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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

58249 7590 05/06/2025

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
05/06/2025	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

PTOL-90A (Rev. 04/07)

APPLICATION NO.	ISSUE DATE	PATENT NO.
17/569,047	06-May-2025	12290598

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

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	05/06/2025	12290598	ELLO-119/08US 342083-2017	8616

58249 7590 04/16/2025

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. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

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 205 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 Center (https://patentcenter.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 Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

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

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Ellodi Pharmaceuticals, L.P., Lawrenceville, NJ;

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.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**04/04/2025 11:21:58 AM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	69869015	AUTHORIZED BY	Matthew Scheideman
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	**E202544B22165540**	**Jules Lange**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1501	UTILITY ISSUE FEE	1290.00	1	1290.00
			TOTAL AMOUNT:	**$1,290.00**

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 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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

P.O. Box 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**04/04/2025 11:21:58 AM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	69869015	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Scheideman

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
ELLO-119_08US_Issue Fee.pdf	1	Issue Fee Payment (PTO-85B)	316 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
ELLO-119_08US_Issue Fee.pdf	C3200B27D86D90160A853CB1C342994397B0D85A964244A708 B950E79BD8DFEC0E530AE850F6AAD7A17D5BA40F8097DC97 A15891DF0A25C2C3320A6CFBF52F46

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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New International Application Filed with the USPTO as a Receiving Office

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

PART B–FEE(S) TRANSMITTAL

Complete and send this form, together with the applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

58249 7590 03/24/2025
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004

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

Certificate of Mailing or Transmission

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

(Typed or printed name)

(Signature)

(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

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	$1,290.00	$0.00	$0.00	$1,290.00	06/24/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
A. Sasan	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/AIA/47 or 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. COOLEY LLP
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: Ellodi Pharmaceuticals, L.P.

(B) RESIDENCE: (CITY and STATE or COUNTRY): Lawrenceville, New Jersey

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)

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

☒ Electronic Payment via the USPTO patent electronic filing system ☐ 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. 50-1283

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29. NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27. NOTE: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status. NOTE: Checking this box will be taken as 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 /Matthew H Scheideman/ Date April 4, 2025

Typed or printed name Matthew H. Scheideman Registration No. 76,605

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

58249 7590 03/24/2025

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

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/24/2025

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

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	$1290	$0.00	$0.00	$1290	06/24/2025

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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 the USPTO patent electronic filing system.

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

58249 7590 03/24/2025

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

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

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	$1290	$0.00	$0.00	$1290	06/24/2025

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1_____
2_____
3_____

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

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document 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)

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

❑ Electronic Payment via the USPTO patent electronic filing system ❑ 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
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

58249 7590 03/24/2025

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

DATE MAILED: 03/24/2025

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) 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));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/569,047	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 RCE and IDS filed on 01/22/25 and the IDS filed on 02/06/25.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 1-19,28 and 31-44 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

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

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

   * Certified copies not received: _____ .

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

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

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

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

Attachment(s)

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

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Notice of Pre-AIA or AIA Status

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

Continued Examination under 37 CFR 1.114

2. 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 allowance, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). 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, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01/22/25 has been entered.

Information Disclosure Statement

3. The information disclosure statements (IDS) filed on 01/22/25 and 02/06/25 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. See attached copies of PTO-1449.

Reasons for Allowance

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

Terminal Disclaimer

5. The terminal disclaimer filed on 07/23/24 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of Patent Numbers 8,771,729 and 9,486,407, as well as the terminal disclaimer filed on 08/09/24 disclaiming the terminal portion of any patent granted on this application which

Dr. Falk Pharma Ex. 1096
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would extend beyond the expiration dates of Patent Numbers 11,266,598; 11,246,828; and 10,632,069 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Closest prior art

6. The closest prior art is Singh *et al.* (US 7,122,198 B1 – Document Number 006 in IDS filed on 07/25/24). Singh *et al.* teach a fast dissolving composition (Abstract), in the form of a compressed tablet which when orally administered dissolves or disperses in the mouth within one minute (Col. 2, lines 30-36 and Col. 24, lines 2-6). The drugs include glucocorticoids such as budesonide (Col. 16, lines 56-58). However, Singh *et al.* do not teach or suggest that their fast dissolving tablet contains about 0.5 mg to about 6 mg of budesonide, the deposition of the corticosteroid in the esophagus, or that the hardness of the tablet is 4-48 N or the friability of not more than 1%, as recited in instant claim 1.

IDS consideration

7. Applicants' IDS submitted on 01/22/25 and 02/06/25 did not change the previous determination of patentability since the references do not teach an orally disintegrating tablet comprising about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide and at least one disintegrant wherein the corticosteroid is deposited in the esophagus, and the tablet has a hardness of 4-48 N or a friability of not more than 1%, as recited in the instant claims.

Updated Search

8. An updated prior art search did not uncover a reference that teaches an orally disintegrating tablet comprising about 0.5 mg to about 6 mg of a corticosteroid selected

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from fluticasone propionate or budesonide and at least one disintegrant wherein the corticosteroid is deposited in the esophagus, and the tablet has a hardness of 4-48 N or a friability of not more than 1%, as recited in the instant claims.

Therefore, the claimed invention is patentable.

Comments

9. 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

10. Claims **1-19, 28, and 31-44** are allowed.

11. 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 on 571-272-6023. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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PGR Petition - USP 12,290,598

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	03/21/2024	AS
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	10/15/2024	AS
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	03/14/2025	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

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
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Search Notes		
Search Notes	**Date**	**Examiner**
Reviewed IDS, prosecution history of related cases, PDP search, DAV continuity data map and inventor info tabs. PE2E Search - including CPC with keyword, inventor, assignee, applicant name, and interference search. STIC/NPL search. Please see the attached history for each search.	03/21/2024	AS
Reviewed IDS, updated PDP search, DAV continuity data map and inventor info tabs. PE2E Search - including CPC with keyword, inventor, assignee, applicant name, and interference search. SciFinder/NPL search. Please see the attached history for each search.	10/15/2024	AS
IPR2024-01197 Reviewed Petition for Inter Partes Review of U.S. Patent No. 8,771,729 on 10/15/24	10/15/2024	AS
Reviewed IDS filed on 01/22/25 and 02/06/25. IPR2024-01197 Reviewed Petition for Inter Partes Review of U.S. Patent No. 8,771,729 on 03/14/25	03/14/2025	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 (fluticasone near2 propionate) same (time period second minute)).clm.	03/21/2024	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

	((("ODT") ((oral$2 intraoral$2 "intra-oral" " intra-orally" oromucosal$2 "oro-mucosal" " oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona $4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene -17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair $4)).clm.	10/15/2024	AS
	N444» AND (hard hardness friability).clm.	10/15/2024	AS
	((("ODT") ((oral$2 intraoral$2 "intra-oral" " intra-orally" oromucosal$2 "oro-mucosal" " oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona $4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene -17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair $4)).clm.	03/14/2025	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

	AND (hard hardness friability).clm.	03/14/2025	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	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)	34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	14 March 2025	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20250314

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	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 (Assistant Examiner)	(Date)	**Total Claims Allowed:** 34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	14 March 2025 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20250314

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	**Art Unit**
	ARADHANA SASAN	1615

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

CLAIMS

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

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	14 March 2025 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20250314

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
			None			

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]
			None				

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.

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Form used in lieu of PTO/SB/08a/b (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	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		001	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), DECISION Granting Institution of Inter Partes Review 35 U.S.C. § 314 dated January 27, 2025, 43 pages.	☐
		002	Inter Partes Review Proceedings No. IPR2025-00052 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 10,632,069 (U.S. Application No. 15/816,154), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		003	Inter Partes Review Proceedings No. IPR2025-00054 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 11,246,828 (U.S. Application No. 16/821,464), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		004	Inter Partes Review Proceedings No. IPR2025-00055 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 9,486,407 (U.S. Application No. 14/294,660), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		005	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 11,260,061 (U.S. Application No. 17/211,119), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	03/14/2025

*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.

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

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

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Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-12059494	08-13-2024	MELTZER; Brian A. 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]
		002	EP-3041476-B1	11-06-2019	ADARE PHARMACEUTICALS INC.		☐
		003	WO-9947144-A1	09-23-1999	PHARMALINK BASLAEKEMEDEL AB		☐

Examiner Signature		Date Considered	

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		004	ALLEN, L.V. and LUNER, P.E., "Magnesium Stearate", Date of Revision: August 9, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 430-433, 7 pages.	☐
		005	ARMSTRONG, N.A., "Mannitol", Date of Revision: August 16, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 449-453, 7 pages.	☐
		006	CONWAY, B.R., "Solid Dosage Forms", In: Pharmaceutical Manufacturing Handbook: Production and Processes (2008); by GAD, Shayne Cox; Ch. 4.1, pages 235-265, 36 pages.	☐
		007	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00052) of U.S. Patent No. 10,632,069 dated October 8, 2024, filed October 24, 2024, 165 pages.	☐
		008	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00054) of U.S. Patent No. 11,246,828 dated October 8, 2024, filed October 24, 2024, 197 pages.	☐
		009	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00055) of U.S. Patent No. 9,486,407 dated October 22, 2024, filed October 24, 2024, 220 pages.	☐
		010	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00056) of U.S. Patent No. 11,260,061 dated October 21, 2024, filed October 24, 2024, 195 pages.	☐
		011	Definition of "Adsorption", McGraw-Hill Dictionary of Scientific and Technical Terms, Sixth Edition (2003); page 41, 3 pages.	☐
		012	EL-ARINI, S.K., et al., "Evaluation of disintegration testing of different fast dissolving tablets using the texture analyzer", Pharm Dev Technol. 2002; 7(3): 361-371.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		013	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Patent Owner's Preliminary Response, dated and filed October 29, 2024, 59 pages.	☐
		014	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Patent Owner's Surreply, dated and filed December 4, 2024, 8 pages.	☐
		015	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petitioner's Reply to Patent Owner's Preliminary Response dated and filed November 26, 2024, 8 pages.	☐
		016	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed November 26, 2024, 4 pages.	☐
		017	Inter Partes Review Proceedings No. IPR2025-00052 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 10,632,069 (U.S. Application No. 15/816,154), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 83 pages.	☐
		018	Inter Partes Review Proceedings No. IPR2025-00054 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 11,246,828 (U.S. Application No. 16/821,464), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 91 pages.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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		019	Inter Partes Review Proceedings No. IPR2025-00055 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 9,486,407 (U.S. Application No. 14/294,660), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 103 pages.	☐
		020	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 11,260,061 (U.S. Application No. 17/211,119), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 107 pages.	☐
		021	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Redline comparison of Dohil (US2007/0111978) and Dohil 2009 (US2009/0191275), Exhibit 1059 filed October 24, 2024, 47 pages.	☐
		022	KHAN et al., "AN APPROACH FOR RAPID DISINTEGRATING TABLET: A REVIEW", IJPRD, 2011 May; Vol 3(3): 21; pages 170-183.	☐
		023	KIBBE, A.H., "Povidone", Date of Revision: August 30, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 611-616, 9 pages.	☐
		024	MARTIN, Alfred, et al., "Adsorption at Solid Interfaces", (with the participation of Pilar Bustamente), In: Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, Fourth Edition (1993); Print. No. 10, Ch. 14, pages 379-386, 11 pages.	☐
		025	MORETON, R.C., "Cellulose, Silicified Microcrystalline", Date of Revision: August 26, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 139-141, 5 pages.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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		026	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Interlocutory Decision dated January 26, 2022, 30 pages.	☐
		027	PRICE, J.C., "Polyethylene Glycol", Date of Revision: August 29, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 545-550, 8 pages.	☐
		028	Prosecution history excerpts from U.S. Application No. 14/917,125 filed September 5, 2014, for CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS; Inventors GOSSELIN, Michael A., issued as U.S. 10,471,071, 123 pages.	☐
		029	Prosecution history excerpts from U.S. Application No. 17/211,119 filed March 24, 2021, for CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS; Inventors GOSSELIN, Michael A., issued as U.S. 11,260,061, 248 pages.	☐
		030	Prosecution history from U.S. Application No. 15/816,154 ('069 Patent) filed November 17, 2017, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 10,632,069, 408 pages.	☐
		031	Prosecution history from U.S. Application No. 16/821,464 ('828 Patent) filed March 17, 2020, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 11,246,828, 369 pages.	☐
		032	ROEDER et al., "Safety and Efficacy of Fluticasone Propionate in the Topical Treatment of Skin Diseases", Skin Pharmacol Physiol (2005); 18 (1): 3-11.	☐
		033	The United States Pharmacopeial Convention, "701 Disintegration", Revision Bulletin, Official August 1, 2008, USP 32 (2009); 3 pages.	☐
		034	U.S. Patent Application No. 18/244,500, inventor MELTZER, Brian A., et al., filed September 11, 2023.	☐

Examiner Signature		Date Considered	

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Sheet 6 of 6

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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		035	U.S. Patent Application No. 18/755,113, inventor MELTZER; Brian A, filed June 26, 2024.	☐
		036	WOOD, A.W., "Sucralose", Date of Revision: August 17, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 742-749, 11 pages.	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	03/14/2025

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L506	16	"12896005"	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:37 AM
L507	0	L506 AND hardness.clm. AND friability.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:37 AM
L508	0	L506 AND hard$4.clm. AND friab$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:38 AM
L509	1	"17569047"	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:38 AM
L510	0	L509 AND hard$4.clm. AND friab$4.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:38 AM
L511	0	L509 AND (hard$4 friab$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/03/14 11:38 AM
L512	11585	(((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 11:39 AM
L513	4294	((((fluticasone near2	(US-PGPUB; USPAT;	OR	ON	ON	2025/03/14

		propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND (hard$4 friab$6)	USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				11:40 AM
L514	134	((((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate,	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 11:40 AM

		17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND (hard$4 friab$6) AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute))					
L515	112	((((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 11:41 AM

		spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND (hardness friability) AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute))					
L516	1	("12059494").pn.	(USPAT)	OR	ON	ON	2025/03/14 11:46 AM
L517	165	((((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 11:59 AM

		jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute))						
L518	683	(((((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND (("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 11:59 AM

		oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid)))					
L519	749115	(A61K9/0065 or A61K31/56 or A61K9/006 or A61K9/0056 or A61K9/08 or A61K45/06 or A61K9/0053 or A61K47/38 or A61K31/58 or A61K31/569 or A61K9/06).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 12:58 PM
L520	588	(A61K31/569 same A61K2300/00).cpcc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 12:59 PM
L521	749115	L519 L520	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 12:59 PM
L522	470	L521 AND ((((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/03/14 12:59 PM

		budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)) AND (("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid)))					
L523	17	((("ELLODI") near3 ("PHARMACEUTICALS") near3 ("L.P"))).AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L524	17	("ELLODI").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L525	76	("EURAND").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L526	69	("APTALIS").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L527	85	("ADARE").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L528	207	((("PERRETT") near3 ("Stephen")) OR (("COHEN") near3 ("Fredric")) OR (("VENKATESH") near3 ("Gopi"))).INV,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:00 PM
L529	332	L523 L524 L525 L526 L527 L528	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:01 PM
L530	26	L529 AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:01 PM

		compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)).clm.					
L531	0	L530 AND (hardness friability).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:01 PM
L532	33	L529 AND (esophag$7).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:02 PM
L533	0	L532 AND (hardness friability).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2025/03/14 01:02 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
			None			

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]
			None				

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.

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		001	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), DECISION Granting Institution of Inter Partes Review 35 U.S.C. § 314 dated January 27, 2025, 43 pages.	☐
		002	Inter Partes Review Proceedings No. IPR2025-00052 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 10,632,069 (U.S. Application No. 15/816,154), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		003	Inter Partes Review Proceedings No. IPR2025-00054 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 11,246,828 (U.S. Application No. 16/821,464), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		004	Inter Partes Review Proceedings No. IPR2025-00055 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 9,486,407 (U.S. Application No. 14/294,660), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 pages.	☐
		005	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), U.S. Patent No. 11,260,061 (U.S. Application No. 17/211,119), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed December 17, 2024, 3 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.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**02/06/2025 03:50:10 PM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	MaxVal Group
PATENT CENTER #	69075934	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
ELLO-119_08US_342083-2017_IDS_Transmittal.pdf		3	-	103 KB
ELLO-119_08US_342083-2017_IDS_Transmittal-TRAN.LET.pdf	(1-2)	2	Transmittal Letter	98 KB
ELLO-119_08US_342083-2017_IDS_Transmittal-IDS.SIZEFEE.pdf	(3-3)	1	Assertion regarding Information Disclosure Statement (IDS) Size Fee (SB/08C)	93 KB
ELLO-119_08US_342083-2017_IDS_SB08_20250205130713.pdf		2	Information Disclosure Statement (IDS) Form (SB08)	105 KB

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

NPL_IPR2024-01197_DECISION_Granting_Request_for_Trial_01-27-2025_43_pgs.pdf	43	Non Patent Literature	2358 KB
NPL_IPR2025-00052_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	3	Non Patent Literature	199 KB
NPL_IPR2025-00054_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	3	Non Patent Literature	201 KB
NPL_IPR2025-00055_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	3	Non Patent Literature	214 KB
NPL_IPR2025-00056_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	3	Non Patent Literature	217 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
ELLO-119_08US_342083-2017_IDS_Transmittal.pdf	A2EE4B08EB7898DF3D8126F349CD1203F9C0FCD3125E7755B02112ED30ABF7C5666058988615C1831539DFE3563FD37E7139682BCF0A2E001C6627ABBB877DDC
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ELLO-119_08US_342083-2017_IDS_Transmittal-IDS.SIZEFEE.pdf	6B7801623FA5B0E75F1D84FA8F99EA5C60067F986C9FFC064A2520C49D937114D58FF9405E6AEFBE9A199C3FFD929492B1CC3F055FAF2BA0D18D0A5D5BE3A795
ELLO-119_08US_342083-2017_IDS_SB08_20250205130713.pdf	0FAE00A4E04EE479492B29057E8C8AFF78430AB73533332CB159A0EFE77751213937D6E65EA76BF3A7414DAFD68104110FB11D03920E028F7616FE44EF89E491
NPL_IPR2024-01197_DECISION_Granting_Request_for_Trial_01-27-2025_43_pgs.pdf	C5FA9BAF7C4FA2DD67D9B929CD6A98977C32343F002EFE80FBE750D7CBBD188865CB32A5F13CC6831FF682D17EBB37E10681C1F103C7EBE2EB4CE4F2F54ECF13
NPL_IPR2025-	74C8F2684983E5E1216FFA0282B582F4022121D0127604CDCB

00052_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	B00695E919A3425B14D835220E390350FAC748C38C44AAAB7D732F3E6DEC3D8915E136AFB6B5C5
NPL_IPR2025-00054_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	4F023DE50EBBFC273AEBA329BBED47294F7F90F13D4E67F275B108793DFC3FAF18246247E6FB0D86D501395D20951C55DECDAA0E91C0A1906C6ADABC55D2C859
NPL_IPR2025-00055_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	355806BD5E25DD37EDF07C8D13DAF475FD414CB068C80A951A936E8484608FF07A8A3AD4F8283A19AF85CDEC1A60C4E074EF7A1138DCF651E151763C2BB200BF
NPL_IPR2025-00056_Related_Matters_Section_12-17-2024_3pgs_EFS.pdf	005EACA8E64E149AE9EB1D7FDB44CA42CB5D99E4AE14149140D88A9758F026A91E26662A9158C0D1C7C8684751802C1B469FA792714BB82038A9161C818E5CC9

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	Examiner:	SASAN, Aradhana

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure set forth in 37 CFR § 1.56, Applicant hereby submits this Information Disclosure Statement ("IDS") along with the attached Form used in lieu of PTO/SB/08 ("SB/08") in compliance with 37 CFR §§ 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.

In accordance with 37 CFR § 1.97(b), no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the time periods:

[ ] within three months from the filing date of this national Application other than a CPA under 37 CFR § 1.53(d);

[ ] within three months from the date of entry of the national stage as set forth in 37 CFR § 1.491 in this international Application;

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

[X] before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR § 1.114.

In agreement with 37 CFR § 1.97(g), this Information Disclosure Statement shall not be construed as a representation that a search has been made.

In agreement with 37 CFR § 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, relevant, analogous, or material to patentability as defined by 37 CFR § 1.56(b).

As required by 37 CFR § 1.98(a)(2), Applicant submits a copy of any foreign patent and non-patent literature document cited on the SB/08.

IDS SIZE FEE - WRITTEN ASSERTION UNDER 37 CFR § 1.98

As required by 37 CFR § 1.98(a)(4), Applicant asserts that with the submission of this Information Disclosure Statement, the cumulative number of items of information that have been provided to the Office during the pendency of the present Application is 513. As the filing of this Information Disclosure Statement does not cause the cumulative number of items of information to exceed any IDS size threshold specified in 37 CFR §§ 1.17(v)(1), (v)(2), or (v)(3), no IDS size fee under 37 CFR § 1.17(v) is required at this time.

The Director is hereby authorized to charge any appropriate fees set forth in 37 CFR § 1.17(p) that may be required by this Information Disclosure Statement, and to credit any overpayment, to Deposit Account No. 50-1283, referencing Docket No. ELLO-119/08US 342083-2017.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the SB/08 to the undersigned. The Examiner is encouraged to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present Application.

Dated: February 6, 2025

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER No. 58249

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

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

Electronic signature: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-12059494	08-13-2024	MELTZER; Brian A. 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]
		002	EP-3041476-B1	11-06-2019	ADARE PHARMACEUTICALS INC.		☐
		003	WO-9947144-A1	09-23-1999	PHARMALINK BASLAEKEMEDEL AB		☐

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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		004	ALLEN, L.V. and LUNER, P.E., "Magnesium Stearate", Date of Revision: August 9, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 430-433, 7 pages.	☐
		005	ARMSTRONG, N.A., "Mannitol", Date of Revision: August 16, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 449-453, 7 pages.	☐
		006	CONWAY, B.R., "Solid Dosage Forms", In: Pharmaceutical Manufacturing Handbook: Production and Processes (2008); by GAD, Shayne Cox; Ch. 4.1, pages 235-265, 36 pages.	☐
		007	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00052) of U.S. Patent No. 10,632,069 dated October 8, 2024, filed October 24, 2024, 165 pages.	☐
		008	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00054) of U.S. Patent No. 11,246,828 dated October 8, 2024, filed October 24, 2024, 197 pages.	☐
		009	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00055) of U.S. Patent No. 9,486,407 dated October 22, 2024, filed October 24, 2024, 220 pages.	☐
		010	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review (IPR2025-00056) of U.S. Patent No. 11,260,061 dated October 21, 2024, filed October 24, 2024, 195 pages.	☐
		011	Definition of "Adsorption", McGraw-Hill Dictionary of Scientific and Technical Terms, Sixth Edition (2003); page 41, 3 pages.	☐
		012	EL-ARINI, S.K., et al., "Evaluation of disintegration testing of different fast dissolving tablets using the texture analyzer", Pharm Dev Technol. 2002; 7(3): 361-371.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		013	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Patent Owner's Preliminary Response, dated and filed October 29, 2024, 59 pages.	☐
		014	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Patent Owner's Surreply, dated and filed December 4, 2024, 8 pages.	☐
		015	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petitioner's Reply to Patent Owner's Preliminary Response dated and filed November 26, 2024, 8 pages.	☐
		016	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petitioner's Supplemental Mandatory Notice: Related Matters Section dated and filed November 26, 2024, 4 pages.	☐
		017	Inter Partes Review Proceedings No. IPR2025-00052 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 10,632,069 (U.S. Application No. 15/816,154), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 83 pages.	☐
		018	Inter Partes Review Proceedings No. IPR2025-00054 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 11,246,828 (U.S. Application No. 16/821,464), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 91 pages.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		019	Inter Partes Review Proceedings No. IPR2025-00055 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 9,486,407 (U.S. Application No. 14/294,660), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 103 pages.	☐
		020	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Petition for Inter Partes Review of U.S. Patent No. 11,260,061 (U.S. Application No. 17/211,119), dated and filed October 24, 2024, and Petitioner Power of Attorney dated 06.08.2024, 107 pages.	☐
		021	Inter Partes Review Proceedings No. IPR2025-00056 filed October 24, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals L.P. (Patent Owner), Redline comparison of Dohil (US2007/0111978) and Dohil 2009 (US2009/0191275), Exhibit 1059 filed October 24, 2024, 47 pages.	☐
		022	KHAN et al., "AN APPROACH FOR RAPID DISINTEGRATING TABLET: A REVIEW", IJPRD, 2011 May; Vol 3(3): 21; pages 170-183.	☐
		023	KIBBE, A.H., "Povidone", Date of Revision: August 30, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 611-616, 9 pages.	☐
		024	MARTIN, Alfred, et al., "Adsorption at Solid Interfaces", (with the participation of Pilar Bustamente), In: Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, Fourth Edition (1993); Print. No. 10, Ch. 14, pages 379-386, 11 pages.	☐
		025	MORETON, R.C., "Cellulose, Silicified Microcrystalline", Date of Revision: August 26, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 139-141, 5 pages.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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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]
		026	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Interlocutory Decision dated January 26, 2022, 30 pages.	☐
		027	PRICE, J.C., "Polyethylene Glycol", Date of Revision: August 29, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 545-550, 8 pages.	☐
		028	Prosecution history excerpts from U.S. Application No. 14/917,125 filed September 5, 2014, for CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS; Inventors GOSSELIN, Michael A., issued as U.S. 10,471,071, 123 pages.	☐
		029	Prosecution history excerpts from U.S. Application No. 17/211,119 filed March 24, 2021, for CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS; Inventors GOSSELIN, Michael A., issued as U.S. 11,260,061, 248 pages.	☐
		030	Prosecution history from U.S. Application No. 15/816,154 ('069 Patent) filed November 17, 2017, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 10,632,069, 408 pages.	☐
		031	Prosecution history from U.S. Application No. 16/821,464 ('828 Patent) filed March 17, 2020, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 11,246,828, 369 pages.	☐
		032	ROEDER et al., "Safety and Efficacy of Fluticasone Propionate in the Topical Treatment of Skin Diseases", Skin Pharmacol Physiol (2005); 18 (1): 3-11.	☐
		033	The United States Pharmacopeial Convention, "701 Disintegration", Revision Bulletin, Official August 1, 2008, USP 32 (2009); 3 pages.	☐
		034	U.S. Patent Application No. 18/244,500, inventor MELTZER, Brian A., et al., filed September 11, 2023.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 6

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		035	U.S. Patent Application No. 18/755,113, inventor MELTZER; Brian A, filed June 26, 2024.	☐
		036	WOOD, A.W., "Sucralose", Date of Revision: August 17, 2005, In: Handbook of Pharmaceutical Excipients, 5th Ed. (2006), Raymond C. Rowe, et al. (eds); pages 742-749, 11 pages.	☐

Examiner Signature		Date Considered	

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

Application Number	17569047	Filing Date	2022-01-05	Docket Number (if applicable)	ELLO-119/08US 342083-201	Art Unit	1615
First Named Inventor	Stephen PERRETT			Examiner Name	A. Sasan		

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 _____

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 50-1283

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Signature of Registered U.S. Patent Practitioner			
Signature	/Jonathan M. Cousin/	Date (YYYY-MM-DD)	2025-01-22
Name	Jonathan M. Cousin	Registration Number	66,418

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

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent 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.

