147], an endoscopy with esophageal biopsies is performed during treatment; Fig 10, pre and post-treatment Esophageal Biopsy results).

Claims 9-10, 13 and 16 lack an inventive step under PCT Article 33(3) as being obvious over Hill.

Regarding claims 9-10, Hill teaches the method of claim 1, as above, but does not specifically teach wherein the patient has previously been administered PPI therapy, wherein the PPI therapy was not effective to substantially improve one or more symptoms of EoE. However, Hill does teach use of a proton pump inhibitor as an additional active agent that provides an additive effect to the corticosteroid therapy toward treating EoE (para [0103]). Based on such teachings in Hill, it would have been obvious to one of ordinary skill in the art to administer the method of Hill to a patient who has previously been administered PPI therapy, wherein the PPI therapy was not effective to substantially improve one or more symptoms of EoE, through routine experimentation, in order to provide substantial improvement of one or more symptoms of EoE in said subject.

Regarding claim 13, Hill teaches the method of claim 1, as above, but does not expressly teach wherein the induction phase results in no episode of food impaction. However, Hill teaches reduced food impaction upon administration of the method of treatment (para [0056]). Hill further teaches determining clinical score during induction phase of the treatment (para [0065]-[0069]) and a reduction of up to 100% reduction in clinical symptom score (para [0182], Fig 7) which includes determining if the subject exhibits symptoms such as food impaction (para [0178]-[0179]). Based on such teachings in Hill, it would have been obvious to one of ordinary skill in the art to administer an effective induction dose of oral corticosteroid to a subject suffering from EoE, in order to prevent episodes of food impaction in said subject.

Regarding claim 16, Hill teaches the method of claim 1, as above, but does not expressly teach wherein the treatment results in no worsening of patient mean weekly scores according to an EEsAI assessment. However, Hill does teach determining clinical symptom scores based on an assessment similar to EEsA1 [See para [0123] of the Applicant's specification for details about EEsAI], which includes monitoring the severity and frequency of dysphagia (para [0178]-[0182]) to assess a patient's response to treatment with oral corticosteroid (para [0017], Fig 7). Based on such teachings in Hill, it would have been obvious to one of ordinary skill in the art to substitute EEsAI to determine the patient's response to treatment with an oral corticosteroid, through routine experimentation, in order to provide a standardized assessment of treatment outcome.

Claims 1-21 and 40-42 have industrial applicability as defined by PCT Article 33(4), because the subject matter can be made or used in industry.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 17/47474

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box No. IV: Lack of Unity

Common technical features:

Groups I-III share the technical feature of a method of treating EoE comprising administering an oral corticosteroid.
This shared technical feature, however, is not a contribution over the prior art as being anticipated by US 2016/0206627 A1 to published on 21 July 2016 to Adare Pharmaceuticals, Inc. (hereinafter 'Adare Pharmaceuticals') which discloses a method of treating EoE in a subject in need thereof, comprising administering an oral corticosteroid to said subject (para [0009], [0013]).

Groups I and II further share the technical feature of administering an oral corticosteroid in an induction phase and a maintenance phase, and monitoring Peak eosinophilic counts in at least one esophageal biopsy and mean weekly scores in a patient-reported outcome assessment which includes the assessment of dysphagia-free days. These shared technical features, however, do not provide a contribution over the prior art as being obvious over Adare Pharmaceuticals in view of the article entitled, 'The natural history of steroid-naive eosinophilic esophagitis in adults treated with endoscopic dilation and proton pump inhibitor therapy over a mean duration of nearly 14 years utility of the method toward producing different types of quinoline-based multi-aromatic ring systems', by Lipka et al. published in GASTROINTESTINAL ENDOSCOPY, 2014, Vol.80, No.4, pp. 592-598 (hereinafter 'Lipka').
Adare Pharmaceuticals teaches a method of treating EoE comprising administering an oral corticosteroid (para [0102], [0104], ODT-FT) and monitoring Peak eosinophilic counts in at least one esophageal biopsy (para [0105], response seen histologically in the decrease of peak eosinophil count), wherein the treating results in no worsening of patient mean weekly scores in a patient-reported outcome assessment (para [0104]-[0106], at least 30% decrease in overall EoE symptom severity, as measured by patient questionaire).
Adare Pharmaceuticals does not expressly teach the assessment of dysphagia-free days, but does teach dysphagia as a symptom of EoE (para [0003]), and further teaches at least 30% decrease in EoE symptom severity in patients, upon administration of the oral corticosteroid (para [0105]). Adare Pharmaceuticals does not specifically teach administering an oral corticosteroid in an induction phase and a maintenance phase. However, Lipka teaches a method of treating EoE comprising administering a therapy in an induction phase and in a maintenance phase, wherein the treatment resulted in dysphagia-free days (pg 594, col 2, para 3 to pg 595, col 1, para 1, Dysphagia resolved in all patients). It would have been obvious to one of ordinary skill in the art to combine the teachings of Lipka with those of Adare Pharmaceuticals to design a protocol for administration of the oral corticosteroid, in order to maximize therapeutic benefit to the treated subject, because both Adare Pharmaceuticals and Lipka teach methods for treating EoE.

As said methods were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the inventions of Groups I-III. Groups I-III thus lack unity under PCT Article 13.

Note reg item 4: Claim 43 is unsearchable because it is a dependent claim and is not drafted in accordance with the second and third sentences of Rule 6.4(a).

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/816,154	Filing Date 11/17/2017	☐ 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 $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ 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	06/10/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	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".	/DEIDRE C KING-WOODWARD/
*** 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.**

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

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/10/2018	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

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

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 09/28/18.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 28-47 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) 28-47 is/are rejected.

8) ☑ Claim(s) 28-43 and 45-47 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED CORRESPONDENCE

Notice of Pre-AIA or AIA status

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

Status of Application

2. The Amendments and Remarks filed on 09/28/18 are acknowledged.

3. Claims 1-26 were previously cancelled. Claim 27 was cancelled; claims 28, 30, 32-34, 36 and 38-40 were amended; and new claims 41-47 were added on 09/28/18.

4. Claims 28-47 are pending and are included in the prosecution.

Information Disclosure Statement

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

Response to Amendments/Arguments

Claim Objections

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

7. In light of the amendment of claim 38, the objection to this claim is withdrawn.

Rejection of claims under 35 USC § 103(a)

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

i. Rejection of claims 27-32 and 36-40 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2009/0131386 A1)

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

iii. Rejection of claims 27-32 and 34-40 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Phillips in view of Rawas-Qalaji et al. (US 2007/0059361 A1)

9. Applicant's arguments were persuasive. Therefore, the rejections have been withdrawn.

10. Applicant cancelled claim 27 and added new independent claim 44. New claim 44 does not recite the limitation regarding the disintegration of the tablet which is faster than the rate of oral disintegration of a conventional solid oral dosage form; but does recite fluticasone and the limitation regarding a "therapeutically effective amount" of the corticosteroid is deposited in the upper gastrointestinal tract.

11. However, upon further consideration of new claim 44, a new ground(s) of rejection is made in view of Dohil et al. (US 2009/0191275 A1).

12. Since the new ground(s) of rejection were necessitated by Applicant's amendment, this action is made FINAL.

New Objections & Rejections Necessitated by Amendment

Claim Objections

13. Claims **28-43** and **45-47** are objected to for the following reasons.

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

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

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

i. In claim **34**, line 1, the term "**claim**" should be added before "44."

ii. In claims **45** and **46**, the article "**the**" should be added after the term "wherein" and before the term "excipient."

iii. In claim **47**, the term "**is**" should be added after the term "excipient."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

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

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

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

i. Claim **45** recites the limitation "... wherein excipient is mannitol."

ii. Claim **46** recites the limitation "... wherein excipient is sucralose."

iii. Claim **47** recites the limitation "... wherein the excipient magnesium stearate ..."

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

Claim Rejections - 35 USC § 102

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

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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

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

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

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

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

Claim Rejections - 35 USC § 103

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

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

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

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

The teaching of Dohil et al. is discussed above.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The teaching of Dohil et al. is discussed above.

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

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

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

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

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

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

Maintained Rejections

Double Patenting

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response to Arguments

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

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

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

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

Conclusion

28. No claims are allowed.

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

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

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

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

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

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

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 15/816,154	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-20090191275-A1	07-2009	Dohil; Ranjan	A61K9/0095	424/490
*	B	US-10105315-B2	10-2018	Meltzer; Brian A.	A61K9/006	1/1
	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
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	06/24/2018	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**
(A61K31/569 same A61K2300/00).cpcc. with keyword	06/24/2018	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 prosecution history of related cases 12896005,14311732,15205390,15680301,14294660, and 14917125. EAST search - including CPC with keyword, inventor, assignee and applicant name search. NPL search - including Google Patents and SciFinder. Please see attached history for each search.	06/24/2018	AS
Updated EAST and STIC/NPL search. Please see attached history for each search.	12/04/2018	AS

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

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

PTO/SB/08b (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 1

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	European Application No. EP 18178891.0, Extended European Search Report dated August 13, 2018, 3 pages.	
	2.	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.	✓

Examiner Signature	/ARADHANA SASAN/	Date Considered	12/03/2018

*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.

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
S236	783	hydroxylpropylcellulose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/10/09 12:38
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S240	2	("9387167" "9849084").pn.	USPAT	OR	ON	2018/12/03 14:47
S241	1	("8407766").pn.	USPAT	OR	ON	2018/12/04 08:53
S242	13474	hill.in.	USPAT	OR	ON	2018/12/04 08:55
S243	8	S242 and inflammatory.ti.	USPAT	OR	ON	2018/12/04 08:55
S244	1	("20090191275").PN.	US-PGPUB; USPAT	OR	ON	2018/12/04 09:01
S245	1	S244 and (oral$2 mouth buccal$2 lingual$2)	US-PGPUB; USPAT	OR	ON	2018/12/04 09:02
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Full search history

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L59       109656 SEA SPE=ON  ABB=ON  PLU=ON  "POLY(VINYLPYRROLIDONE)"+NT,PFT,LT,
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                E GASTROINTESTINAL INFLAMMATION+ALL/CT
                E GASTROENTERITIS/CT
L62         54525 SEA SPE=ON  ABB=ON  PLU=ON  GASTROENTERITIS+NT,PFT,LT,OLD/CT
                E ESOPHAGITIS/CT
L63          3350 SEA SPE=ON  ABB=ON  PLU=ON  ESOPHAGITIS+NT,PFT,LT,OLD/CT
                E EOSINOPHILIA/CT
L64          6519 SEA SPE=ON  ABB=ON  PLU=ON  EOSINOPHILIA+NT,PFT,LT,OLD/CT
L65            85 SEA SPE=ON  ABB=ON  PLU=ON  "EOSINOPHILIC ESOPHAGITIS"+NT,PFT,L
                  T,OLD/CT
                E ADHESIVES/CT
L66        275075 SEA SPE=ON  ABB=ON  PLU=ON  ADHESIVES+NT,PFT,LT,OLD/CT
                E DISINTEGRANTS/CT
L67          7429 SEA SPE=ON  ABB=ON  PLU=ON  DISINTEGRANTS+NT,PFT,LT,OLD/CT
                E EXCIPIENTS/CT
L68         27074 SEA SPE=ON  ABB=ON  PLU=ON  EXCIPIENTS+NT,PFT,LT,OLD/CT
                E PHARMACEUTICAL TABLETS/CT
L69        147325 SEA SPE=ON  ABB=ON  PLU=ON  "PHARMACEUTICAL TABLETS"+NT,PFT,LT,
                  OLD/CT
L70           256 SEA SPE=ON  ABB=ON  PLU=ON  ((L1 OR L2 OR L3) OR L6 OR L45 OR
                  BUDESONIDE OR PULMICORT)(L)((L7 OR L8 OR L9 OR L10 OR L11 OR
                  L12 OR L13 OR L14 OR L15 OR L16 OR L17 OR L18 OR L19 OR L20 OR
                  L21 OR L22 OR L23 OR L24 OR L25 OR L26 OR L27 OR L28 OR L29 OR
                  L30 OR L31 OR L32 OR L33 OR L34 OR L35 OR L36 OR L37 OR L38 OR
                  L39 OR L40 OR L41 OR L42 OR L43) OR (L46 OR L47 OR L48 OR L49
                  OR L50 OR L51 OR L52 OR L53 OR L54 OR L55 OR L56 OR L57 OR L58
                  OR L59 OR L60) OR ADHESIV? OR DISINTEGRANT? OR EXCIPIENT)
L71             2 SEA SPE=ON  ABB=ON  PLU=ON  ((L1 OR L2 OR L3) OR L6 OR L45 OR
                  BUDESONIDE OR PULMICORT) AND (L66 OR ADHESI?) AND (L67 OR
                  DISINTEGRA?) AND (L68 OR EXCIPIENT)
                D L71 1-2 AU
L72           207 SEA SPE=ON  ABB=ON  PLU=ON  ((L1 OR L2 OR L3) OR L6 OR L45 OR
                  BUDESONIDE OR PULMICORT)(L)((L66 OR L67 OR L68) OR ADHESI? OR
                  DISINTEGRA? OR EXCIPIENT)
L73           143 SEA SPE=ON  ABB=ON  PLU=ON  L70 AND (L71 OR L72)
L74           139 SEA SPE=ON  ABB=ON  PLU=ON  L70 (L)((L66 OR L67 OR L68) OR
                  ADHESI? OR DISINTEGRA? OR EXCIPIENT)
L75           139 SEA SPE=ON  ABB=ON  PLU=ON  L73 AND L74
L76             5 SEA SPE=ON  ABB=ON  PLU=ON  (L71 OR L75) AND (L61 OR LYOPHIL?
                  OR FREEZ?(2A)(DRY OR DRIED OR DRYER))
L77             2 SEA SPE=ON  ABB=ON  PLU=ON  L70 (L) (L61 OR LYOPHIL? OR
                  FREEZ?(2A)(DRY OR DRIED OR DRYER))
                D L77 1-2 AU
L78            13 SEA SPE=ON  ABB=ON  PLU=ON  L70 AND (L61 OR LYOPHIL? OR
                  FREEZ?(2A)(DRY OR DRIED OR DRYER))
L79            10 SEA SPE=ON  ABB=ON  PLU=ON  (L71 OR (L75 OR L76 OR L77 OR
                  L78)) AND ((L62 OR L63 OR L64 OR L65) OR GASTROENTERITIS OR
                  GASTROENTERI? OR GASTRITI? OR INFLAM?(3A)(GASTR? OR INTESTIN?
                  OR ESOPHAG? OR AESOPHAG?) OR AESOPHAGIT? OR ESOPHAGIT? OR
                  EOSINOPHIL? OR EOSINOPHILIC ESOPHAGITIS)
L80             2 SEA SPE=ON  ABB=ON  PLU=ON  (L71 OR (L76 OR L77 OR L78)) AND
                  L79
```