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	Examiner:	SASAN, Aradhana

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure set forth in 37 CFR § 1.56, Applicant hereby submits this Information Disclosure Statement along with the attached Form used in lieu of PTO/SB/08 ("SB/08") in compliance with 37 CFR §§ 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.

In accordance with 37 CFR § 1.97(b), no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the time periods:

[ ] within three months from the filing date of this national Application other than a CPA under 37 CFR § 1.53(d);

[ ] within three months from the date of entry of the national stage as set forth in 37 CFR § 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 CFR § 1.114.

In agreement with 37 CFR § 1.97(g), this Information Disclosure Statement shall not be construed as a representation that a search has been made.

In agreement with 37 CFR § 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, relevant, analogous, or material to patentability as defined by 37 CFR § 1.56(b).

As required by 37 CFR § 1.98(a)(2), Applicant submits a copy of any foreign patent and non-patent literature document cited on the SB/08.

As authorized by 37 CFR § 1.98(a)(2)(ii), Applicant does not submit a copy of any U.S. publication or patent information cited on the SB/08.

As authorized by the Waiver of the Copy Requirement set forth in 37 CFR § 1.98(a) for cited pending U.S. patent applications, issued October 19, 2004, Applicant does not submit a copy of any pending unpublished U.S. patent application cited on the SB/08, because a copy is stored in the USPTO's Image File Wrapper system and can be readily viewed by Examiners and the Applicant.

As specified in 37 CFR § 1.98(a)(4), Applicant asserts that the total number of items of information exceeded 200 prior to the filing of the instant Information Disclosure Statement. As such, Applicant believes under § 1.98(a)(1), no applicable size fee under 37 CFR § 1.17(v) is required.

REMARKS

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

The Examiner is encouraged 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 appropriate fees set forth in 37 CFR § 1.17(p) that may be required by this Information Disclosure Statement, and to credit any overpayment, to Deposit Account No. 50-1283, referencing Docket No. ELLO-119/08US 342083-2017.

Dated: January 22, 2025

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER No. 58249

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

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Electronic signature: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**01/22/2025 04:36:26 PM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	MaxVal Group
PATENT CENTER #	68861704	AUTHORIZED BY	Jonathan Cousin
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	**E20251LG37249812**	**Jules Lange**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1801	REQUEST FOR CONTINUED EXAMINATION (RCE) - 1ST REQUEST (SEE 37 CFR 1.114)	1500.00	1	1500.00
			TOTAL AMOUNT:	**$1,500.00**

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 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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**01/22/2025 04:36:26 PM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	MaxVal Group
PATENT CENTER #	68861704	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 52

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
ELLO-119_08US_342083-2017_IDS_Transmittal.pdf	3	Transmittal Letter	102 KB
ELLO-119_08US_342083-2017_IDS_SB08_20250122112037.pdf	6	Information Disclosure Statement (IDS) Form (SB08)	136 KB
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FOR_EP3041476B1_EFS.pdf	32	Foreign Reference	2014 KB
FOR_WO9947144A1_EFS.pdf	21	Foreign Reference	836 KB
NPL_ALLEN-and-LUNER_revised2005_2006_	7	Non Patent Literature	9890 KB

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PGR Petition - USP 12,290,598

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NPL_ARMSTRONG-Mannitol_2006_7pgs.pdf	7	Non Patent Literature	7196 KB
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NPL_DECL-ALAN_PARR_10-08-2024_165_pgs_Part2.pdf	76	Non Patent Literature	21861 KB
NPL_DECL-ALAN_PARR_10-08-2024_165_pgs_Part1.pdf	89	Non Patent Literature	24410 KB
NPL_IPR2025-00054_DECL-ALAN_PARR_10-08-2024_197_pgs_Part2.pdf	86	Non Patent Literature	24502 KB
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NPL_IPR2025-00052_Petition_10-24-2024_83_pgs.pdf	83	Non Patent Literature	9981 KB
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Digest

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ELLO-119_08US_RCE.pdf	25FE95D1740EFD4424318DAC5940ACF91098E01AAFEB14845870F749F7FE997C37A154E77E87F7408E92439793BE4B61CBA0865F9EDF6075D3E9362A4A560D3D

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

58249 7590 10/22/2024

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

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/22/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/22/2025

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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 the USPTO patent electronic filing system.

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

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

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

58249 7590 10/22/2024
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	01/22/2025

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1_____
2_____
3_____

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

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document 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)

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

❑ Electronic Payment via the USPTO patent electronic filing system ❑ 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
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

EXAMINER
SASAN, ARADHANA

ART UNIT	PAPER NUMBER
1615	

58249 7590 10/22/2024

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

DATE MAILED: 10/22/2024

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) 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));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Notice of Allowability	Application No. 17/569,047	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 See Continuation Sheet.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 1-19,28 and 31-44 . 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

Continuation of 1. This communication is responsive to: the Amendments, Remarks, and Terminal Disclaimer filed on 07/23/24, and the Terminal Disclaimer filed on 08/09/24

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Notice of Pre-AIA or AIA Status

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

Status of Application

2. The Amendments, Remarks and Terminal Disclaimer filed on 07/23/24 and the Terminal Disclaimer filed on 08/09/24 are acknowledged.

3. Claims 20-27 and 29-30 were previously cancelled.

4. Claims 1-3, 5, 8-12, 18-19, and 28 were amended.

5. New claims 31-44 were added.

6. Claims 1-19, 28, and 31-44 are pending.

Information Disclosure Statement

7. The information disclosure statement (IDS) filed on 07/25/24 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.

Withdrawn Objections and Rejections

8. In light of the amendment of claims 1, 18-19, and 28, the objections and rejection under 35 U.S.C. 112(b) are withdrawn.

Reasons for Allowance

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

Terminal Disclaimer

10. The terminal disclaimer filed on 07/23/24 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Patent Numbers 8,771,729 and 9,486,407, as well as the terminal disclaimer filed on 08/09/24 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of Patent Numbers 11,266,598; 1,246,828; and 10,632,069 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Closest prior art

11. The closest prior art is Singh *et al.* (US 7,122,198 B1 – Document Number 006 in IDS filed on 07/25/24). Singh *et al.* teach a fast dissolving composition (Abstract), in the form of a compressed tablet which when orally administered dissolves or disperses in the mouth within one minute (Col. 2, lines 30-36 and Col. 24, lines 2-6). The drugs include glucocorticoids such as budesonide (Col. 16, lines 56-58). However, Singh *et al.* do not teach or suggest that their fast dissolving tablet contains about 0.5 mg to about 6 mg of budesonide, the deposition of the corticosteroid in the esophagus, or that the hardness of the tablet is 4-48 N or the friability of not more than 1%, as recited in instant claim 1.

Updated Search

12. An updated prior art search did not uncover a reference that teaches an orally disintegrating tablet comprising about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide and at least one disintegrant wherein the corticosteroid is deposited in the esophagus, and the tablet has a hardness of 4-48 N or a friability of not more than 1%, as recited in the instant claims.

Therefore, the claimed invention is patentable.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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 **1-19, 28,** and **31-44** 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 on 571-272-6023. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	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

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	15 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	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)**					

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	15 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	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

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 34	
/ARADHANA SASAN/ Primary Examiner, Art Unit 1615 (Primary Examiner)	15 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	03/21/2024	AS
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	10/15/2024	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

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
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Search Notes		
Search Notes	**Date**	**Examiner**
Reviewed IDS, prosecution history of related cases, PDP search, DAV continuity data map and inventor info tabs. PE2E Search - including CPC with keyword, inventor, assignee, applicant name, and interference search. STIC/NPL search. Please see the attached history for each search.	03/21/2024	AS
Reviewed IDS, updated PDP search, DAV continuity data map and inventor info tabs. PE2E Search - including CPC with keyword, inventor, assignee, applicant name, and interference search. SciFinder/NPL search. Please see the attached history for each search.	10/15/2024	AS
IPR2024-01197 Reviewed Petition for Inter Partes Review of U.S. Patent No. 8,771,729 on 10/15/24	10/15/2024	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (fluticasone near2 propionate) same (time period second minute)).clm.	03/21/2024	AS
	((("ODT") ((oral$2 intraoral$2 "intra-oral" " intra-orally" oromucosal$2 "oro-mucosal" " oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona $4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene -17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair $4)).clm.	10/15/2024	AS
	N444» AND (hard hardness friability).clm.	10/15/2024	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

CAS SciFinder

Task History

Initiating Search

October 15, 2024, 1:01 PM

References: From Selected Result(s)

Filtered By:

Search Within Results: orally disintegrating tablet

Search Tasks

Task	Search Type	View
Exported: Returned Reference Results + Filters (12)	References	View Results

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CAS SciFinder

References (12)

View in CAS SciFinder

1

A new formulation for orally disintegrating tablets using a suspension spray-coating method

8 Substances • 0 Reactions • 60 Citations

By: Okuda, Y.; Irisawa, Y.; Okimoto, K.; Osawa, T.; Yamashita, S.

International Journal of Pharmaceutics (2009), 382(1-2), 80-87 | Language: English, Database: CAplus and MEDLINE

The aim of this study was to design a new orally disintegrating tablet (ODT) that has high tablet hardness and a fast oral disinte gration rate using a new prepar ation method. To obtain rapid disinte gration granules (RDGs), a saccharide, such as trehalose, mannitol, or lactose, was spray-coated with a suspension of corn starch using a fluidized-bed granulator (suspension method). As an addnl. disintegrant, crospovidone, light anhydrous silicic acid, or hydroxypropyl starch was also included in the suspension. The RDGs obtained possessed extremely large surface areas, narrow particle size distrib ution, and numerous micro-pores. When tableting these RDGs, it was found that the RDGs increased tablet hardness by decreasing plastic deform ation and increasing the contact frequency between granules. In all tablets, a linear relationship was observed between tablet hardness and oral disinte gration time. From each linear correl ation line, a slope (D/H value) and an intercept (D/H_0 value) were calculated Tablets with small D/H and D/H_0 values could disintegrate immedi ately in the oral cavity regardless of the tablet hardness and were considered to be appropriate for ODTs. Therefore, these values were used as key parameters to select better ODTs. Of all the RDGs prepared in this study, mannitol spray-coated with a suspension of corn starch and crospo vidone (2.5:1 weight/weight ratio) showed most appropriate properties for ODTs; fast in vivo oral disintegration time, and high tablet hardness. In conclusion, this simple method to prepare superior formulations for new ODTs was established by spray-coating mannitol with a suspension of approp riate disinte grants.

Keywords: drug tablet spray coating disintegrant disintegration mouth

Substances (8) | Reactions (0) | Citing (60)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

2

The use of the SeDeM Diagram expert system to determine the suitability of diluents-disintegrants for direct compression and their use in formulation of ODT

14 Substances • 0 Reactions • 46 Citations

By: Aguilar-Diaz, Johnny Edward; Garcia-Montoya, Encarnacion; Perez-Lozano, Pilar; Suna-Negre, Jose Maria; Minarro, Montserrat; Tico, Jose Ramon

European Journal of Pharmaceutics and Biopharmaceutics (2009), 73(3), 414-423 | Language: English, Database: CAplus and MEDLINE

The new SeDeM Diagram expert system was used to analyze the suitability of 43 excipients for direct compression with disintegrant properties from eight chem. families. The SeDeM Diagram expert system is a new method for use in tablet preformulation and formulation studies. It provides the profile of a substance in powder form in terms of its suitability for direct compression. This study, which was based on the current concept of "Quality by Design ICH Q8", evaluated the pharmacotech. properties of disintegrants in powder form and selected the candidates that were most suitable for direct compression and their use in formulation of orally disintegrating tablets (ODT). To achieve this, each disintegrant and its chem. families were individually analyzed. It was concluded that nine disintegrants had an SeDeM value with the index of good compression (IGC) over 5. Most of these disintegrants were from the microcellulose family. Other disintegrants had indexes that were close to 5. It is assumed that these excipients can be used in direct compression, when they are added to other excipients.

Keywords: disintegrant compressibility disintegration diluent Avicel

Substances (14) Reactions (0) Citing (46)

3

Composition of and method for preparing orally disintegrating tablets

27 Substances • 0 Reactions • 2 Citations

Assignee: Mallinckrodt Inc.

World Intellectual Property Organization, WO2008079342 A2 2008-07-03 | Language: English, Database: CAplus

An improved orally dissolving tablet (ODT) and method of manufacture is provided. The improved ODT disclosed herein are prepared by direct compression of a mixture of pharmaceutical excipients including at least one water-insoluble hydrophobic inorganic salt in combination with at least one water-insoluble inorganic salt with less hydrophobicity compared to the water-insoluble hydrophobic inorganic salt component. These components may be formed into granules, and may include other commonly used excipients. In an illustrative embodiment, the granules are formed into tablets by direct compression, optionally using a lubricant. The fast disintegrating tablets prepared using these components exhibit desirable performance properties such as sufficient hardness, low friability, quick disintegration time and good mouth-feel when compared to conventional ODT. A further advantage is that the improved ODT may be manufactured using commonly available manufacturing equipment for granulation, blending and tableting. Thus, fast-disintegrating tablets were prepared from dry blend comprising 600 g of spray-dried mannitol, 100 g of Crospovidone XL-10, 160 g of hydrophobically modified calcium silicate, and 130 g of talc blended for 30 min, and then lubricated with 10 g of magnesium stearate dihydrate for 5 min. The lubricated blend was compressed into tablets at a main compression force of 15 kilonewtons and a precompression force of 1000 newtons at 60 rpm.

Keywords: tablet oral disintegration dosage controlled release hardness friability solubility

PatentPak available

Substances (27) Reactions (0) Citing (2)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

4

Design, development, and optimization of orally disintegrating tablets of etoricoxib using vacuum-drying approach

8 Substances • 0 Reactions • 7 Citations

By: Patel, Dharmesh; Shah, Mohit; Shah, Sunny; Shah, Tejal; Amin, Avani

PDA journal of Pharmaceutical Science and Technology (2008), 62(3), 224-232 | Language: English, Database: CAplus and MEDLINE

Etoricoxib is a cyclooxygenase 2 (COX-2) inhibitor that selectively inhibits the COX-2 enzyme and decreases the incidences of side effects associated with these agents. It is commonly prescribed for acute pain, gouty arthritis, and rheumatoid arthritis. Conventional tablets of etoricoxib are not capable of rapid action, which is required for faster drug effect onset and immediate relief from pain. Thus, the aim of the present investigation is to formulate orally disintegrating tablets (ODTs) of etoricoxib. A combination of the superdisintegrants with a sublimation technique was used to prepare the tablets. Tablets were prepared using a direct compression method employing superdisintegrants such as low substituted hydroxylpropyl Me cellulose (L-HPMC), low substituted hydroxylpropyl cellulose (L-HPC), crospovidone, croscarmellose sodium, and sodium starch glycolate. Tablets of etoricoxib prepared using L-HPC exhibited the least friability and disintegration time (~65 s). To decrease the disintegration time further, a sublimation technique was used along with the superdisintegrants for the preparation of ODTs. The use of subliming agents including camphor, menthol, and thymol was explored. The addition of camphor lowered the disintegration time (~30 s) further, but the percent friability was increased. A 3^2 full factorial design was employed to study the joint influence of the amount of superdisintegrant (L-HPC) and the amount of subliming agent (camphor) on the percent of friability and the disintegration time. The results of multiple linear regression anal. revealed that for obtaining an effective ODT of etoricoxib, higher percentages of L-HPC and camphor should be used. Checkpoint batches were prepared to validate the evolved math. model. A response surface plot is also presented to graphically represent the effect of the independent variables on the percent of friability and the disintegration time. The approach using the optimization technique helped to produce a detailed understanding of the effects of formulation parameters.

Keywords: etoricoxib vacuum drying technique tablet disintegration sublimation camphor; low substituted hydroxylpropyl cellulose friability

Substances (8) Reactions (0) Citing (7)

5

Advantages and quality control of orally disintegrating tablets

0 Substances • 0 Reactions • 19 Citations

By: Olmez, Senem Sevtap; Vural, Imran

FABAD journal of Pharmaceutical Sciences (2009), 34(3), 167-172 | Language: English, Database: CAplus

A review. Orally disintegrating tablets (ODTs) are most preferred and accepted solid dosage forms by the patients. These tablets disintegrate in the saliva in the mouth within a short period of time and offer an advantage for populations who have difficulty in swallowing. Quality control of orally disintegrating tablets can be done by friability, porosity, hardness, wetting time, water absorption capacity, in vitro disintegration test and dissolution test. This article summarizes advantages and in vitro quality control tests of orally disintegrated tablets.

Keywords: review oral disintegrating tablet drug delivery system

Substances (0) Reactions (0) Citing (19)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

6

Comparative effects of different cellulosic-based directly compressed orodispersable tablets on oral bioavailability of famotidine

7 Substances • 0 Reactions • 67 Citations

By: Abdelbary, A.; Elshafeey, A. H.; Zidan, G.
Carbohydrate Polymers (2009), 77(4), 799-806 | Language: English, Database: CAplus

Famotidine is a potent H_2-receptor antagonist most commonly used by elderly patients. Orodispersible tablets (ODT) are gaining popularity over conventional tablets due to their convenience and suitability for patients having dysphagia. The purpose of this study is to prepare famotidine ODT using the economic direct-compression method. A 3^2 full factorial design was used to evaluate the influence of different excipients on the properties and in vitro dissolution of famotidine ODT. Two factors were studied for their qual. effects, namely, disintegrants and diluents. Disintegrants were studied in 3 levels viz. Ac-Di-Sol, sodium starch glycolate (Primojel) and low-substituted hydroxypropyl cellulose (L-HPC). Fillers were studied in 3 levels viz. mannitol, spray dried lactose and Avicel PH 101. The ODTs were prepared by direct compression and were evaluated for hardness, drug content, uniformity of weight, in vitro disintegration time, oral disintegration time, wetting time and in vitro dissolution Maximum dissolution and min. oral disintegration time (11.4 s) were observed in F7 prepared using L- HPC and mannitol. Furthermore, in human volunteers it showed significant increase in bioavailability compared to Servipep with mean $AUC_{(0-\infty)}$ 117.1 ng/mL and 82.71 ng/mL, resp., and its relative bioavailability was 141.57%. Hence, ODT (F7) could possibly be used to overcome the drawbacks of conven tional famotidine tablets in elderly patients with significant increase in oral bioavailability.

Keywords: orodispersible tablet disintegrant excipient famotidine dissolution oral bioavailability

Substances (7) | Reactions (0) | Citing (67)

7

Effect of the type of lubricant on the characteristics of orally disintegrating tablets manufactured using the phase transition of sugar alcohol

9 Substances • 0 Reactions • 35 Citations

By: Kuno, Yoshio; Kojima, Masazumi; Nakagami, Hiroaki; Yonemochi, Etsuo; Terada, Katsuhide
European Journal of Pharmaceutics and Biopharmaceutics (2008), 69(3), 986-992 | Language: English, Database: CAplus and MEDLINE

The aim of this study was to evaluate the effect of lubricants on the characteristics of orally disintegrating (OD) tablets manufa ctured using the phase transition of sugar alc. OD tablets were produced by directly compressing a mixture containing lactose-xylitol granules, disintegrant, glidant and lubricant, and subsequent heating. The effect of the type of lubricant on the tablet characteristics was evaluated using magnesium stearate (Mg-St), sodium stearyl fumarate (SSF), and talc as lubricants. The hardness of the tablets increased to ca. 6 kp as a result of heating, regardless of the kind of lubricant. The oral disintegration time of the tablets containing Mg-St or SSF increased with an increase in the hardness. In contrast, the oral disintegration time of the tablets containing talc was not changed despite of an increase in hardness. The water absorption rate of the tablets containing talc was much faster than that of the tablets containing other lubricants. The surface free energy measur ement showed that the polarity of the tablet components containing talc was remarkably increased by heating. The water absorption rate of the tablets containing talc was also increased by heating. These results indicate that a more hydrophilic surface might be attained by heating the talc. Consequently, talc was demonstrated to be the most desirable lubricant for the prepar ation of OD tablets based on the principle of the phase transition of sugar alc.

Keywords: magnesium stearate sodium stearyl fumarate talc heating disintegration tablet; Polyplasdone XL Aerosil 200 phase transition xylitol lactose

Substances (9) | Reactions (0) | Citing (35)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

8

Fast dispersible/slow releasing ibuprofen tablets

11 Substances • 0 Reactions • 100 Citations

By: Fini, Adamo; Bergamante, Valentina; Ceschel, Gian Carlo; Ronchi, Celestino; Fonseca de Moraes, Carlos Alberto
European journal of Pharmaceutics and Biopharmaceutics (2008), 69(1), 335-341 | Language: English, Database: CAplus and MEDLINE

Eight formulations were developed containing ibuprofen in the form of orally disintegrating tablets. To prevent bitter taste and side effects of the drug, the drug was associated with Phospholipon 80H, a saturated lecithin, by wet granul ation. The granules were then coated using different film forming agents (Kollicoat SR 30, Amprac 01, Kollidon 90F, Eudragit RD 100) obtaining four lots 1-4. Coated granules were then formulated with a sweetener (Aspartame), a mannitol-based diluent (Pearlitol SD 200) and Kollidon CL (1-4K) or Explotab (1-4E) were added as superdisintegrants and compacted under low compre ssion force. The eight lots of tablets, 1-4K and 1-4E, were assessed if suitable as oral disintegrating tablets by determination of a range of technol. parame ters. Wetting and disintegregation time matched with the requirements of EP IV Ed., for almost all these formula tions. Dissolution profiles suggested that the combined action of the hydrophobic lecithin and the coating delay the release of the drug from tablets with respect to when it is free or in the form of simple granules. By an appropriate combination of excipients it was thus possible to obtain orally disintegrating tablets and a delayed release of ibuprofen using simple and conven tional techniques.

Keywords: ibuprofen tablet formulation Phospholipon 80H Kollicoat SR 30D aspartame; palatability dispersion Amprac 01 Eudragit RD 100 Kollidon CL

Substances (11) Reactions (0) Citing (100)

9

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

0 Substances • 0 Reactions • 15 Citations

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

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

Keywords: review orally disintegrating tablet sweetness dissolution mouth

Substances (0) Reactions (0) Citing (15)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

10

Formulation and evaluation of orally disintegrating tablets of buspirone

10 Substances • 0 Reactions • 20 Citations

By: Rajitha, K.; Kumar, Shravan Y.; Adukondalu, D.; Gannu, Ramesh; Rao, Madhusudan Y.
International Journal of Pharmaceutical Sciences and Nanotechnology (2009), 1(4), 327-334 | Language: English, Database: CAplus

Buspirone is a classical anxiolytic agent. The present investigation deals with formulation of orodispersible tablets (ODT) of buspirone that disintegrate in the oral cavity upon contact with saliva and thereby should improve therap eutic efficacy. The O DTs were prepared by wet granulation and direct compression techniques. The optimized formulation was also prepared by freeze drying method. The influence of superdisintegrants, crospovidone, croscarmellose sodium and sodium starch glycolate at three levels on disintegration time, wetting time and water absorption ratio were studied. Tablets were evaluated for weight and thickness variation, disintegration time, drug content, in vitro dissol ution, wetting time and water absorption ratio. The in vitro disintegration time (DT) of the best ODTs was found to be 35 and 30 S by direct compre ssion and by freeze drying methods, resp. Tablets containing crospovidone exhibit quick disinte gration time than tablets containing croscarmellose sodium and sodium starch glycolate. Good correlation was observed between water absorption ratio and D T. Thus, directly compressible rapidly disinte grating tablets of buspirone with shorter disinte gration time and sufficient hardness could be prepared using crospo vidone and other excipients at optimum concentration

Keywords: buspirone tablet formulation anxiolytic superdisintegrant

Substances (10) | Reactions (0) | Citing (20)

11

Orally disintegrating tablets. The effect of recent FDA guidance on ODT technologies and application

0 Substances • 0 Reactions • 3 Citations

By: McLaughlin, Rosie; Banbury, Susan; Crowley, Kieran
Pharmaceutical Technology (2009), (Suppl.), S18, S20-S25 | Language: English, Database: CAplus

A review. The authors describe the various available technologies used in orally disintegrating tablets (ODTs). They also discuss the recent implications of the US Food and Drug Administ ration's Guidance for Industry: Orally Disintegrating Tablets.

Keywords: review lyophilization compression oral disintegrating tablet

Substances (0) | Reactions (0) | Citing (3)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

12

In vitro and in vivo evaluation of nimesulide lyophilized orally disintegrating tablets

9 Substances • 0 Reactions • 138 Citations

By: Shoukri, Ragula Ali; Ahmed, Iman Saad; Shamma, Rehab N.

European Journal of Pharmaceutics and Biopharmaceutics (2009), 73(1), 162-171 | Language: English, Database: CAplus and MEDLINE

Development of a lyophilized orally disintegrating tablet (ODT) that enhanced the in vitro dissolution and in vivo absorption of nimesulide (NM), a drug with poor solubility and poor bioavailability, is presented. The ODTs were prepared by freeze-drying an aqueous dispersion of NM containing a matrix former, a sugar alc., and a collapse protectant. In addition, different disintegration accelerators were tested. The influence of formulation parameters on the disintegration time and in vitro dissolution of NM from ODTs along with other tablet characteristics was investigated. Results obtained from disintegration and dissolution studies showed that lyophilized ODTs disintegrated within few seconds and showed significantly faster dissolution rate of NM compared to the plain powder drug and NM in com. available immediate release tablet Sulide. The ODTs were also examined using differential scanning calorimetry, X-ray diffraction, and scanning electron microscope. Stability results, after 12-mo storage of selected ODTs at 25° and 60% relative humidity, were satisfactory. The extent of absorption of NM from a selected ODT when compared to an conventional immediate release tablet as a reference after administration of 100 mg oral dose of NM was determined in healthy subjects using a randomized crossover design. In this study, the rate of absorption of NM from ODT was faster than that from the reference tablet, had a significantly higher ($p = 0.012$) peak plasma concentration, and shortened time to C_{max} by 1 h ($p = 0.029$). The extent of absorption expressed by AUC was 62% larger when compared to the com. available tablet.