```
L81          23 SEA SPE=ON  ABB=ON  PLU=ON  L71 OR (L76 OR L77 OR L78 OR L79
                OR L80)
L82          11 SEA SPE=ON  ABB=ON  PLU=ON  L81 AND PATENT/DT
L83          12 SEA SPE=ON  ABB=ON  PLU=ON  L81 NOT L82
L84           6 SEA SPE=ON  ABB=ON  PLU=ON  L82 AND (AD<20091002 OR PD<20091002
                 OR PRD<20091002)
L85           6 SEA SPE=ON  ABB=ON  PLU=ON  L83 AND (AY<2010 OR PY<2010 OR
                PRY<2010 OR REVIEW/DT)
L86          12 SEA SPE=ON  ABB=ON  PLU=ON  (L84 OR L85)
                D L86 1-12 AU
L87         274 SEA SPE=ON  ABB=ON  PLU=ON  VENKATESH G?/AU
L88          89 SEA SPE=ON  ABB=ON  PLU=ON  PERRETT S?/AU
L89         676 SEA SPE=ON  ABB=ON  PLU=ON  COHEN F?/AU
L90           1 SEA SPE=ON  ABB=ON  PLU=ON  L87 AND L88 AND L89
L91           3 SEA SPE=ON  ABB=ON  PLU=ON  (L87 OR L88 OR L89 OR L90) AND
                ((L1 OR L2 OR L3) OR L6 OR L45 OR BUDESONIDE OR PULMICORT)
L92           5 SEA SPE=ON  ABB=ON  PLU=ON  (L87 OR L88 OR L89 OR L90) AND
                ((L62 OR L63 OR L64 OR L65) OR GASTROENTERITIS OR GASTROENTERI?
                 OR GASTRITI? OR INFLAM?(3A)(GASTR? OR INTESTIN? OR ESOPHAG?
                OR AESOPHAG?) OR AESOPHAGIT? OR ESOPHAGIT? OR EOSINOPHIL? OR
                EOSINOPHILIC ESOPHAGITIS)
L93         100 SEA SPE=ON  ABB=ON  PLU=ON  (L87 OR L88 OR L89 OR L90) AND
                ((L7 OR L8 OR L9 OR L10 OR L11 OR L12 OR L13 OR L14 OR L15 OR
                L16 OR L17 OR L18 OR L19 OR L20 OR L21 OR L22 OR L23 OR L24 OR
                L25 OR L26 OR L27 OR L28 OR L29 OR L30 OR L31 OR L32 OR L33 OR
                L34 OR L35 OR L36 OR L37 OR L38 OR L39 OR L40 OR L41 OR L42 OR
                L43) OR (L46 OR L47 OR L48 OR L49 OR L50 OR L51 OR L52 OR L53
                OR L54 OR L55 OR L56 OR L57 OR L58 OR L59 OR L60) OR ADHESIV?
                OR DISINTEGRANT? OR EXCIPIENT)
L94          65 SEA SPE=ON  ABB=ON  PLU=ON  (L90 OR L91 OR L92 OR L93) AND
                (L69 OR TABLET OR PILL OR CAPSUL? OR LOZENG? OR DRAGEE OR
                TROCHE)
L95          39 SEA SPE=ON  ABB=ON  PLU=ON  (L90 OR L91 OR L92 OR L93) AND
                (L69 OR TABLET OR PILL OR CAPSUL? OR LOZENG? OR DRAGEE OR
                TROCHE)(L)((L66 OR L67 OR L68) OR ADHESI? OR DISINTEGRA? OR
                EXCIPIENT)
L96          25 SEA SPE=ON  ABB=ON  PLU=ON  (L90 OR L91 OR L92 OR L93) AND
                (L69 OR TABLET OR PILL OR CAPSUL? OR LOZENG? OR DRAGEE OR
                TROCHE)(L)(THU OR DGN OR DMA OR PAC OR PKT OR MOA)/RL
L97          25 SEA SPE=ON  ABB=ON  PLU=ON  (L94 OR L95) AND L96
L98           4 SEA SPE=ON  ABB=ON  PLU=ON  (L90 OR L91 OR L92) AND (L93 OR
                L94 OR L95 OR L96 OR L97)
L99          28 SEA SPE=ON  ABB=ON  PLU=ON  (L90 OR L91 OR L92) OR (L96 OR L97
                OR L98)

     FILE 'MEDLINE, BIOSIS, EMBASE, DRUGU, WPIX' ENTERED AT 10:59:50 ON 12 JUN
     2018
L100          5 SEA SPE=ON  ABB=ON  PLU=ON  L90
L101          3 SEA SPE=ON  ABB=ON  PLU=ON  (L87 OR L88 OR L89 OR L90) AND (L1
                OR BUDESONIDE OR PULMICORT)
L102         19 SEA SPE=ON  ABB=ON  PLU=ON  (L87 OR L88 OR L89 OR L90) AND
                (GASTROENTERITIS OR GASTROENTERI? OR GASTRITI? OR INFLAM?(3N)(G
                ASTR? OR INTESTIN? OR ESOPHAG? OR AESOPHAG?) OR AESOPHAGIT? OR
                ESOPHAGIT? OR EOSINOPHIL? OR EOSINOPHILIC ESOPHAGITIS)
L103          4 SEA SPE=ON  ABB=ON  PLU=ON  (L100 OR L101 OR L102) AND (TABLET
                OR PILL OR CAPSUL? OR LOZENG? OR DRAGEE OR TROCHE)
L104          1 SEA SPE=ON  ABB=ON  PLU=ON  (L100 OR L101 OR L102 OR L103) AND
```

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                (LYOPHIL? OR FREEZ?(2N)(DRY OR DRIED OR DRYER))
L105          4 SEA SPE=ON  ABB=ON  PLU=ON  (L100 OR L101 OR L102 OR L103 OR
                L104) AND (ADHESIV? OR DISINTEGRANT? OR EXCIPIENT)
L106         19 SEA SPE=ON  ABB=ON  PLU=ON  (L100 OR L101 OR L102 OR L103 OR
                L104 OR L105)
L107       2952 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR BUDESONIDE OR PULMICORT)(L)(
                GASTROENTERITIS OR GASTROENTERI? OR GASTRITI? OR INFLAM?(3N)(GA
                STR? OR INTESTIN? OR ESOPHAG? OR AESOPHAG?) OR AESOPHAGIT? OR
                ESOPHAGIT? OR EOSINOPHIL? OR EOSINOPHILIC ESOPHAGITIS)
L108        623 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR BUDESONIDE OR PULMICORT)(L)(
                ADHESIV? OR DISINTEGRANT? OR EXCIPIENT)
L109        103 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR BUDESONIDE OR PULMICORT)
                (L) (LYOPHIL? OR FREEZ?(2N)(DRY OR DRIED OR DRYER))
L110          2 SEA SPE=ON  ABB=ON  PLU=ON  L107 AND L108 AND L109
L111         70 SEA SPE=ON  ABB=ON  PLU=ON  L107 AND (L108 OR L109)
L112         70 SEA SPE=ON  ABB=ON  PLU=ON  L107 (L) (L108 OR L109)
L*** DEL      0 S L110-L112 AND (L11 OR L15 OR L18 OR L21 OR L24 OR L27 OR L30
L113         47 SEA SPE=ON  ABB=ON  PLU=ON  (L110 OR L111 OR L112) AND
                (AY<2010 OR PY<2010 OR PRY<2010 OR REVIEW/DT)
               D STAT QUERY L86
               D QUE L113

     FILE 'HCAPLUS, MEDLINE, BIOSIS, EMBASE, DRUGU, WPIX' ENTERED AT 11:09:04
     ON 12 JUN 2018
L114         53 DUP REM L86 L113 (6 DUPLICATES REMOVED)
                    ANSWERS '1-12' FROM FILE HCAPLUS
                    ANSWER '13' FROM FILE MEDLINE
                    ANSWERS '14-16' FROM FILE DRUGU
                    ANSWERS '17-53' FROM FILE WPIX
               D L114 1-12 IBIB ED ABS HITRN
               D L114 13 IBIB ED ABS HIT
               D L114 14-16 IBIB ABS HIT
               D L114 17-53 IBIB ED ABS HIT
               D QUE L99
               D QUE L106
L115         41 DUP REM L99 L106 (6 DUPLICATES REMOVED)
                    ANSWERS '1-28' FROM FILE HCAPLUS
                    ANSWERS '29-30' FROM FILE MEDLINE
                    ANSWERS '31-36' FROM FILE BIOSIS
                    ANSWERS '37-39' FROM FILE EMBASE
                    ANSWER '40' FROM FILE DRUGU
                    ANSWER '41' FROM FILE WPIX
               D L115 1-41 IBIB ED ABS HITRN


     FILE HOME

     FILE REGISTRY
     Property values tagged with IC are from the ZIC/VINITI data file
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     STRUCTURE FILE UPDATES:   11 JUN 2018  HIGHEST RN 2226750-60-1
     DICTIONARY FILE UPDATES:  11 JUN 2018  HIGHEST RN 2226750-60-1

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/816,154	Filing Date 11/17/2017	☐ 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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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

AMENDMENT 09/28/2018	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 19	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

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ 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.
** 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 number found in the appropriate box in column 1.

SLIE
DEIDRE C. KING-WOODWARD

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

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

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

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

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

Electronic Acknowledgement Receipt

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

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_05US_Response.pdf	229339 041586df42db60bdc4795af0e66f1323fe937c24	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	5	10
	Claims	2	4
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	229339	

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

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.

REMARKS

I. Status of Claims

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

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

II. Claim Objections

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

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

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

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

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

[1] NFOA, page 2, paragraph 6.i.
[2] NFOA, page 2, paragraph 6.ii.

topical corticosteroid (budesonide or fluticasone, or salts, solvates, or esters thereof), which topically deposits a "therapeutically effective amount" of the corticosteroid on the upper gastrointestinal (GI) tract after administration to topically treat inflammation. Because fluticasone and budesonide (and salts, solvates and esters thereof) act topically (i.e., they do not act systemically), these corticosteroids must be delivered topically to the tissue of the upper GI tract to treat inflammation.[3] Prior to Applicant's invention, liquid dosage forms, such as those disclosed in *Phillips* and in the evidence of record[4], were the standard of care to treat inflammation of the upper GI tract, because such liquid dosage forms allowed the corticosteroid to "reach the targeted and/or inflamed portion of the gastrointestinal tract …"[5].

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

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

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

While *Phillips* does mention solid dosage forms, *Phillips* is directed primarily to liquid dosage forms containing, for example, preservatives,[9] isotonic agents,[10] surfactants[11] that promote efficient dispersion of a corticosteroid in a liquid composition,[12] and viscosity

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[3] Applicant's specification, page 4, lines 9-21
[4] *See also* U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017).
[5] *Phillips*, paragraph [0060]
[6] NFOA, page 3.
[7] NFOA, page 4.
[8] NFOA, page 4.
[9] *Phillips* at, e.g., paragraphs [0009], [0031], [0035], and [0075]
[10] *Phillips* at, e.g., paragraphs [0007], [0010], [0015], [0031] and [0034]
[11] *Phillips* at, e.g., paragraph [0010], [0031], [0033], and [0073]
[12] *Phillips* at, e.g., paragraph [0031]

enhancing agents[13] that provide a liquid composition with a high viscosity.[14] To this end, *Phillips* teaches that a liquid dosage form allows for the corticosteroid to "reach the targeted and/or inflamed portion of the gastrointestinal tract …",[15] and the viscosity of the liquid dosage form is critical to achieving the necessary contact ("increased viscosity of the composition allows the composition to be in contact with the esophagus for an extended period of time following administration."[16]). Indeed, out of the 122 paragraphs in *Phillips*, only 6 paragraphs mention a solid dosage form. The other 118 paragraphs are directed solely to liquid dosage forms. This is because, at the time of the present invention, liquids dosage forms were the standard of care for the treatment of inflammation of the upper GI tract.

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

1. No Motivation to Select a Solid Dosage Form

As discussed above, at the time of the present invention, liquid dosage forms[18] effectively treated inflammation of upper GI tract – and this was the standard of care. There is no teaching or suggestion in *Phillips* that liquid dosage forms were ineffective, or that that there were particular problems that solid dosage forms could address but liquid dosage forms cannot. As such, the skilled artisan would have no motivation to modify the standard of care and select a solid dosage form from *Phillips*.

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[13] *See*, *Phillips*, paragraph [0029]
[14] *See*, *Phillips*, paragraph [0043]
[15] *Phillips*, paragraph [0060]
[16] *Phillips*, paragraph [0021]; see also paragraphs [0029] and [0039], and paragraphs [0040]-[0044]
[17] *Phillips* at paragraph [0085]
[18] *Phillips*, paragraph [0060]; *See also* U.S. Pub. 2009/0149433; U.S. Pub. 2009/0123550; Kumari and Rajendran, Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008); and Teitelbaum, et al. Gastroenterology (2002), 122(5): 1216-1225, which were cited in the IDS filed on December 20, 2017)

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

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

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

However, Applicant surprisingly and unexpectedly discovered that an ODT can

[19] *Phillips*, paragraph [0060]
[20] *Phillips*, paragraph [0021]; see also paragraphs [0029] and [0039], and paragraphs [0040]-[0044] teaches

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

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

The Examiner cites to *Venkatesh* as allegedly teaching an ODT that is free of lubricant as recited in claim 33.[21] This rejection is respectfully traversed.

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

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

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

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

IV. Double Patenting Rejections

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

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

[21] NFOA, page 8.
[22] NFOA, page 10.
[23] *Rawas-Qalaji*, Abstract (emphasis added).

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

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

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

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

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

CONCLUSION

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

Dated: September 28, 2018

Respectfully submitted,
COOLEY LLP

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Washington, DC 20004
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By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

AMENDMENT TO THE CLAIMS:

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

1.-26. (Cancelled)

27. (Cancelled)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 1 of 1

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	European Application No. EP 18178891.0, Extended European Search Report dated August 13, 2018, 3 pages.	
	2.	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.	✓

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:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin/Corrine Cunningham
Attorney Docket Number:	ADAR-119/05US 325049-2804

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt

EFS ID:	33864325
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin
Filer Authorized By:	
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	28-SEP-2018
Filing Date:	17-NOV-2017
Time Stamp:	15:53:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$240
RAM confirmation Number	100118INTEFSW00006418501283
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	ADAR-119_05US_IDSTransmittal.pdf	118068 a8e392e36c06e79204ad54e41ec8a76314c6921f	no	5
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119_05US_SB08.pdf	151931 86c9aa4c2f7d0f0dc4e7082e624f2c83b563631d	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	EP18178891_EESR.pdf	112352 6b5302c4b6ff64fa406f6edb6edbc7f5f40172b4	no	4
Warnings:					
Information:					
4	Non Patent Literature	Novopulmon_E_Novolizer_Dec_23_2011_9_pages.pdf	525863 a108c932195ca8605e3aafe973f3cf9def8a85fa	no	9
Warnings:					
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5	Fee Worksheet (SB06)	fee-info.pdf	30553 f7f2786b9b9ec0c73ecc6ab198bdae60b58687ca	no	2
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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.: ADAR-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1615
Filed:	November 17, 2017	Examiner:	SASAN, Aradhana

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 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 $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 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.

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:

- U.S. Patent No. 8,771,729 issued July 8, 2014;
- U.S. Patent No. 9,486,407 issued November 8, 2016;
- U.S. Patent No. 9,387,167 issued July 12, 2016;
- U.S. Patent No. 9,849,084, issued December 26, 2017;
- U.S. Patent Appln. No. 15/680,301 (pending); and
- U.S. Patent Appln. No. 14/917,125 (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 28, 2018

Respectfully submitted,
COOLEY LLP

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

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www.uspto.gov

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

91543 7590 06/28/2018

Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DISTRICT OF COLUMBIA 20004
UNITED STATES OF AMERICA

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/28/2018	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

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

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 02/23/18.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 27-40 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 27-40 is/are rejected.

8) ☑ Claim(s) 27 and 38 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED CORRESPONDENCE

Notice of Pre-AIA status

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

Status of Application

2. The amendment filed on 02/23/18 is acknowledged.

3. Claims 1-26 were cancelled.

4. New claims 27-40 were added and are included in the prosecution.

Information Disclosure Statement

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

Claim Objections

6. Claims **27** and **38** are objected to because of the following informalities:

   i. In claim **27**, line 5, the period following "Disintegration Test" should be replaced by a comma.

   ii. In claim **38**, the comma at the end of the sentence should be replaced with a period.

   Appropriate correction is required.

Claim Rejections - 35 USC § 103

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The teaching of Phillips is discussed above.

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

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

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

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

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

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

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

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

The teaching of Phillips is discussed above.

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

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

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

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

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

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

Double Patenting

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

15. No claims are allowed.

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

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

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

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 15/816,154	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-20180133145-A1	05-2018	MELTZER; Brian A.	A61K9/006	1/1
	B					
	C					
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	F					
	G					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*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
	15/816,154	Perrett et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	Date	Examiner
(A61K9/0065 or A61K47/38 or A61K9/08 or A61K31/58 or A61K9/0053 or A61K31/56 or A61K45/06 or A61K31/569 or A61K9/006 or A61K9/0056 or A61K9/06).cpc. with keyword	06/24/2018	AS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
(A61K31/569 same A61K2300/00).cpcc. with keyword	06/24/2018	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 prosecution history of related cases 12896005,14311732,15205390,15680301,14294660, and 14917125. EAST search - including CPC with keyword, inventor, assignee and applicant name search. NPL search - including Google Patents and SciFinder. Please see attached history for each search.	06/24/2018	AS

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

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Patents (budesonide) (tablet) (disintegrating) (topical) (adhesive) before:priorit Sign in

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Conjugates of dithiocarbamates with pharmacologically active agents and uses ...

Grant US5916918A · Ching-San Lai · Medinox, Inc.
Priority 1997-06-04 · Filing 1997-06-04 · Grant 1999-06-29 · Publication 1999-06-29
In accordance with the present invention, there are provided conjugates of nitric oxide scavengers (e.g., dithiocarbamates, or "DC") and pharmacologically active agents (e.g., NSAIDs). invention conjugates provide a new class of pharmacologically active agents (e.g., anti-inflammatory agents) ...

Solid carriers for improved delivery of hydrophobic active ingredients in ...

Grant US6569845B2 · Mahesh V. Patel · Lipocine, Inc.
Priority 1999-11-23 · Filing 2001-03-06 · Grant 2003-05-27 · Publication 2003-05-27
The present invention provides solid pharmaceutical compositions for improved delivery of a wide variety of pharmaceutical active ingredients contained therein or separately administered. In one embodiment, the solid pharmaceutical composition includes a solid carrier, the solid carrier including ...

Gastrointestinal drug delivery system

Grant US5840332A · E. Itzhak Lerner · Perio Products Ltd.
Priority 1996-01-18 · Filing 1996-01-18 · Grant 1998-11-24 · Publication 1998-11-24
A gastrointestinal delivery system is provided. The system comprises a drug in combination with a core material, the core being surrounded by a water-insoluble or relatively water-insoluble coating material in which particulate water-insoluble material is embedded. When the delivery device enters ...

Antimicrobial compositions containing colloids of oligodynamic metals

Grant US7179846B2 · Richard N. Terry · C. R. Bard, Inc.
Priority 1999-12-15 · Filing 2003-08-26 · Grant 2007-02-20 · Publication 2007-02-20
The present invention relates to antimicrobial compositions, methods for the production of these compositions, and use of these compositions with medical devices, such as catheters, and implants. The compositions of the present invention advantageously provide varying release kinetics for the ...

Pharmaceutical oral patch for controlled release of pharmaceutical agents in ...

Grant US6197333B1 · E. Itzhak Lerner · Perio Products Ltd.
Priority 1997-07-24 · Filing 1997-07-24 · Grant 2001-03-06 · Publication 2001-03-06
The invention is directed to a controlled-release solid composition for the oral cavity or "pharmaceutical oral patch" that adheres to hard dental surfaces, such as teeth and dentures, and releases an active pharmaceutical agent into the oral cavity. Release of the agent is for a predetermined ...

Pharmaceutical multiple unit particulate formulation in the form of coated ...

Grant US5958468A · Tomas Norling · Dumex-Alpharma A/S
Priority 1994-06-15 · Filing 1995-08-01 · Grant 1999-09-28 · Publication 1999-09-28
A pharmaceutical multiple unit particulate formulation in the form of coated cores which includes a pharmaceutically acceptable carrier selected from calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, kaolin, sodium hydrogen carbonate, sodium sulfate, barium ...

Methods for preparing coated drug particles and pharmaceutical formulations ...

Grant US6984404B1 · James D. Talton · University Of Florida Research Foundation, Inc.
Priority 1998-11-18 · Filing 1999-11-18 · Grant 2006-01-10 · Publication 2006-01-10
Disclosed are methods using pulsed laser ablation to prepare coated drug particles of uniform size and thickness. The coated drug particles ranged in size from several nanometers to several millimeters in diameter size, and were coated with organic polymer particle having average diameter sizes ...

Particle size analysis in pharmaceutics: principles, methods and applications

Google Scholar · www.researchgate.net · Shekunov B · Pharmaceutical research
Publication 2007
... efficiency of nanosuspensions. For example, nanosuspensions of budesonide (mean size 500 nm) showed a significant increase in FPF by 53--66% compared to microsuspensions (mean size 4 μm) (21). Nanoparticles of poorly ...

Drug nanocrystals of poorly soluble drugs produced by high pressure homogenisation

Google Scholar · www.sciencedirect.com · Keck C · European Journal of Pharmaceutics and Biopharmaceutics
Publication 2006
Skip to main content ...

Polymers for mucoadhesive drug delivery system: a current status