Keywords: disintegration nimesulide freeze drying dissolution tablet bioavailability pharmacokinetics

Substances (9) | Reactions (0) | Citing (138)

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(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-5252337	10-12-1993	POWELL; Thomas C.	
		002	US-5639475	06-17-1997	BETTMAN; Marie Jean et al.	
		003	US-6139865	10-31-2000	FRIEND; David R. et al.	
		004	US-6495160	12-17-2002	ESPOSITO; Pierandrea et al.	
		005	US-6534549	03-18-2003	NEWTON; John Michael et al.	
		006	US-7122198	10-17-2006	SINGH; Amarjit et al.	
		007	US-7125564	10-24-2006	CHEN; Li-Lan H. et al.	
		008	US-7229641	06-12-2007	CHERUKURI; S. Rao	
		009	US-11896710	02-13-2024	MELTZER; Brian A. et al.	
		010	US-20060105038	05-18-2006	LAI; Jin-Wang et al.	
		011	US-20090264392	10-22-2009	WARNDAHL; Roger et al.	
		012	US-20120164080	06-28-2012	HILL; Malcolm et al.	
		013	US-20230414498	12-28-2023	MELTZER; Brian A. et al.	
		014	US-20240207288	06-27-2024	EAGLE; Gina	

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]
		015	CA-1027864-A	03-14-1978	HOECHST AG.		☐

Examiner Signature		Date Considered	

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

FOREIGN PATENT DOCUMENTS

Examiner Initials*		Cite No.[1]	Foreign Patent Document Country Code[2]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]
		016	CN-102665722-A	09-12-2012	EURAND INC.		☒
		017	CN-105392497-A	03-09-2016	REGENERON PHARMA.		☒
		018	CN-1186428-A	07-01-1998	ASTRA AB.		☒
		019	EP-2482822-B1	08-01-2018	ADARE PHARMACEUTICALS INC.		☐
		020	JP-2006516646-A	07-06-2006	ELAN PHARMA INT LTD.		☒
		021	WO-0044351-A1	08-03-2000	SCHERER CORP R P.		☐
		022	WO-2015006571-A1	01-15-2015	REGENERON PHARMA., et al.		☐
		023	WO-9632095-A1	10-17-1996	ASTRA AB., 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.

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		024	Budenofalk®, Budenofalk® 3mg, Dr. Falk Pharma GMBH, Brochure (6th Revised Edition 2005), 136 pages.	☐
		025	Budenofalk®, Budesonide Budenofalk® 3mg, First-line-corticosteroid, Dr. Falk Pharma GMBH, Advertisement (2007), 1 page.	☐
		026	Curriculum Vitae of Alan F. Parr, Pharm.D., Ph.D., filed July 22, 2024 in Petition for Inter Partes Review of U.S. Patent No. 8,771,729 filed July 22, 2024, 12 pages.	☐
		027	DANCKWERTS, M.D., "Intraoral Drug Delivery: A Comparative Review," American Journal of Drug Delivery (2003 Sep); 1(3): 171-186.	☐
		028	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review of U.S. Patent No. 8,771,729 dated April 17, 2024, filed July 22, 2024, 174 pages.	☐
		029	Dr. Falk Pharma, "Where medicine and pharmaceuticals meet - a tried and trusted link", Dr. Falk Pharma GmbH, Brochure (2008), 29 pages.	☐
		030	"DRAFT Guidance: Guidance for Industry: Orally Disintegrating Tablets," U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007 April, 6 pages.	☐
		031	ELSING et al., "Budesonide for the treatment of obstructive eosinophilic jejunitis," Z. Gastroenterology 2007 Feb; 45(2): 187-189.	☐
		032	FAUBION JR., et al., "Treatment of eosinophilic esophagitis with inhaled corticosteroids". Journal of Pediatric Gastroenterology and Nutrition. 1998 Jul 1; 27(1): 90-93, 6 pages.	☐
		033	FU et al., "Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies," Critical Reviews in Therapeutic Drug Carrier Systems (2004); 21(6): 433-475.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		034	Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2006, Ch. 38, pages 1014-1015, pages 1246-1256, 15 pages.	☐
		035	"Guidance for Industry: Orally Disintegrating Tablets," U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008 December, 6 pages.	☐
		036	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petition for Inter Partes Review of U.S. Patent No. 8,771,729, dated and filed July 22, 2024, including Exhibits and Petitioner Power of Attorney dated March 24, 2024, 1079 pages.	☐
		037	International Preliminary Report on Patentability for International Application No. PCT/US2022/025297 dated November 02, 2023, 8 pages.	☐
		038	KOLKMAN et al., "Evaluation of oral budesonide in the treatment of active distal ulcerative colitis," Drugs of Today 2004 Jul; 40(7): 589-601.	☐
		039	NOEL et al., "Clinical and immunopathologic effects of swallowed fluticasone for eosinophilic esophagitis," Clinical Gastroenterology and Hepatology 2004 Jul; 2(7): 568-575.	☐
		040	Notice of Publication of FDA Guidance for Industry on Orally Disintegrating Tablets, Federal Register, Vol. 73, No. 242 at 76366, December 16, 2008, 1 page.	☐
		041	Opposition Proceedings in European Patent No. 2482822 B1 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare Development I, L.P.'s (now Ellodi Pharmaceuticals, L.P.) Response to Grounds of Opposition dated September 20, 2019, 27 pages.	☐
		042	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	☐

Examiner Signature		Date Considered	

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		043	Prosecution history excerpts from U.S. Application No. 12/896,005, filed October 1, 2010, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 8,771,729, 119 pages.	☐
		044	Prosecution history excerpts from U.S. Application No. 15/816,154 filed November 17, 2017, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 10,632,069, 90 pages.	☐
		045	Prosecution history excerpts from U.S. Application No. 17/236,295 filed April 21, 2021, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 11,266,598, 65 pages.	☐
		046	SHUKLA et al., "Mouth Dissolving Tablets I: An overview of formulation technology," Scientia Pharmaceutica (2009 Mar 6); 77(2): 309-326.	☐
		047	SIEWERT et al., "Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide," Digestive and Liver Disease 2006 Jan; 38(1): 55-59. Epub 2005 Dec 1.	☐
		048	SVOBODA et al., "Oral formulations of budesonide: a novel treatment for inflammatory bowel disease," Drugs of Today (Barc). 2008 Nov; 44(11): 857-863.	☐
		049	TAN et al., "Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets," European Journal of Gastroenterology & Hepatology 2001 Apr; 13(4): 425-427.	☐
		050	The United States Pharmacopeia, "701 Disintegration", USP 32 (2009); NF 27, Volume 1, pages 262-263, 4 pages.	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	10/15/2024

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L471	16	"12896005"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:30 AM
L472	38059	((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) AND ((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:35 AM
L473	161	L472 AND (deposit$4 locat$4 collect$4) near5 esophag$5	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	ON	ON	2024/10/15 11:35 AM

			IBM_TDB)				
L474	442	L472 AND (deposit$4 locat$4 collect$4) near5 esophag$5	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:36 AM
L475	124352	((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) AND ((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:36 AM

		budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)					
L476	966	((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:36 AM
L477	37	L476 AND (deposit$4 locat$4 collect$4) near5	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	OR	ON	ON	2024/10/15 11:37 AM

		esophag$5	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L478	23	L477 AND (hardness friability)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:37 AM
L479	22	L477 AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) near5 (hard hardness friability))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:38 AM
L480	109	((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2024/10/15 11:44 AM

		compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)).clm.	SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L481	0	L480 AND ((deposit$4 locat$4 collect$4) near5 esophag$5).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:45 AM
L482	11	480 AND (hardness friability).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2024/10/15 11:45 AM

			CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L483	17	((("ELLODI") near3 ("PHARMACEUTICALS") near3 ("L.P"))).AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L484	17	("ELLODI").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L485	76	("EURAND").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L486	69	("APTALIS").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L487	84	("ADARE").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L488	206	((("PERRETT") near3 ("Stephen")) OR (("COHEN") near3 ("Fredric")) OR (("VENKATESH") near3 ("Gopi"))).INV,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L489	331	483 484 485 486 487 488	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:47 AM
L490	26	489 AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:48 AM

		brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)).clm.					
L491	0	490 AND (hardness friability).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:48 AM
L492	25	490 AND (esophag$7).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:48 AM
L493	0	490 AND (esophag$7).clm. AND (hard hardness friab$10).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:48 AM
L494	742023	(A61K9/0065 or A61K31/56 or A61K9/006 or A61K9/0056 or A61K9/08 or A61K45/06 or A61K9/0053 or A61K47/38 or A61K31/58 or A61K31/569 or A61K9/06).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:49 AM
L495	586	(A61K31/569 same A61K2300/00).cpcc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/15 11:49 AM
L496	160560	494 495	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:49 AM
L497	45	496 AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:50 AM

		mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute)) .clm. AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4))					
L498	30	497 AND (esophag$10)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:50 AM
L499	25	497 AND (esophag$10) AND (hard hardness friab$10)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/15 11:50 AM
L500	14	("11896710" OR "20060105038" OR "20090264392" OR "20120164080" OR "20230414498" OR "20240207288" OR "5252337" OR "5639475" OR "6139865" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:51 AM

		"6495160" OR "6534549" OR "7122198" OR "7125564" OR "7229641").pn.					
L501	6	500 AND ((("ODT") ((oral$2 intraoral$2 "intra-oral" "intra-orally" oromucosal$2 "oro-mucosal" "oro-mucosally" mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4 melt$4) WITH (tablet$4 compress$4 compact$4 pill lozenge dragee solid))) WITH (time period second minute))	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:52 AM
L502	5	501 AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:53 AM
L503	4	502 AND (esophag$10)	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:53 AM
L504	3	502 AND (esophag$10)	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15

		AND (hard hardness friab$10)					11:53 AM
L505	2	504 AND (((fluticasone near2 propionate) flovent$4 cutivate$4 flixotide$4 Flonase$4 Flixonase$4 Flunase$4 Flusonal$4 Fluspiral$4 Flutide$4 flutivate$4 asmatil$4 axotide$4 brethal$4 fluinol$4 atemur$4 inalacor$4 rinosone$4 trialona$4 ubizol$4 zoflut$4 fluxonal$4 skyron$4 xhance$4 armonair$4 respiclick$4 prestwick$10 "S-(Fluoromethyl) 6alpha,9-difluoro-11beta,17-dihydroxy-16alpha-methyl-3-oxoandrosta-1,4-diene-17beta-carbothioate, 17-propionate") OR (budesonide pulmicort$4 entocort$4 rhinocort$4 preferid$4 budeson$4 cortivent$4 micronyl$4 respule spirocort$4 OR bidien$4 uceris$4 budesonidum budecort$4 fvolir$4 jorveza$4 eltair$4)) near5 (mg milligram dose dosage concentration quantity dosing)	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/15 11:54 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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APPROVAL LETTER

APPLICATION #	FILING DATE	APPLICANT/PATENT UNDER REEXAMINATION
17/569,047	01/05/2022	Stephen PERRETT

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Electronic terminal disclaimer filed on 08/09/2024

☑ Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

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PGR Petition - USP 12,290,598

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**08/09/2024 04:55:57 PM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	66724507	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	45 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic-Approved	18 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	479936058EDF04359A491DBFE39051BB802C4028CBFBFAEA1CB6CF03E441AB2E513784BF5D94625ED5F1C756BF123A6F68E284258F6202D274CA742B05004AA5
grantLetter.pdf	C6016FE68BF169DF2FE356A22D4E7697F97E3B6F1BCFB4C61

FEC22A436C628861C891465C3BB22EE57D36A64C5A4F9F7FB
1A570552DCF67C2E600CD5D9178E7D

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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 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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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

APPLICATION #	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #
17569047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

- ☑ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action
- ☑ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent interest
ELLODI PHARMACEUTICALS, L.P.	100%
Total	**100%**

The owner(s) of 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 any patent granted on pending reference Application Number(s)

Application #	Filing Date

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. 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 any patent granted on the reference application 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 any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: 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 shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of 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)

Patent #
11246828
11266598
10632069

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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

Applicant claims the following entity status:
Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statemnts 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.

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

Signature	Name	Registration #
/Matthew Scheideman/	Matthew Scheideman	76605

* 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.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**08/09/2024 04:55:57 PM Z ET**	**ELLO-119/08US 342083-2017**

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	66724507	AUTHORIZED BY	Jonathan Cousin
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	**E202489G56286897**	**Matthew Scheideman**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	**$170.00**

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.

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PGR Petition - USP 12,290,598

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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PGR Petition - USP 12,290,598

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	Examiner:	SASAN, Aradhana

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure set forth in 37 CFR § 1.56, Applicant hereby submits the following information in compliance with 37 CFR §§ 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.

In accordance with **37 CFR § 1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 CFR § 1.97(b), but before the mailing of any of the following: a final action under 37 CFR § 1.113; a notice of allowance under 37 CFR § 1.311; or action that otherwise closes prosecution in this Application.

This Information Disclosure Statement is accompanied by the fee set forth under 37 CFR § 1.17(p) in the amount of $260.00, in accordance with 37 CFR § 1.97(c).

In agreement with 37 CFR § 1.97(g), this Information Disclosure Statement shall not be construed as a representation that a search has been made.

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In agreement with 37 CFR § 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, relevant, analogous, or material to patentability as defined by 37 CFR § 1.56(b).

As required by **37 CFR § 1.98(a)(2)**, Applicant submits a copy of any Foreign Patent and Non-Patent Literature information cited on the attached Form used in lieu of PTO/SB/08.

As authorized by 37 CFR § 1.98(a)(2)(ii), Applicant does not submit a copy of any U.S. Publication or Patent information cited on the attached Form used in lieu of PTO/SB/08.

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 encouraged 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 appropriate fees set forth in 37 CFR § 1.17(p) that may be required by this Information Disclosure Statement, and to credit any overpayment, to Deposit Account No. 50-1283, referencing Docket No. ELLO-119/08US 342083-2017.

Dated: July 25, 2024

Respectfully submitted,
COOLEY LLP

Electronic signature: /Jonathan M. Cousin/

Jonathan Cousin
Reg. No. 66,418

USPTO CUSTOMER NO. 58249

COOLEY LLP
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Washington, DC 20004

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

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	07/25/2024 09:47:59 PM Z ET	ELLO-119/08US 342083-2017

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	MaxVal Group
PATENT CENTER #	66524508	AUTHORIZED BY	Jonathan Cousin
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	E20247OL54488403	Donna Doyle

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	260.00	1	260.00
			TOTAL AMOUNT:	$260.00

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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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**07/25/2024 09:47:59 PM Z ET**	**ELLO-119/08US 342083-2017**

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CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 39

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
ELLO-119_08US_342083-2017_IDS_Transmittal.pdf	2	Transmittal Letter	101 KB
FOR_CA1027864A_EFS.pdf	14	Foreign Reference	433 KB
FOR_CN102665722A_EFS.pdf	21	Foreign Reference	1613 KB
FOR_CN105392497A_EFS.pdf	24	Foreign Reference	1709 KB
FOR_CN1186428A_EFS.pdf	11	Foreign Reference	618 KB
FOR_EP2482822B1_EFS.pdf	14	Foreign Reference	1169 KB

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FOR_JP2006516646A_EFS.pdf	47	Foreign Reference	2292 KB
FOR_WO0044351A1_EFS.pdf	38	Foreign Reference	1328 KB
FOR_WO2015006571A1_EFS.pdf	36	Foreign Reference	2740 KB
FOR_WO9632095A1_EFS.pdf	18	Foreign Reference	631 KB
NPL_Budeonfalk-Brochure_2005_136_pgs.pdf	136	Non Patent Literature	5797 KB
NPL_DANCKWERTS-Intraoral_Drug_AJDD_2003.pdf	16	Non Patent Literature	1047 KB
NPL_FAUBION.pdf	6	Non Patent Literature	1170 KB
NPL_FU-OralIY_Disintegrating_2004.pdf	43	Non Patent Literature	2513 KB
NPL_IPRP_PCTUS2022025297_2Nov2023_EFS.pdf	8	Non Patent Literature	331 KB
NPL_NOEL-Clinical_and_2004.pdf	8	Non Patent Literature	559 KB
SHUKLA-Mouth_Dissolving_2009.pdf	18	Non Patent Literature	192 KB
Budeonfalk-Advertisement_2007_1_pg.pdf	1	Non Patent Literature	1124 KB
SVOBODA-Oral_Formulations_DoT_200	7	Non Patent Literature	1621 KB

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PGR Petition - USP 12,290,598

8.pdf			
ELSING-Budesonide_for_Z-Gastroenterology_2007.pdf	3	Non Patent Literature	3161 KB
Dr_Falk_Pharma-Where_Medicine_Brochure_2008_29_pgs.pdf	29	Non Patent Literature	10793 KB
DRAFT_Guidance_FDA_2007_6_pgs.pdf	6	Non Patent Literature	142 KB
Oppn_2482822_EPOs_Dec_revoking_Patent_08-25-2024_23_pgs.pdf	31	Non Patent Literature	10763 KB
Guidance_for_Industry_2008_6_pgs.pdf	6	Non Patent Literature	137 KB
SIEWERT-Eosinophilic_Digest_Liv_Dis_2006.pdf	5	Non Patent Literature	6097 KB
Notice-of-Pub-of-FDA_76366_2008_1_pg.pdf	1	Non Patent Literature	1343 KB
The-US-Pharmacopeia-Disintegration_2009.pdf	4	Non Patent Literature	4553 KB
TAN-Eosinophilic_gastroenteritis_EJGH_2001.pdf	3	Non Patent Literature	3881 KB
KOLKMAN-Drugs_of_Today_2004.pdf	13	Non Patent Literature	3580 KB
Oppn_2482822_Adares_Response_to_Grounds_of_Opposition_09-20-2019_27_pgs.pdf	27	Non Patent Literature	12748 KB

Goodman_and_Gilmans_2006_15_pgs.pdf	15	Non Patent Literature	968 KB
Decl-Alan_F_Parr_04-17-2024_174_pgs.pdf	174	Non Patent Literature	783 KB
CV-AlanF_Farr_07-22-2024_12_pgs.pdf	12	Non Patent Literature	8697 KB
Prosecution_history_excerpts_US_Application_No_15816154_90_pgs.pdf	90	Non Patent Literature	673 KB
Prosecution_history_excerpts_US_Application_No_17236295_65_pgs.pdf	65	Non Patent Literature	495 KB
Prosecution_history_excerpts_US_Application_No_12896005_119_pgs.pdf	119	Non Patent Literature	1545 KB
IPR_2024-01197_Petition_07-22-2024_1079_pgs_1-of-2-parts.pdf	500	Non Patent Literature	15515 KB
IPR_2024-01197_Petition_07-22-2024_1079_pgs_2-of-2-parts.pdf	579	Non Patent Literature	22735 KB
ELLO-119_08US_342083-2017_IDS_SB08_20240725131103.pdf	5	Information Disclosure Statement (IDS) Form (SB08)	135 KB

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Digest

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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

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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 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.

From the INTERNATIONAL BUREAU

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NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION TREATY)

(PCT Rule 44bis.1(c))

To:

TUSCAN, Michael
Cooley LLP
1299 Pennsylvania Ave.
Suite 700
Washington, District of Columbia 20004
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing *(day/month/year)* 02 November 2023 (02.11.2023)	
Applicant's or agent's file reference ELLO-168-01WO-342083-2035	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2022/025297	19 April 2022 (19.04.2022)	20 April 2021 (20.04.2021)

Applicant
ELLODI PHARMACEUTICALS, L.P.

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Sun Hwa Lee e-mail pct.team1@wipo.int Telephone No. +41 22 338 74 01

Form PCT/IB/326 (revised January 2020)

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference ELLO-168-01WO-342083-2035	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2022/025297	International filing date *(day/month/year)* 19 April 2022 (19.04.2022)	Priority date *(day/month/year)* 20 April 2021 (20.04.2021)
International Patent Classification (IPC) or national classification and IPC See relevant information in Form PCT/ISA/237		
Applicant ELLODI PHARMACEUTICALS, L.P.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 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 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

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 24 October 2023 (24.10.2023)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Sun Hwa Lee e-mail pct.team1@wipo.int

Form PCT/IB/373 (revised January 2020)

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
COOLEY LLP
1299 PENNSYLVANIA AVE.
SUITE 700
WASHINGTON, DC 20004

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	JUL 29 2022

Applicant's or agent's file reference	FOR FURTHER ACTION
ELLO-168-01WO-342083-2035	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2022/025297	19 April 2022	20 April 2021

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

IPC(8) - A61K 31/565; A61K 31/56; A61K 9/00; A61P 1/00 (2022.01)
CPC - A61K 31/565; A61K 31/56; A61K 9/0053; A61K 9/0056; A61K 9/006; A61K 9/0065; A61K 9/0095; A61K 9/20; A61K 31/341; A61K 31/4439; A61K 31/573; A61K 31/575; A61K 31/58; A61K 45/06; A61K 47/32; A61K 47/36; A61P 1/00; A61P 1/04; A61P 1/06; A61P 25/00; A61P 29/00; A61P 37/08 (2022.05)

Applicant ELLODI PHARMACEUTICALS, L.P.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	23 June 2022	Taina Matos PCT Helpdesk: 571-272-4300 Telephone No. 571-272-4300

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

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Additional comments:

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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. 6-11, 13-25, 27-54

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. 6-11, 13-25, 27-54 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 6-11, 13-25, and 27-54 are multiple dependent claims 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. 6-11, 13-25, 27-54

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

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

☐ See Supplemental Box for further details.

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

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

1. Statement

Novelty (N)	Claims	2-5	YES
	Claims	1, 12, 26	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-5, 12, 26	NO
Industrial applicability (IA)	Claims	1-5, 12, 26	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 12, and 26 lack novelty under PCT Article 33(2) as being anticipated by US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals").

Regarding Claim 1, Adare Pharmaceuticals discloses a method of topically treating an esophageal stricture in a patient in need thereof with a corticosteroid (in some embodiments, the corticosteroid is deposited topically in the upper gastrointestinal tract...the compositions and methods disclosed herein substantially remove strictures, Col. 3, Lns. 5-7; see also Col. 25, Lns. 61-62), comprising: (a) detecting the esophageal stricture (in some embodiments, the patient diagnosed with EoE has an esophageal stricture, Col. 43, Lns. 61-62); and then (b) orally administering the corticosteroid (in some embodiments, the present disclosure provides for administering the oral corticosteroid composition to a patient while laying down, Col. 2, Lns. 55-57), wherein a therapeutically effective amount of the oral corticosteroid contacts the esophageal stricture (orally disintegrating compositions...after being swallowed...the corticosteroid dissolved or suspended therein contacts the esophagus as the liquid traverses the esophageal tract, Col. 9, Lns. 2-9), thereby reducing the severity of the esophageal stricture (the compositions and methods disclosed herein substantially remove strictures, Col. 25, Lns. 61-62).

Regarding Claim 12, Adare Pharmaceuticals discloses the method of claim 1, wherein the oral corticosteroid is administered about 30 minutes or less before target sleep time (the oral corticosteroid may be administered about 30 minutes or less before target sleep time, Col. 46, Lns. 23-24).

Regarding Claim 26, Adare Pharmaceuticals discloses the method of claim 1, wherein the patient has eosinophilic esophagitis (EoE), gastroesophageal reflux disease (GERD), non-erosive reflux disease (NERD), erosive esophagitis, Barrett's esophagus, eosinophilic gastroenteritis, hypereosinophilic syndrome, corrosive chemical esophagitis, radiation-induced esophagitis, chemotherapy-induced esophagitis, transient drug-induced esophagitis, persistent drug-induced esophagitis, Crohn's disease of the esophagus, post-surgical resection of the esophagus; or pseudomembranous esophagitis (inflammatory gastrointestinal disorders which may be treated according to the present disclosure include EoE, Col. 20, Lns. 29-34).

Claims 2 and 3 lack an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile").

Regarding Claim 2, Adare Pharmaceuticals discloses the method of claim 1.
Adare Pharmaceuticals fails to explicitly disclose wherein the detecting in step (a) comprises inserting an endoscope into the patient's esophagus.
Gentile, in the analogous field of esophageal stricture detection and treatment (Summary), teaches wherein the detecting in step (a) comprises inserting an endoscope into the patient's esophagus (oesophageal strictures may be diagnosed at upper gastrointestinal endoscopy, p. 1334, left column, first Para.). Gentile also teaches that the mechanism of dysphagia in EoE is probably multifactorial, including increased mucosal stickiness, loss of oesophageal distensibility, and importantly, oesophageal fibrosis with stricture and ring formation, Gentile, p. 1334, left column, first Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals with the teaching of Gentile. The motivation for doing so would have been to perform an upper gastrointestinal endoscopy to investigate the cause of dysphagia in patients suffering from EoE, as suggested by Gentile.

Regarding Claim 3, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the endoscope has a diameter of about 8-10 mm, or about 9 mm.
Gentile, in the analogous field of esophageal stricture detection and treatment (Summary), teaches wherein the endoscope has a diameter of about 8-10 mm, or about 9 mm (endoscopic narrowing was defined by the use of the terms 'narrowing,' 'stricture' or 'resistance' to passing the standard 9-10 mm scope to traverse the oesophageal lumen, p. 1335, left column, second Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of Gentile since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to use a standard 9-10 mm endoscope to traverse the esophageal lumen and thereby assess the degree of esophageal narrowing, as suggested by Gentile.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 12 are objected to under under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1 and 12 are indefinite for the following reason(s):

Regarding claims 1 and 12, "the oral corticosteroid" lacks antecedent basis". For the purpose of the Written Opinion proposed, "the oral corticosteroid" has been analyzed as "the corticosteroid".

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Supplemental Box

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

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile") and US 10,869,592 to UroViu Corp. (hereinafter, "UroViu").

Regarding Claim 4, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the esophageal stricture is detected visually using a video display on the endoscope.
UroViu, in the analogous field of surgical endoscopes for medical procedures (Abstract), teaches wherein the esophageal stricture is detected visually using a video display on the endoscope (a handheld surgical endoscope has a disposable, single-use handle and a touch-sensitive display screen that is supported by the handle, Abstract). UroViu further teaches that the endoscope 100 includes an elongated cannula 120 with a distal tip 112 for inserting into a hollow cavity or organ of the body...and one or more LED light sources for viewing the organ or cavity into which it is inserted, UroViu, Col. 6, Lns. 31-39).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of UroViu. The motivation for doing so would have been to create a surgical endoscope having a display screen thereon for easy and convenient viewing of an organ or cavity during use of the endoscope, as suggested by UroViu.

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile") and Takita et al. (hereinafter, "Takita").