Google Scholar · www.tandfonline.com · Asane G · Drug development and industrial pharmacy
Publication 2008
Page 1. Drug Development and Industrial Pharmacy, 34:1246--1266, 2008 Copyright © Informa UK, Ltd. ISSN: 0363-9045 print / 1520-5762 online DOI: 10.1080/03639040802026012 1246 LDDI Polymers for Mucoadhesive Drug Delivery System: A Current Status ...

Pharmaceutical approaches to colon targeted drug delivery systems

Google Scholar • sites.ualberta.ca • Chourasia M • J Pharm Pharm Sci

Publication 2003

... Two prodrugs, dexamethasone-β-D-glucuronide (DXgird) and **Budes**- onide-β-D-glucuronide (BUDgird) were administered by intragastric infusion to conventional and colitic rats. In addition, dexamethasone and **Budesonide** were adminis- tered either intragastrically or ...

Drug delivery technologies and future directions

Google Scholar • alfresco.ubm-us.net • Verma R • Pharmaceutical Technology

Publication 2001

Page 1. Pharmaceutical Technology FEBRUARY 2001 1 he number of products based on new drug delivery systems has sig- nificantly increased in the past few years, and this growth is expected to continue in the near future ...

Colonic drug targeting

Google Scholar • www.tandfonline.com • Kinget R • Journal of drug targeting

Publication 1998

... Tozer, 1992). This ap- proach has been further extended with the devel- opment of glycoside prodrugs of **budesonide** and menthol (Friend, 1995), and with dexamethasone- poly(L-aspartate) (Leopold and Friend, 1994). A class ...

Approaches and opportunities in colon-specific drug delivery

Google Scholar • www.dl.begellhouse.com • Rubinstein A • Critical Reviews™ in Therapeutic Drug Carrier Systems

Publication 1995

... transit of the **tablets** through the ileo-cecal function was unaffected by **tablet** size ... Profound delay was observed only for 13 mm **tablets** discharged from the fed stomach."3'5l ... are beclomethasone dipropionate (used in local delivery in asthma management),77 **budesonide**•78 and ...

Methods for coating particles and particles produced thereby



Grant US6406745B1 • James D. Talton • Nanosphere, Inc.

Priority 1999-06-07 • Filing 2000-06-06 • Grant 2002-06-18 • Publication 2002-06-18

Methods of coating core materials by providing target materials and core materials; ablating the target materials to form ablated particulate target materials; and coating the core materials with said ablated particulate target materials; wherein the method is performed at a pressure of about 10 ...

Composition and pharmaceutical dosage form for colonic drug delivery using ...



Grant US6413494B1 • Seung Seo Lee • Samyang Corporation

Priority 1998-07-23 • Filing 1999-05-25 • Grant 2002-07-02 • Publication 2002-07-02

A colonic drug delivery composition contains a first polysaccharide and a second polysaccharide wherein both polysaccharide are degradable by colonic enzymes and are mixed at a environmental pH of about 7 or above, without use of a cross-linking agent. A colon selective pharmaceutical composition ...

Electroprocessed material made by simultaneously electroprocessing a natural ...



Grant US7374774B2 • Gary L. Bowlin • Virginia Commonwealth University Intellectual Property Foundation

Priority 1999-08-31 • Filing 2003-09-22 • Grant 2008-05-20 • Publication 2008-05-20

The invention is directed to novel compositions comprising an electroprocessed material and a substance, their formation and use. The electroprocessed material can, for example, be one or more natural materials, one or more synthetic materials, or a combination thereof. The substance can be one or ...

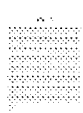
Novel oral colon-specific drug delivery systems for pharmacotherapy of peptide and nonpeptide drugs

Google Scholar • journals.prous.com • Reddy S • Drugs Today

Publication 1999

... model of ulcerative colitis and Crohn's colitis (131), and the efficacy of **budesonide**-b-D ... Either matrix **tablets** (212) or compression-coated **tablets** comprised of natural pectin (164, 211 ... when applied as compression-coated, was capable of protecting a core **tablet** during conditions ...

Combination therapy using a TNF binding protein for treating TNF-mediated ...



Grant US6309820B1 • Alison M. Bendele • Amgen Inc.

Priority 1996-12-06 • Filing 1999-06-04 • Grant 2001-10-23 • Publication 2001-10-23

The invention relates to methods for treating or preventing acute and/or septic shock. The method comprises administering to patients in need thereof therapeutically effective amounts of a TNF binding protein and a Fas antigen. In a preferred embodiment, the TNF binding protein is sTNFR-I or sTNFR ...

Compounds for enzyme inhibition



Grant US7417042B2 • Mark S. Smyth • Proteolix, Inc.

Priority 2004-08-06 • Filing 2005-08-08 • Grant 2008-08-26 • Publication 2008-08-26

Peptide-based compounds including heteroatom-containing, three-membered rings efficiently and selectively inhibit specific activities of N-terminal nucleophile (Ntn) hydrolases. The activities of those Ntn having multiple activities can be differentially inhibited by the compounds described. For ...

Method and composition for repairing and promoting regeneration of mucosal ...

Grant US6838071B2 • Rongxiang Xu • Rongxiang Xu

Priority 2001-06-28 • Filing 2001-10-30 • Grant 2004-02-03 • Publication 2004-02-03



The present invention provides novel compositions and methods for protecting and promoting cell growth and restoring physiological structure and function to mucosal tissue of the body, especially mucosa in the gastrointestinal tract. The composition can be used as a pharmaceutical or nutraceutical ...

Composition for enzyme inhibition



Grant US7737112B2 • Evan R. Lewis • Onyx Therapeutics, Inc.
Priority 2004-12-07 • Filing 2005-12-07 • Grant 2010-06-15 • Publication 2010-06-15
Compositions comprising one or more practically insoluble proteasome inhibitors and a cyclodextrin, particularly a substituted cyclodextrin, substantially increase the solubility of these proteasome inhibitors and facilitate their administration. Such compositions optionally comprise a buffer.

Fast-dispersing dosage forms containing fish gelatin



Grant US6709682B1 • Owen Murray • R. P. Scherer Technologies, Inc.
Priority 1999-04-06 • Filing 2000-04-07 • Grant 2004-03-23 • Publication 2004-03-23
The invention disclosed herein relates to a pharmaceutical composition comprising a carrier and an active ingredient, wherein the carrier is fish gelatin and the composition is a fast-dispersing dosage form designed to release the active ingredient rapidly on contact with a fluid. In one ...

Compounds for enzyme inhibition



Grant US7687466B2 • Han-Jie Zhou • Proteolix, Inc.
Priority 2005-11-09 • Filing 2006-11-09 • Grant 2010-03-30 • Publication 2010-03-30
Peptide-based compounds including heteroatom-containing, three-membered rings efficiently and selectively inhibit specific activities of N-terminal nucleophile (Ntn) hydrolases associated with the proteasome. The peptide-based compounds include an epoxide or aziridine, and functionalization at the ...

Solution polymerization processes to prepare a polymer that degrades to release ...



Grant US7662864B2 • Sussela Kanamathareddy • Rutgers, The State University Of New Jersey
Priority 2003-06-04 • Filing 2004-06-04 • Grant 2010-02-16 • Publication 2010-02-16
Anhydride polymers that release active or activatable agent(s) have pre-selected properties such as molecular weight, flexibility, hardness, adhesiveness, and other valuable properties. The polymers are suitable for use in compositions, formulations, coatings, devices, and the like that benefit ...

Compounds which modulate the CB2 receptor



Grant US7598397B2 • Renee Zindell • Boehringer Ingelheim International GmbH
Priority 2005-12-15 • Filing 2006-12-08 • Grant 2009-09-29 • Publication 2009-09-29
Compounds are provided which bind to and are agonists, antagonists or inverse agonists of the CB2 receptor, the compounds having the general formula wherein, R 1 , R 2 , A, Y, X, Ar 1 and Ar 2 have the meanings given in the specification, and the preparation and use thereof. The compounds are valuable ...

Benzimidazole derivatives



Grant US7132438B2 • Alexander David Frenkel • Amgen Inc.
Priority 2001-10-09 • Filing 2002-10-09 • Grant 2006-11-07 • Publication 2006-11-07
Compounds, pharmaceutical compositions and methods are provided that are useful in the treatment of inflammatory and immune-related conditions or disorders. In particular, the invention provides compounds which modulate the expression and/or function of proteins involved in inflammation, immune ...

Compounds modulating c-kit and c-fms activity and uses therefor



Grant US7846941B2 • Chao Zhang • Plexxikon, Inc.
Priority 2005-05-17 • Filing 2006-05-16 • Grant 2010-12-07 • Publication 2010-12-07
Compounds active on the receptor protein tyrosine kinases c-kit and c-fms are provided herewith. Also provided herewith are compositions useful for treatment of c-kit mediated diseases or condition and c-fms-mediated diseases or condition, and methods for the use thereof.

Crystalline pharmaceutical and methods of preparation and use thereof



Grant US8080562B2 • John Sumler • Sarcode Bioscience Inc.
Priority 2006-04-15 • Filing 2009-04-15 • Grant 2011-12-20 • Publication 2011-12-20
Novel crystalline polymorphic forms, Forms A, B, C, D, and E of a compound of Formula I, which has been found to be a potent inhibitor of LFA-1, are disclosed. Methods of preparation and uses thereof in the treatment of LFA-1 mediated diseases are also disclosed in this invention.

1, 3-bis-(substituted-phenyl)-2-propen-1-ones and their use to treat VCAM-1 ...



Grant US6608101B1 • Liming Ni • Atherogenics, Inc.
Priority 2000-06-20 • Filing 2001-06-20 • Grant 2003-08-19 • Publication 2003-08-19
It has been discovered certain 1,3-bis-(substituted-phenyl)-2-propen-1-ones, including compounds of formula (I) inhibit the expression of VCAM-1, and thus can be used to treat a patient with a disorder mediated by VCAM-1. Examples of inflammatory disorders that are mediated by VCAM-1 include, but ...

Colonic delivery of drugs

Grant US5656286A • David R. Friend • Cibus Pharmaceutical, Inc.
Priority 1995-06-07 • Filing 1995-06-07 • Grant 1997-08-12 • Publication 1997-08-12



... are useful. For example, it may help improve flowability, **adhesion**, **disintegration**, stability, hardness and other characteristics that are desirable. ... suitable amount to a subject in need thereof. A particularly preferred aspect is the process for preparing such composition in the form of a **tablet**.

Method for treating a brain cancer with ifenprodil



Grant US8058243B2 • Mike Tyers • Hsc Research And Development Limited Partnership
Priority 2006-10-13 • Filing 2007-10-12 • Grant 2011-11-15 • Publication 2011-11-15
A clonogenic neurosphere assay is described that carries out high throughput screens (HTS) to identify potent and/or selective modulators of proliferation, differentiation and/or renewal of neural precursor cells, neural progenitor cells and/or self-renewing and multipotent neural stem cells (NSCs ...

Solid carriers for improved delivery of active ingredients in pharmaceutical ...



Application US20060034897A1 • Mahesh Patel • Mahesh Patel
Priority 1999-11-23 • Filing 2005-08-02 • Publication 2006-02-16
The present invention provides solid pharmaceutical compositions for improved delivery of a wide variety of pharmaceutical active ingredients contained therein or separately administered. In one embodiment, the solid pharmaceutical composition includes a solid carrier, the solid carrier including ...

Solid carriers for improved delivery of active ingredients in pharmaceutical ...



Application US20030180352A1 • Mahesh Patel • Patel Mahesh V.
Priority 1999-11-23 • Filing 2002-05-30 • Publication 2003-09-25
The present invention provides solid pharmaceutical compositions for improved delivery of a wide variety of active ingredients contained therein or separately administered. In one embodiment, the solid pharmaceutical composition includes a solid carrier, the solid carrier including a substrate and ...

Poly(amino acid) targeting moieties



Application US20090074828A1 • Frank Alexis • Massachusetts Institute Of Technology
Priority 2007-04-04 • Filing 2008-04-04 • Publication 2009-03-19
The present invention generally relates to polymers and macromolecules, in particular, to polymers useful in particles such as nanoparticles. One aspect of the invention is directed to a method of developing nanoparticles with desired properties. In one set of embodiments, the method includes ...

Pharmaceutical formulations and systems for improved absorption and multistage ...



Application US20030077297A1 • Feng-Jing Chen • Feng-Jing Chen
Priority 1999-02-26 • Filing 2002-02-11 • Publication 2003-04-24
The present invention pertains to pharmaceutical formulations and systems for delivery of active agents, wherein a first fraction of an active agent is suspended in a vehicle and a second fraction of active agent is solubilized in the vehicle, with the suspended fraction representing about 5 wt. % ...

Methods and products for enhancing immune responses using imidazoquinoline ...



Application US20030139364A1 • Arthur Krieg • University Of Iowa Research Foundation
Priority 2001-10-12 • Filing 2002-10-15 • Publication 2003-07-24
The invention involves administration of an imidazoquinoline agent in combination with another therapeutic agent. The combination of drugs may be administered in synergistic amounts or in various dosages or at various time schedules. The invention also relates to kits and compositions concerning ...

CpG-like nucleic acids and methods of use thereof



Application US20030181405A1 • Christian Schetter • Christian Schetter
Priority 2000-12-08 • Filing 2002-05-06 • Publication 2003-09-25
Immunostimulatory compositions described as CpG-like nucleic acids are provided, including nucleic acids having immunostimulatory characteristics of CpG nucleic acid, despite certain substitutions of C, G, or C and G of the CpG dinucleotide. The substitutions can include, among others, exchange of ...

Sterilized nanoparticulate glucocorticosteroid formulations



Application US20070178951A1 • John Pruitt • Elan Pharma International, Ltd.
Priority 2006-01-27 • Filing 2006-01-27 • Publication 2007-08-02
The invention is directed sterile to compositions of glucocorticosteroids useful in the prophylaxis and chronic treatment of asthma and other allergic and inflammatory conditions in adults and pediatric patients.

Methods and compositions related to the modulation of intercellular junctions



Application US20060067927A1 • Aarthi Chandrasekaran • Massachusetts Institute Of Technology
Priority 2004-06-29 • Filing 2005-06-29 • Publication 2006-03-30
The invention relates to compositions and methods for the modulation of the permeability of the epithelial cell barrier complex. In particular, the invention provides compositions and methods for using polysaccharides, preferably glycosaminoglycans, and agents that modify cell surface ...

Local Delivery of Drugs or Substances Using Electronic Permeability Increase

Application US20080188837A1 • Ziv Belsky • Ziv Belsky
Priority 2004-12-14 • Filing 2005-12-14 • Publication 2008-08-07



An apparatus is provided for use in conjunction with a drug delivered to a gastrointestinal (GI) tract of a subject. The apparatus includes an ingestible capsule, which includes one or more electrodes, and a control component, adapted to drive the electrodes to apply an electrical current that ...

Maximizing effectiveness of substances used to improve health and well being



Application US20040062802A1 · Victor Hermelin · Hermelin Victor M.
Priority 1998-04-02 · Filing 2003-09-29 · Publication 2004-04-01
The present disclosure relates to novel dosage forms, drug delivery regimens, methods and pharmaceutical compositions which optimize the therapeutic effects of active therapeutic substances through the application of the concept of uneven dosing.

Electroprocessing of materials useful in drug delivery and cell encapsulation



Application US20040018226A1 · Gary Wnek · Wnek Gary E.
Priority 1999-02-25 · Filing 2003-04-07 · Publication 2004-01-29
The invention is directed to novel compositions comprising an electroprocessed material and a substance, their formation and use. The electroprocessed material can, for example, be one or more natural materials, one or more synthetic materials, or a combination thereof. The substance can be one or ...

Compositions and methods for the inhibition of bone growth and resorption



Application US20050249697A1 · Kathryn Ulrich · Ulrich Kathryn E
Priority 2003-09-24 · Filing 2004-09-24 · Publication 2005-11-10
A composition, or article for inhibition of bone growth and resorption comprises an anti-inflammatory agent(s), optionally other agents and carriers, monomer(s), oligomer(s), polymer(s), salt(s), mixtures(s), dispersion(s) and/or blend(s) thereof, which composition, device, or implant upon polymer ...

Controlled-release emulsion compositions



Application US20070104778A1 · Hongxia Zeng · Hongxia Zeng
Priority 2005-11-07 · Filing 2006-11-07 · Publication 2007-05-10
The present invention is directed to controlled-release composition containing a solubilized material comprising an active agent and at least one oil-based surfactant capable of solubilizing the active agent, the solubilized material dispersed in a controlled-release particulate matrix.

Immunomodulatory combinations



Application US20050118325A1 · David Hammerbeck · 3M Innovative Properties Company
Priority 2003-12-30 · Filing 2004-12-30 · Publication 2005-07-21
The present invention provides immunomodulatory combinations that includes an IRM component and a therapeutic agent, each in an amount that, when in combination with the other, is effective for inducing an immune response in a subject.

Methods and related compositions for reduction of fat and skin tightening



Application US20060127468A1 · Michael Kolodney · Kolodney Michael S
Priority 2004-05-19 · Filing 2005-11-23 · Publication 2006-06-15
Compositions and methods useful in the reduction of localized fat deposits and tightening of loose skin in subjects in need thereof using pharmacologically active detergents are disclosed. The pharmacologically active detergent compositions can additionally include anti-inflammatory agents, ...

Nanoparticulate corticosteroid and antihistamine formulations



Application US20060216353A1 · Gary Liversidge · Elan Pharma International Limited
Priority 2005-03-23 · Filing 2006-03-23 · Publication 2006-09-28
Compositions comprising a nanoparticulate corticosteroid and an antihistamine are described. The compositions are useful in the prophylaxis and chronic treatment of asthma in adults and pediatric patients and for the relief of allergic conjunctivitis, symptoms of seasonal allergic rhinitis in ...

Medical devices employing novel polymers



Application US20060188546A1 · Karen Giroux · Polymerix Corporation
Priority 1997-09-10 · Filing 2003-11-18 · Publication 2006-08-24
Medical devices with at least one surface comprising a polymer or polymers on the surface are provided. The polymer or polymers are capable of breaking down (e.g., including, but not limited to, hydrolyzing) in the physiologic milieu to form an active agent or agents under physiologic conditions. ...

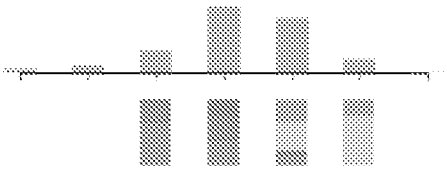
Multi-particulate, modified-release composition



Application US20060210631A1 · Ashish Patel · Patel Ashish A
Priority 2005-03-21 · Filing 2005-03-21 · Publication 2006-09-21
A multi-particulate, modified-release pharmaceutical composition for the oral administration of an active ingredient to the colon, wherein said particles comprise: (a) a core comprising an active ingredient or a pharmaceutically acceptable salt or ester thereof, and optionally one or more ...

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University Of Virginia Patent Foundation		1.6%

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Bibliographic Data

Application No: 15/816,154

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.
11/17/2017	424	1615	ADAR-119/05US 325049-2804
RULE			

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CONTINUING DATA

This application 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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
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Sheet 2 of 8

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	47.	2017/0071855	03-16-2017	Perrett et al.	

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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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	49.	CL 3827-2008 (corresponds to US 2009/0169620)	12-21-2007	EURAND, INC.		
	50.	DE 2323215 A1 (corresponds to US 3,929,768)	11-29-1973	AP Bofors		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	51.	DE 4129535 A1 (and English Abstract)	03-12-1992	Especialidades Latinas Medicamentos Universales S.A.		✓
	52.	EP 0057401 A1	08-11-1982	Schering Corporation		
	53.	EP 0440372 A1	08-07-1991	Pfizer Limited et al.		
	54.	EP 1595533 A1	11-16-2005	NIPPON SHINKAYU CO LTD.		
	55.	JP 2003-261439 A (English Abstract)	09-16-2003	ASAHI KASEI CORP		✓
	56.	JP 2006-516616 A (corresponds to WO 2004/067004 A1)	07-06-2006			
	57.	JP 2006-77018 A (and English Abstract)	03-26-2006	KYOWA HAKKO KOGYO CO. LTD.		✓
	58.	JP H11-511162 A (English Abstract)	09-28-1999			✓
	59.	JP 11-130679 A (and English Abstract)	05-18-1999	AVENTIS PHARMA DEUTSCHLAND GMBH		✓
	60.	JP 2001-524094 A (corresponds to WO 1998/047535 A1)	11-27-2001			
	61.	JP 2002-521321 A (corresponds to US 7,033,606)	07-16-2002			