Regarding Claim 5, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the esophageal stricture is detected because the endoscope cannot pass through the patient's esophagus.
Takita, in the analogous field of esophageal stricture detection and treatment (Abstract), teaches wherein the esophageal stricture is detected because the endoscope cannot pass through the patient's esophagus (esophageal strictures are common after endoscopic submucosal dissection, ESD, of extensive tumors...and patients who have undergone ESD for such lesions often develop a post-ESD stricture that a transoral scope cannot pass through, p. 163, left column, first Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of Takita. The motivation for doing so would have been to identify an esophageal stricture based on the inability of a transoral endoscope to pass through the esophageal lumen, as suggested by Takita.

Claims 1-5, 12, and 26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-5252337	10-12-1993	POWELL; Thomas C.	
		002	US-5639475	06-17-1997	BETTMAN; Marie Jean et al.	
		003	US-6139865	10-31-2000	FRIEND; David R. et al.	
		004	US-6495160	12-17-2002	ESPOSITO; Pierandrea et al.	
		005	US-6534549	03-18-2003	NEWTON; John Michael et al.	
		006	US-7122198	10-17-2006	SINGH; Amarjit et al.	
		007	US-7125564	10-24-2006	CHEN; Li-Lan H. et al.	
		008	US-7229641	06-12-2007	CHERUKURI; S. Rao	
		009	US-11896710	02-13-2024	MELTZER; Brian A. et al.	
		010	US-20060105038	05-18-2006	LAI; Jin-Wang et al.	
		011	US-20090264392	10-22-2009	WARNDAHL; Roger et al.	
		012	US-20120164080	06-28-2012	HILL; Malcolm et al.	
		013	US-20230414498	12-28-2023	MELTZER; Brian A. et al.	
		014	US-20240207288	06-27-2024	EAGLE; Gina	

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]
		015	CA-1027864-A	03-14-1978	HOECHST AG.		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

FOREIGN PATENT DOCUMENTS

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		016	CN-102665722-A	09-12-2012	EURAND INC.		☒
		017	CN-105392497-A	03-09-2016	REGENERON PHARMA.		☒
		018	CN-1186428-A	07-01-1998	ASTRA AB.		☒
		019	EP-2482822-B1	08-01-2018	ADARE PHARMACEUTICALS INC.		☐
		020	JP-2006516646-A	07-06-2006	ELAN PHARMA INT LTD.		☒
		021	WO-0044351-A1	08-03-2000	SCHERER CORP R P.		☐
		022	WO-2015006571-A1	01-15-2015	REGENERON PHARMA., et al.		☐
		023	WO-9632095-A1	10-17-1996	ASTRA AB., et al.		☐

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Sheet 3 of 5

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First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

NON-PATENT LITERATURE DOCUMENTS

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		024	Budenofalk®, Budenofalk® 3mg, Dr. Falk Pharma GMBH, Brochure (6th Revised Edition 2005), 136 pages.	☐
		025	Budenofalk®, Budesonide Budenofalk® 3mg, First-line-corticosteroid, Dr. Falk Pharma GMBH, Advertisement (2007), 1 page.	☐
		026	Curriculum Vitae of Alan F. Parr, Pharm.D., Ph.D., filed July 22, 2024 in Petition for Inter Partes Review of U.S. Patent No. 8,771,729 filed July 22, 2024, 12 pages.	☐
		027	DANCKWERTS, M.D., "Intraoral Drug Delivery: A Comparative Review," American Journal of Drug Delivery (2003 Sep); 1(3): 171-186.	☐
		028	Declaration of Alan F. Parr, Pharm.D., Ph.D., in Support of Petition for Inter Partes Review of U.S. Patent No. 8,771,729 dated April 17, 2024, filed July 22, 2024, 174 pages.	☐
		029	Dr. Falk Pharma, "Where medicine and pharmaceuticals meet - a tried and trusted link", Dr. Falk Pharma GmbH, Brochure (2008), 29 pages.	☐
		030	"DRAFT Guidance: Guidance for Industry: Orally Disintegrating Tablets," U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007 April, 6 pages.	☐
		031	ELSING et al., "Budesonide for the treatment of obstructive eosinophilic jejunitis," Z. Gastroenterology 2007 Feb; 45(2): 187-189.	☐
		032	FAUBION JR., et al., "Treatment of eosinophilic esophagitis with inhaled corticosteroids". Journal of Pediatric Gastroenterology and Nutrition. 1998 Jul 1; 27(1): 90-93, 6 pages.	☐
		033	FU et al., "Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies," Critical Reviews in Therapeutic Drug Carrier Systems (2004); 21(6): 433-475.	☐

Examiner Signature		Date Considered	

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Sheet 4 of 5

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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		034	Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2006, Ch. 38, pages 1014-1015, pages 1246-1256, 15 pages.	☐
		035	"Guidance for Industry: Orally Disintegrating Tablets," U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008 December, 6 pages.	☐
		036	Inter Partes Review Proceedings No. IPR2024-01197 filed July 22, 2024, Dr. Falk Pharma GMBH (Petitioner) vs. Ellodi Pharmaceuticals LP (Patent Owner), U.S Patent No. 8,771,729 (U.S. Application No. 12/896,005), Petition for Inter Partes Review of U.S. Patent No. 8,771,729, dated and filed July 22, 2024, including Exhibits and Petitioner Power of Attorney dated March 24, 2024, 1079 pages.	☐
		037	International Preliminary Report on Patentability for International Application No. PCT/US2022/025297 dated November 02, 2023, 8 pages.	☐
		038	KOLKMAN et al., "Evaluation of oral budesonide in the treatment of active distal ulcerative colitis," Drugs of Today 2004 Jul; 40(7): 589-601.	☐
		039	NOEL et al., "Clinical and immunopathologic effects of swallowed fluticasone for eosinophilic esophagitis," Clinical Gastroenterology and Hepatology 2004 Jul; 2(7): 568-575.	☐
		040	Notice of Publication of FDA Guidance for Industry on Orally Disintegrating Tablets, Federal Register, Vol. 73, No. 242 at 76366, December 16, 2008, 1 page.	☐
		041	Opposition Proceedings in European Patent No. 2482822 B1 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare Development I, L.P.'s (now Ellodi Pharmaceuticals, L.P.) Response to Grounds of Opposition dated September 20, 2019, 27 pages.	☐
		042	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	☐

Examiner Signature		Date Considered	

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Sheet 5 of 5

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, Aradhana
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		043	Prosecution history excerpts from U.S. Application No. 12/896,005, filed October 1, 2010, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 8,771,729, 119 pages.	☐
		044	Prosecution history excerpts from U.S. Application No. 15/816,154 filed November 17, 2017, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 10,632,069, 90 pages.	☐
		045	Prosecution history excerpts from U.S. Application No. 17/236,295 filed April 21, 2021, for ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS; Inventors PERRETT, Stephen et al., issued as U.S. 11,266,598, 65 pages.	☐
		046	SHUKLA et al., "Mouth Dissolving Tablets I: An overview of formulation technology," Scientia Pharmaceutica (2009 Mar 6); 77(2): 309-326.	☐
		047	SIEWERT et al., "Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide," Digestive and Liver Disease 2006 Jan; 38(1): 55-59. Epub 2005 Dec 1.	☐
		048	SVOBODA et al., "Oral formulations of budesonide: a novel treatment for inflammatory bowel disease," Drugs of Today (Barc). 2008 Nov; 44(11): 857-863.	☐
		049	TAN et al., "Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets," European Journal of Gastroenterology & Hepatology 2001 Apr; 13(4): 425-427.	☐
		050	The United States Pharmacopeia, "701 Disintegration", USP 32 (2009); NF 27, Volume 1, pages 262-263, 4 pages.	☐

Examiner Signature		Date Considered	

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UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	07/23/2024 05:15:30 PM Z ET	ELLO-119/08US 342083-2017

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	66467779	AUTHORIZED BY	Jonathan Cousin
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	E20247MH16006068	Jules Lange

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1202	EACH CLAIM IN EXCESS OF 20	100.00	14	1400.00
1251	EXTENSION FOR RESPONSE WITHIN FIRST MONTH	220.00	1	220.00
			TOTAL AMOUNT:	$1,620.00

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 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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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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PGR Petition - USP 12,290,598

UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**07/23/2024 05:15:30 PM Z ET**	**ELLO-119/08US 342083-2017**

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PATENT CENTER #	66487779	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 3

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
ELLO-119_08US Response to Non-Final Office Action.pdf		10	-	213 KB
ELLO-119_08US Response to Non-Final Office Action-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	125 KB
ELLO-119_08US Response to Non-Final Office Action-CLM.pdf	(2-6)	5	Claims	147 KB
ELLO-119_08US Response to Non-Final Office Action-REM.pdf	(7-10)	4	Applicant Arguments/Remarks Made in an Amendment	156 KB

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
ELLO-119_08US Response to Non-Final Office Action.pdf	9219CE980A0A0197F7F5BF0F9CDF43417C213534E766DE39651774CF0E13C862CF0D975A10734F40D2C83E9092393482FF51F1388A34F089C1BE5C2066D2BC09
ELLO-119_08US Response to Non-Final Office Action-A....pdf	86C0253C20240E1365A02FA1C52FDEEDF7B3B0891FE5596B70A007BF3B5953DF3CE2712D3FABEEF28CFCEEFF5E766DD8B3600A8532533DF535BA0863B3581148
ELLO-119_08US Response to Non-Final Office Action-CLM.pdf	624729524F4AEA1C7118089A7E38DAD7624D1B0454FD5656B2D72206C5BD0071193CDE19E9179B124060C8C681B1BB2A471E11FB4977FB60F3F7A0F0ADFC9040
ELLO-119_08US Response to Non-Final Office Action-REM.pdf	0C1D84AD1B469656AF1A752E4B9884FF5DFFD646BE975304DD1B1AE30E6C8722675C611F92FAE165444C1F0F0C32081757775DAAA5354E101E6EE6FC339C1A5D

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New Applications Under 35 U.S.C. 111

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen PERRETT	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	Examiner:	Sasan, Arandhana

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

AMENDMENT/RESPONSE TO OFFICE ACTION

In response to the Non-final Office Action dated March 26, 2024, to which the deadline for responding is July 26, 2024, with a one-month extension of time, Applicant submits the following Amendments and Remarks, and respectfully requests reconsideration of the application in view thereof.

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

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

Remarks begin on page 7 of this paper.

IN THE CLAIMS:

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

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

(i) about [[1]]0.5 mg to about 6 mg of ~~fluticasone propionate~~ a corticosteroid selected from fluticasone propionate or budesonide; and

(ii) at least one disintegrant;

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

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

wherein the orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%.

2. (Currently Amended) The orally disintegrating tablet of claim 1, comprising about [[1]]0.5 mg to about 2 mg of ~~fluticasone propionate~~ the corticosteroid.

3. (Currently Amended) The orally disintegrating tablet of claim 1, comprising about 3 mg of ~~fluticasone propionate~~ the corticosteroid.

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

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

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

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

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

9. (Currently Amended) The orally disintegrating tablet of claim [[5]]2, ~~comprising about 1 mg to about 2 mg of fluticasone propionate~~ wherein the corticosteroid is budesonide.

10. (Currently Amended) The orally disintegrating tablet of claim 5, wherein the orally disintegrating tablet comprises ~~comprising~~ about 3 mg of fluticasone propionate.

11. (Currently Amended) The orally disintegrating tablet of claim [[8]]3, ~~comprising about 1 mg to about 2 mg of fluticasone propionate~~wherein the corticosteroid is fluticasone propionate.

12. (Currently Amended) The orally disintegrating tablet of claim 8, wherein the orally disintegrating tablet comprises ~~comprising~~ about 3 mg of fluticasone propionate.

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

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

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

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

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

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

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

20-27. (Cancelled)

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

29-30. (Cancelled)

31. (New) The method of claim 28, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.

32. (New) The method of claim 28, wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.

33. (New) The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a hardness of 4-48 N.

34. (New) The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a friability of not more than 1%.

35. (New) The orally disintegrating tablet of claim 1, wherein the orally disintegrating has a hardness of 4-48 N and a friability of not more than 1%.

36. (New) The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a friability of not more than 0.6%.

37. (New) The orally disintegrating tablet of claim 35, wherein the orally disintegrating tablet has a friability of not more than 0.6%.

38. (New) The orally disintegrating tablet of claim 37, wherein the orally disintegrating tablet has a thickness of 2-2.8 mm.

39. (New) The orally disintegrating tablet of claim 14, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.

40. (New) The orally disintegrating tablet of claim 16, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.

41. (New) The method of claim 28, wherein the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.

42. (New) The method of claim 28, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

43. (New) The orally disintegrating tablet of claim 38, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.

44. (New) The orally disintegrating tablet of claim 38, wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.

REMARKS

I. Status of the Claims

Upon entry of these amendments, claims 1-19, 28, and 31-44 are pending in the present application. Claims 20-27, 29, and 30 were previously cancelled, without prejudice or disclaimer.

In this response, claims 1-3, 5, 8-12, 18, 19, and 28 have been amended. Claim 1 has been amended to recite "about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide", to further specify that a therapeutically effective amount of the corticosteroid is deposited topically in the "esophagus", and to state that the "orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%." Conforming amendments were made the dependent claims. Support for the claim amendments can be found throughout the application as originally filed, for example in Example 1.

Claim 8 has been amended to correct a clerical error.

Claims 1, 18, 19, and 28 have been amended to refer to an "orally disintegrating tablet."

Claim 28 has been further amended to refer to "a patient."

Claims 31-44 are newly added and recite additional properties of the orally disintegrating tablet.

No new matter is added. Entry of the present amendments is therefore respectfully requested.

The above-noted amendments are supported by the application as originally filed and do not introduce any new matter. The amendments are made without prejudice to the prosecution of any canceled or amended subject matter in one or more continuing application(s).

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

II. Claim Objections

The Examiner has objected to claim 28 stating that the article "a" should be added before the term "patient" in line 1. Applicant has amended claim 28 as suggested by the Examiner, thus rendering this objection moot, and respectfully requests withdrawal of the claim objection.

III. Claim Rejections Under 35 U.S.C. § 112

Claims 1, 18-19, and 28 stand rejected under 35 U.S.C. § 112 as being indefinite because of the inconsistent usage of the terms “dispersing” and “disintegrating”.

In response, these claims have been amended to recite “disintegrating”.

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

IV. The Nonstatutory Double Patenting Rejections are Overcome

Claims 1-19 and 28 stand rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-40 of U.S. Patent No. 8,771,729 B2.

Claims 1-19 and 28 stand rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-42 of U.S. Patent No. 9,486,407 B2.

Without acquiescing to the merits of the rejections, terminal disclaimers over U.S. Patent Nos. 8,771,729 and 9,486,407 are submitted herewith along with the requisite fee. Withdrawal of the nonstatutory double patenting rejections is therefore respectfully requested.

V. The Statutory Double Patenting Rejection is Overcome

Claims 1-19 and 28 stand rejected under 35 U.S.C. 101 as claiming the same invention as claims 1-19 and 28 of U.S. Patent No. 11,266,598 B2.

As noted above, claim 1 has been amended to recite “about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide”, to further specify that a therapeutically effective amount of the corticosteroid is deposited topically in the “esophagus”, and to state that the “orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%.”

For at least the foregoing reasons, Applicant submits that claim 1 and the claims that depend therefrom are not coextensive in scope with the claims of U.S. Patent No. 11,266,598, and therefore respectfully requests withdrawal of the double patenting rejection under 35 U.S.C. § 101.

CONCLUSION

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

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283 referencing Docket No. ELLO-119/08US 342083-2017. However, the Director is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 23, 2024

Respectfully submitted,
COOLEY LLP

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	07/23/2024 05:05:50 PM Z ET	ELLO-119/08US 342083-2017

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	8616	FILED BY	Jules Lange
PATENT CENTER #	66466024	AUTHORIZED BY	Jonathan Cousin
CUSTOMER #	58249	FILING DATE	01/05/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Stephen PERRETT

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 501283	E20247MH06235258	Jonathan Cousin

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	$170.00

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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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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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/569,047	**07/23/2024 05:05:50 PM Z ET**	**ELLO-119/08US 342083-2017**

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PATENT CENTER #	66486024	FILING DATE	01/05/2022
CUSTOMER #	58249	FIRST NAMED INVENTOR	Stephen PERRETT
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Jonathan Cousin

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	49 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic-Approved	19 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	CE8061D3047E6C025CE7BB31E4A2563850AEFA5B956EB07E6E1B9680E8B395F5657D18D6B71C15B77F043CB85FA61E80FB

	152FCB5C69BF013A7FE811F4A57AC3
grantLetter.pdf	0B08F44D1AFBB968C19A2EE71DAC5DFC31CB86BAC6802827 AE1A99E139A3340A12FCBFFE24ABFEF8D1C08238FD6D8B4D C863395E9800ED42D82D3CDE5B1CA595

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.

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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.

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APPROVAL LETTER

APPLICATION #	FILING DATE	APPLICANT/PATENT UNDER REEXAMINATION
17/569,047	01/05/2022	Stephen PERRETT

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Electronic terminal disclaimer filed on 07/23/2024

☑ Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

APPLICATION #	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #
17569047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017

Title of Invention

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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

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

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

The owner(s) of 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 any patent granted on pending reference Application Number(s)

Application #	Filing Date

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. 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 any patent granted on the reference application 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 any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: 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 shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of 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)

Patent #
9486407
8771729

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) included with Electronic Terminal Disclaimer request.

Applicant claims the following entity status:
Regular Undiscounted

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I hereby declare that all statements made herein of my own knowledge are true and that all statemnts 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.

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

Signature	Name	Registration #
/Jonathan M. Cousin/	Jonathan Cousin	66418

* 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.

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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
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/569,047	Filing Date 01/05/2022	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ 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	07/23/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 34	Minus	** 20	= 14		x $100 =	1400
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	1400

		(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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/TRINA RIDDICK/
*** 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.

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PGR Petition - USP 12,290,598

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017	8616

58249 7590 03/26/2024

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
03/26/2024	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. 17/569,047	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 07/18/22.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 1-19 and 28 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-19 and 28 is/are rejected.

8) ☑ Claim(s) 28 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

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

Status of Application

2. The preliminary amendment filed on 07/18/22 is acknowledged.

3. Claims 20-27 and 29-30 were cancelled.

4. Claims 1-19 and 28 are pending and are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed on 08/11/22 (2 IDSs); 11/18/22; 02/01/23 (2 IDSs); and 10/02/23 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. Claim **28** is objected to because of the following informalities: In claim 28, line 1, the article "a" should be added before the term "patient." Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

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

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

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8. Claims **1**, **18-19**, and **28** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

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

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

11. Claim **28** recites the limitation "... the orally **dispersing** tablet ..." (in line 2) (emphasis added). Claim 28 is dependent on claim 1, and the preamble of claim 1 recites "An orally **disintegrating** tablet ..." (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

12. 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 conflicting claims 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

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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); *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 nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

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The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) 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 www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

13. **Claims 1-19 and 28 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 8,771,729 B2 ("the '729 Patent")**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally disintegrating tablet (ODT) comprising about 1 mg to about 6 mg of fluticasone propionate, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

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

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

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

Another difference is that claim 29 of the '729 Patent recites a method for treating an inflammatory condition of the gastrointestinal (GI) tract whereas instant claim 1 is drawn to an orally disintegrating tablet (ODT).

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

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

14. **Claims 1-19 and 28 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 9,486,407 B2 ("the '407 Patent").**

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an ODT comprising about 1 mg to about 6 mg of fluticasone propionate, and at least one disintegrant, wherein the ODT disintegrates within 60 seconds when tested using the USP <701> method for disintegration time, and therefore, encompass overlapping or coextensive subject matter.

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

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

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

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

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

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

Statutory Double Patenting

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no

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longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. **Claims 1-19 and 28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-19 and 28 of prior U.S. Patent No. 11,266,598 B2 ("the '598 Patent")**. This is a statutory double patenting rejection.

17. Please note that the term "dispersing" is recited in line 6 of instant claim 1, line 1 of instant claim 18, line 1 of instant claim 19, and line 2 of instant claim 28. The term "disintegrating" is recited in claims 1, 18, 19, and 28 of the '598 Patent. Despite the different terminology, the same invention is being claimed in both the '598 Patent and the instant application since the orally disintegrating tablet disperses or disintegrates or breaks apart in both cases.

Conclusion

18. No claims are allowed.

19. 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.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-6023. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

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PGR Petition - USP 12,290,598

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc. with keywords	03/21/2024	AS

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

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

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

Search Notes		
Search Notes	**Date**	**Examiner**
Reviewed IDS, prosecution history of related cases, PDP search, DAV continuity data map and inventor info tabs. PE2E Search - including CPC with keyword, inventor, assignee, applicant name, and interference search. STIC/NPL search. Please see the attached history for each search.	03/21/2024	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/569,047	PERRETT et al.
	Examiner	Art Unit
	ARADHANA SASAN	1615

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	((("ODT") ((oral$2 mouth buccal$2 cheek saliva$4) near5 (dispers$8 disintegra$4 dissol$4 break$4) near5 (tablet$4 compress$4 compact$4 pill lozenge dragee))) same (fluticasone near2 propionate) same (time period second minute)).clm.	03/21/2024	AS

/ARADHANA SASAN/ Primary Examiner, Art Unit 1615	

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 on 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 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.

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

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Application No.: 17/569,047 **Docket No.:** ELLO-119/08US 342083-2017

[] 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 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 on the attached Form used in lieu of PTO/SB/08.

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

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

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

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

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

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

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

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00; or

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

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[] 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.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

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. §1.97(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:

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

and

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

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

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

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

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

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

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

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Application No.: 17/569,047 **Docket No.:** ELLO-119/08US 342083-2017

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

Cooley Docket No.	Case Status	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date
ELLO-119/01US	Registered	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014
ELLO-119/02US	Registered	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016
ELLO-119/03US	Registered	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016
ELLO-119/04US	Registered	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017
ELLO-119/05US	Registered	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020
ELLO-119/06US	Registered	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020	11,246,828	2/15/2022
ELLO-119/07US	Registered	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021	11,266,598	3/8/2022

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.

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

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Application No.: 17/569,047 **Docket No.:** ELLO-119/08US 342083-2017

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.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1283, under Order No. ELLO-119/08US 342083-2017 from which the undersigned is authorized to draw.

Dated: February 1, 2023

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

COOLEY LLP
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By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Dou Yeon Youn
Reg. No. 79,828

280788158 v1

/ARADHANA SASAN/ 03/21/2024

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L445	1	"17569047"	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 12:13 PM
L446	16	"12896005"	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 12:13 PM
L447	15	446 AND (fluticasone near2 propionate)	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 12:15 PM
L448	3	446 AND (fluticasone near2 propionate).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 12:15 PM
L449	109	("10076494" OR "10105315" OR "10176301" OR "10272037" OR "10471071" OR "10632069" OR "11026887" OR "11166961" OR "11246828" OR "11260061" OR "11266598" OR "20010006625" OR "20010014340" OR "20030050312" OR "20030054036" OR "20030099701" OR "20030215500" OR "20040009212" OR "20040053902" OR "20040106663" OR "20040228919" OR "20040265375" OR "20050009848" OR "20050112188" OR "20050232988" OR "20060051414" OR "20060134054" OR "20060292099" OR "20070020330" OR "20070059361" OR "20070111978" OR "20090074862" OR "20090123390" OR "20090123550" OR "20090123551" OR "20090131386" OR "20090149433" OR "20090155360" OR "20090169620" OR "20090181099" OR "20090191275" OR "20100034894" OR "20100215753" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:03 PM

		"20100216754" OR "20110081411" OR "20110097401" OR "20110123460" OR "20110129530" OR "20120128764" OR "20120282335" OR "20130296286" OR "20130310661" OR "20140187523" OR "20140228714" OR "20140287051" OR "20140303131" OR "20150209432" OR "20150231156" OR "20160045518" OR "20160078186" OR "20160206627" OR "20160213681" OR "20170071855" OR "20170183719" OR "20180071211" OR "20180133145" OR "20180153802" OR "20190008760" OR "20190201333" OR "20200016171" OR "20200214979" OR "20200368147" OR "20200381097" OR "20210205328" OR "20210244660" OR "20210275438" OR "20210346278" OR "20220110945" OR "3705172" OR "3929768" OR "4080448" OR "4335121" OR "4363806" OR "4472393" OR "4985418" OR "5135740" OR "5278175" OR "5403893" OR "5446070" OR "5482934" OR "5776433" OR "5863910" OR "6171617" OR "6316027" OR "6596298" OR "6596311" OR "6740332" OR "7033606" OR "8077288" OR "8545881" OR "8580300" OR					

		"8679545" OR "8771729" OR "8932596" OR "9387167" OR "9486407" OR "9782347" OR "9849084" OR "9867780").pn.					
L450	2	("0000001" OR "0000002").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:05 PM
L452	2	("10869592" "20220347189").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:05 PM
L453	1	("20160324772").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:06 PM
L455	1	("11684571").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:07 PM
L456	10	((("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 (fluticasone near2 propionate) SAME (time period second minute)).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/03/21 03:14 PM
L457	12	((("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 (fluticasone near2 propionate) SAME (time period second minute)).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/21 03:15 PM
L458	88	((("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 (fluticasone near2 propionate) SAME (time period second minute))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2024/03/21 03:15 PM

			SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L459	15	((("ELLODI") near3 ("PHARMACEUTICALS") near3 ("L.P"))).AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L460	15	("ELLODI").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L461	76	("EURAND").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L462	69	("APTALIS").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L463	81	("ADARE").AS,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L464	204	((("PERRETT") near3 ("Stephen")) OR (("COHEN") near3 ("Fredric")) OR (("VENKATESH") near3 ("Gopi"))).INV,AANM.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:15 PM
L465	325	459 460 461 462 463 464	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:16 PM
L466	10	465 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 (fluticasone near2 propionate) SAME (time period second minute)).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/03/21 03:16 PM
L467	12	((("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 (fluticasone near2 propionate) SAME (time period second minute)).clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/21 03:21 PM

L468	88	((("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 (fluticasone near2 propionate) SAME (time period second minute))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/21 03:21 PM
L469	3117384	(A61K9/0065 OR A61K9/0053 OR A61K9/0056 OR A61K9/006 OR A61K9/08 OR A61K31/56 OR A61K31/569 OR A61K31/58 OR A61K45/06 OR A61K47/38 OR A61K9/06 OR A61P1/00 OR A61P1/04 OR A61P11/00 OR A61P11/04 OR A61P29/00 OR A61P31/04 OR A61P31/10 OR A61P31/12 OR A61P37/02 OR A61K31/573 OR A61K47/34 OR A61K9/2054 OR A61K9/10 OR A61K9/107).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/21 03:22 PM
L470	83	469 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 (fluticasone near2 propionate) SAME (time period second minute))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/03/21 03:22 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Full Search History