	62.	JP 2003-292459 A (with English Abstract, and English translation)	10-15-2003	PHARMA POWER BIOTEC CO LTD		✓
	63.	JP 2003-509359 A (corresponds to WO 2001/019342 A2	03-11-2003	GLAXO GROUP LTD		
	64.	JP 2009-173552 A (English Abstract)	08-06-2009	LION CORP		✓
	65.	JP 2009-519793 (English Abstract)	05-21-2009			✓

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	66.	JP 2009-521523 A (English Abstract)	06-04-2009	JUBILANT ORGANOSYS LIMITED		✓
	67.	JP S56-138200 A (corresponds to US 4,335,121)	10-28-1981	GLAXO GROUP LTD		
	68.	KR 2006-0123160 A (English Abstract)	12-01-2006	ALZA CORP.		✓
	69.	WO 1997/006786 A1	02-27-1997	R.P. SCHERER LIMITED		
	70.	WO 1998/047535 A1	10-29-1998	WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED		
	71.	WO 2000/064450 A1	11-02-2000	LEO PHARM PROD LTD.		
	72.	WO 2003/093344 A1	11-13-2003	JANSSEN PHARMACEUTICAL N.V.		
	73.	WO 2001/019342 A2	03-22-2001	GLAXO GROUP LIMITED		
	74.	WO 2004/064810 A1 (with English Abstract)	08-05-2004	NIPPON SHINYAKU CO., LTD.		✓
	75.	WO 2004/067004 A1	08-12-2004	OREXO AB		
	76.	WO 2004/069225 A1	08-19-2004	ELAN PHARMA INTERNATIONAL LTD.		
	77.	WO 2002/092057 A1 (with English Abstract)	11-21-2002	YAMANOUCHI PHARMACEUTICAL CO., LTD.		✓
	78.	WO 2005/087194 A1	09-22-2005	SCHERING AKTIENGESELLSCHAFT		
	79.	WO 2007/071179 A1 (with English Abstract)	06-28-2007	QUANTUM HI-TECH (BEIJING) RESEARCH INSTITUTE		✓
	80.	WO 2007/074472 A2	07-05-2007	JUBILANT ORGANOSYS LIMITED		
	81.	WO 2008/098634 A1	08-21-2008	POLICHEM S.A.		
	82.	WO 2009/064457 A2	05-22-2009	MERITAGE PHARMA, INC.		
	83.	WO 2009/064458 A2	05-22-2009	MERITAGE PHARMA, INC.		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	84.	WO 2009/064819 A2	05-22-2009	MERITAGE PHARMA, INC.		
	85.	WO 2009/098595 A2	08-13-2009	FOAMIX LTD.		
	86.	WO 2010/144865 A2	12-16-2010	MERITAGE PHARMA, INC.		
	87.	WO 2011/041509 A1	04-07-2011	EURAND, INC.		
	88.	WO 2015/034678 A2	03-12-2015	APTALIS PHARMATECH, INC.		
	89.	WO 2015/035114 A1	03-12-2015	APTALIS PHARMATECH, INC.		
	90.	ZA 6805392 (corresponds to US 3,705,172)	06-04-1969	Farbenfabriken Bayer AG		

Examiner Signature		Date Considered	

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Sheet 6 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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	91.	AHMED and SHAH, "Formulation of low dose medicines—theory and practice." Am. Pharm. Rev (2000), 3(3): 9-14.	
	92.	DILGER, K., et al. "Active eosinophilic esophagitis is associated with impaired elimination of budesonide by cytochrome P450 3A enzymes." Digestion. 2013; 87(2):110-117. doi: 10.1159/000346403. Epub 2013 Jan 25.	
	93.	BOWER et al., "Manifestations and Treatment of Laryngeal Sarcoidosis". Am. Rev. Respir. Dis., 122(2): 325-332 (1980).	
	94.	CAMPIERIA et al., "Oral budesonide is as effective as oral prednisolone in active Crohn's disease," Gut, 41: 209-214 (1997).	
	95.	European Application No. EP 10821232.5, Extended European Search Report dated February 6, 2014, 10 pages.	
	96.	European Application No. EP 14184844.0, Extended European Search Report dated February 9, 2015, 7 pages.	
	97.	European Application No. EP 14842811.3, Extended European Search Report dated March 23, 2017, 6 pages.	
	98.	Eurasian Application No. 201491358, Search Report (with English translation), issued January 22, 2015, 4 pages.	✓
	99.	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.	✓
	100.	TAKAKU, Fumimaro, et al. Manual of Therapeutic Agents 2007, Published 2007, p. 617-619 (and English translation/summary of pertinent paragraphs), 5 pages.	✓
	101.	Georgia Application No. AP 2010012674, Search Report (with English translation) dated November 28, 2013, 11 pages.	✓
	102.	KUMARI and RAJENDRAN, "Effect of topical nasal steroid spray in the treatment of non-specific recurrent/chronic pharyngitis-a trial study." Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008).	
	103.	MAHMOUDI et al. "Effect of drug particle size on blend segregation and content uniformity". Contributed poster, AAPS Annual Meeting (USA) 2010, 1 page. (non-English)	

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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	104.	MAHMOUDI et al. "Influence of filler in blend uniformity of micronized drugs". Contributed poster, AAPS Annual Meeting (USA) 2010, 1 page.	
	105.	Malaysian Application No. PI 2012001434, Search Report dated January 29, 2016, 1 page.	
	106.	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).	
	107.	Merck Index, "Budesonide," 14th Edition, p. 240 (2006)	
	108.	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006)	
	109.	Merck Index, "Clotrimazole," 14th Edition, p. 407 (2006)	
	110.	Merck Index, "Mometasone Furoate," 14th Edition, pp. 1077-1078 (2006)	
	111.	Merck Index, "Voriconazole," 14th Edition, p. 1728 (2006)	
	112.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	
	113.	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	
	114.	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	
	115.	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	
	116.	PCT Application No. PCT/US2014/052073, Written Opinion of the International Searching Authority dated November 20, 2014.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 8

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Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
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	117.	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	
	118.	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	
	119.	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	
	120.	PCT Application No. PCT/US2014/054203, International Preliminary Report on Patentability dated March 8, 2016.	
	121.	Taiwanese Application No. TW 099133628, Search Report (English translation) dated November 16, 2014, 9 pages.	✓
	122.	Taiwanese Application No. TW 104107443, Search Report (English translation) dated May 29, 2015, 1 page.	✓
	123.	TEITELBAUM et al. "Eosinophilic esophagitis in children: immunopathological analysis and response to fluticasone propionate." Gastroenterology (2002), 122(5): 1216-1225.	
	124.	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	
	125.	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	
	126.	YALKOWSKY and BOLTON. "Particle size and content uniformity." Pharmaceutical Research, 7(9): 962-966 (1990).	

Examiner Signature	/ARADHANA SASAN/	Date Considered	06/23/2018

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Task History

Task Began June 24, 2018 09:50 AM

Explore references by research topic: orally dispersing tablet with budesonide

Research Topic:	orally dispersing tablet with budesonide
Result Count:	3

Candidates Selected (ID 1)

2 references were found containing the two concepts "orally dispersing tablet" and "budesonide".

Answer Type:	*References*
Result Count:	*2*

1. Oral disintegrating tablet and its preparation method and method for improving the hardness and disintegration of oral disintegrating tablets and application of salts in preparing oral disintegrating tablets with high hardness and rapid disintegration

By Ma, Jun; Liu, Xiaoyan; Tang, Zhenqin; Gao, Xueqin
From Faming Zhuanli Shenqing (2018), CN 108066305 A 20180525, Language: Chinese, Database: CAPLUS

The invention discloses an oral disintegrating tablet and its prepn. method and method for improving the hardness and disintegration of oral disintegrating tablets and application of salts in prepg. oral disintegrating tablets with high hardness and rapid disintegration, and the oral disintegrating tablet has good hardness and disintegration performance. The above oral disintegrating tablet includes a tablet matrix and a plurality of coated pellets dispersed in the tablet matrix, and the coated pellets include a pellet core contg. active ingredients and at least one layer of coating covering on the surface of the pellet core.

~0 Citings

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2. Taste-masked oral formulations of influenza antivirals

By Pilgaonkar, Pratibha Sudhir; Rustomjee, Maharukh Tehmasp; Gandhi, Anilkumar Surendrakumar
From PCT Int. Appl. (2010), WO 2010143207 A1 20101216, Language: English, Database: CAPLUS

The present invention relates to taste-masked oral formulations of influenza antivirals. The taste-masked pharmaceutical formulations for oral administration comprise one or more influenza antivirals, at least one taste-masking agent and at least one pharmaceutically acceptable excipient. Further, the taste-masked influenza antiviral formulations of the present invention are provided in the form of dispersible tablets, effervescent tablets, orally disintegrating tablets, chewable tablets, bite-dispersion tablets or the like, wherein the bitter taste of influenza antivirals is masked thereby providing palatable formulations. Thus, dispersible tablets of taste-masked oseltamivir phosphate comprised (in mg/unit): taste-masked oseltamivir phosphate granules 190.92 equiv to 45 mg oseltamivir base, microcryst. cellulose 100.08, hydroxyethyl cellulose 65, crospovidone 55, hydroxypropyl cellulose 18, mannitol 25, copovidone 14, aspartame 20, vanilla flavor 5, colloidal silicon dioxide 4, magnesium stearate 3.

~4 Citings

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Task History

Task Began June 24, 2018 09:50 AM

Explore references by research topic: tablet with budesonide

Research Topic:	tablet with budesonide
Result Count:	5

Candidates Selected (ID 2)

19 references were found containing "tablet with budesonide" as entered.
Automatically removed 1 duplicate MEDLINE answer(s)

Answer Type:	*References*
Result Count:	*18*

1. Formulation and evaluation of liquisolid tablet of budesonide

By Aher, S. S.; Pagar, P. R.; Saudagar, R. B.
From International Journal of Current Research (2016), 8(7), 35093-35102. Language: English, Database: CAPLUS

The limited soly. of drugs is a challenging issue for industry, during the development of the solid dosage form. Liquisolid technique is a novel and promising approach to overcome this problem. This technique is an efficient method for formulating water insol. and poorly water sol. drugs. The liquisolid technique is based upon the dissolving the insol. drug in the nonvolatile solvent and admixt. of drug loaded solns. with appropriate carrier and coating materials to convert into acceptably flowing and compressible powder. The use of non-volatile solvent causes improved wettability and ensures mol. dispersion of drug in the formulation and leads to enhance soly. Purpose of this study is to develop novel liquisolid technique to enhance the dissoln. rate of Budesonide. Liquisolid tablet prepd. by using Avicel PH 102, Aerosil 200 and sodium starch glycolate were employed as carrier, coating material and disintegrant resp. The interaction between drug and excipients in prepd. LS compacts were studied by differential scanning calorimetry (DSC) and Powder X- ray diffraction (PXRD).The prepd. LS compacts were evaluated for their flow properties such as bulk d., tapped d., angle of repose, Carr's compressibility index and Hausner's ratio. The drug release rates of LS compacts were distinctly higher as compared to directly compressed conventional tablets, which show significant benefit of LS in increasing wetting properties and surface area of drug available for dissoln. LS compact system showed acceptable flowability, Carr's compressibility index and Hausner's ratio. The DSC and XRD studies conforms the no significant interaction between the drug and excipients used in LS compacts. From this study it concludes that the LS technique is a promising alternative for improvement of dissoln. property of water-insol. drugs.

~0 Citings

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2. Clinical observation of standard myrtle oil capsule combined with loratadine as adjuvant therapy for children with chronic purulent sinusitis

By Lin, Kaichun; Zhou, Jian
From Erke Yaoxue Zazhi (2015), 21(3), 24-26. Language: Chinese, Database: CAPLUS, DOI:10.13407/j.cnki.jpp.1672-108X.2015.03.009

Objective: To investigate the efficacy of std. myrtle oil capsule combined with loratadine tablet as adjuvant therapy for children with chronic purulent sinusitis, in addn. to conventional treatment. Methods: Ninety cases of chronic purulent sinusitis children were randomly divided into two groups for prospective study. The control group received conventional amoxicillin/clavulanate potassium chewable tablet and budesonide nasal spray, while the treatment group received std. myrtle oil capsule combined with loratadine in addn. to conventional treatment. All these drugs were given in the regular dose for 4 wk, and the efficacy of two groups was evaluated. Results: There were no significant differences between the two groups before treatment in age compn., gender compn., duration of disease, rate of headaches, nasal congestion, paranasal sinus tenderness, or middle nasal secretions ($P > 0.05$). There were significant differences between the two groups after treatment in rate of headache, nasal congestion, paranasal sinus tenderness, waters-view radiograph, and middle nasal secretions ($P < 0.05$). The total effective rate of the treatment group was 84.44%, which was significantly higher than that of the control group (68.89%) ($P < 0.05$). Conclusion: Std. myrtle oil capsule combined with loratadine tablet as adjuvant therapy can improve the efficacy of conventional antibiotics and nasal hormonal spray for children with chronic purulent sinusitis.

~0 Citings

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3. Clinical observation of montelukast combined with budesonide and terbutaline in treatment of acute attack of asthma

By Li, Cao-ni
From Xiandai Yaowu Yu Linchuang (2015), 30(10), 1225-1228. Language: Chinese, Database: CAPLUS, DOI:10.7501/j.issn.1674-5515.2015.10.010

The aim is to investigate the clin. efficacy of montelukast combined with budesonide and terbutaline in treatment of acute attack of asthma. Patients(100 cases) with acute attack of asthma in Shangluo Central Hospital from May 2012 to May 2015 were randomly divided into control and treatment groups, and each group had 50 cases. The patients in the control group inhaled budesonide aerosol on the basis of symptomatic treatment, 0.5 mg/time, three times daily, and they were also po administered with terbutaline sulfate tablets, 2.5 mg/time, three times daily. The patients in the treatment group were po administered with montelukast sodium chewable tablets on the basis of the control group, 10 mg/time, once daily. Two groups were treated for 7 d. After treatment, the efficacy was evaluated, and symptoms disappearing time, frequency of asthma attack, and the improvement of lung function in two groups were compared. After treatment, the efficacies in the control and treatment groups were 88.0% and 98.0%, resp., and there were differences between two groups($P<0.05$). After treatment, cough disappearing time, moist rales disappearing time, wheezing disappearing time, wheezing sound disappearing time, attack frequency of daytime and nighttime in the treatment group were shorter than those in the control group, and there were differences between two groups($P<0.05$). After treatment, FEV_1% Pred, FVC, and PEF in two groups were significantly increased, and the difference was statistically significant in the same group($P<0.05$). After treatment, FEV_1% Pred, FVC and PEF in the treatment group were higher than those in the control group, with significant difference between two groups($P<0.05$). Montelukast combined with budesonide and terbutaline had distinct clin. effect in treatment of acute attack of asthma, and could effectively improve lung function and clin. symptoms of acute asthma patients, which had certain clin. application value.

~0 Citings

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4. Formulation development and in vitro evaluation of pulsatile release tablet of budesonide

By Jeganath, S.; Senthilkumaran, K.
From World Journal of Pharmaceutical Research (2015), 4(1), 1197-1208, 12 pp.. Language: English, Database: CAPLUS

The objective of this study was to develop a ileo caecal targeted drug delivery of budesonide for the treatment of IBD. Budesonide were selected as model std. drugs to treat IBD. Budesonide is a potent, synthetic non-halogenated corticosteroid with high topical anti-inflammatory effect and little systemic effects. Tablets were prepd. by using Crospovidone and Eudragit L30D coating for the burst release in the ileo caecal region. The formulations were evaluated for pharmacopoeial quality control tests and all the phys. parameters evaluated were within the acceptable limits. Formulation F11 was proved to be good drug content, dimensional stability, lag time and drug release in the ileo caecal region as compared to the other formulations. Stability studies were carried out on the optimized formulation F11 for period of 3 mo at 40°C/75 %RH. Finally it was obsd. that there was no change in physiochem. and phys. properties as well as in drug release profile even after storage at 45 °C and 75 % for three months.

~0 Citings

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5. Colonic delivery of compression coated budesonide tablets using ethyl cellulose and eudragit rlpo polymer mixture

By Sopan, Shendge Raosaheb; Sayyad, Fahim J.
From International Journal of Pharma and Bio Sciences (2013), 4(2), 45-57. Language: English, Database: CAPLUS

Budesonide contg. Et cellulose /eudragit RLPO compression coated tablets were prepd. and there in vitro behavior tested for colonic delivery. Budesonide is an antiinflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineral corticoid activity. Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in ulcerative colitis, crohn's disease and inflammatory bowel disease. In this study, each 150 mg core tablet of budesonide was compression coated with 60% Et cellulose and 40% eudragit RLPO, 70% Et cellulose and 30% eudragit RLPO and 80% Et cellulose and 20% eudragit RLPO at a coat wt. of 200 mg, 250 mg and 300 mg resp. Drug release studies were carried out in pH 6.8 phosphate buffer IP soln. The Eudragit RLPO/Ethyl cellulose envelope was found to be a good delivery system for budesonide to be delivered to the colon.

~0 Citings

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6. Clinical application of montelukast sodium tablets combined with budesonide in treating asthma children

By Wang, Fen; Huan, Peng; Zhao, Bo
From Shiyong Linchuang Yiyao Zazhi (2013), 17(16), 77-79. Language: Chinese, Database: CAPLUS, DOI:10.7619/jcmp.201316029

The objective of this paper is to explore the clin. effect of montelukast sodium tablets combined with budesonide in treating asthma children. One hundred and twenty eight asthma children were randomly divided into control group and observation group. The control group was given inhaled budesonide treatment, and the observation group received montelukast sodium tablets combined with budesonide therapy. The course of treatment was 3 mo. Clin. effect, lung function and adverse reaction rate were compared between the two groups. Results showed that the efficacy rate of treatment in the observation group was 90.9%, much higher than the control group (69.4%, P<0.05). After treatment, FEV1/FVC and PEF in the observation group were superior to those in the control group (P< 0.05). There was no significant difference in adverse reaction rate between the two groups (7.6% vs 6.5%, P<0.05). It was concluded that montelukast sodium tablets combined with budesonide for asthma children greatly improves the clin. effect and lung function.

~0 Citings

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7. Influence and effects of budesonide sprays on Th1/Th2 cytokines of patients with allergic rhinitis

By Yu, Suping; Luo, Lifei
From Zhongguo Yaoshi (Wuhan, China) (2013), 16(5), 709-711. Language: Chinese, Database: CAPLUS

The influence and effects of budesonide sprays on Th1/Th2 cytokines of patients with allergic rhinitis were obsd. Eighty patients were divided into two groups: the control group (loratadine dispersible tablet) and observation group (loratadine dispersible tablet+budesonide spray). The changes of interleukin 4 (IL-4) and interferon-γ (IFN-γ) in two groups before and after therapy were compared. The clin. effects and side effects were obsd. After therapy for 4 wk, IL-4 in two groups decreased obviously, and IFN-γ levels increased (P<0.01 or 0.05). The changes of IL-4 and IFN-γ were more obvious in observation group than the control group. The total effective rate in observation group was higher than the control group (P<0.05). The difference of side effect rate in two groups had no statistical significance (P>0.05). The results showed that budesonide sprays were safe and effective to relieve clin. symptoms, and the mechanism might be related with Th1/Th2 cytokines.

~0 Citings

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8. Formulation and evaluation of oral colon targeted tablet of budesonide

By Pawar, Pruthviraj S.; Saleem, M. A.
From Pharmacia Lettre (2013), 5(3), 1-12. Language: English, Database: CAPLUS