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=> d his full

     (FILE 'HOME' ENTERED AT 13:03:33 ON 15 MAR 2024)
               D CLUSTER
               D SET
               D SEL

     FILE 'REGISTRY' ENTERED AT 13:06:39 ON 15 MAR 2024
L1             1 SEA SPE=ON  ABB=ON  PLU=ON  FLUTICASONE/CN
               D RN
L2            24 SEA SPE=ON  ABB=ON  PLU=ON  90566-53-3/CRN
L3            24 SEA SPE=ON  ABB=ON  PLU=ON  FLUTICASONE
L4             1 SEA SPE=ON  ABB=ON  PLU=ON  FLUTICASONE PROPIONATE/CN
               D RN
L5            32 SEA SPE=ON  ABB=ON  PLU=ON  80474-14-2/CRN
L6             6 SEA SPE=ON  ABB=ON  PLU=ON  FLUTICASONE PROPIONATE
L7             2 SEA SPE=ON  ABB=ON  PLU=ON  MANNITOL/CN
               D RN 1-2
L8           541 SEA SPE=ON  ABB=ON  PLU=ON  69-65-8/CRN
L9            40 SEA SPE=ON  ABB=ON  PLU=ON  87-78-5/CRN
L10        14766 SEA SPE=ON  ABB=ON  PLU=ON  MANNITOL
L11            1 SEA SPE=ON  ABB=ON  PLU=ON  PVPP/CN
               D RN
L12          396 SEA SPE=ON  ABB=ON  PLU=ON  9003-39-8/CRN
L13            1 SEA SPE=ON  ABB=ON  PLU=ON  PVPP

     FILE 'HCAPLUS' ENTERED AT 13:11:45 ON 15 MAR 2024
               E FLUTICASONE/CT
               D SEL
L14         2415 SEA SPE=ON  ABB=ON  PLU=ON  FLUTICASONE+NT,PFT,LT,OLD/CT
L15         3534 SEA SPE=ON  ABB=ON  PLU=ON  "FLUTICASONE PROPIONATE"+NT,PFT,LT,
               OLD/CT
               E MANNITOL/CT
               D SEL
L16        80621 SEA SPE=ON  ABB=ON  PLU=ON  MANNITOL+NT,PFT,LT,OLD/CT
               E PVPP/CT
               D SEL
               E PVPP+ALL/CT
               D SEL
               E POLY(VINYLPYRROLIDONE)/CT
               D SEL
L17       174125 SEA SPE=ON  ABB=ON  PLU=ON  "POLY(VINYLPYRROLIDONE)"+NT,PFT,LT,
               OLD/CT
               E DISINTIGRANTS/CT
               D SEL
               E DISINTEGRANT/CT
               D SEL
L18        15123 SEA SPE=ON  ABB=ON  PLU=ON  DISINTEGRANTS+NT,PFT,LT,OLD/CT
               E DISPERSANTS/CT
               D SEL
               E DISPERSANTS+ALL/CT
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                D SEL
                E DISPERSING AGENTS/CT
                D SEL
L19       235948 SEA SPE=ON  ABB=ON  PLU=ON  "DISPERSING AGENTS"+NT,PFT,LT,OLD/C
                 T
                E PARTICLE SIZE/CT
                D SEL
L20       764405 SEA SPE=ON  ABB=ON  PLU=ON  "PARTICLE SIZE"+NT,PFT,LT,OLD/CT
                E GRANULAR PHARMACEUTICALS/CT
                D SEL
                E GRANULAR PHARMACEUTICALS+ALL/CT
                D SEL
                E PHARMACEUTICAL GRANULES/CT
                D SEL
L21        52487 SEA SPE=ON  ABB=ON  PLU=ON  "PHARMACEUTICAL GRANULES"+NT,PFT,LT
                 ,OLD/CT
                E EOSINOPHILIC ESOPHAGITIS/CT
                D SEL
L22         1005 SEA SPE=ON  ABB=ON  PLU=ON  "EOSINOPHILIC ESOPHAGITIS"+NT,PFT,L
                 T,OLD/CT
L23           63 SEA SPE=ON  ABB=ON  PLU=ON  ((L1 OR L2 OR L3 OR L4 OR L5 OR
                 L6) OR (L14 OR L15) OR FLUTICASONE? OR FLUTICASONE PROPIONATE)
                 AND ((L7 OR L8 OR L9 OR L10) OR L16 OR MANNITOL?) AND ((L11 OR
                 L12 OR L13) OR L17 OR PVPP OR POLYVINYLPYRROLIDONE OR "POLY(VIN
                 YLPYRROLIDONE)" OR CROSPOVIDONE)
L24           44 SEA SPE=ON  ABB=ON  PLU=ON  L23 AND ((L4 OR L5 OR L6) OR L15
                 OR FLUTICASONE PROPIONATE)
L25            2 SEA SPE=ON  ABB=ON  PLU=ON  (L23 OR L24) AND (L18 OR DISINTEGRA
                 ?) AND (L19 OR DISPERS?)
L26           27 SEA SPE=ON  ABB=ON  PLU=ON  (L23 OR L24 OR L25) AND (L20 OR
                 PARTIC?)
L27           10 SEA SPE=ON  ABB=ON  PLU=ON  (L23 OR L24 OR L25 OR L26) AND
                 (L21 OR GRANUL? OR GRAIN)
L28            2 SEA SPE=ON  ABB=ON  PLU=ON  (L24 OR L25 OR L26 OR L27) AND
                 (L22 OR EOSINOPHILIC ESOPHAGITIS)
L29            6 SEA SPE=ON  ABB=ON  PLU=ON  (L24 OR L25 OR L26 OR L27) AND
                 (L22 OR EOSINOPHILIC ESOPHAGITIS OR ESOPHAGITIS)
L30            4 SEA SPE=ON  ABB=ON  PLU=ON  L26 AND L27
L31            9 SEA SPE=ON  ABB=ON  PLU=ON  L24 AND (L25 OR (L28 OR L29 OR
                 L30))
L32           10 SEA SPE=ON  ABB=ON  PLU=ON  L25 OR (L28 OR L29 OR L30 OR L31)
                D L25 1-2 AU
                E US 2022-0339098/PN
                D SEL
L33            1 SEA SPE=ON  ABB=ON  PLU=ON  US 2022-0339098/PN
                D AU
                SEL RN
                D SEL

     FILE 'REGISTRY' ENTERED AT 13:28:23 ON 15 MAR 2024
L34          106 SEA SPE=ON  ABB=ON  PLU=ON  (57-50-1/BI OR 616-45-5/BI OR
                 9003-01-4/BI OR 9003-39-8/BI OR 9004-32-4/BI OR 9004-34-6/BI
                 OR 9005-32-7/BI OR 100-79-8/BI OR 10043-01-3/BI OR 102-76-1/BI
                 OR 102190-94-3/BI OR 104227-87-4/BI OR 105-53-3/BI OR 105-54-4/
                 BI OR 105-58-8/BI OR 105-60-2/BI OR 105102-22-5/BI OR 108-32-7/
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                BI OR 109-99-9/BI OR 11138-66-2/BI OR 118-71-8/BI OR 1190-39-2/
                BI OR 123-25-1/BI OR 124832-26-4/BI OR 12619-70-4/BI OR
                126544-47-6/BI OR 134-62-3/BI OR 137234-62-9/BI OR 1398-61-4/BI
                 OR 1400-61-9/BI OR 141-78-6/BI OR 162808-62-0/BI OR 16325-47-6
                /BI OR 166663-25-8/BI OR 171228-49-2/BI OR 175865-60-8/BI OR
                235114-32-6/BI OR 23593-75-1/BI OR 24817-92-3/BI OR 24980-41-4/
                BI OR 25086-15-1/BI OR 25189-55-3/BI OR 25248-42-4/BI OR
                25322-68-3/BI OR 26009-03-0/BI OR 26023-30-3/BI OR 26202-08-4/B
                I OR 26680-10-4/BI OR 31621-87-1/BI OR 3385-03-3/BI OR
                39809-25-1/BI OR 4419-39-0/BI OR 4740-78-7/BI OR 50-70-4/BI OR
                51333-22-3/BI OR 52350-85-3/BI OR 52352-27-9/BI OR 52814-38-7/B
                I OR 53783-83-8/BI OR 54-42-2/BI OR 5464-28-8/BI OR 56-81-5/BI
                OR 57-55-6/BI OR 585-88-6/BI OR 59227-89-3/BI OR 59277-89-3/BI
                OR 60-01-5/BI OR 61951-99-3/BI OR 63-42-3/BI OR 64-17-5/BI OR
                661-19-8/BI OR 67-63-0/BI OR 67-64-1/BI OR 67-68-5/BI OR
                67-71-0/BI OR 69-65-8/BI OR 69-79-4/BI OR 69304-47-8/BI OR
                70-00-8/BI OR 717913-32-1/BI OR 7226-23-5/BI OR 77-93-0/BI OR
                77-94-1/BI OR 78-93-3/BI OR 78644-42-5/BI OR 78666-19-0/BI OR
                79-10-7/BI OR 79-41-4/BI OR 80474-14-2/BI OR 818-38-2/BI OR
                82410-32-0/BI OR 84625-61-6/BI OR 86386-73-4/BI OR 87-99-0/BI
                OR 872-50-4/BI OR 9000-69-5/BI OR 9001-92-7/BI OR 9004-57-3/BI
                OR 9004-64-2/BI OR 9004-67-5/BI OR 9012-76-4/BI OR 9050-36-6/BI
                 OR 90566-53-3/BI OR 9063-38-1/BI OR 9068-38-6/BI OR 97-64-3/BI
                )
L35           2 SEA SPE=ON  ABB=ON  PLU=ON  L34 AND (L1 OR L2 OR L3 OR L4 OR
                L5 OR L6)
L36           1 SEA SPE=ON  ABB=ON  PLU=ON  L34 AND (L7 OR L8 OR L9 OR L10)
L37           1 SEA SPE=ON  ABB=ON  PLU=ON  L34 AND (L11 OR L12 OR L13)

     FILE 'HCAPLUS' ENTERED AT 13:29:59 ON 15 MAR 2024
L38          49 SEA SPE=ON  ABB=ON  PLU=ON  L35 AND L36 AND L37
L39           7 SEA SPE=ON  ABB=ON  PLU=ON  L38 AND (L22 OR EOSINOPHILIC
                ESOPHAGITIS OR ESOPHAGITIS)
L40         409 SEA SPE=ON  ABB=ON  PLU=ON  VENKATESH, G?/AU
L41         127 SEA SPE=ON  ABB=ON  PLU=ON  PERRETT, S?/AU
L42         762 SEA SPE=ON  ABB=ON  PLU=ON  COHEN, F?/AU
L43           1 SEA SPE=ON  ABB=ON  PLU=ON  L40 AND L41 AND L42
L44           3 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND
                ((L1 OR L2 OR L3 OR L4 OR L5 OR L6) OR (L14 OR L15) OR
                FLUTICASONE? OR FLUTICASONE PROPIONATE)
L45           3 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND
                (L22 OR EOSINOPHILIC ESOPHAGITIS OR ESOPHAGITIS)
L46           3 SEA SPE=ON  ABB=ON  PLU=ON  (L43 OR L44 OR L45)

     FILE 'MEDLINE, BIOSIS, EMBASE' ENTERED AT 13:33:21 ON 15 MAR 2024
L47           7 SEA SPE=ON  ABB=ON  PLU=ON  L43
L48           0 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND (L1
                OR L4 OR FLUTICASONE? OR FLUTICASONE PROPIONATE)
L49           3 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND
                (EOSINOPHILIC ESOPHAGITIS OR ESOPHAGITIS)
L50          10 SEA SPE=ON  ABB=ON  PLU=ON  (L47 OR L48 OR L49)

     FILE 'WPINDEX' ENTERED AT 13:34:37 ON 15 MAR 2024
L51           2 SEA SPE=ON  ABB=ON  PLU=ON  L40 AND L41 AND L42
L52           4 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND (L1
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               OR L4 OR FLUTICASONE? OR FLUTICASONE PROPIONATE)
L53          4 SEA SPE=ON  ABB=ON  PLU=ON  (L40 OR L41 OR L42 OR L43) AND
               (EOSINOPHILIC ESOPHAGITIS OR ESOPHAGITIS)
L54          5 SEA SPE=ON  ABB=ON  PLU=ON  (L51 OR L52 OR L53)
L55          7 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR L4 OR FLUTICASONE? OR
               FLUTICASONE PROPIONATE) AND (L7 OR MANNITOL) AND (L11 OR PVPP
               OR CROSPOVIDONE OR POLYVINYLPOLYPYRROLIDONE)
L56          7 SEA SPE=ON  ABB=ON  PLU=ON  L55 AND (DISINTEGRA? OR  DISPERS?)

L57          7 SEA SPE=ON  ABB=ON  PLU=ON  (L55 OR L56) AND (GRANUL? OR GRAIN
               OR PARTIC?)
L58          3 SEA SPE=ON  ABB=ON  PLU=ON  (L55 OR L56 OR L57) AND (EOSINOPHIL
               IC ESOPHAGITIS OR ESOPHAGITIS)
               D SCAN
L59          7 SEA SPE=ON  ABB=ON  PLU=ON  (L55 OR L56 OR L57 OR L58)

     FILE 'MEDLINE, BIOSIS, EMBASE' ENTERED AT 13:41:16 ON 15 MAR 2024
L60          1 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR L4 OR FLUTICASONE? OR
               FLUTICASONE PROPIONATE) AND (L7 OR MANNITOL) AND (L11 OR PVPP
               OR CROSPOVIDONE OR POLYVINYLPOLYPYRROLIDONE)
L61          0 SEA SPE=ON  ABB=ON  PLU=ON  L60 AND (DISINTEGRA? OR DISPERS?)

L62          0 SEA SPE=ON  ABB=ON  PLU=ON  (L60 OR L61) AND (GRANUL? OR GRAIN
               OR PARTIC?)
L63          0 SEA SPE=ON  ABB=ON  PLU=ON  (L60 OR L61 OR L62) AND (EOSINOPHIL
               IC ESOPHAGITIS OR ESOPHAGITIS)
L64          1 SEA SPE=ON  ABB=ON  PLU=ON  (L60 OR L61 OR L62 OR L63)
               D AU
               D STAT QUERY L32
               D STAT QUERY L64
               D STAT QUERY L59

     FILE 'HCAPLUS, EMBASE, WPINDEX' ENTERED AT 13:43:29 ON 15 MAR 2024
L65         15 DUP REM L32 L64 L59 (3 DUPLICATES REMOVED)
                    ANSWERS '1-10' FROM FILE HCAPLUS
                    ANSWER '11' FROM FILE EMBASE
                    ANSWERS '12-15' FROM FILE WPINDEX
               D L65 1-10 IBIB ED ABS HITRN HITSTR
               D L65 11 IBIB ED ABS HIT
               D L65 12-15 IBIB ED ABS HIT
               D STAT QUERY L46
               D STAT QUERY L50
               D STAT QUERY L54

     FILE 'HCAPLUS, BIOSIS, WPINDEX' ENTERED AT 13:44:53 ON 15 MAR 2024
L66         15 DUP REM L46 L50 L54 (3 DUPLICATES REMOVED)
                    ANSWERS '1-3' FROM FILE HCAPLUS
                    ANSWERS '4-13' FROM FILE BIOSIS
                    ANSWERS '14-15' FROM FILE WPINDEX
               D L66 1-3 IBIB ED ABS HITRN
               D L66 4-13 IBIB ED ABS HIT
               D L66 14-15 IBIB ED ABS HIT
               D STAT QUERY L39
               D L39 1-7 IBIB ED ABS HITRN HITSTR
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FILE HOME

FILE REGISTRY
Property values tagged with IC are from the ZIC/VINITI data file provided by InfoChem.

STRUCTURE FILE UPDATES: 14 MAR 2024 HIGHEST RN 3030629-32-1
DICTIONARY FILE UPDATES: 14 MAR 2024 HIGHEST RN 3030629-32-1

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http://www.cas.org/legal/infopolicy

TSCA Inventory information is current through February 2024.

Please note that search-term pricing does apply when conducting SmartSELECT searches.

REGISTRY includes numerically searchable data for experimental and predicted properties as well as tags indicating availability of experimental property data in the original document. For information on property searching in REGISTRY, refer to:

http://www.cas.org/training/stn/database-specific

FILE HCAPLUS

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FILE COVERS 1907 - 15 Mar 2024 VOL 186 ISS 2
FILE LAST UPDATED: 14 Mar 2024 (20240314/ED)

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http://www.cas.org/legal/infopolicy

Huge expansion of patent authority coverage in CA/Caplus provides more complete patent families, expanded invention coverage. See NEWS for details.

This file contains CAS Registry Numbers for easy and accurate substance identification.

FILE MEDLINE

```
 FILE COVERS 1946 TO DATE.
 FILE LAST UPDATED: 14 Mar 2024 (20240314/UP).

 MEDLINE(R) is a registered trademark of the U.S. National Library of
 Medicine (NLM).

 Effective January 22, 2024, the 2024 version of the MeSH thesaurus is
 now available in Medline.  The MeSH thesaurus is a great resource for
 the latest biomedical search terminology.

 This file contains CAS Registry Numbers for easy and accurate
 substance identification.  See HELP CASRN within Medline for further
 information.

 See HELP RANGE before carrying out any RANGE search.

FILE BIOSIS
FILE COVERS 1926 TO DATE.
CAS REGISTRY NUMBERS AND CHEMICAL NAMES (CNs) PRESENT
FROM JANUARY 1926 TO DATE.

RECORDS LAST ADDED: 13 March 2024 (20240313/ED)

BIOSIS has been augmented with 1.8 million archival records from 1926
through 1968.  These records have been re-indexed to match current
BIOSIS indexing.

FILE EMBASE
 FILE COVERS: Embase-originated material 1947 to 15 Mar 2024 (20240315/ED)
              Unique MEDLINE content 1948 to present

Information on the current version of Emtree, the EMBASE thesaurus,
is available in HELP EMTREE.

This file contains CAS Registry Numbers for easy and accurate
substance identification.

FILE WPINDEX

FILE LAST UPDATED: 15 Mar 2024 (20240315/UP)
FILE COVERS 1963 TO DATE

>>> FOR THE LATEST DERWENT WORLD PATENTS INDEX (DWPI), DCR AND
    DWPIM STN USER DOCUMENTATION, PLEASE VISIT:
    https://www.stn-international.com/reference_information_dwpi <<<

======================================================================
+++ A new and enhanced version of the Derwent World Patents Index
    is now available including citations.
    If you run DCR structure searches or if you like to learn more,
    please see
    https://www.stn-international.com/en/DWPIRelease.pdf
    or contact your STN customer support.  +++
======================================================================
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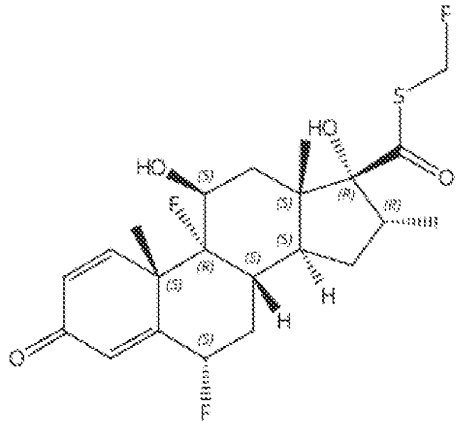
>>> Register links are available in the display field application details (ADT) for patent publication and application numbers, see HELP REGISTER for details. <<<

>>> Unitary patent information is available since DWPI update 2023/058 including new EP C0 family members with associated UP participating states, see HELP UNITARYPATENT. <<<

CAS Registry Information

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L1   ANSWER 1 OF 1  REGISTRY  COPYRIGHT 2024 ACS on STN
RN   90566-53-3  REGISTRY
ED   Entered STN:  16 Nov 1984
CN   Androsta-1,4-diene-17-carbothioic acid,
     6,9-difluoro-11,17-dihydroxy-16-methyl-3-oxo-, S-(fluoromethyl) ester,
     (6α,11β,16α,17α)-  (CA INDEX NAME)
OTHER NAMES:
CN   Fluticasone
CN   VR 506
FS   STEREOSEARCH
DR   220589-36-6
MF   C22 H27 F3 O4 S
CI   COM
LC   STN Files:   ADISINSIGHT, ADISNEWS, BIOSIS, BIOTECHNO, CA, CAPLUS,
       CASBIOACTIVI, CASFORMULTNS, CASREACT, CHEMCATS, CHEMLIST, CIN, EMBASE,
       IPA, MEDLINE, RTECS*, TOXCENTER, USPAT2, USPATFULL
         (*File contains numerically searchable property data)
     Other Sources:   WHO
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Absolute stereochemistry shown

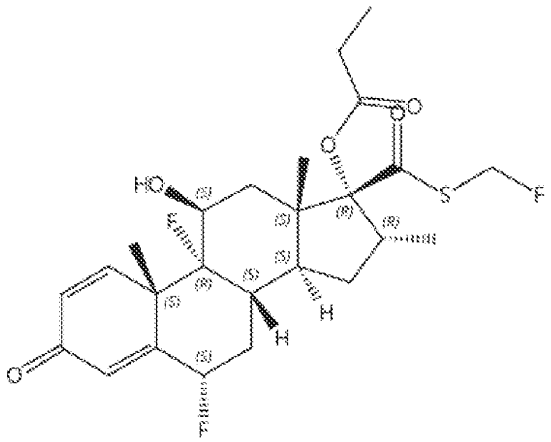
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**PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT**

            2366 REFERENCES IN FILE CA (1907 TO DATE)
              59 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
            2415 REFERENCES IN FILE CAPLUS (1907 TO DATE)


=> d L4 1 ide


L4   ANSWER 1 OF 1  REGISTRY  COPYRIGHT 2024 ACS on STN
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RN 80474-14-2 REGISTRY
ED Entered STN: 16 Nov 1984
CN Androsta-1,4-diene-17-carbothioic acid,
6,9-difluoro-11-hydroxy-16-methyl-3-oxo-17-(1-oxopropoxy)-,
S-(fluoromethyl) ester, (6α,11β,16α,17α)- (CA
INDEX NAME)
OTHER NAMES:
CN Atemur Mite
CN Axotide
CN CCI 18781
CN Cutivate
CN Cutivate cream
CN Cyclesonide
CN F 9428
CN Flixonase
CN Flixonase Nasal Spray
CN Flixotide
CN Flixotide Disk
CN Flixotide Disks
CN Flixotide Inhaler
CN Flonase
CN Flonase Aq
CN Flovent
CN Flovent Diskus
CN Flovent Rotadisk
CN Flunase
CN Fluticasone 17-propionate
CN Fluticasone propionate
CN Fluticone
CN Flutide
CN Flutide N
CN Flutivate
CN Rotadisk
CN Zoflut
FS STEREOSEARCH
MF C25 H31 F3 O5 S
CI COM
SR CA
LC STN Files: ADISINSIGHT, ADISNEWS, BIOSIS, BIOTECHNO, CA, CAPLUS,
CASBIOACTIVI, CASFORMULTNS, CASREACT, CBNB, CHEMCATS, CHEMLIST, CIN,
EMBASE, IMSRESEARCH, IPA, MEDLINE, PATDPASPC, PIRA, PS, RTECS*,
TOXCENTER, USPAT2, USPATFULL
(*File contains numerically searchable property data)



Absolute stereochemistry shown

PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

3455 REFERENCES IN FILE CA (1907 TO DATE)
21 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
3535 REFERENCES IN FILE CAPLUS (1907 TO DATE)

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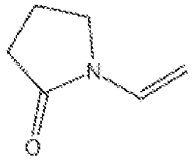
L11 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2024 ACS on STN
RN 9003-39-8 REGISTRY
ED Entered STN: 16 Nov 1984
CN 2-Pyrrolidinone, 1-ethenyl-, homopolymer (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN 2-Pyrrolidinone, 1-vinyl-, polymers (8CI)
OTHER NAMES:
CN 1-Vinyl-2-pyrrolidinone polymer
CN 1-Vinyl-2-pyrrolidone homopolymer
CN 1-Vinyl-2-pyrrolidone polymer
CN 1-Vinylpyrrolidin-2-one homopolymer
CN 1230B
CN 143RP
CN 40K
CN 40K (vinyl polymer)
CN 7TS13
CN 856568G
CN A 16697
CN ACP 10
CN Agent AT 717
CN Agrimer 15
CN Agrimer 30
CN Agrimer 60L
CN Agrimer 90
CN Agrimer ATF

CN Agrimer K 30
CN Albigen A
CN Aldacol Q
CN Antaron P 804
CN Antitox Vana
CN Aqua 65JL
CN Aqua-Quench EC/WE
CN Arostit TL 0280
CN AT 717
CN B 7509
CN BASF-K 85
CN Bolinan
CN Cevian A 88036
CN Creejus K 30
CN Creejus K 50
CN Creejus K 90
CN Cross P.V.P.
CN Deltaspeed AF
CN Discol K 30L
CN Disintex 200
CN Divergan EF
CN Divergan F
CN Divergan RS
CN Epocros WS 560
CN Flexithix
CN Gaftex AE-K 15
CN Ganex P 804
CN Hemodesis
CN Hemodez
CN Hemodez N
CN Hemodez-N
CN PVPP
ADDITIONAL NAMES NOT AVAILABLE IN THIS FORMAT - Use FCN, FIDE, or ALL for DISPLAY
AR 25249-54-1
DR 9015-62-7, 9080-59-5, 29386-94-5, 41724-41-8, 53026-73-6, 53026-74-7, 53200-27-4, 61932-72-7, 65931-56-8, 111214-46-1, 116404-61-6, 121414-75-3, 132778-04-2, 132778-05-3, 132834-20-9, 153631-61-9, 170473-90-2, 496908-06-6, 730985-60-1, 862983-74-2, 878051-55-9, 956148-96-2, 1173909-53-9, 1229193-79-6, 1234714-82-9, 1303541-78-7, 1310675-91-2, 1337987-71-9, 1394151-52-0, 1431958-26-7, 1694674-42-4, 1918127-90-8, 2062651-26-5, 2083718-66-3, 2083718-67-4, 2088158-90-9, 2100274-29-9, 2169285-59-8
MF (C6 H9 N O)x
CI PMS, COM
PCT Polyvinyl
SR CA
LC STN Files: ADISNEWS, BIOSIS, BIOTECHNO, CA, CABA, CAPLUS, CASBIOACTIVI, CASFORMULTNS, CASREACT, CBNB, CHEMCATS, CHEMLIST, CIN, EMBASE, ENCOMPLIT, ENCOMPLIT2, ENCOMPPAT, ENCOMPPAT2, IFIALL, IPA, MEDLINE, PIRA, RTECS*, TOXCENTER, USPAT2, USPATFULL, USPATOLD
(*File contains numerically searchable property data)
Other Sources: DSL**, TSCA**, WHO
(**Enter CHEMLIST File for up-to-date regulatory information)

Dr. Falk Pharma Ex. 1096
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CM 1

CRN 88-12-0
CMF C6 H9 N O

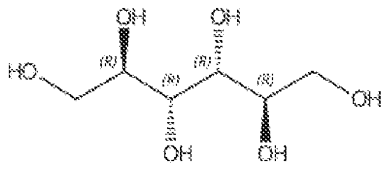


PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

166864 REFERENCES IN FILE CA (1907 TO DATE)
10960 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
174142 REFERENCES IN FILE CAPLUS (1907 TO DATE)

=> d L7 ide

L7 ANSWER 1 OF 2 REGISTRY COPYRIGHT 2024 ACS on STN
RN 87-78-5 REGISTRY
ED Entered STN: 16 Nov 1984
CN Mannitol (CA INDEX NAME)
OTHER NAMES:
CN DL-Mannitol
CN NSC 9256
FS STEREOSEARCH
DR 133-43-7, 5149-40-6, 36413-61-3
MF C6 H14 O6
CI COM
SR CA
LC STN Files: ADISNEWS, BIOSIS, BIOTECHNO, CA, CAPLUS, CASBIOACTIVI, CASFORMULTNS, CASREACT, CBNB, CHEMCATS, CHEMLIST, CIN, EMBASE, IFIALL, NAPRALERT, PIRA, REAXYSFILE*, RTECS*, TOXCENTER, USPAT2, USPATFULL, USPATOLD
(*File contains numerically searchable property data)
Other Sources: DSL**, EINECS**, TSCA**
(**Enter CHEMLIST File for up-to-date regulatory information)



Relative stereochemistry shown

PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

1093 REFERENCES IN FILE CA (1907 TO DATE)
21 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
1268 REFERENCES IN FILE CAPLUS (1907 TO DATE)

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-20160324772	11-10-2016	GREINWALD; Roland 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]
		002	EP-2886108-A1	06-24-2015	FALK PHARMA GMBH [DE]		☐

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.

280842766 v1

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. 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 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		003	SODIKOFF et al., "Therapeutic strategies in eosinophilic esophagitis: Induction, maintenance and refractory disease", Best Pract Res Clin Gastroenterol. (2015 Oct); 29(5): 829-839.	☐
		004	STRAUMANN et al., "Budesonide is effective in adolescent and adult patients with active eosinophilic esophagitis", Gastroenterology (2010 Nov); 139(5): 1526-1537.	☐
		005	STRAUMANN et al., "Long-term budesonide maintenance treatment is partially effective for patients with eosinophilic esophagitis", Clin Gastroenterol Hepatol. (2011 May); 9(5): 400-409.	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	03/21/2024

*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.

280842766 v1

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 documents, Cite Numbers 142, 144, 145, 146, 170, 174, 181, 188, 195, 214, 228, 229, 230, 285, 286, 287, 288, 289, 308, 309, 327, 328, 329, 330, 331, 332, 333, 334, 337, 346, 361, 363, 372, 385, 386, and 387 on the attached Form used in lieu of PTO/SB/08 is enclosed.

[X] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 except for Cite Numbers 142, 144, 145, 146, 170, 174, 181, 188, 195, 214, 228, 229, 230, 285, 286, 287, 288, 289, 308, 309, 327, 328, 329, 330, 331, 332, 333, 334, 337, 346, 361, 363, 372, 385, 386, and 387, referred to above are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). 16/821,464 (U.S. Patent No. 11,246,828), 15/816,154 (U.S. Patent No. 10,632,069), 15/205,390

273468986

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

(U.S. Patent No. 9,849,084), 14/311,732 (U.S. Patent No. 9,387,167) and/or 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 on the attached Form used in lieu of PTO/SB/08.

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

[] Enclosed is a copy of pending patent Application 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.

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Application No.: 17/569,047 **Docket No.:** ELLO-119/08US 342083-2017

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

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

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

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

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

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

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

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

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

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

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

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

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

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

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

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

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

and

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

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

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

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

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

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

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

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Application No.: 17/569,047 **Docket No.:** ELLO-119/08US 342083-2017

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. ELLO-119/08US 342083-2017.

Dated: August 11, 2022

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Matthew Scheideman
Reg. No. 76,605

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/ARADHANA SASAN/ 03/21/2024

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-10869592	12-22-2020	OUYANG et al.	
		002	US-20220347189	11-03-2022	NEZAMIS; James 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]
		003	WO-2022225892-A1	10-27-2022	ELLODI PHARMACEUTICALS L P [US]		☐

Examiner Signature		Date Considered	

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NON-PATENT LITERATURE DOCUMENTS

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		004	GENTILE et al., "Oesophageal narrowing is common and frequently under-appreciated at endoscopy in patients with oesophageal eosinophilia". Alimentary Pharmacology & Therapeutics (2014 Dec); 40(11-12): 1333-1340. Epub 2014 Oct 7.	☐
		005	German Patent Complaint Proceedings in the Regional Court, Mannheim, Ellodi Pharmaceuticals, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, communication from the Regional Court of Mannheim giving Dr. Falk Pharma GmbH the opportunity to comment on the withdrawal of the complaint, dated July 12, 2022, and Machine English translation, 2 pages.	☒
		006	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Notice of termination of proceedings dated August 16, 2022, and English translation, 2 pages.	☒
		007	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Withdrawal of cancellation action dated July 20, 2022, 1 page.	☐
		008	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 25, 2022 regarding Termination of opposition proceedings, 1 page.	☐
		009	Opposition Proceedings in European Patent No. EP 3086782 (Appln. No. 14814872.9), (in the name of Dr. Falk Pharma GmbH) filed by Ellodi Pharmaceuticals, L.P. on June 26, 2019; Written decision on rejection of the opposition dated May 9, 2022, and English translation, 63 pages.	☒

Examiner Signature		Date Considered	

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		010	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Decision to discontinue the opposition proceedings dated September 5, 2022, 2 pages.	☐
		011	PCT/US2022/025297, International Search Report and Written Opinion mailed July 29, 2022, 10 pages.	☐
		012	TAKITA et al., "Successful esophageal endoscopic submucosal dissection with a transoral endoscope after stepwise scope bougienage of post-endoscopic submucosal dissection stricture". JGH Open (2020 Oct 22); 5(1): 163-165. eCollection 2021 Jan.	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	03/21/2024

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Examiner Name	SASAN, ARADHANA
Attorney Docket Number	ELLO-119/08US 342083-2017

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		001	US-11684571	06-27-2023	MELTZER; Brian A. et al.	

FOREIGN PATENT DOCUMENTS

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		002	JP-2006524650-A	11-02-2006	SYNTHON BV.		☒

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Examiner Name	SASAN, ARADHANA
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		003	DELLON E.S., "Safety and Efficacy of Budesonide Oral Suspension Maintenance Therapy in Patients With Eosinophilic Esophagitis", Clin Gastroenterol Hepatol. 2019 Mar; 17(4): 666-673.e8. Epub 2018 Jun 12.	☐
		004	Extended European Search Report for European Application No. EP 20873169.5 dated September 22, 2023, 9 pages.	☐
		005	HIRANO, I., et al. "Randomised clinical trial: the safety and tolerability of fluticasone propionate orally disintegrating tablets versus placebo for eosinophilic oesophagitis", Aliment Pharmacol Ther. 2020 Apr;51(8):750-759. Epub 2020 Mar 9.	☐
		006	KONIKOFF, et al., "A Randomized, Double-Blind, Placebo-Controlled Trial of Fluticasone Propionate for Pediatric Eosinophilic Esophagitis". Gastroenterology. 2006 Nov; 131(5): 1381-1391. Epub 2006 Aug 16.	☐
		007	SCHOEPFER, et al., "Delay in diagnosis of eosinophilic esophagitis increases risk for stricture formation in a time-dependent manner". Gastroenterology. 2013 Dec; 145(6): 1230-1236. Epub 2013 Aug 13.	☐
		008	STRAUMANN et al., "Budesonide Orodispersible Tablets Maintain Remission in a Randomized, Placebo-Controlled Trial of Patients With Eosinophilic Esophagitis". Gastroenterology. 2020 Nov; 159(5): 1672-1685. e5. Epub 2020 Jul 25.	☐

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Bibliographic Data

Application No: 17/569,047

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.
01/05/2022	424	1615	ELLO-119/08US 342083-2017
RULE			

APPLICANTS

Ellodi Pharmaceuticals, L.P., Lawrenceville, NJ, UNITED STATES

INVENTORS

Stephen PERRETT, Princeton, NJ, UNITED STATES

Fredric Jay COHEN, Washington Crossing, PA, UNITED STATES

Gopi M. VENKATESH, Vandalia, OH, UNITED STATES

CONTINUING DATA

This application is a CON of 16821464 03/17/2020 PAT 11246828

16821464 is a CON of 15816154 11/17/2017 PAT 10632069

15816154 is a CON of 15205390 07/08/2016 PAT 9849084

15205390 is a CON of 14311732 06/23/2014 PAT 9387167

14311732 is a DIV of 12896005 10/01/2010 PAT 8771729

12896005 has PRO of 61247642 10/01/2009

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

01/18/2022

STATE OR COUNTRY

UNITED STATES

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PGR Petition - USP 12,290,598

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Art Unit	1615
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		001	US-3705172	12-05-1972	BUCHEL; Karl-Heinz et al.	
		002	US-3929768	12-30-1975	BRATTSAND; Ralph Lennart et al.	
		003	US-4080448	03-21-1978	MIRSKY; Louis H.	
		004	US-4335121	06-15-1982	PHILLIPPS; Gordon H. et al.	
		005	US-4363806	12-14-1982	BERGSTROM; Karl O. et al.	
		006	US-4472393	09-18-1984	SHAPIRO; Elliot L.	
		007	US-4985418	01-15-1991	RICHARDS; David A.	
		008	US-5135740	08-04-1992	KATZ; Martin et al.	
		009	US-5278175	01-11-1994	RAY; Stephen J. et al.	
		010	US-5403893	04-04-1995	TANAKA; Toyoichi et al.	
		011	US-5446070	08-29-1995	MANTELLE; Juan A.	
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		013	US-5776433	07-07-1998	TZOU; Tsi-Zong et al.	
		014	US-5863910	01-26-1999	BOLONICK et al.	
		015	US-6171617	01-09-2001	GRUBER; Peter	
		016	US-6316027	11-13-2001	JOHNSON; Edward Stewart et al.	
		017	US-6596298	07-22-2003	LEUNG; Sau-Hung Spence et al.	
		018	US-6596311	07-22-2003	DOBETTI; Luca	
		019	US-6740332	05-25-2004	ZYCK; Daniel J. et al.	
		020	US-7033606	04-25-2006	BESSE; Jerome et al.	
		021	US-8077288	12-13-2011	KAWASHIMA; Haruna	
		022	US-8545881	10-01-2013	VENKATESH; Gopi M. et al.	

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		023	US-8580300	11-12-2013	WILHELM; Rudolf et al.	
		024	US-8679545	03-25-2014	DOHIL; Ranjan et al.	
		025	US-8771729	07-08-2014	PERRETT; Stephen et al.	
		026	US-8932596	01-13-2015	BENHAMOU; Pierre-Henri et al.	
		027	US-9387167	07-12-2016	PERRETT; Stephen et al.	
		028	US-9486407	11-08-2016	PERRETT; Stephen et al.	
		029	US-9782347	10-10-2017	DOHIL; Ranjan et al.	
		030	US-9849084	12-26-2017	PERRETT; Stephen et al.	
		031	US-9867780	01-16-2018	GREINWALD; Roland et al.	
		032	US-10076494	09-18-2018	PEVZNER et al.	
		033	US-10105315	10-23-2018	MELTZER; Brian A. et al.	
		034	US-10176301	01-08-2019	HILL; Malcolm et al.	
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		037	US-10632069	04-28-2020	PERRETT; Stephen et al.	
		038	US-11026887	06-08-2021	BRIAN; A. Meltzer et al.	
		039	US-11166961	11-09-2021	MICHAEL; A. Gosselin et al.	
		040	US-11246828	02-15-2022	STEPHEN; Perrett et al.	
		041	US-11260061	03-01-2022	GOSSELIN; Michael A. et al.	
		042	US-11266598	03-08-2022	PERRETT; Stephen et al.	
		043	US-20010006625	07-05-2001	BOHN; Manfred et al.	
		044	US-20010014340	08-16-2001	OHTA; Motohiro et al.	

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		045	US-20030050312	03-13-2003	HJORTH; Thyge Borup et al.	
		046	US-20030054036	03-20-2003	LIGGINS; Richard et al.	
		047	US-20030099701	05-29-2003	TAKAISHI; Yuuki et al.	
		048	US-20030215500	11-20-2003	OHTA; Motohiro et al.	
		049	US-20040009212	01-15-2004	TSAI; Tsui-Min	
		050	US-20040053902	03-18-2004	SMITH; C. Steven	
		051	US-20040106663	06-03-2004	TALLEY; John Jeffrey et al.	
		052	US-20040228919	11-18-2004	HOUGHTON; Christian G. et al.	
		053	US-20040265375	12-30-2004	PLATTEEUW; Johannes J. et al.	
		054	US-20050009848	01-13-2005	BRANTL; Victor	
		055	US-20050112188	05-26-2005	ELIAZ; Rom Ezer et al.	
		056	US-20050232988	10-20-2005	VENKATESH; Gopi M. et al.	
		057	US-20060051414	03-09-2006	RAMALHO; Maria Julia Caeiro et al.	
		058	US-20060134054	06-22-2006	KULKARNI; Mohan G. et al.	
		059	US-20060292099	12-28-2006	MILBURN; Michael et al.	
		060	US-20070020330	01-25-2007	DANG; Phuong Grace et al.	
		061	US-20070059361	03-15-2007	RAWAS-QALAJI; Mutasem et al.	
		062	US-20070111978	05-17-2007	DOHIL; Ranjan et al.	
		063	US-20090074862	03-19-2009	SCHIOPPI; Luigi et al.	
		064	US-20090123390	05-14-2009	HILL; Malcolm	
		065	US-20090123550	05-14-2009	PHILLIPS; Elaine et al.	

Examiner Signature		Date Considered	

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PGR Petition - USP 12,290,598

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Sheet 4 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		066	US-20090123551	05-14-2009	PHILLIPS; Elaine et al.	
		067	US-20090131386	05-21-2009	PHILLIPS; Elaine	
		068	US-20090149433	06-11-2009	PHILLIPS; Elaine	
		069	US-20090155360	06-18-2009	VENKATESH; Gopi M. et al.	
		070	US-20090169620	07-02-2009	VENKATESH; Gopi M. et al.	
		071	US-20090181099	07-16-2009	DOHIL; Ranjan et al.	
		072	US-20090191275	07-30-2009	DOHIL; Ranjan et al.	
		073	US-20100034894	02-11-2010	SZYMCZAK; Christopher E. et al.	
		074	US-20100215753	08-26-2010	SHERWOOD; Bob et al.	
		075	US-20100216754	08-26-2010	HILL; Malcolm	
		076	US-20110081411	04-07-2011	PERRETT; Stephen et al.	
		077	US-20110097401	04-28-2011	PHILLIPS; Elaine et al.	
		078	US-20110123460	05-26-2011	WILHELM; Rudolf et al.	
		079	US-20110129530	06-02-2011	VENKATESH; Gopi M. et al.	
		080	US-20120128764	05-24-2012	VENKATESH; Gopi et al.	
		081	US-20120282335	11-08-2012	VENKATESH; Gopi M. et al.	
		082	US-20130296286	11-07-2013	DOHIL; Ranjan et al.	
		083	US-20130310661	11-21-2013	JEDWAB; Michael Reuben et al.	
		084	US-20140187523	07-03-2014	DOHIL; Ranjan et al.	
		085	US-20140228714	08-14-2014	CHAU; Thomas T.K. et al.	
		086	US-20140287051	09-25-2014	PERRETT; Stephen et al.	
		087	US-20140303131	10-09-2014	PERRETT; Stephen et al.	

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Sheet 5 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		088	US-20150209432	07-30-2015	KONDA; Kishore Kumar et al.	
		089	US-20150231156	08-20-2015	PHILLIPS; Elaine et al.	
		090	US-20160045518	02-18-2016	DOHIL; Ranjan et al.	
		091	US-20160078186	03-17-2016	HILL; Malcolm et al.	
		092	US-20160206627	07-21-2016	GOSSELIN; Michael A. et al.	
		093	US-20160213681	07-28-2016	SANTUS; Giancarlo et al.	
		094	US-20170071855	03-16-2017	PERRETT; Stephen et al.	
		095	US-20170183719	06-29-2017	ROTHENBERG; Marc E. et al.	
		096	US-20180071211	03-15-2018	DOHIL; Ranjan et al.	
		097	US-20180133145	05-17-2018	MELTZER; Brian A. et al.	
		098	US-20180153802	06-07-2018	PERRETT; Stephen et al.	
		099	US-20190008760	01-10-2019	BRIAN; A. Meltzer et al.	
		100	US-20190201333	07-04-2019	DOHIL; Ranjan et al.	
		101	US-20200016171	01-16-2020	MICHAEL; A. Gosselin et al.	
		102	US-20200214979	07-09-2020	STEPHEN; Perrett et al.	
		103	US-20200368147	11-26-2020	BRIAN; A. Meltzer et al.	
		104	US-20200381097	12-03-2020	MELTZER; Brian A.	
		105	US-20210205328	07-08-2021	GOSSELIN; Michael A. et al.	
		106	US-20210244660	08-12-2021	PERRETT; Stephen et al.	
		107	US-20210275438	09-09-2021	MELTZER; Brian A. et al.	
		108	US-20210346278	11-11-2021	MELTZER; Brian A. et al.	
		109	US-20220110945	04-14-2022	GOSSELIN; Michael A. et al.	

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Sheet 6 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	110	CA-2430481-A1	06-13-2002	SAMYANG CORP [KR]		☐
	**	111	CA-2704946-A1	05-22-2009	MERITAGE PHARMA INC [US]		☐
	**	112	CA-2776164-A1	04-07-2011	APTALIS PHARMATECH INC [US]		☐
	**	113	CL-38272008	12-21-2007	EURAND, INC.		☐
	**	114	DE-202010018594-U1	02-16-2018	ADARE PHARMACEUTICALS INC [US]		☒
	**	115	DE-2323215-A1	11-29-1973	BOFORS AB.		☐
	**	116	DE-4129535-A1	03-12-1992	ELMU SA [ES]		☒
	**	117	DE-60202794-T2	05-18-2006	ETHYPHARM HOUDAN [FR]		☒
	**	118	EP-0057401-A1	08-11-1982	SCHERING CORP [US]		☐
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Sheet 7 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	120	EP-1310243-A1	05-14-2003	ASTRAZENECA AB [SE]		☐
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	**	126	JP-11130679-A	05-18-1999	HOECHST MARION ROUSSEL DEUTSCHE GMBH.		☒
	**	127	JP-2001524094-A	11-27-2001	WEST PHARM SERV DRUG RES LTD., et al.		☐
	**	128	JP-2002521321-A	07-16-2002	BESSE JEROME, et al.		☒
	**	129	JP-2003261439-A	09-16-2003	ASAHI KASEI CORP.		☒
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Sheet 8 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	131	JP-2003509359-A	03-11-2003	GLAXO GROUP LTD.		☐
	**	132	JP-2006077018-A	03-23-2006	KYOWA HAKKO KOGYO KK.		☒
	**	133	JP-2006516616-A	07-06-2006	OREXO AB.		☒
	**	134	JP-2009173552-A	08-06-2009	LION CORP.		☒
	**	135	JP-2009519793-A	05-21-2009	QUANTUM HI TECH BEIJING RES IN., et al.		☒
	**	136	JP-2009521523-A	06-04-2009	JUBILANT ORGANOSYS LTD.		☒
	**	137	JP-2011503073-A	01-27-2011	MERITAGE PHARMA INC.		☒
	**	138	JP-2013506683-A	02-28-2013	APTALIS PHARMATECH INC.		☒
	**	139	JP-H11511162-A	09-28-1999	SCHERER LTD., et al.		☒
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	**	141	KR-20060123160-A	12-01-2006	ALZA CORP [US]		☒

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Sheet 9 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		142	KR-20100087007-A	08-02-2010	MERITAGE PHARMA INC [US]		☒
	**	143	KR-20120104975-A	09-24-2012	APTALIS PHARMATECH INC [US]		☒
		144	KR-20160058829-A	05-25-2016	ADARE PHARMACEUTICALS INC [US]		☒
		145	RU-2011134040-A	02-20-2013	NESTEC SA.		☒
		146	RU-2016104400-A	08-16-2017	REGENERON PHARMA.		☒
	**	147	WO-0064450-A1	11-02-2000	LEO PHARM PROD LTD [DK], et al.		☐
	**	148	WO-0119342-A2	03-22-2001	GLAXO GROUP LTD [GB], et al.		☐
	**	149	WO-02092057-A1	11-21-2002	YAMANOUCHI PHARMA CO LTD [JP], et al.		☒
	**	150	WO-03039520-A1	05-15-2003	ETHYPHARM SA [FR], et al.		☒
	**	151	WO-03093344-A1	11-13-2003	JANSSEN PHARMACEUTICA NV [BE], et al.		☐
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Sheet 10 of 39

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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	153	WO-2004067004-A1	08-12-2004	OREXO AB [SE], et al.		☐
	**	154	WO-2004069225-A1	08-19-2004	ELAN PHARMA INT LTD [IE], et al.		☐
	**	155	WO-2004091585-A1	10-28-2004	SYNTHON BV [NL], et al.		☐
	**	156	WO-2005087194-A1	09-22-2005	SCHERING AG [DE], et al.		☐
	**	157	WO-2007071179-A1	06-28-2007	QUANTUM HI TECH BEIJING RES IN [CN], et al.		☒
	**	158	WO-2007074472-A2	07-05-2007	JUBILANT ORGANOSYS LTD [IN], et al.		☐
	**	159	WO-2008098634-A1	08-21-2008	POLICHEM SA [LU], et al.		☐
	**	160	WO-2009064457-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	161	WO-2009064458-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	162	WO-2009064819-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	163	WO-2009086046-A1	07-09-2009	EURAND INC [US], et al.		☐

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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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Examiner Initials*		Cite No.[1]	Foreign Patent Document Country Code[2]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]
	**	164	WO-2009098595-A2	08-13-2009	FOAMIX LTD [IL], et al.		☐
	**	165	WO-2010021636-A1	02-25-2010	UNIV CALIFORNIA., et al.		☐
	**	166	WO-2010144865-A2	12-16-2010	MERITAGE PHARMA INC [US], et al.		☐
	**	167	WO-2011041509-A1	04-07-2011	EURAND INC [US], et al.		☐
	**	168	WO-2015034678-A2	03-12-2015	APTALIS PHARMATECH INC [US]		☐
	**	169	WO-2015035114-A1	03-12-2015	APTALIS PHARMATECH INC [US]		☐
		170	WO-2017189805-A1	11-02-2017	ABBVIE INC [US]		☐
	**	171	WO-2018035393-A1	02-22-2018	ADARE PHARMACEUTICALS INC [US]		☐
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	**	173	WO-2021067585-A1	04-08-2021	ADARE PHARMACEUTICALS US L P [US], et al.		☐
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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	175	WO-9706786-A1	02-27-1997	SCHERER LTD R P [GB], et al.		☐
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Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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Sheet 15 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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Art Unit	1615
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	**	216	European Application No. EP 14184844.0, Extended European Search Report dated February 9, 2015, 7 pages.	☐
	**	217	European Application No. EP 14842811.3, Extended European Search Report dated March 23, 2017, 6 pages.	☐
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	**	238	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Writ as filed, dated February 11, 2020, and English translation, 5 pages.	☐

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	239	German Patent Infringement Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Patent Complaint dated July 3, 2019, with English translation, 107 pages.	☐
	**	240	German Utility Model Cancellation Action, Request for Cancellation, filed by Dr. Falk Pharma GmbH on March 1, 2019 with the German Patent Office, in connection with DE Patent No. 202010018594 U1 in the name of Adare Pharmaceuticals, Inc., and English translation, 21 pages.	☐
	**	241	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Statement of Grounds of Appeal dated February 26, 2021 (and English translation), and Exhibit B817 - Current EPA register extract on D5 dated 27 November 2020, 117 pages.	☐
	**	242	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Adare - Further Submission as filed dated July 12, 2019, and English translation, 56 pages.	☐
	**	243	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Auxiliary Request I-IV (marked-up) dated and as filed July 1, 2020, and English translation, 17 pages.	☐
	**	244	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Official Communication - Interlocutory Notice dated January 22, 2020 (and English translation), 12 pages.	☒
	**	245	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Dr. Falk and Summons dated July 2, 2020, and English translation, 18 pages.	☒

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	**	246	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Pleadings as filed dated October 17, 2019, and English translation, 25 pages.	☐
	**	247	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Submission of Dr. Falk - Pleadings dated September 13, 2019 (and English translation), 27 pages.	☒
	**	248	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Adare's Response dated April 6, 2020 to Interlocutory Decision, and English translation, 29 pages.	☐
	**	249	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Communication from Adare to German Patent Office, Auxiliary Requests 1 and 2 (clean, marked-up and English translations) as filed April 6, 2020, 23 pages.	☒
	**	250	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Submission of Dr. Falk - response to Adare and summons, dated July 8, 2020 (and English translation), 11 pages.	☒
	**	251	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, submission/Response by Dr. Falk Pharma GmbH dated April 8, 2020 (and English translation), 18 pages.	☒
	**	252	HAHM and AUGSBURGER, Orally Disintegrating Tablets and Related Tablet Formulations, Pharmaceutical Dosage Forms: Tablets, Third Edition, Ch. 9, Volume 2, Herausgeber: (eds) Larry L. Augsburger, Stephen W. Hoag, CRC Press (2008), 21 pages.	☐

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	**	254	Handbook of Pharmaceutical Excipients (2009); Sixth Edition, ISBN 978 1 58212 135 2, (eds.) ROWE, et al., Cover Page, Print/Copyright and Preface Pages, 4 pages.	☐