Colon targeted tablets of budesonide were prepd. using pectin, guar gum as enzyme dependent polymers along with HPMC, HEC as time dependent polymers followed by pH dependent polymers like Eudragit S100 and Cellulose acetate phthalate. Fast dissolving core tablet of budesonide was prepd. by using CCS as a superdisintegrant by direct compression method which showed rapid release within 2 min. The compression coating was done over the core tablets by using pectin, guar gum, HPMC and HEC in different ratios by direct compression method. The enteric coating was done on the compression coated tablets by using ES100 and CAP in different ratios by dip coating method. The FTIR of drug-polymer and polymer-polymer was studied and revealed the compatibility of drug-polymer and polymer-polymer. The tablets were studied for post compression parameters like thickness, hardness, friability, wt. variation, and drug content were in acceptable range of pharmacopeial specification. In vitro swelling and in vitro drug release studies were carried out at different pH (1.2, 6.8 and 7.4). The compression coated formulation C1 (pectin: guar gum 1:2), C2 (HPMC: HEC 1:2) and C3 (HPMC, HEC: pectin, guar gum 2:1) showed good swelling (493.42%, 411.08% and 393.61%) up to 18, 20 and 21 h resp. PH dependent polymers ES100: CAP in the ratio 2:1 as an enteric coating material applied over compression-coated tablet was capable of protecting the drug from being released in physiol. environment of stomach and small intestine. This study proved that Budesonide compression-coated tablet, enteric coated with ES100: CAP in the ratio 2:1 may be beneficial in the treatment of irritable bowel syndrome and nocturnal asthma.

~3 Citings

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9. Active Eosinophilic Esophagitis Is Associated with Impaired Elimination of Budesonide by Cytochrome P450 3A Enzymes

By Dilger, Karin; Lopez-Lazaro, Luis; Marx, Claudia; Bussmann, Christian; Straumann, Alex
From Digestion (2013), 87(2), 110-117. Language: English, Database: CAPLUS, DOI:10.1159/000346403

Background/Aims: Topically administered glucocorticoids such as budesonide have the potential of being established as first-line medical treatment of eosinophilic esophagitis (EoE). Safety of budesonide is based on high elimination by cytochrome P 450 3A (CYP3A) enzymes. We aimed to investigate systemic absorption and elimination of a new budesonide formulation in patients with active EoE in comparison with healthy controls. Methods: After single and multiple doses of orodispersible budesonide (4 mg/day) the parent drug, its CYP3A-dependent metabolites, and endogenous cortisol were detd. in 12 adult patients with active EoE and 12 healthy controls. An approved ileal-release formulation of budesonide was taken for ref. Molar ratios of metabolite formation in plasma were used as indexes of CYP3A metabolic function. Results: CYP3A-dependent metabolite formation was significantly reduced in patients with active EoE as compared to healthy controls. Impaired biotransformation was reflected by a significantly higher extent of budesonide absorption and elongated elimination half-life in EoE patients. Comparison of morning serum cortisol levels at baseline with those after 1 wk of treatment with budesonide revealed a significant decrease in EoE patients but not in healthy subjects. Conclusion: Active EoE is assocd. with reduced elimination of budesonide via CYP3A, the major subfamily of drug-metabolizing enzymes in humans.

~9 Citings

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10. Formulation and evaluation of colonic compression coated tablet of budesonide

By Jadhav, J. R.; Salunkhe, K. S.; Burute, G. D.; Chaudhari, S. R.
From Journal of Pharmacy Research (2012), 5(5), 2783-2788. Language: English, Database: CAPLUS

The aim of current study was to investigate the in-vitro performance of compress coated tablet of Budesonide. A novel colon targeted tablet formulation was developed by press coating of Budesonide with guar gum and Eudragit S-100 as barrier layer. The entire device was enteric coated so that variability in gastric emptying time can be overcome and a colon specific release can be achieved. Different ratios of polymers were selected to achieve suitable lag time for the treatment of Crohn's disease and ulcerative colitis. In-vitro release studies for prepd. tablets were carried out for 2 h in 1.2 pH phosphate buffer, 3 h in pH 6.8 phosphate buffer and 6 h in simulated colonic fluid. In vitro studies revealed that the tablet coated with guar gum and Eudragit S-100 have limited drug release in stomach and small intestinal environment and released max. amt. of drug in the colonic environment, colon specific release has been achieved from tablet of F5 formulation (0:100) which not given release in stomach and small intestine and about 98.87% drug release in the colon.

~1 Citing

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11. Development and evaluation of a novel pellet-based tablet system for potential colon delivery of budesonide

By Varshosaz, Jaleh; Emami, Jaber; Tavakoli, Naser; Minaiyan, Mohsen; Rahmani, Nakisa; Dorkoosh, Farid
From Journal of Drug Delivery (2012), 905191, 7 pp., Language: English, Database: CAPLUS, DOI:10.1155/2012/905191

Budesonide, a potent glucocorticoid, is used for the treatment of inflammatory bowel diseases. Current available oral formulations of budesonide have low efficacy against ulcerative colitis because of the premature drug release in the upper part of the gastrointestinal tract. In this paper a pH- and time-controlled colon-targeted pellet-based tablet of budesonide was established. Pellet cores were prepd. by extrusion-spheronization method and further coated with xanthan gum (barrier layer), Eudragit NE30D and L30D55 combination (inner layer), and Eudragit FS30 (as enteric layer) sequentially to achieve the required release profile. The coated pellets then compressed into tablets using inert tabletting granules of Cellactose or Pearlitol. Release studies, performed in simulated gastric, intestinal, and colon pH were used in sequence to mimic the gastrointestinal transit. The influence of formulation variables like barrier layer thickness, inner layer compn., and enteric coat thickness on drug release were investigated and the coated pellets that contained 12% wt. gain in xanthan gum layer, Eudragit L30D55 and Eudragit NE30D with a ratio of 3:7 in inner layer with 30% wt. gain and 25% wt. gain in Eudragit FS layer were found to protect the drug release in stomach and small intestine and 83.35 ± 2.4 of budesonide was released at 24 h. The drug release from the tablets prepd. using 40% Cellactose 80 as tableting excipient was found to be closely similar to that of uncompressed pellets.

~2 Citings

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12. 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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13. Preparation and in vitro/in vivo evaluation of dextran matrix tablets of budesonide in experimental ulcerative colitis in rats

By Ahmadi, Fatemeh; Varshosaz, Jaleh; Emami, Jaber; Tavakoli, Naser; Minaiyan, Mohsen; Mahzouni, Parvin; Dorkoosh, Farid
From Drug Delivery (2011), 18(2), 122-130. Language: English, Database: CAPLUS, DOI:10.3109/10717544.2010.520352

Budesonide is an anti-inflammatory drug of choice for treatment of ulcerative colitis which affects the rectum and a part of or the entire colon. Delivery of budesonide specifically to the colon would increase the efficacy of the drug and reduce the side-effects. The aim of this study was to develop an oral matrix system formulation for budesonide to deliver the major part of the drug to the colon for treatment of ulcerative colitis that has not been reported before. Directly compressed matrix tablets were prepd. using different mol. wts. of dextran and three ratios of drug-to-polymer. The phys. properties of the tablets including wt. variation, hardness, content uniformity, and release profile in HCl 0.1 N, phosphate buffer pH 7.4 and 6.8 contg. 4% rat caecal and colonic contents were studied. The efficacy of the desired formulation was also evaluated against acetic acid-induced colitis in rats. Phys. properties of the tablets were in the ranges recommended by official refs. More than 10% of the drug was released in HCl 0.1 N and pH 7.4, while a very drastic increase was obsd. after exposure to pH 6.8 contg. rat caecal contents. The efficacy of the selected formulation against rat-induced colitis was also increased in comparison to the non-targeted formulation of budesonide. In conclusion, matrix tablets with a 1:10 drug-to-dextran ratio with high mol. wt. could deliver the drug specifically to the colon and are promising for treatment of ulcerative colitis.

~5 Citings

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14. Budenoside-containing pharmaceutical formulation for treating the upper digestive tract

By Proels, Markus.; Wilhelm, Rudolf
From Eur. Pat. Appl. (2010), EP 2151235 A1 20100210, Language: German, Database: CAPLUS

The invention relates to an effervescent tablet for prepg. a mouth rinsing soln., wherein the effervescent tablet exhibits a high release rate of budesonide. A high availability of the active ingredient during use as a mouth rinsing soln. on the inflamed mucosa of the upper digestive tract is thereby achieved. The advantage of the formulation according to the invention lies in the bioavailability comparable to oral forms of administration, which makes safe use over a long time period possible. Thus a effervescent tablet contained (mg): budesonide 3; sodium dihydrogen citrate 67; disodium hydrogen citrate 15; sodium hydrogen carbonate 45; Povidon K25 2; docusate sodium 0.05; aspartame 1; mannitol 5.95; Macrogol 6000 5; butanamide 0.9; magnesium stearate 0.1.

~2 Citings

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15. Budenoside-containing pharmaceutical formulation for treating the upper digestive tract

By Wilhelm, Rudolf; Proels, Markus
From PCT Int. Appl. (2010), WO 2010009961 A1 20100128, Language: German, Database: CAPLUS

The invention relates to an effervescent tablet for prepg. a mouth rinsing soln., wherein the effervescent tablet exhibits a high release rate of budesonide. A high availability of the active ingredient during use as a mouth rinsing soln. on the inflamed mucosa of the upper digestive tract is thereby achieved. The advantage of the formulation according to the invention lies in the bioavailability comparable to oral forms of administration, which makes safe use over a long time period possible. Thus a effervescent tablet contained (mg): budesonide 3; sodium dihydrogen citrate 67; disodium hydrogen citrate 15; sodium hydrogen carbonate 45; Povidon K25 2; docusate sodium 0.05; aspartam 1; mannitol 5.95; Macrogol 6000 5; butanamide 0.9; magnesium stearate 0.1.

~1 Citing

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16. Evaluation on colon-targeting characteristics of budesonide colonic localization tablet in rat

By Liu, Hui; Pan, Weisan
From Zhongguo Yaoxue Zazhi (Beijing, China) (2008), 43(23), 1804-1807. Language: Chinese, Database: CAPLUS

Colon-targeting effects of budesonide colonic localization tablet were evaluated by comparing budesonide concn. in gastrointestinal tissue after oral administration of different budesonide prepns. The different tissue fluids were sampled, and the HPLC method was used to det. the budesonide concn. in stomach, small intestine, large intestine tissue after budesonide localization tablet, budesonide tablet and budesonide suspension were administrated in rats, resp. With oral administration of budesonide localization tablets, the peak concn. of budesonide [c_{max} = (7.17 ± 2.32) μg/g^{-1}] in large intestine tissue was reached at the 6 h, and it was significantly higher than that of suspension group (1.37 ± 0.82) μg/g^{-1} and common tablet group (0.47 ± 0.18) μg/g^{-1}. By investigating the effects of different oral prepns. on the gastrointestinal tissue distribution of budesonide in rats at the same time, budesonide was found only in the large intestine tissue, but no drug was distributed in the stomach and the small intestine tissue with oral administration of budesonide localization tablet. The budesonide colonic localization tablet has conspicuous colon-targeting property.

~0 Citings

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17. Inhaled budesonide prevents acute mountain sickness in young Chinese men

By Chen Guo-Zhu; Zheng Cheng-Rong; Qin Jun; Yu Jie; Zhang Ji-Hang; Dong Jun-Qing; Guo Wen-Yun; Lu Wei; Zeng Ying; Huang Lan; et al
From The Journal of emergency medicine (2015), 48(2), 197-206, Language: English, Database: MEDLINE

BACKGROUND: Oral glucocorticoids can prevent acute mountain sickness (AMS). Whether inhaled budesonide (BUD) can prevent AMS remains unknown. OBJECTIVE: Our aim was to investigate the effectiveness of BUD in AMS prevention. METHODS: Eighty subjects were randomly assigned to receive budesonide (BUD, inhaled), procaterol tablet (PT), budesonide/formoterol (BUD/FM, inhaled), or placebo tablet (n = 20 in each group). Subjects were treated for 3 days before ascending from 500 m to 3700 m within 2.5 h by air. Lake Louis AMS questionnaire, blood pressure, heart rate, and oxygen saturation (SpO2) were examined at 20, 72, and 120 h after high-altitude exposure. Pulmonary function was measured at 20 h after exposure. RESULTS: Compared with placebo, BUD significantly reduced the incidence of AMS (70% vs. 25% at 20 h, $p < 0.05$; both 10% vs. 5% at 72 and 120 h, both $p > 0.05$) without side effects. The relative risk was 0.357, and the risk difference was 0.45. Mean SpO2 was higher in BUD, BUD/FM, and PT groups than in the placebo group at 20 h ($p < 0.05$). SpO2 in all 80 subjects dropped after ascent (98.1% to 88.12%, $p < 0.01$) and increased gradually, but it was still lower at 120 h than at baseline (92.04% vs. 98.1%, $p < 0.01$). Pulmonary function did not differ among the four groups at 20 h. CONCLUSION: BUD can prevent AMS without side effects. The alleviation of AMS may be related to increased blood oxygen levels rather than pulmonary function.

~1 Citing

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18. Turbinoplasty with quantic molecular resonance in the treatment of persistent moderate-severe allergic rhinitis: Comparative analysis of efficacy

By Di Rienzo Businco Lino; Di Rienzo Businco Andrea; Ventura Luca; Laurino Salvatore; Lauriello Maria
From American journal of rhinology & allergy (2014), 28(2), 164-8, Language: English, Database: MEDLINE

BACKGROUND: Allergic rhinitis (AR) presents as the main and most invasive symptom in the blocking of the nose. This condition is almost always related to hypertrophy of the inferior turbinates. When the medical treatments are found to be insufficient to solve the obstructive symptom of the patient, the quality of life is considerably impaired and it is often necessary to submit the patient to a surgical approach. In the present study we aimed to establish the efficacy and safety of a new technique recently introduced for the shrinkage of hypertrophic turbinates using a specific device, based on a new radiofrequency energy that does not produce thermal mucosal damage, viz., quantic molecular resonance (QMR) in a group of patients with persistent moderate-severe allergic rhinitis, in addition to standard medical treatment (nasal steroid and oral antihistamine). METHODS: All patients were randomly assigned to two homogeneous groups (group A, control subjects; group B, treated patients); each group included 145 individuals. During the study, both groups received standard medications (ebastine, 10-mg tablet, and budesonide nasal spray at 100 micrograms/nostril per day) for 90 days. Before the medical treatment, patients in group B underwent inferior endoscopic turbinoplasty using QMR. All of the patients enrolled in this study were submitted to a complete otorhinolaryngologic evaluation with objective clinical examination (basal rhinomanometry, nasal provocation test rhinomanometry, and mucociliary transport time), endoscopy, and questionnaires (22-item Sino-Nasal Outcome Test and visual analog scale for nasal symptoms). RESULTS: Greater efficacy has been achieved using a combined approach with the association of medical and QMR treatment, compared with medical treatment alone, in the control of AR associated with hypertrophy of the inferior turbinates, in particular in the reduction of turbinate volume at rhinoendoscopy. CONCLUSION: QMR inferior turbinoplasty, in conjunction with medical therapy, improves the nasal flow, without any thermal mucosal damage, more effectively when compared with medical treatment alone in persistent moderate-to-severe AR. In particular, local reactivity, as measured with nasal provocation test, was noticeably reduced.

~3 Citings

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
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First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	9,849,084	12-26-2017	Perrett et al.	
	2.	2006/0051414	03-09-2006	Ramalho 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.**

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

PTO/SB/08b (07-09)
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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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	BRUNNER, et al., "Gastrointestinal transit, release and plasma pharmacokinetics of a new oral budesonide formulation." British Journal of Clinical Pharmacology (2005); 61(1): 31-38.	
	4.	FALCOZ, et al., "Bioavailability of Orally Administered Micronised Fluticasone Propionate." Clinical Pharmacokinetics (2000); 39 Suppl. 1: 9-15.	
	5.	HAM, et al., "Quantitation of esophageal transit by means of ^{81m}Kr." European Journal of Nuclear Medicine (1984); 9: 362-365.	

Examiner Signature	/ARADHANA SASAN/	Date Considered	06/23/2018

*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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EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S202	9	"12896005"	US-PGPUB; USPAT	OR	ON	2018/06/05 09:01
S203	0	"15816154"	US-PGPUB; USPAT	OR	ON	2018/06/05 09:46
S205	2	("20060051414"|"9849084").PN.	US-PGPUB; USPAT	OR	ON	2018/06/23 17:36
S206	47	("20010006625"|"20010014340"|"20030054036"|"20030099701"|"20030215500"|"20040009212"|"20040053902"|"20040106663"|"20040265375"|"20050009848"|"20050112188"|"20050232988"|"20070059361"|"20090074862"|"20090123550"|"20090123551"|"20090131386"|"20090149433"|"20090155360"|"20090169620"|"20100215753"|"20110081411"|"20110097401"|"20120282335"|"20140287051"|"20140303131"|"20160206627"|"20170071855"|"3705172"|"3929768"|"4080448"|"4335121"|"4363806"|"4472393"|"5135740"|"5278175"|"5403893"|"5446070"|"5482934"|"5776433"|"6316027"|"6596298"|"6740332"|"7033606"|"8771729"|"9387167"|"9486407").PN.	US-PGPUB; USPAT	OR	ON	2018/06/23 17:37
S207	28	("20010006625"|"20010014340"|"20030054036"|"20030099701"|"20030215500"|"20040009212"|"20040053902"|"20040106663"|"20040265375"|"20050009848"|"20050112188"|"20050232988"|"20070059361"|"20090074862"|"20090123550"|"20090123551"|"20090131386"|"20090149433"|"20090155360"|"20090169620"|"20100215753"|"20110081411"|"20110097401"|"20120282335"|"20140287051"|"20140303131"|"20160206627"|"20170071855").PN.	US-PGPUB; USPAT	OR	ON	2018/06/23 17:37
S208	19	("3705172"|"3929768"|"4080448"|"4335121"|"4363806"|"4472393"|"5135740"|"5278175"|"5403893"|"5446070"|"5482934"|"5776433"|"6316027"|"6596298"|"6740332"|"7033606"|"8771729"|"9387167"|"9486407").PN.	US-PGPUB; USPAT	OR	ON	2018/06/23 17:37
S209	1	"15816154"	US-PGPUB; USPAT	OR	ON	2018/06/23 19:28
S210	600259	(A61K31/569 OR A61K2300/00 OR A61K31/56 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/0065 OR A61K9/06 OR A61K9/08).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:28

EAST Search History (Prior Art)

S211	396	(A61K31/569 same A61K2300/00).cpcc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:29
S212	600259	S210 S211	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:29
S213	0	S212 and ((oral$2 mouth buccal$2) near3 (dispers$8 disintegra$4 dissol$4 break$4) near3 (tablet$4 compress$4 compact$4 pill lozenge dragee) near3 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near3 (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:33
S214	6	S212 and ((oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) near10 (tablet$4 compress$4 compact$4 pill lozenge dragee) near20 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near25 (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:34
S215	622	S212 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) near10 (tablet$4 compress$4 compact$4 pill lozenge dragee) near20 (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) near25 (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:35
S216	622	S212 and ("ODT" (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:36
S217	6	S212 and ((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:36

EAST Search History (Prior Art)

S218	13	((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/23 19:37
S219	15	((Stephen) near2 (PERRETT)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S220	18	((Fredric) near2 (COHEN)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S221	122	((Gopi) near2 (VENKATESH)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S222	147	(APTALIS ADARE EURAND).AS.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S223	53	(APTALIS ADARE EURAND).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S224	4	((Stephen) near2 (PERRETT)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S225	2	((Fredric) near2 (COHEN)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S226	19	((Gopi) near2 (VENKATESH)).AANM.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S227	223	S219 S220 S221 S222 S223 S224 S225 S226	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:37
S228	4	S227 and ((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount))	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:38
S229	4	S227 and ((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4) with (mg milligram quantity weight wt "wt." amount)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2018/06/23 19:38

EAST Search History (Prior Art)

S230	43	(((("ODT") (oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee)) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/24 07:42