	**	255	International Preliminary Report on Patentability for International Application No. PCT/US2017/047474, dated February 19, 2019, 8 pages.	☐
	**	256	JORVEZA (budesonide) Update by the Committee for Medicinal Products for Human Use (CHMP), Summary of opinion1 (post authorisation) dated March 26, 2020, European Medicines Agency, 1 page.	☐
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First Named Inventor	Stephen PERRETT
Art Unit	1615
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	**	262	Langdon, BA and Mullamey, (2006) Handbook of Pharmaceutical Excipients. (eds.) Rowe, R.C., Sheskey, PJ and Owen, S.C., London: Pharmaceutical Press and American Pharmacists Association (extract - pages 53-55 and 742-743), 14 pages.	☐
	**	263	LEE, Geoffrey, Professor, Report of Professor Geoffrey Lee, Ph.D. on measurement of disintegration time of "Jorveza 1 mg orodispersible tablet" dated November 15, 2019, 16 pages.	☐
	**	264	LI, Xiaowei, et al., "Advances in Injectable Thermosensitive Polymers". Polymer Bulletin, No. 3, pages 109-115, June 30, 2015 (with English Abstract), 7 pages.	☒
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First Named Inventor	Stephen PERRETT
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	**	278	New World Encyclopedia, "Gastrointestinal tract", https://web.archive.org/web/20090917122455/https://www.newworldencyclopedia.or..., July 8, 2019, 7 pages.	☐
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	**	280	NISHIMURA, S., et al. "Factors associated with esophageal candidiasis and its endoscopic severity in the era of antiretroviral therapy." PLoS One (2013); 8(3): e58217, 6pgs.	☐

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	**	281	Novopulmon E Novolizer, Instructions for the medical use of the medicament, [Instrukciya po medicinskomu primeneniyu preparata Novopulmon 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.	☐
	**	282	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	☐
	**	283	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated April 6, 2021, enclosing Patentee's Response to Submissions dated March 30, 2021, and English translation, 9 pages.	☐
	**	284	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Appeal No. T1954/21-3.3.01 dated January 4, 2022, 20 pages.	☐
		285	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Interlocutory Decision dated January 5, 2022, and English translation, 43 pages.	☒
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		287	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO's Communication dated November 18, 2021 enclosing Opponent's, Dr. Falk Pharma GmbH's Further Submissions dated November 15, 2021, and English translation, 21 pages.	☒

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		288	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Interlocutory Decision dated February 14, 2022, 61 pages.	☐
		289	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Minutes of Oral Proceedings dated February 14, 2022, 15 pages.	☐
	**	290	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, D18 - Dr F's novelty table 2020, 2 pages.	☐
	**	291	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication - communication of notice of opposition dated May 13, 2019, 1 page.	☐
	**	292	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.	☐
	**	293	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated September 26, 2019, transmitting Adare's submission filed September 20, 2019, 88 pages.	☐
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	**	295	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Patentee, Adare Development I, L.P.'s Response dated December 16, 2019 in response to further submissions filed by Dr. Falk Pharma GmbH on 10/29/2019, 16 pages.	☐
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	**	298	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, Consolidated List of Cited Opposition Documents, 1 page.	☐
	**	299	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated July 24, 2020 regarding oral proceedings, 6 pages.	☐
	**	300	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated March 25, 2020 transmitting communication from Dr. Falk Pharma GmbH dated March 20, 2020, and English translation, 34 pages.	☐
	**	301	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication re Summons to Attend Oral Proceedings and Preliminary Opinion, dated July 2, 2020, and English translation, 18 pages.	☐

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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	302	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Adare's Written Submissions in Preparation for Oral Proceedings on April 23, 2021, dated February 23, 2021, 25 pages.	☐
	**	303	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 2, 2019, transmitting Notice of Opposition filed June 26, 2019, 43 pages.	☒
	**	304	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 22, 2020 regarding date of oral proceedings, 3 pages.	☒
	**	305	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated November 19, 2019, with Patentee's response to Opposition dated November 8, 2019, and English translation, 22 pages.	☒
	**	306	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication to Adare regarding oral proceedings dated March 2, 2020, and English translation, 14 pages.	☒
	**	307	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, Patentee, Dr. Falk's Written Submissions, Auxiliary Request I and Test Report Jorveza® 1 mg (dated August 18, 2020, produced by Patentee, Dr. Falk Pharma), filed September 10, 2020, and English translation, 22 pages.	☐
		308	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; communication from the European Patent Office (EPO) dated May 18, 2022 enclosing Opponent's response to appeal dated May 12, 2022 and D27, and English translation, 44 pages.	☒

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		309	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Ellodi's Withdrawal of Appeal dated July 11, 2022, 3 pages.	☐
	**	310	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication - Minutes of Oral Proceeding, dated August 25, 2021, and English translation, 11 pages.	☐
	**	311	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare - Letter to EPO re Oral Proceedings dated July 17, 2020, 5 pages.	☐
	**	312	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Adare's Communication to the EPO re oral proceedings, dated August 11, 2020, 4 pages.	☐
	**	313	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Written Submission from Adare (Proprietor) dated July 17, 2020, 126 pages.	☐
	**	314	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding notice of opposition, 1 page.	☐
	**	315	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication re oral proceedings, dated August 5, 2020, 1 page.	☐
	**	316	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication re Oral Proceedings dated July 13, 2020, 3 pages.	☐

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	**	317	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's consolidated list of cited opposition documents, July 18, 2020, 1 page.	☐
	**	318	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to Attend Oral Hearing and Preliminary Opinion in opposition dated February 13, 2020, 15 pages.	☐
	**	319	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to attend oral proceedings dated February 13, 2020, 13 pages.	☐
	**	320	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Patentee in Preparation for Oral Proceedings on March 8, 2021, dated January 8, 2021, with Auxiliary Requests 1-14, 52 pages.	☐
	**	321	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharm a GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	☐
	**	322	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication in connection with Summons to attend oral proceedings, dated November 20, 2020, 12 pages.	☐
	**	323	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Falk's Communication to the EPO re oral proceedings, dated August 12, 2020, 3 pages.	☒

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	**	324	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Opponent's response to Summons dated July 17, 2020, and English translation, 15 pages.	☒
	**	325	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Opponent's submissions dated March 1, 2021, and English translation, 11 pages.	☐
	**	326	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Opponent in response to the Summons to attend Oral Proceedings, dated and filed December 8, 2020, and English translation, 37 pages.	☐
		327	Opposition Proceedings in European Patent No. EP 2886108, Appeal No. T0611/22-3.3.07 (Appln. No. 13199278.6), (in the name of Dr. Falk Pharma GmbH) filed by Ellodi Pharmaceuticals, L.P. on November 6, 2019; EPO Communication dated May 27, 2022 confirming Termination of Appeal Proceedings filed May 16, 2022, 4 pages.	☐
		328	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Adare Development I, L.P., on November 6, 2019, Dr. Falk Pharma's Response to Summons and Adare's Written Submissions and clean and marked versions of Auxiliary Requests I and II, dated December 18, 2020, and English translation, 26 pages.	☒
		329	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Datasheet for the decision of 14 October 2019, Case Number T 1621/16 - 3.3.06, Application No. 09163237.2, 28 pages.	☐
		330	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Ellodi's Notice of Appeal against decision filed March 4, 2022, 5 pages.	☐

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		331	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Ellodi's Withdrawal of Appeal filed May 16, 2022, 3 pages.	☐
		332	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 22, 2022 confirming withdrawal of appeal as filed July 14, 2022 by Opponent, 4 pages.	☐
		333	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated June 20, 2022 enclosing Opponent's Grounds of Appeal dated June 10, 2022, and English translation, 27 pages.	☒
		334	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Withdrawal of Appeal filed by Ellodi Pharmaceuticals, L.P. dated June 14, 2022, 3 pages.	☐
	**	335	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated February 22, 2021 enclosing Opponent's Submissions (and English translation), dated February 16, 2021, 11 pages.	☐
	**	336	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 29, 2020 advising of and enclosing Notice of Opposition filed by Dr. Falk Pharma GmbH on July 22, 2020, 82 pages.	☐
		337	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Appeal filed by Ellodi Pharmaceuticals, L.P. dated April 22, 2022, 5 pages.	☐

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	**	338	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Opposition and Statement of Grounds of Opposition (with English translation of Statement of Grounds of Opposition), and Consolidated List of references relied upon, filed July 22, 2020, 513 pages.	☐
	**	339	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Adare's Response to Opposition dated .January 11, 2021, 15 pages.	☐
	**	340	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Ellodi Pharmaceuticals, L.P.'s Written Submission in Preparation for Oral Proceedings on December 8, 2021 with new Auxiliary Requests 1-3, dated October 8, 2021, 51 pages.	☐
	**	341	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Adare's Response to the Grounds of Opposition, filed November 2, 2020, 78 pages.	☐
	**	342	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Consolidated List of References dated and filed December 8, 2020, 1 page.	☐
	**	343	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated June 22, 2020, 1 page.	☐
	**	344	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated May 8, 2020, 1 page.	☐

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	**	345	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Further Written Submissions dated and filed December 8, 2020, and English translation, 30 pages.	☐
		346	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Submission/Withdrawal of Opposition dated July 20, 2022, and English translation, 2 pages.	☒
	**	347	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Statement of Grounds of Opposition filed on April 28, 2020, and English translation, 38 pages.	☐
	**	348	Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Decision (and English translation) dated October 26, 2020, pronounced in the oral hearing of 21 July 2020, 45 pages.	☐
	**	349	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	☐
	**	350	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	☐
	**	351	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	☐
	**	352	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	☐
	**	353	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	☐

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	**	355	PCT Application No. PCT/US2014/054203, International Preliminary Report on Patentability dated March 8, 2016.	☐
	**	356	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	☐
	**	357	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	☐
	**	358	PCT Application No. PCT/US2019/019040, International Preliminary Report on Patentability, dated August 27, 2020, 8 pages.	☐
	**	359	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	☐
	**	360	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	☐
		361	PCT/US2020/053778, International Preliminary Report on Patentability mailed April 5, 2022, 7 pages.	☐
	**	362	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	☐
		363	PCT/US2021/042566, International Search Report and Written Opinion, mailed November 5, 2021, 9 pages.	☐
	**	364	PELLE, et al., "Using defined daily doses to study the use of antibacterials in UK hospitals". Hosp Pharm (2006); 13: 133-136.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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LLO-119_08US - _342083.2017_ Ellodi Pharmaceuticals_ Inc. -

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

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Sheet 36 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

****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]
	**	365	PONCHEL, Gilles, "Formulation of oral mucosal drug delivery systems for the systemic delivery of bioactive materials". Advanced Drug Delivery Reviews, Volume 13, Issues 1-2, January-February 1994, Pages 75-87.	☐
	**	366	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	☐
	**	367	REMEDIOS, et al., "Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate". Gastrointestinal Endoscopy (2006); 63(1): 3-12.	☐
	**	368	ROBERTSON, et al., "Oesophageal transit of small tablets", J. Pharm. Pharmacol. (1988); 40: 595-596.	☐
	**	369	SCHAEFER, et al., "Comparison of Oral Prednisone and Topical Fluticasone in the Treatment of Eosinophilic Esophagitis: A Randomized Trial in Children". Clinical Gastroenterology and Hepatology (2008); 6: 165-173.	☐
	**	370	SCHOEPFER, et al., "Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis". Gastroenterology (2014 Dec 1); 147(6): 1255-1266.	☐
	**	371	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	☐
		372	SJOSTROM and CAIRNCROSS, "What Makes Flavor Leadership." Food Technology (1953); (7) 2: 56-58.	☐
	**	373	Supplementary European Search Report in European Patent Application No. EP 20192973.4, dated November 18, 2020, 5 pages.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 37 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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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]
	**	374	TAFT, et al., "The adult eosinophilic oesophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	☐
	**	375	Taiwanese Application No. TW 099133628, Search Report (English translation) dated November 16, 2014, 9 pages.	☒
	**	376	Taiwanese Application No. TW 104107443, Search Report (English translation) dated May 29, 2015,1 page.	☐
	**	377	TAKAKU, Fumimaro, et al. Manual of Therapeutic Agents 2007, Published 2007, p. 617-619 (and English translation/summary of pertinent paragraphs), 5 pages.	☒
	**	378	TAYEBI and MORTAZAVI, "Formulation and Evaluation of a Novel Matrix-Type Orally Disintegrating Ibuprofen Tablet". Iran J Pharm Res. (2011 Summer); 10(3): 469-479.	☐
	**	379	TEITELBAUM et al. "Eosinophilic esophagitis in children: immunopathological analysis and response to fluticasone propionate." Gastroenterology (2002), 122(5): 1216-1225.	☒
	**	380	THORBURN and FERGUSON, "Topical corticosteroids and lesions of the oral mucosa". Advanced Drug Delivery Reviews, Volume 13, Issues 1-2, January-February 1994, Pages 135-149.	☐
	**	381	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Replica dated July 19, 2019, and English translation, 25 pages.	☒
	**	382	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Complaint dated July 3, 2019, and English translation, 34 pages.	☐

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Sheet 38 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	383	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, submission by Dr. Falk Pharma GmbH - statement of defense, dated May 24, 2019, and English translation, 16 pages.	☒
	**	384	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk - Rejoinder dated September 13, 2019 (English translation), 8 pages.	☒
		385	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Defendant's Consent to Withdrawal filed July 15, 2022, and English translation, 2 pages.	☒
		386	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Order concerning value under dispute dated July 20, 2022, and English translation, 2 pages.	☒
		387	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Withdrawal Submission filed by Ellodi Pharmaceuticals, L.P., dated July 11, 2022, and English translation, 2 pages.	☒
	**	388	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB1 "Breakdown of Features", and English translation, 2 pages.	☒
	**	389	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB4 - Letter from Lederer & Keller dated September 27, 2018 regarding European Patent No. 2211896, and Machine English translation, 28 pages.	☒

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Sheet 39 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	390	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	☐
	**	391	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis - Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	☐
	**	392	WEBB, Paul A., "Surface Area, Porosity, and Related Physical Characteristics". In book: Pharmaceutical Dosage Forms: Tablets, 3rd Edition, Vol. 3, CRC Press, Taylor and Francis Group, Boca Raton, London, New York (2008); Chapter 11, pgs. 277-302.	☐
	**	393	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	☐
	**	394	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	☐
	**	395	WEN, Hong, (ed. SWARBICK, James) "Adsorption at Solid Surfaces: Pharmaceutical Applications". Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1 (2007); pgs. 34-38, 7 pages.	☐
	**	396	Wikipedia, "Retard", https://de.wikipedia.org/wiki/Retard, June 13, 2019, and Google machine translation, 7 pages.	☐
	**	397	YALKOWSKY and BOLTON. "Particle size and content uniformity." Pharmaceutical Research, 7(9): 962-966 (1990).	☐

Examiner Signature	/ARADHANA SASAN/	Date Considered	03/21/2024

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Sheet 1 of 2

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-11684571	06-27-2023	MELTZER; Brian A. 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]
		002	JP-2006524650-A	11-02-2006	SYNTHON BV.		☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		003	DELLON E.S., "Safety and Efficacy of Budesonide Oral Suspension Maintenance Therapy in Patients With Eosinophilic Esophagitis", Clin Gastroenterol Hepatol. 2019 Mar; 17(4): 666-673.e8. Epub 2018 Jun 12.	☐
		004	Extended European Search Report for European Application No. EP 20873169.5 dated September 22, 2023, 9 pages.	☐
		005	HIRANO, I., et al. "Randomised clinical trial: the safety and tolerability of fluticasone propionate orally disintegrating tablets versus placebo for eosinophilic oesophagitis", Aliment Pharmacol Ther. 2020 Apr;51(8):750-759. Epub 2020 Mar 9.	☐
		006	KONIKOFF, et al., "A Randomized, Double-Blind, Placebo-Controlled Trial of Fluticasone Propionate for Pediatric Eosinophilic Esophagitis". Gastroenterology. 2006 Nov; 131(5): 1381-1391. Epub 2006 Aug 16.	☐
		007	SCHOEPFER, et al., "Delay in diagnosis of eosinophilic esophagitis increases risk for stricture formation in a time-dependent manner". Gastroenterology. 2013 Dec; 145(6): 1230-1236. Epub 2013 Aug 13.	☐
		008	STRAUMANN et al., "Budesonide Orodispersible Tablets Maintain Remission in a Randomized, Placebo-Controlled Trial of Patients With Eosinophilic Esophagitis". Gastroenterology. 2020 Nov; 159(5): 1672-1685. e5. Epub 2020 Jul 25.	☐

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EFS ID:	48667860
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Dou Yeon Youn /Teanne Nguyen
Filer Authorized By:	Dou Yeon Youn
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	02-OCT-2023
Filing Date:	05-JAN-2022
Time Stamp:	15:18:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

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1	Transmittal Letter	ELLO-119_08US_342083-2017_IDS_Transmittal.pdf	3540245 9e6af0af242d63f93847e96116308b9eb23f3a59	no	5

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3	Foreign Reference	JP2006524650A_EFS.pdf	1141783 b49cc1ea1480034e61cce203ee89050862bb802f	no	25
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4	Non Patent Literature	Dellon_Safety_Efficacy_2018_16pgs_EFS.pdf	4996436 ce8b8426ca612ad07133881d9c370b13d0e9514e	no	16
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7	Non Patent Literature	KONIKOFF_Clinical_2006_11_EFS.pdf	1345397 807558c8fcb3e27dbe763571a4500d7abfe1477a	no	11
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9	Non Patent Literature	Straumann_2020_EFS.pdf	4254929 c6611c9367c0e2d4155288a5a282173d76d8b8d9	no	19
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Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 on 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 No(s). ____ to which the above-identified application claims priority under 35 U.S.C. §120.

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[] 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 No. and mailed on .

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

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

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

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

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

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00; 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.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

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

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

and

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

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

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

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

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

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

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: October 2, 2023

Respectfully submitted,
COOLEY LLP

Electronic signature: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Dou Yeon Youn
Reg. No. 79,828

USPTO CUSTOMER NO. 58249

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

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

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-20160324772	11-10-2016	GREINWALD; Roland 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]
		002	EP-2886108-A1	06-24-2015	FALK PHARMA GMBH [DE]		☐

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.

280842766 v1

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		003	SODIKOFF et al., "Therapeutic strategies in eosinophilic esophagitis: Induction, maintenance and refractory disease", Best Pract Res Clin Gastroenterol. (2015 Oct); 29(5): 829-839.	☐
		004	STRAUMANN et al., "Budesonide is effective in adolescent and adult patients with active eosinophilic esophagitis", Gastroenterology (2010 Nov); 139(5): 1526-1537.	☐
		005	STRAUMANN et al., "Long-term budesonide maintenance treatment is partially effective for patients with eosinophilic esophagitis", Clin Gastroenterol Hepatol. (2011 May); 9(5): 400-409.	☐

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.

280842766 v1

Electronic Acknowledgement Receipt

EFS ID:	47463974
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Dou Yeon Youn /Cheryl Campbell
Filer Authorized By:	Dou Yeon Youn
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	01-FEB-2023
Filing Date:	05-JAN-2022
Time Stamp:	18:13:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119_08US_342083-2017_IDS_Transmittal.pdf	149964 42a2428e2493ae2ca56199a2b82a8c0620cadcba	no	6

Warnings:

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119_08US_342083-2017_IDS_SB08_20230119121128.pdf	95884 700e96a3e4fab8805a9d2c81f52aae68c0bec9fa	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	EP2886108A1_EFS.pdf	729538 ed314a73ecca3ce18d9b383e33107f769cbb08b5	no	14
Warnings:					
Information:					
4	Non Patent Literature	SODIKOFF_BestPracRes_2015_29_EFS.pdf	1146908 d114a1c2e4ee9bd1ed6a3946a5b255d71786efed	no	11
Warnings:					
Information:					
5	Non Patent Literature	STRAUMANN_Gastroenterology_2010_139_EFS.pdf	1588539 37582cb0a9c9d19abd4a5b0e96c2cde79c92f2f4	no	13
Warnings:					
Information:					
6	Non Patent Literature	STRAUMANN_ClinicGastroHep_2011_9_EFS.pdf	1405576 cdbb3077473ec11a8d5e8759bdc8707c0eb2e04e	no	11
Warnings:					
Information:					
		Total Files Size (in bytes):	5116409		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 on 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 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 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 on the attached Form used in lieu of PTO/SB/08.

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

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

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

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

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

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

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

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00; 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.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

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

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

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

[] Fee under 37 C.F.R. §1.17(p) in the amount of $104.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $52.00;

and

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

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

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

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

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

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

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

Cooley Docket No.	Case Status	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date
ELLO-119/01US	Registered	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014
ELLO-119/02US	Registered	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016
ELLO-119/03US	Registered	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016
ELLO-119/04US	Registered	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017
ELLO-119/05US	Registered	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020
ELLO-119/06US	Registered	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020	11,246,828	2/15/2022
ELLO-119/07US	Registered	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021	11,266,598	3/8/2022

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 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.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1283, under Order No. ELLO-119/08US 342083-2017 from which the undersigned is authorized to draw.

Dated: February 1, 2023

Respectfully submitted,
COOLEY LLP

By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Dou Yeon Youn
Reg. No. 79,828

USPTO CUSTOMER NO. 58249

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

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

Form used in lieu of PTO/SB/08a/b (07-09)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-10869592	12-22-2020	OUYANG et al.	
		002	US-20220347189	11-03-2022	NEZAMIS; James 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]
		003	WO-2022225892-A1	10-27-2022	ELLODI PHARMACEUTICALS L P [US]		☐

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

(Use as many sheets as necessary)

Sheet 2 of 3

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		004	GENTILE et al., "Oesophageal narrowing is common and frequently under-appreciated at endoscopy in patients with oesophageal eosinophilia". Alimentary Pharmacology & Therapeutics (2014 Dec); 40(11-12): 1333-1340. Epub 2014 Oct 7.	☐
		005	German Patent Complaint Proceedings in the Regional Court, Mannheim, Ellodi Pharmaceuticals, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, communication from the Regional Court of Mannheim giving Dr. Falk Pharma GmbH the opportunity to comment on the withdrawal of the complaint, dated July 12, 2022, and Machine English translation, 2 pages.	☒
		006	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Notice of termination of proceedings dated August 16, 2022, and English translation, 2 pages.	☒
		007	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Withdrawal of cancellation action dated July 20, 2022, 1 page.	☐
		008	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 25, 2022 regarding Termination of opposition proceedings, 1 page.	☐
		009	Opposition Proceedings in European Patent No. EP 3086782 (Appln. No. 14814872.9), (in the name of Dr. Falk Pharma GmbH) filed by Ellodi Pharmaceuticals, L.P. on June 26, 2019; Written decision on rejection of the opposition dated May 9, 2022, and English translation, 63 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.

277893064 v1

Form used in lieu of PTO/SB/08a/b (07-09)
Approved for use through 05/31/2024. 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 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	PERRETT; Stephen
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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]
		010	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Decision to discontinue the opposition proceedings dated September 5, 2022, 2 pages.	☐
		011	PCT/US2022/025297, International Search Report and Written Opinion mailed July 29, 2022, 10 pages.	☐
		012	TAKITA et al., "Successful esophageal endoscopic submucosal dissection with a transoral endoscope after stepwise scope bougienage of post-endoscopic submucosal dissection stricture". JGH Open (2020 Oct 22); 5(1): 163-165. eCollection 2021 Jan.	☐

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.

277893064 v1

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
COOLEY LLP
1299 PENNSYLVANIA AVE.
SUITE 700
WASHINGTON, DC 20004

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)* JUL 29 2022
Applicant's or agent's file reference ELLO-168-01WO-342083-2035	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2022/025297	International filing date *(day/month/year)* 19 April 2022
Applicant ELLODI PHARMACEUTICALS, L.P.	

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

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

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

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
   (Facsimile No.: +41 22 338 82 70)

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

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

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

4. **Reminders**

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

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