S231	43	((("ODT") ((oral$2 mouth buccal$2) near10 (dispers$8 disintegra$4 dissol$4 break$4) with (tablet$4 compress$4 compact$4 pill lozenge dragee))) with (budesonide pulmicort$4 rhinocort$4 entocort$4 uceris$4 symbicort$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/24 07:43
S232	62	((("ODT") ((oral$2 mouth buccal$2) 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$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/24 07:44
S233	38	(US-20140303131-$ or US-20050009848-$ or US-20070059361-$ or US-20090123550-$ or US-20090131386-$ or US-20090169620-$ or US-20140287051-$ or US-20110081411-$ 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-$).did. or (US-8771729-$ or US-5000956-$ or US-5049387-$ or US-5077054-$ or US-5776432-$ or US-5863910-$ or US-5980867-$ 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-$).did. or (KR-20120057841-$). did. or (US-20110027331-$ or WO-0059565-$ or GB-2409160-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	ON	2018/06/24 08:31
S234	1	"15680301"	US-PGPUB	OR	ON	2018/06/24 08:41
S235	1	"14917125"	US-PGPUB	OR	ON	2018/06/24 08:50

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804

CONFIRMATION NO. 4432

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

PUBLICATION NOTICE



Title:ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Publication No.US-2018-0153802-A1
Publication Date:06/07/2018

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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	9,849,084	12-26-2017	Perrett et al.	
	2.	2006/0051414	03-09-2006	Ramalho et al.	

Examiner Signature		Date Considered	

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Sheet 2 of 2

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Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	BRUNNER, et al., "Gastrointestinal transit, release and plasma pharmacokinetics of a new oral budesonide formulation." British Journal of Clinical Pharmacology (2005); 61(1): 31-38.	
	4.	FALCOZ, et al., "Bioavailability of Orally Administered Micronised Fluticasone Propionate." Clinical Pharmacokinetics (2000); 39 Suppl. 1: 9-15.	
	5.	HAM, et al., "Quantitation of esophageal transit by means of ^{81m}Kr." European Journal of Nuclear Medicine (1984); 9: 362-365.	

Examiner Signature		Date Considered	

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Docket No.: ADAR-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1629
Filed:	November 17, 2017	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, 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 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 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.

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:

- U.S. Patent No. 8,771,729 issued July 8, 2014;
- U.S. Patent No. 9,486,407 issued November 8, 2016;
- U.S. Patent No. 9,387,167 issued July 12, 2016;
- U.S. Patent Appln. No. 15/205,390 (allowed);
- U.S. Patent Appln. No. 15/680,301 (pending); and
- U.S. Patent Appln. No. 14/917,125 (pending).

The Examiner is encouraged to review pending or issued claims, the file history, including art made of record, as well as any substantive actions in the above application(s) and patent(s), including any Restriction Requirements, Office Actions, Responses, Appeals, Appeal Briefs, Examiner's Replies, Notice(s) of Allowance or Issuance in the above application(s) and patent(s), prior to taking any action in the subject application. Applicant(s) further request that the Examiner continue to evaluate the above application(s) throughout prosecution of the subject application and as needed.

Applicants understand that due to modern and easy access by the Examiner to U.S. applications and their prosecution history on PAIR, or other electronic databases available to the Examiner, there is no need for Applicants to submit copies of any paper in the file wrapper for any U.S. application.

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 Director is hereby requested and authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 50-1283 which the undersigned is authorized to draw.

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 16, 2018

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 91543

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:	32343339
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin
Filer Authorized By:	
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	16-APR-2018
Filing Date:	17-NOV-2017
Time Stamp:	12:27:37
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	Information Disclosure Statement (IDS) Form (SB08)	ADAR-119_05US_SB08.pdf	160405 51ebbfc9be39ad17c26cea13881f83a554d88fe9	no	2

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	BRUNNER_2005.pdf	172100 db635cc15ff2dba61c9148eda68a5a87d3c4d4ad	no	8
Warnings:					
Information:					
3	Non Patent Literature	FALCOZ_2000.pdf	77398 e87bd6bd1f789c9ec08e35f9c1f11a8a9f8d4818	no	7
Warnings:					
Information:					
4	Non Patent Literature	HAM_1984.pdf	102521 60d341ac29c7293806b267a4738ee698fb211417	no	4
Warnings:					
Information:					
5	Transmittal Letter	ADAR-119_05US_IDSTransmittal.pdf	120326 b3986f9d6d6028046889c0be8f3215fb7b5d78ef	no	5
Warnings:					
Information:					
			Total Files Size (in bytes):	632750	

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 APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/816,154

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))	14 minus 20 =	*			OR	x 100 =	0.00
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
			TOTAL			TOTAL	1720

* If the difference in column 1 is less than zero, enter "0" in column 2.

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.

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
15/816,154	11/17/2017	1629	1880	ADAR-119/05US 325049-2804	14	1

CONFIRMATION NO. 4432

UPDATED FILING RECEIPT

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

OC000000097683007

Date Mailed: 03/01/2018

Receipt is acknowledged of this non-provisional 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 APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Inventor(s)

Stephen Perrett, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi Venkatesh, Vandalia, OH;

Applicant(s)

Adare Pharmaceuticals, Inc., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 91543

Domestic Priority data as claimed by applicant

This application 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: No

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: 12/01/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/816,154**

Projected Publication Date: 06/07/2018

Non-Publication Request: No

Early Publication Request: No

Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

514

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

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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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	PERRETT, Stephen, et al.	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1629
Filed:	November 17, 2017	Examiner:	*NA*

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

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

RESPONSE TO NOTICE TO FILE MISSING PARTS AND PRELIMINARY AMENDMENT

This paper is submitted in response to the Notice to File Missing Parts, mailed December 5, 2017, setting an initial deadline for reply of February 5, 2018. Filed herewith is a petition for a one month extension of time to extend the period for reply to March 5, 2018. Accordingly, this paper is timely filed by March 5, 2018. Also filed herewith is a preliminary amendment to the claims. Applicants respectfully request reconsideration of the above-identified application in view of the following proposed amendments and remarks.

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

Amendments to the Claims begin on page **3** of this paper; and

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

AMENDMENT TO THE SPECIFICATION

Please amend the first paragraph of the specification, starting on line 3, as follows:

-- The present application is a continuation application of U.S. Patent Application Serial No. 15/205,390, filed July 8, 2016, now U.S. Patent No. 9,849,084, which is a continuation application of 14/311,732, filed June 23, 2014, now U.S. Patent 9,387,167, which is a divisional application of U.S. Patent Application Serial No. 12/896,005, filed October 1, 2010, now U.S. Patent No. 8,771,729, and claims priority to U.S. Provisional Application No. 61/247,642, filed October 1, 2009, the disclosures of each of which [[is]] are herein incorporated by reference in its entirety for all purposes.

AMENDMENT TO THE CLAIMS:

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

1.-26. (Cancelled)

27. (New) An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a salt, solvate, or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity,

wherein said tablet disintegrates faster than the rate of oral disintegration of a conventional solid dosage form when tested using the USP <701> Disintegration Test.

wherein upon administration budesonide, or the salt, solvate, or ester thereof, is deposited topically in the upper gastrointestinal tract.

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

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

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

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

32. (New) The orally dispersing tablet of claim 27, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, sucralose, maltose, cyclodextrin, polyvinyl pyrrolidone, magnesium stearate, and combinations thereof.

33. (New) The orally dispersing tablet of claim 27, which is free of lubricant.

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

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

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

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

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

39. (New) The orally dispersing tablet of claim 27 comprising from 0.01 mg to 20 mg budesonide.

40. (New) The orally dispersing tablet of claim 27 comprising from 2 mg to 20 mg budesonide.

REMARKS

Claims 1-26 were pending at the time the Notice to File Missing Parts was mailed on December 5, 2017. By this amendment, claims 1-26 are cancelled without prejudice or disclaimer. Claims 27-40 are newly added. Support for new claims 27-40 can be found throughout the specification as-filed, for example on page 3, ll. 14-25, page 4, ll. 18-21, and page 13, line 4 to page 15, line 9. Entry thereof is respectfully requested.

Upon entry of the present amendments claims 27-40 are pending. There are total of 14 claims with one independent claim. Thus, Applicant notes the $2,220.00 payment requested in the Notice to file Missing Parts has been reduced as outlined below.

Basic Filing Fee	$300.00
Surcharge Fee	$160.00
Search Fee	$660.00
Examination Fee	$760.00
Excess claim fee over 20 (0 x $40)	$0.00
Total	**$1,880.00**

Accordingly, Applicant submits $1,880.00 in response to the Notice to File Missing Parts.

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

Respectfully submitted,
COOLEY LLP

Dated: February 23, 2018

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004
Tel: (202) 728-7126
Fax: (202) 842-7899

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

Electronic Patent Application Fee Transmittal

Application Number:	15816154
Filing Date:	17-Nov-2017
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Filer:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804

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:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
		Total in USD ($)		**2080**

Electronic Acknowledgement Receipt

EFS ID:	31871780
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin
Filer Authorized By:	
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	23-FEB-2018
Filing Date:	17-NOV-2017
Time Stamp:	16:49:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$2080
RAM confirmation Number	022618INTEFSW00003680501283
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		ADAR-119_05US_Response.pdf	192597 899f168d042996daa044786de79dd63c27ef3ab4	yes	6

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Applicant Response to Pre-Exam Formalities Notice	1	1
Specification	2	2
Claims	3	4
Applicant Arguments/Remarks Made in an Amendment	5	6

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	39021 395df562882137fe487d932d561ed7c5ac0ff4ee	no	2

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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

(Use as many sheets as necessary)

Sheet 1 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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.	8,771,729	07-08-2014	Perrett et al.	
	18.	9,387,167	07-12-2016	Perrett et al.	
	19.	9,486,407	11-08-2016	Perrett et al.	
	20.	2001/0006625	07-05-2001	Bohn et al.	
	21.	2001/0014340	08-16-2001	Ohta, et al.	
	22.	2003/0054036	03-20-2003	Liggins et al.	
	23.	2003/0099701	05-29-2003	Takaishi et al.	
	24.	2003/0215500	11-20-2003	Ohta et al.	
	25.	2004/0053902	03-18-2004	Smith, Steven C.	
	26.	2004/0009212	01-15-2004	Tsai, Tsui-min	
	27.	2004/0106663	06-03-2004	Talley et al.	
	28.	2004/0265375	12-30-2004	Platteeuw, et al.	
	29.	2005/0009848	01-13-2005	Brantl	

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Sheet 2 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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	30.	2005/0112188	05-26-2005	Elias	
	31.	2005/0232988	10-20-2005	Venkatesh et al.	
	32.	2007/0059361	03-15-2007	Rawas-Qalaji et al.	
	33.	2009/0074862	03-19-2009	Schioppi, et al.	
	34.	2009/0123550	05-14-2009	Phillips et al.	
	35.	2009/0123551	05-14-2009	Phillips et al.	
	36.	2009/0131386	05-21-2009	Phillips	
	37.	2009/0149433	06-11-2009	Phillips	
	38.	2009/0155360	06-18-2009	Venkatesh et al.	
	39.	2009/0169620	07-02-2009	Venkatesh et al.	
	40.	2010/0215753	08-26-2010	Sherwood et al.	
	41.	2011/0081411	04-07-2011	Perrett et al.	
	42.	2011/0097401	04-28-2011	Phillips et al.	
	43.	2012/0282335	11-08-2012	Venkatesh et al.	
	44.	2014/0287051	09-25-2014	Perrett et al.	
	45.	2014/0303131	10-09-2014	Perrett et al.	
	46.	2016/0206627	07-21-2016	Gosselin et al.	
	47.	2017/0071855	03-16-2017	Perrett et al.	

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	48.	CA 2430481 A1	06-13-2002	SAMYANG CORPORATION		
	49.	CL 3827-2008 (corresponds to US 2009/0169620)	12-21-2007	EURAND, INC.		
	50.	DE 2323215 A1 (corresponds to US 3,929,768)	11-29-1973	AP Bofors		

Examiner Signature		Date Considered	

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Sheet 3 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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	51.	DE 4129535 A1 (and English Abstract)	03-12-1992	Especialidades Latinas Medicamentos Universales S.A.		✓
	52.	EP 0057401 A1	08-11-1982	Schering Corporation		
	53.	EP 0440372 A1	08-07-1991	Pfizer Limited et al.		
	54.	EP 1595533 A1	11-16-2005	NIPPON SHINKAYU CO LTD.		
	55.	JP 2003-261439 A (English Abstract)	09-16-2003	ASAHI KASEI CORP		✓
	56.	JP 2006-516616 A (corresponds to WO 2004/067004 A1)	07-06-2006			
	57.	JP 2006-77018 A (and English Abstract)	03-26-2006	KYOWA HAKKO KOGYO CO. LTD.		✓
	58.	JP H11-511162 A (English Abstract)	09-28-1999			✓
	59.	JP 11-130679 A (and English Abstract)	05-18-1999	AVENTIS PHARMA DEUTSCHLAND GMBH		✓
	60.	JP 2001-524094 A (corresponds to WO 1998/047535 A1)	11-27-2001			
	61.	JP 2002-521321 A (corresponds to US 7,033,606)	07-16-2002			
	62.	JP 2003-292459 A (with English Abstract, and English translation)	10-15-2003	PHARMA POWER BIOTEC CO LTD		✓
	63.	JP 2003-509359 A (corresponds to WO 2001/019342 A2	03-11-2003	GLAXO GROUP LTD		
	64.	JP 2009-173552 A (English Abstract)	08-06-2009	LION CORP		✓
	65.	JP 2009-519793 (English Abstract)	05-21-2009			✓

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

FOREIGN PATENT DOCUMENTS

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	66.	JP 2009-521523 A (English Abstract)	06-04-2009	JUBILANT ORGANOSYS LIMITED		✓
	67.	JP S56-138200 A (corresponds to US 4,335,121)	10-28-1981	GLAXO GROUP LTD		
	68.	KR 2006-0123160 A (English Abstract)	12-01-2006	ALZA CORP.		✓
	69.	WO 1997/006786 A1	02-27-1997	R.P. SCHERER LIMITED		
	70.	WO 1998/047535 A1	10-29-1998	WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED		
	71.	WO 2000/064450 A1	11-02-2000	LEO PHARM PROD LTD.		
	72.	WO 2003/093344 A1	11-13-2003	JANSSEN PHARMACEUTICAL N.V.		
	73.	WO 2001/019342 A2	03-22-2001	GLAXO GROUP LIMITED		
	74.	WO 2004/064810 A1 (with English Abstract)	08-05-2004	NIPPON SHINYAKU CO., LTD.		✓
	75.	WO 2004/067004 A1	08-12-2004	OREXO AB		
	76.	WO 2004/069225 A1	08-19-2004	ELAN PHARMA INTERNATIONAL LTD.		
	77.	WO 2002/092057 A1 (with English Abstract)	11-21-2002	YAMANOUCHI PHARMACEUTICAL CO., LTD.		✓
	78.	WO 2005/087194 A1	09-22-2005	SCHERING AKTIENGESELLSCHAFT		
	79.	WO 2007/071179 A1 (with English Abstract)	06-28-2007	QUANTUM HI-TECH (BEIJING) RESEARCH INSTITUTE		✓
	80.	WO 2007/074472 A2	07-05-2007	JUBILANT ORGANOSYS LIMITED		
	81.	WO 2008/098634 A1	08-21-2008	POLICHEM S.A.		
	82.	WO 2009/064457 A2	05-22-2009	MERITAGE PHARMA, INC.		
	83.	WO 2009/064458 A2	05-22-2009	MERITAGE PHARMA, INC.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 8

Complete if Known	
Application Number	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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	84.	WO 2009/064819 A2	05-22-2009	MERITAGE PHARMA, INC.		
	85.	WO 2009/098595 A2	08-13-2009	FOAMIX LTD.		
	86.	WO 2010/144865 A2	12-16-2010	MERITAGE PHARMA, INC.		
	87.	WO 2011/041509 A1	04-07-2011	EURAND, INC.		
	88.	WO 2015/034678 A2	03-12-2015	APTALIS PHARMATECH, INC.		
	89.	WO 2015/035114 A1	03-12-2015	APTALIS PHARMATECH, INC.		
	90.	ZA 6805392 (corresponds to US 3,705,172)	06-04-1969	Farbenfabriken Bayer AG		

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Sheet 6 of 8

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First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	91.	AHMED and SHAH, "Formulation of low dose medicines—theory and practice." Am. Pharm. Rev (2000), 3(3): 9-14.	
	92.	DILGER, K., et al. "Active eosinophilic esophagitis is associated with impaired elimination of budesonide by cytochrome P450 3A enzymes." Digestion. 2013; 87(2):110-117. doi: 10.1159/000346403. Epub 2013 Jan 25.	
	93.	BOWER et al., "Manifestations and Treatment of Laryngeal Sarcoidosis". Am. Rev. Respir. Dis., 122(2): 325-332 (1980).	
	94.	CAMPIERIA et al., "Oral budesonide is as effective as oral prednisolone in active Crohn's disease," Gut, 41: 209-214 (1997).	
	95.	European Application No. EP 10821232.5, Extended European Search Report dated February 6, 2014, 10 pages.	
	96.	European Application No. EP 14184844.0, Extended European Search Report dated February 9, 2015, 7 pages.	
	97.	European Application No. EP 14842811.3, Extended European Search Report dated March 23, 2017, 6 pages.	
	98.	Eurasian Application No. 201491358, Search Report (with English translation), issued January 22, 2015, 4 pages.	✓
	99.	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.	✓
	100.	TAKAKU, Fumimaro, et al. Manual of Therapeutic Agents 2007, Published 2007, p. 617-619 (and English translation/summary of pertinent paragraphs), 5 pages.	✓
	101.	Georgia Application No. AP 2010012674, Search Report (with English translation) dated November 28, 2013, 11 pages.	✓
	102.	KUMARI and RAJENDRAN, "Effect of topical nasal steroid spray in the treatment of non-specific recurrent/chronic pharyngitis-a trial study." Indian Journal of Otolaryngology and Head & Neck Surgery, 60(3): 199-201 (2008).	
	103.	MAHMOUDI et al. "Effect of drug particle size on blend segregation and content uniformity". Contributed poster, AAPS Annual Meeting (USA) 2010, 1 page. (non-English)	

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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	15/816,154
Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	104.	MAHMOUDI et al. "Influence of filler in blend uniformity of micronized drugs". Contributed poster, AAPS Annual Meeting (USA) 2010, 1 page.	
	105.	Malaysian Application No. PI 2012001434, Search Report dated January 29, 2016, 1 page.	
	106.	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).	
	107.	Merck Index, "Budesonide," 14th Edition, p. 240 (2006)	
	108.	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006)	
	109.	Merck Index, "Clotrimazole," 14th Edition, p. 407 (2006)	
	110.	Merck Index, "Mometasone Furoate," 14th Edition, pp. 1077-1078 (2006)	
	111.	Merck Index, "Voriconazole," 14th Edition, p. 1728 (2006)	
	112.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	
	113.	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	
	114.	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	
	115.	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	
	116.	PCT Application No. PCT/US2014/052073, Written Opinion of the International Searching Authority dated November 20, 2014.	

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.

PTO/SB/08b (07-09)
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Sheet 8 of 8

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Filing Date	November 17, 2017
First Named Inventor	PERRETT, Stephen
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Examiner Name	Not Yet Assigned
Attorney Docket Number	ADAR-119/05US 325049-2804

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]
	117.	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	
	118.	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	
	119.	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	
	120.	PCT Application No. PCT/US2014/054203, International Preliminary Report on Patentability dated March 8, 2016.	
	121.	Taiwanese Application No. TW 099133628, Search Report (English translation) dated November 16, 2014, 9 pages.	✓
	122.	Taiwanese Application No. TW 104107443, Search Report (English translation) dated May 29, 2015, 1 page.	✓
	123.	TEITELBAUM et al. "Eosinophilic esophagitis in children: immunopathological analysis and response to fluticasone propionate." Gastroenterology (2002), 122(5): 1216-1225.	
	124.	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	
	125.	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	
	126.	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.**

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Electronic Acknowledgement Receipt

EFS ID:	31283858
Application Number:	15816154
International Application Number:	
Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen Perrett
Customer Number:	91543
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/05US 325049-2804
Receipt Date:	20-DEC-2017
Filing Date:	17-NOV-2017
Time Stamp:	14:13:40
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	ADAR_119_05US_IDS.pdf	117457 5381edcbaebc29c4fb06d6db120dfceb4c971b8f	no	5

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR_119_05US_SB08.pdf	241789 7fa1c7f569e373a4ac38ee8648df633086c91ca3	no	8
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
			Total Files Size (in bytes):	359246	

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-119/05US 325049-2804
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	4432
Application No.:	15/816,154	Group Art Unit:	1629
Filed:	November 17, 2017	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.

[] 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.

[X] No copies of the 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). 15/205,390 (allowed), 14/294,660 (U.S. Patent No. 9,468,407), 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.

[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 $180.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $90.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $45.00; 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 $180.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $90.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $45.00;

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 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.

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:

- U.S. Patent No. 8,771,729 issued July 8, 2014;
- U.S. Patent No. 9,486,407 issued November 8, 2016;
- U.S. Patent No. 9,387,167 issued July 12, 2016;
- U.S. Patent Appln. No. 15/205,390 (allowed);
- U.S. Patent Appln. No. 15/680,301 (pending); and
- U.S. Patent Appln. No. 14/917,125 (pending).

The Examiner is encouraged to review pending or issued claims, the file history, including art made of record, as well as any substantive actions in the above application(s) and patent(s), including any Restriction Requirements, Office Actions, Responses, Appeals, Appeal Briefs, Examiner's Replies, Notice(s) of Allowance or Issuance in the above application(s) and patent(s), prior to taking any action in the subject application. Applicant(s) further request that the Examiner continue to evaluate the above application(s) throughout prosecution of the subject application and as needed.

Applicants understand that due to modern and easy access by the Examiner to U.S. applications and their prosecution history on PAIR, or other electronic databases available to the Examiner, there is no need for Applicants to submit copies of any paper in the file wrapper for any U.S. application.

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 Director is hereby requested and authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 50-1283 which the undersigned is authorized to draw.

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: December 20, 2017

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 91543

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

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

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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/816,154	11/17/2017	Stephen Perrett	ADAR-119/05US 325049-2804

CONFIRMATION NO. 4432

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

FORMALITIES LETTER

OC000000095835498

Date Mailed: 12/05/2017

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of $ **480** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

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

- $ **280** basic filing fee.
- $ **140** surcharge.
- $ **600** search fee.
- $ **720** examination fee.
- $ **480** for **6** total claims over 20.

- $(**0**) previous unapplied payment amount.
- $ **2220** TOTAL FEE BALANCE DUE.

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

Replies should be mailed to:

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

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

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

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

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

/ttruong/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/816,154

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	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6			OR	x 80 =	480
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 420 =	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	2080

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.

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
15/816,154	11/17/2017	1629	0.00	ADAR-119/05US 325049-2804	26	1

CONFIRMATION NO. 4432

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

FILING RECEIPT

OC000000095835497

Date Mailed: 12/05/2017

Receipt is acknowledged of this non-provisional 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 APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Inventor(s)

Stephen Perrett, Princeton, NJ;
Fredric Jay Cohen, Washington Crossing, PA;
Gopi Venkatesh, Vandalia, OH;

Applicant(s)

Adare Pharmaceuticals, Inc., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 91543

Domestic Priority data as claimed by applicant

This application is a CON of 15/205,390 07/08/2016
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: No

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: 12/01/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/816,154**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

514

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.

PTO/AIA/15 (03-13)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	ADAR-119/05US 325049-2804
First Inventor	PERRETT, Stephen
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Express Mail 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* **32**] 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 Sheets* **5**] *(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 PARTS

10. ☐ **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. ☒ **37 CFR 3.73(c) Statement** ☒ **Power of Attorney** *(when there is an assignee)*
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: 91543 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Jonathan M. Cousin/	Date	November 17, 2017
Name (Print/Type)	Jonathan M. Cousin	Registration No. (Attorney/Agent)	66418

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.

American LegalNet, Inc. www.FormsWorkFlow.com

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/05US 325049-2804
	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	142 Leabroock Lane		
Address 2			
City	Princeton	State/Province	NJ
Postal Code	08540	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	52 Bailey Drive		
Address 2			
City	Washington Crossing	State/Province	PA
Postal Code	18977	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gopi		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-119/05US 325049-2804
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

City	Vandalia	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

Address 1	780 Waldsmith Way		
Address 2			
City	Vandalia	**State/Province**	OH
Postal Code	45377	**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	91543		
Email Address	zpatdcdocketing@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	ADAR-119/05US 325049-2804	**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-119/05US 325049-2804
	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	91543		

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	15205390	2016-07-08

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15205390	Continuation of	14311732	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)
14311732	Division of	12896005	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)
12896005	Claims benefit of provisional	61247642	2009-10-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/05US 325049-2804
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/05US 325049-2804
	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-119/05US 325049-2804
	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, Inc.		
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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ADAR-119/05US 325049-2804
	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)	2017-11-17
First Name	Jonathan M.	Last Name	Cousin	Registration Number	66418

Additional Signature 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-119/05US 325049-2804
	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

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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.

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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.

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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.

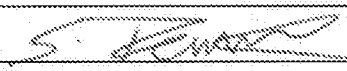
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LEGAL NAME OF INVENTOR

Inventor: Stephen PERRETT Date (Optional): 10 May 2016

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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☒ United States application or PCT international application number 14/311,732 filed on June 23, 2014.

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I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

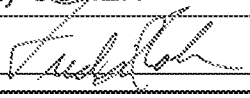
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LEGAL NAME OF INVENTOR

Inventor: Fredric Jay COHEN Date (Optional): 11 May 2016

Signature: 

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Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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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.

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LEGAL NAME OF INVENTOR

Inventor: Gopi VENKATESH Date (Optional): Aug 20, 2014

Signature: G. M Venkatesh

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Attorney Docket No. ADAR-119 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	See Attached Schedule A
Serial No.:	See Attached Schedule A
Filed:	See Attached Schedule A
FOR:	SEE ATTACHED SCHEDULE A

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

POWER BY ASSIGNEE AND STATEMENT UNDER 37 C.F.R. §3.73(c)

The Assignee of the entire right, title, and interest in and to the applications in Schedule A hereby grants the registered practitioners of Cooley LLP included in the Customer Number provided below power to act, prosecute, and transact all business in the U.S. Patent and Trademark Office in connection with the applications in Schedule A, any applications claiming priority to the applications in Schedule A, and any patents issuing therefrom.

The Assignee certifies that to the best of its knowledge and belief it is the owner of the entire right, title, and interest in and to the applications in Schedule A as evidenced by:

☐ An assignment document, a copy of which is enclosed herewith and is being recorded with the U.S. Patent and Trademark Office concurrently herewith;

☒ An assignment previously recorded in the U.S. Patent and Trademark Office at Reel **See Schedule A**, Frame **See Schedule A**.

Please direct all telephone calls and correspondence to:

CUSTOMER NUMBER: 91543

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004
Tel: (202) 842-7839
Fax: (202) 842-7899

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the Assignee.

Date: 2 Oct 2015

Signature:

Name: [illegible]

Title: IP MANAGER

Company: Adare Pharmaceuticals, Inc.

SCHEDULE A

Applications

Title	Patent/Application Serial Number	Filing Date	Reel/Frame
ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	61/247,642	October 1, 2009	023462 / 0611 036307 / 0725
ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	12/896,005	October 1, 2010	025530 / 0062 025530 / 0272 027028 / 0048
ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	14/294,660	June 3, 2014	036279 / 0804 036314 / 0203
ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	14/311,732	June 23, 2014	036279 / 0866 036314 / 0231

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a divisional application of U.S. Patent Application Serial No. 12/896,005, filed October 1, 2010, and claims priority to U.S. Provisional Application No. 61/247,642, filed October 1, 2009, the disclosures of which is herein incorporated by reference in its entirety for all purposes.

TECHNICAL FIELD OF THE INVENTIONS

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

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.

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.

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.

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

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.

In another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, and a pharmaceutically acceptable substantially non-aqueous liquid.

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.

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.

In yet another embodiment, the present invention is direction to a composition in solid or liquid form additionally comprising cyclodextrins.

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

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.

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).

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.

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").

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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".

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

Examples of suitable disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrilin potassium, sodium starch glycolate, starch, pregelatinized starch, and carboxymethyl starch (e.g. Primogel® and Explotab®).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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, acielovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, durunavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate, etravirine, famciclovir, fosamprenavir, ganciclocvir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, loviride, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon α-2a, pegylated interferon α-2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegrvir, ritonavir, ribavirin, rimantadine, rlipivirine, saquinavir, stampidine,

stavudine, tenofovir, tipranavir, TNX-355, trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

In 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.

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).

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.

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%.

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%.

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.).

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.

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.

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.

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.

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.

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.

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.

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

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%.

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

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.

The tablets are tested in the USP <701> Disintegration test and disintegrate in about 60 seconds or less.

EXAMPLE 2

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.

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.

The film, resulting from the application of this gel to a mucosal surface adheres to the surface and requires mechanical effort for its removal.

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

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

3. The liquid pharmaceutical composition of claim 2, wherein the liquid is selected from the group consisting of alcohols, oils; glycols; glycol ethers; pyrrolidones; polyethylene glycols, glycerol and combinations thereof.

4. The liquid pharmaceutical composition of claim 3, wherein the liquid is selected from the group consisting of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof.

5. The liquid pharmaceutical composition of claim 1, further comprising a phase change agent dissolved or suspended in said liquid, wherein after administration to a patient, said composition undergoes a change in physical properties of the composition upon contact with the gastrointestinal tract of said patient, whereby contact of the corticosteroid with the gastrointestinal tract of the patient is enhanced and/or prolonged.

6. The liquid pharmaceutical composition of claim 5, wherein after administration to a patient, said composition precipitates onto the mucosa of the gastrointestinal tract of the patient, whereby deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

7. The liquid pharmaceutical composition of claim 5, wherein after administration to a patient, said composition forms a gel on contact with the mucosa of the gastrointestinal tract of the patient, whereby the deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.

8. The liquid pharmaceutical composition of claim 1, wherein after administration to a patient, said composition increases in viscosity upon contact with the mucosa of the gastrointestinal tract of the patient, whereby the residence time of the corticosteroid on the mucosa of the intestinal tract is prolonged.

9. The liquid pharmaceutical composition of claim 5, wherein said phase change agent is a poorly water-soluble polymer.

10. The liquid pharmaceutical composition of claim 5, wherein said phase change agent is a thermosensitive polymer whose aqueous viscosity changes in the range of about 15 – 40°C.

11. The liquid pharmaceutical composition of claim 5, wherein said phase change agent increases in viscosity upon contact with the fluids of the oropharynx.

12. The liquid pharmaceutical composition of claim 5, wherein the phase change agent is a polymer selected from the group consisting of poly(N-isopropylacrylamide), poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol) and mixtures thereof.

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

14. The pharmaceutical composition of claim 7, wherein said liquid is water-miscible and said phase change agent is a bio-gelling polymer having a low water-solubility.

15. The pharmaceutical composition of claim 14, wherein said water-miscible solvent is selected from the group consisting of ethanol, isopropyl alcohol, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol, propylene glycol, polyethylene glycol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, diethyl carbonate,

propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, and combinations thereof.

16. The pharmaceutical composition of claim 14, wherein said bio-gelling polymer is selected from the group consisting of polylactides, polyglycolides, polycaprolactones, polydioxannones, polycarbonates, polyhydroxybutyrates, polyalkyene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, cellulose derivatives, cellulose esters, methacrylic acid and methacrylate polymers, and copolymers, terpolymers and mixtures thereof.

17. The pharmaceutical composition of claim 16, wherein said bio-gelling polymer is ethylcellulose.

18. The pharmaceutical composition of claim 11, wherein said increase in viscosity is at least 50%.

19. The pharmaceutical composition of claim 11, wherein said increase in viscosity is at least 100%.

20. The pharmaceutical composition of claim 11, wherein said increase in viscosity is at least 200%.

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

22. The method of claim 21, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.

23. The method of claim 21, wherein said condition is eosinophilic esophagitis.

24. The method of claim 21, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

25. The method of claim 21, wherein said condition is viral or bacterial pharyngitis.

26. The method of claim 21, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

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 Acknowledgement Receipt

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Confirmation Number:	4432
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	91543
Filer:	Jonathan M. Cousin
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	ADAR-119_05US_UtilityTransmittal.pdf	240276 40264bc7dcd4e95a39b7c0923f295297079ddeb7	no	1

Warnings:

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2	Application Data Sheet	ADAR-119_05US_ADS.pdf	124804 8a114362a09806a1e850a418aa8ce4d733386501	no	9
Warnings:					
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3	Oath or Declaration filed	ADAR-119_05US_Decs.pdf	6438834 55b3a45e97fa44844c7809e9ddd1504cc43ba401	no	5
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Specification	1	27
Claims	28	31
Abstract	32	32

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