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

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

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

Form PCT/ISA/220 (revised January 2019)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION
ELLO-168-01WO-342083-2035	see Form PCT/ISA/220 as well as, where applicable, item 5 below.

International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2022/025297	19 April 2022	20 April 2021

Applicant

ELLODI PHARMACEUTICALS, L.P.

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

   ☒ the text is approved as submitted by the applicant.

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

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

   ☒ the text is approved as submitted by the applicant.

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

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

   a. the figure of the **drawings** to be published with the abstract is Figure No. 1

   ☒ as suggested by the applicant.

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

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

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

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/025297

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.: 6-11, 13-25, 27-54
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/025297

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 31/565; A61K 31/56; A61K 9/00; A61P 1/00 (2022.01)

CPC - A61K 31/565; A61K 31/56; A61K 9/0053; A61K 9/0056; A61K 9/006; A61K 9/0065; A61K 9/0095; A61K 9/20; A61K 31/341; A61K 31/4439; A61K 31/573; A61K 31/575; A61K 31/58; A61K 45/06; A61K 47/32; A61K 47/36; A61P 1/00; A61P 1/04; A61P 1/06; A61P 25/00; A61P 29/00; A61P 37/08 (2022.05)

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 10,105,315 B2 (ADARE PHARMACEUTICALS INC) 23 October 2018 (23.10.2018) entire document	1, 12, 26 --- 2-5
Y	GENTILE et al., Oesophageal narrowing is common and frequently under-appreciated at endoscopy in patients with oesophageal eosinophilia, Aliment. Pharmacol. Ther., 7 Oct 2014, Vol. 40, Pgs. 1333-1340. Entire document	2-5
Y	US 10,869,592 B2 (UROVIU CORP) 22 December 2020 (22.12.2020) entire document	4
Y	TAKITA et al., Successful esophageal endoscopic submucosal dissection with a transoral endoscope after stepwise scope bougienage of post-endoscopic submucosal dissection stricture, JHG Open, 22 Oct 2020, Vol. 5, No. 1, Pgs. 163-165. Entire document	5

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 June 2022	JUL 29 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn. ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Taina Matos Telephone No. PCT Helpdesk: 571-272-4300

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL TUSCAN
COOLEY LLP
1299 PENNSYLVANIA AVE.
SUITE 700
WASHINGTON, DC 20004

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	JUL 29 2022
Applicant's or agent's file reference ELLO-168-01WO-342083-2035	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2022/025297	19 April 2022	20 April 2021

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

IPC(8) - A61K 31/565; A61K 31/56; A61K 9/00; A61P 1/00 (2022.01)

CPC - A61K 31/565; A61K 31/56; A61K 9/0053; A61K 9/0056; A61K 9/006; A61K 9/0065; A61K 9/0095; A61K 9/20; A61K 31/341; A61K 31/4439; A61K 31/573; A61K 31/575; A61K 31/58; A61K 45/06; A61K 47/32; A61K 47/36; A61P 1/00; A61P 1/04; A61P 1/06; A61P 25/00; A61P 29/00; A61P 37/08 (2022.05)

Applicant ELLODI PHARMACEUTICALS, L.P.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	23 June 2022	Taina Matos PCT Helpdesk: 571-272-4300 Telephone No. 571-272-4300

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Additional comments:

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

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. 6-11, 13-25, 27-54

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. 6-11, 13-25, 27-54 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 6-11, 13-25, and 27-54 are multiple dependent claims 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. 6-11, 13-25, 27-54

☐ 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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

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

1. Statement

Novelty (N)	Claims	2-5	YES
	Claims	1, 12, 26	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-5, 12, 26	NO
Industrial applicability (IA)	Claims	1-5, 12, 26	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 12, and 26 lack novelty under PCT Article 33(2) as being anticipated by US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals").

Regarding Claim 1, Adare Pharmaceuticals discloses a method of topically treating an esophageal stricture in a patient in need thereof with a corticosteroid (in some embodiments, the corticosteroid is deposited topically in the upper gastrointestinal tract...the compositions and methods disclosed herein substantially remove strictures, Col 3, Lns. 5-7; see also Col. 25, Lns. 61-62), comprising: (a) detecting the esophageal stricture (in some embodiments, the patient diagnosed with EoE has an esophageal stricture, Col. 43, Lns. 61-62); and then (b) orally administering the corticosteroid (in some embodiments, the present disclosure provides for administering the oral corticosteroid composition to a patient while laying down, Col. 2, Lns. 55-57), wherein a therapeutically effective amount of the oral corticosteroid contacts the esophageal stricture (orally disintegrating compositions...after being swallowed...the corticosteroid dissolved or suspended therein contacts the esophagus as the liquid traverses the esophageal tract, Col. 9, Lns. 2-9), thereby reducing the severity of the esophageal stricture (the compositions and methods disclosed herein substantially remove strictures, Col. 25, Lns. 61-62).

Regarding Claim 12, Adare Pharmaceuticals discloses the method of claim 1, wherein the oral corticosteroid is administered about 30 minutes or less before target sleep time (the oral corticosteroid may be administered about 30 minutes or less before target sleep time, Col. 46, Lns. 23-24).

Regarding Claim 26, Adare Pharmaceuticals discloses the method of claim 1, wherein the patient has eosinophilic esophagitis (EoE), gastroesophageal reflux disease (GERD), non-erosive reflux disease (NERD), erosive esophagitis, Barrett's esophagus, eosinophilic gastroenteritis, hypereosinophilic syndrome, corrosive chemical esophagitis, radiation-induced esophagitis, chemotherapy-induced esophagitis, transient drug-induced esophagitis, persistent drug-induced esophagitis, Crohn's disease of the esophagus, post-surgical resection of the esophagus; or pseudomembranous esophagitis (inflammatory gastrointestinal disorders which may be treated according to the present disclosure include EoE, Col. 20, Lns. 29-34).

Claims 2 and 3 lack an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile").

Regarding Claim 2, Adare Pharmaceuticals discloses the method of claim 1.
Adare Pharmaceuticals fails to explicitly disclose wherein the detecting in step (a) comprises inserting an endoscope into the patient's esophagus.
Gentile, in the analogous field of esophageal stricture detection and treatment (Summary), teaches wherein the detecting in step (a) comprises inserting an endoscope into the patient's esophagus (oesophageal strictures may be diagnosed at upper gastrointestinal endoscopy, p. 1334, left column, first Para.). Gentile also teaches that the mechanism of dysphagia in EoE is probably multifactorial, including increased mucosal stickiness, loss of oesophageal distensibility, and importantly, oesophageal fibrosis with stricture and ring formation, Gentile, p. 1334, left column, first Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals with the teaching of Gentile. The motivation for doing so would have been to perform an upper gastrointestinal endoscopy to investigate the cause of dysphagia in patients suffering from EoE, as suggested by Gentile.

Regarding Claim 3, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the endoscope has a diameter of about 8-10 mm, or about 9 mm.
Gentile, in the analogous field of esophageal stricture detection and treatment (Summary), teaches wherein the endoscope has a diameter of about 8-10 mm, or about 9 mm (endoscopic narrowing was defined by the use of the terms 'narrowing,' 'stricture' or 'resistance' to passing the standard 9-10 mm scope to traverse the oesophageal lumen, p. 1335, left column, second Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of Gentile since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to use a standard 9-10 mm endoscope to traverse the esophageal lumen and thereby assess the degree of esophageal narrowing, as suggested by Gentile.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 12 are objected to under under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1 and 12 are indefinite for the following reason(s):

Regarding claims 1 and 12, "the oral corticosteroid" lacks antecedent basis". For the purpose of the Written Opinion proposed, "the oral corticosteroid" has been analyzed as "the corticosteroid".

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2022/025297

Supplemental Box

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

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile") and US 10,869,592 to UroViu Corp. (hereinafter, "UroViu").

Regarding Claim 4, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the esophageal stricture is detected visually using a video display on the endoscope.
UroViu, in the analogous field of surgical endoscopes for medical procedures (Abstract), teaches wherein the esophageal stricture is detected visually using a video display on the endoscope (a handheld surgical endoscope has a disposable, single-use handle and a touch-sensitive display screen that is supported by the handle, Abstract). UroViu further teaches that the endoscope 100 includes an elongated cannula 120 with a distal tip 112 for inserting into a hollow cavity or organ of the body...and one or more LED light sources for viewing the organ or cavity into which it is inserted, UroViu, Col. 6, Lns. 31-39).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of UroViu. The motivation for doing so would have been to create a surgical endoscope having a display screen thereon for easy and convenient viewing of an organ or cavity during use of the endoscope, as suggested by UroViu.

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over US 10,105,315 to Adare Pharmaceuticals Inc. (hereinafter, "Adare Pharmaceuticals") in view of Gentile et al. (hereinafter, "Gentile") and Takita et al. (hereinafter, "Takita").

Regarding Claim 5, modified Adare Pharmaceuticals discloses the method of claim 2.
Adare Pharmaceuticals fails to explicitly disclose wherein the esophageal stricture is detected because the endoscope cannot pass through the patient's esophagus.
Takita, in the analogous field of esophageal stricture detection and treatment (Abstract), teaches wherein the esophageal stricture is detected because the endoscope cannot pass through the patient's esophagus (esophageal strictures are common after endoscopic submucosal dissection, ESD, of extensive tumors...and patients who have undergone ESD for such lesions often develop a post-ESD stricture that a transoral scope cannot pass through, p. 163, left column, first Para.).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adare Pharmaceuticals, as modified, with the teaching of Takita. The motivation for doing so would have been to identify an esophageal stricture based on the inability of a transoral endoscope to pass through the esophageal lumen, as suggested by Takita.

Claims 1-5, 12, and 26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Electronic Acknowledgement Receipt

EFS ID:	47051260
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Haruka Kanesaka
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	18-NOV-2022
Filing Date:	05-JAN-2022
Time Stamp:	15:59:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-119_08US_342083-2017_IDS_Transmittal_Under_197b.pdf	126457 e4d3813aca1697bea7deae295a921b55ca8dbc05	no	5

Warnings:

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-119_08US_342083-2017_IDS_SB08_20221117164944.pdf	128330 75972613c39575a2bce7625e10c0ed94c79b0b77	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	GENTILE_et_al_Aliment_Pharmacol_Ther_2014_1333-1340_EFS.pdf	4580320 d162afb24c8ea76eac2e95435f4c9b4133f98e3d	no	8
Warnings:					
Information:					
4	Non Patent Literature	DE_Patent_Complaint_Proceedings_7_O_75_19_O_Comm_opportunity_to_comment_07-12-2022_2pgs.pdf	108877 25c0c9bf01bace27378e8a5317abffe7b8c8e4f9	no	2
Warnings:					
Information:					
5	Non Patent Literature	DE_UM_Model_Notice-of-termination-of-proceedings_08-16-2022_2pgs.pdf	315094 8b54db47ddc1d9d27385ef2566f3c9c0d3128891	no	2
Warnings:					
Information:					
6	Non Patent Literature	DE_UM_Model_Cancellation-Withdrawal-of-cancellation_07-20-2022_1pg.pdf	100133 ef18c149f3cfc9543497a68b7dd2fdf0e963fc52	no	1
Warnings:					
Information:					
7	Non Patent Literature	Oppn_2482822_EPO_termination-of-proceedings_07-25-2022_1pg.pdf	120056 7b7ecc3fb704c57f1211a490f5b290c6651225c4	no	1
Warnings:					
Information:					
8	Non Patent Literature	Oppn_3086782_Written_decision_05-09-2022_63pgs.pdf	10984308 2d8d53ab585e10236765428054e0cdb7b04f83ed	no	63
Warnings:					
Information:					

9	Non Patent Literature	Oppn_3403654_decision-to-discontinue-opp-proceedings_09-05-2022_2pgs.pdf	532962 8e2d158d63d7d6850c7152f5c57995a0ec92a064	no	2
Warnings:					
Information:					
10	Non Patent Literature	ISRWO_PCTUS2022025297_July_29_2022_10_pages_EFS.pdf	3897650 54170476ca513427669f78011851203ce1ab07cb	no	10
Warnings:					
Information:					
11	Non Patent Literature	TAKITA_et_al_JHG_Open_2020_163-165_EFS.pdf	1938679 37cf147f0c6e75ccc85d725d8920be5c8d8fd41f	no	3
Warnings:					
Information:					
12	Foreign Reference	WO2022225892A1.pdf	12819435 39aaa9b4e051e1a8a7abb4f54fba6d31f0327112	no	58
Warnings:					
Information:					
		Total Files Size (in bytes):	35652301		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	PERRETT, Stephen	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 on the attached Form used in lieu of PTO/SB/08 is enclosed.

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

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

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PGR Petition - USP 12,290,598

[] 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 on the attached Form used in lieu of PTO/SB/08.

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

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

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

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

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

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

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

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

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

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

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

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

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

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

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

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

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

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

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

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

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

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

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

and

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

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

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

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

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

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

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.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1283, under Order No. ELLO-119/08US 342083-2017 from which the undersigned is authorized to draw.

Dated: November 18, 2022

Respectfully submitted,
COOLEY LLP

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

USPTO CUSTOMER NO. 58249

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017

CONFIRMATION NO. 8616

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

PUBLICATION NOTICE



Title:ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Publication No.US-2022-0339098-A1
Publication Date:10/27/2022

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

(Use as many sheets as necessary)

Sheet 1 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		001	US-3705172	12-05-1972	BUCHEL; Karl-Heinz et al.	
		002	US-3929768	12-30-1975	BRATTSAND; Ralph Lennart et al.	
		003	US-4080448	03-21-1978	MIRSKY; Louis H.	
		004	US-4335121	06-15-1982	PHILLIPPS; Gordon H. et al.	
		005	US-4363806	12-14-1982	BERGSTROM; Karl O. et al.	
		006	US-4472393	09-18-1984	SHAPIRO; Elliot L.	
		007	US-4985418	01-15-1991	RICHARDS; David A.	
		008	US-5135740	08-04-1992	KATZ; Martin et al.	
		009	US-5278175	01-11-1994	RAY; Stephen J. et al.	
		010	US-5403893	04-04-1995	TANAKA; Toyoichi et al.	
		011	US-5446070	08-29-1995	MANTELLE; Juan A.	
		012	US-5482934	01-09-1996	CALATAYUD; Jose et al.	
		013	US-5776433	07-07-1998	TZOU; Tsi-Zong et al.	
		014	US-5863910	01-26-1999	BOLONICK et al.	
		015	US-6171617	01-09-2001	GRUBER; Peter	
		016	US-6316027	11-13-2001	JOHNSON; Edward Stewart et al.	
		017	US-6596298	07-22-2003	LEUNG; Sau-Hung Spence et al.	
		018	US-6596311	07-22-2003	DOBETTI; Luca	
		019	US-6740332	05-25-2004	ZYCK; Daniel J. et al.	
		020	US-7033606	04-25-2006	BESSE; Jerome et al.	
		021	US-8077288	12-13-2011	KAWASHIMA; Haruna	
		022	US-8545881	10-01-2013	VENKATESH; Gopi M. 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.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		023	US-8580300	11-12-2013	WILHELM; Rudolf et al.	
		024	US-8679545	03-25-2014	DOHIL; Ranjan et al.	
		025	US-8771729	07-08-2014	PERRETT; Stephen et al.	
		026	US-8932596	01-13-2015	BENHAMOU; Pierre-Henri et al.	
		027	US-9387167	07-12-2016	PERRETT; Stephen et al.	
		028	US-9486407	11-08-2016	PERRETT; Stephen et al.	
		029	US-9782347	10-10-2017	DOHIL; Ranjan et al.	
		030	US-9849084	12-26-2017	PERRETT; Stephen et al.	
		031	US-9867780	01-16-2018	GREINWALD; Roland et al.	
		032	US-10076494	09-18-2018	PEVZNER et al.	
		033	US-10105315	10-23-2018	MELTZER; Brian A. et al.	
		034	US-10176301	01-08-2019	HILL; Malcolm et al.	
		035	US-10272037	04-30-2019	DOHIL; Ranjan et al.	
		036	US-10471071	11-12-2019	GOSSELIN; Michael A. et al.	
		037	US-10632069	04-28-2020	PERRETT; Stephen et al.	
		038	US-11026887	06-08-2021	BRIAN; A. Meltzer et al.	
		039	US-11166961	11-09-2021	MICHAEL; A. Gosselin et al.	
		040	US-11246828	02-15-2022	STEPHEN; Perrett et al.	
		041	US-11260061	03-01-2022	GOSSELIN; Michael A. et al.	
		042	US-11266598	03-08-2022	PERRETT; Stephen et al.	
		043	US-20010006625	07-05-2001	BOHN; Manfred et al.	
		044	US-20010014340	08-16-2001	OHTA; Motohiro 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.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		045	US-20030050312	03-13-2003	HJORTH; Thyge Borup et al.	
		046	US-20030054036	03-20-2003	LIGGINS; Richard et al.	
		047	US-20030099701	05-29-2003	TAKAISHI; Yuuki et al.	
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		050	US-20040053902	03-18-2004	SMITH; C. Steven	
		051	US-20040106663	06-03-2004	TALLEY; John Jeffrey et al.	
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		057	US-20060051414	03-09-2006	RAMALHO; Maria Julia Caeiro et al.	
		058	US-20060134054	06-22-2006	KULKARNI; Mohan G. et al.	
		059	US-20060292099	12-28-2006	MILBURN; Michael et al.	
		060	US-20070020330	01-25-2007	DANG; Phuong Grace et al.	
		061	US-20070059361	03-15-2007	RAWAS-QALAJI; Mutasem et al.	
		062	US-20070111978	05-17-2007	DOHIL; Ranjan et al.	
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		065	US-20090123550	05-14-2009	PHILLIPS; Elaine et al.	

Examiner Signature		Date Considered	

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Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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
		066	US-20090123551	05-14-2009	PHILLIPS; Elaine et al.	
		067	US-20090131386	05-21-2009	PHILLIPS; Elaine	
		068	US-20090149433	06-11-2009	PHILLIPS; Elaine	
		069	US-20090155360	06-18-2009	VENKATESH; Gopi M. et al.	
		070	US-20090169620	07-02-2009	VENKATESH; Gopi M. et al.	
		071	US-20090181099	07-16-2009	DOHIL; Ranjan et al.	
		072	US-20090191275	07-30-2009	DOHIL; Ranjan et al.	
		073	US-20100034894	02-11-2010	SZYMCZAK; Christopher E. et al.	
		074	US-20100215753	08-26-2010	SHERWOOD; Bob et al.	
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		076	US-20110081411	04-07-2011	PERRETT; Stephen et al.	
		077	US-20110097401	04-28-2011	PHILLIPS; Elaine et al.	
		078	US-20110123460	05-26-2011	WILHELM; Rudolf et al.	
		079	US-20110129530	06-02-2011	VENKATESH; Gopi M. et al.	
		080	US-20120128764	05-24-2012	VENKATESH; Gopi et al.	
		081	US-20120282335	11-08-2012	VENKATESH; Gopi M. et al.	
		082	US-20130296286	11-07-2013	DOHIL; Ranjan et al.	
		083	US-20130310661	11-21-2013	JEDWAB; Michael Reuben et al.	
		084	US-20140187523	07-03-2014	DOHIL; Ranjan et al.	
		085	US-20140228714	08-14-2014	CHAU; Thomas T.K. et al.	
		086	US-20140287051	09-25-2014	PERRETT; Stephen et al.	
		087	US-20140303131	10-09-2014	PERRETT; Stephen et al.	

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Sheet 5 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		088	US-20150209432	07-30-2015	KONDA; Kishore Kumar et al.	
		089	US-20150231156	08-20-2015	PHILLIPS; Elaine et al.	
		090	US-20160045518	02-18-2016	DOHIL; Ranjan et al.	
		091	US-20160078186	03-17-2016	HILL; Malcolm et al.	
		092	US-20160206627	07-21-2016	GOSSELIN; Michael A. et al.	
		093	US-20160213681	07-28-2016	SANTUS; Giancarlo et al.	
		094	US-20170071855	03-16-2017	PERRETT; Stephen et al.	
		095	US-20170183719	06-29-2017	ROTHENBERG; Marc E. et al.	
		096	US-20180071211	03-15-2018	DOHIL; Ranjan et al.	
		097	US-20180133145	05-17-2018	MELTZER; Brian A. et al.	
		098	US-20180153802	06-07-2018	PERRETT; Stephen et al.	
		099	US-20190008760	01-10-2019	BRIAN; A. Meltzer et al.	
		100	US-20190201333	07-04-2019	DOHIL; Ranjan et al.	
		101	US-20200016171	01-16-2020	MICHAEL; A. Gosselin et al.	
		102	US-20200214979	07-09-2020	STEPHEN; Perrett et al.	
		103	US-20200368147	11-26-2020	BRIAN; A. Meltzer et al.	
		104	US-20200381097	12-03-2020	MELTZER; Brian A.	
		105	US-20210205328	07-08-2021	GOSSELIN; Michael A. et al.	
		106	US-20210244660	08-12-2021	PERRETT; Stephen et al.	
		107	US-20210275438	09-09-2021	MELTZER; Brian A. et al.	
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PGR Petition - USP 12,290,598

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Sheet 6 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	110	CA-2430481-A1	06-13-2002	SAMYANG CORP [KR]		☐
	**	111	CA-2704946-A1	05-22-2009	MERITAGE PHARMA INC [US]		☐
	**	112	CA-2776164-A1	04-07-2011	APTALIS PHARMATECH INC [US]		☐
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	**	114	DE-202010018594-U1	02-16-2018	ADARE PHARMACEUTICALS INC [US]		☒
	**	115	DE-2323215-A1	11-29-1973	BOFORS AB.		☐
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Sheet 7 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	120	EP-1310243-A1	05-14-2003	ASTRAZENECA AB [SE]		☐
	**	121	EP-1323417-A1	07-02-2003	YAMANOUCHI PHARMA CO LTD [JP]		☐
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	**	127	JP-2001524094-A	11-27-2001	WEST PHARM SERV DRUG RES LTD., et al.		☐
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Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	131	JP-2003509359-A	03-11-2003	GLAXO GROUP LTD.		☐
	**	132	JP-2006077018-A	03-23-2006	KYOWA HAKKO KOGYO KK.		☒
	**	133	JP-2006516616-A	07-06-2006	OREXO AB.		☒
	**	134	JP-2009173552-A	08-06-2009	LION CORP.		☒
	**	135	JP-2009519793-A	05-21-2009	QUANTUM HI TECH BEIJING RES IN., et al.		☒
	**	136	JP-2009521523-A	06-04-2009	JUBILANT ORGANOSYS LTD.		☒
	**	137	JP-2011503073-A	01-27-2011	MERITAGE PHARMA INC.		☒
	**	138	JP-2013506683-A	02-28-2013	APTALIS PHARMATECH INC.		☒
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Sheet 9 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		142	KR-20100087007-A	08-02-2010	MERITAGE PHARMA INC [US]		☒
	**	143	KR-20120104975-A	09-24-2012	APTALIS PHARMATECH INC [US]		☒
		144	KR-20160058829-A	05-25-2016	ADARE PHARMACEUTICALS INC [US]		☒
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		146	RU-2016104400-A	08-16-2017	REGENERON PHARMA.		☒
	**	147	WO-0064450-A1	11-02-2000	LEO PHARM PROD LTD [DK], et al.		☐
	**	148	WO-0119342-A2	03-22-2001	GLAXO GROUP LTD [GB], et al.		☐
	**	149	WO-02092057-A1	11-21-2002	YAMANOUCHI PHARMA CO LTD [JP], et al.		☒
	**	150	WO-03039520-A1	05-15-2003	ETHYPHARM SA [FR], et al.		☒
	**	151	WO-03093344-A1	11-13-2003	JANSSEN PHARMACEUTICA NV [BE], et al.		☐
	**	152	WO-2004064810-A1	08-05-2004	NIPPON SHINYAKU CO LTD [JP], et al.		☒

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Sheet 10 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	153	WO-2004067004-A1	08-12-2004	OREXO AB [SE], et al.		☐
	**	154	WO-2004069225-A1	08-19-2004	ELAN PHARMA INT LTD [IE], et al.		☐
	**	155	WO-2004091585-A1	10-28-2004	SYNTHON BV [NL], et al.		☐
	**	156	WO-2005087194-A1	09-22-2005	SCHERING AG [DE], et al.		☐
	**	157	WO-2007071179-A1	06-28-2007	QUANTUM HI TECH BEIJING RES IN [CN], et al.		☒
	**	158	WO-2007074472-A2	07-05-2007	JUBILANT ORGANOSYS LTD [IN], et al.		☐
	**	159	WO-2008098634-A1	08-21-2008	POLICHEM SA [LU], et al.		☐
	**	160	WO-2009064457-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	161	WO-2009064458-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	162	WO-2009064819-A2	05-22-2009	MERITAGE PHARMA INC [US], et al.		☐
	**	163	WO-2009086046-A1	07-09-2009	EURAND INC [US], et al.		☐

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Sheet 11 of 39

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Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	164	WO-2009098595-A2	08-13-2009	FOAMIX LTD [IL], et al.		☐
	**	165	WO-2010021636-A1	02-25-2010	UNIV CALIFORNIA., et al.		☐
	**	166	WO-2010144865-A2	12-16-2010	MERITAGE PHARMA INC [US], et al.		☐
	**	167	WO-2011041509-A1	04-07-2011	EURAND INC [US], et al.		☐
	**	168	WO-2015034678-A2	03-12-2015	APTALIS PHARMATECH INC [US]		☐
	**	169	WO-2015035114-A1	03-12-2015	APTALIS PHARMATECH INC [US]		☐
		170	WO-2017189805-A1	11-02-2017	ABBVIE INC [US]		☐
	**	171	WO-2018035393-A1	02-22-2018	ADARE PHARMACEUTICALS INC [US]		☐
	**	172	WO-2019165138-A1	08-29-2019	ADARE DEV I L P [US]		☐
	**	173	WO-2021067585-A1	04-08-2021	ADARE PHARMACEUTICALS US L P [US], et al.		☐
		174	WO-2022020464-A1	01-27-2022	ELLODI PHARMACEUTICALS L P [US]		☐

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	175	WO-9706786-A1	02-27-1997	SCHERER LTD R P [GB], et al.		☐
	**	176	WO-9847535-A1	10-29-1998	DANBIOSYST UK [GB], et al.		☐
	**	177	ZA-6805392	06-04-1969	FARBENFABRIKEN BAYER AG.		☐

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Sheet 13 of 39

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First Named Inventor	Stephen PERRETT
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Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	178	ACEVES, et al., "Oral viscous budesonide: a potential new therapy for eosinophilic esophagitis in children". Am J Gastroenterol. (2007 Oct); 102(10): 1-9. Epub 2007 Jun 20.	☐
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	**	180	AHMED and SHAH, "Formulation of low dose medicines - theory and practice." Am. Pharm. Rev (2000); 3(3): 9-14.	☐
		181	AHMED, Monjur, "Eosinophilic esophagitis in adults: An update". World J Gastrointest Pharmacol Ther. (2016 May 6); 7(2): 207-213.	☐
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	**	183	Auszug von European Pharmacopeia 6.0 (English language) 2.9.8; 23 July 2007, 2 pages.	☐
	**	184	Auszug von European Pharmacopeia 8.0 (German language) 2.9.8; 15 July 2013, 1 page.	☐
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First Named Inventor	Stephen PERRETT
Art Unit	1615
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Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	187	[Author Unknown] Definition of sustained-release (downloaded from Merriam-Webster online athttps://www.merriam-webster.com/dictionary/sustainedrelease#medicalDictionary); accessed 7/31/2019, 1 page.	☐
		188	[Author unknown] DrugBank Accession Number, first approved 1990, DrugBank Accession Number DB00588, https://go.drugbank.com/drugs/DB00588, 14 pages.	☐
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	**	192	[Author Unknown] Povidone (polyvinylpyrrolidone (PVP)) compound summary (downloaded from Wikipedia at https://en.wikipedia.org/wiki/Polyvinylpyrrolidone); accessed 7/31/2019, 5 pages.	☐
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Sheet 15 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		195	BAUER, et al., "106 Chapter 5 Methods and Basic Operations". Lehrbuch der Pharmazeutischen Technologie (Textbook of pharmaceutical technology), With an introduction to biopharmacy (2006); (eds) LIPPOLD, et al., 8th revised and updated edition, and English translation, 12 pages.	☒
	**	196	BEVERIDGE, et al., "Novel Therapeutic Approaches to Eosinophilic Esophagitis". Gastroenterology & Hematology (2020 Jun); 16(6): 294-301.	☐
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Sheet 16 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	205	DALEY-YATES, Peter T. "Inhaled corticosteroids: potency, dose equivalence and therapeutic index." British Journal of Clinical Pharmacology (2015); 80(3): 372-380.	☐
	**	206	Declaration of Stephen Perrett, MBA, Ph.D. dated July 16, 2020, 6 pages.	☐
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First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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		214	European Application No. EP 19757814.9, Extended European Search Report dated November 4, 2021, 11 pages.	☐
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	**	233	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Pleadings as filed, dated December 16, 2019, and English translation, 66 pages.	☒
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	**	236	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk - statement of defense, filed October 7, 2019 (and English translation), 14 pages.	☒
	**	237	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Submission of Dr. Falk dated February 10, 2020, 6 pages, in German and English.	☐
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Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

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	**	239	German Patent Infringement Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Patent Complaint dated July 3, 2019, with English translation, 107 pages.	☐
	**	240	German Utility Model Cancellation Action, Request for Cancellation, filed by Dr. Falk Pharma GmbH on March 1, 2019 with the German Patent Office, in connection with DE Patent No. 202010018594 U1 in the name of Adare Pharmaceuticals, Inc., and English translation, 21 pages.	☐
	**	241	German Utility Model Cancellation Proceedings DE 20201 018594 U1, Dr. Falk Pharma GmbH (Plaintiff/Respondent) vs. Adare Pharmaceuticals US, L.P. / Ellodi Pharmaceuticals L.P. (Patentee/Appellant), Statement of Grounds of Appeal dated February 26, 2021 (and English translation), and Exhibit B817 - Current EPA register extract on D5 dated 27 November 2020, 117 pages.	☐
	**	242	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Adare - Further Submission as filed dated July 12, 2019, and English translation, 56 pages.	☐
	**	243	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Auxiliary Request I-IV (marked-up) dated and as filed July 1, 2020, and English translation, 17 pages.	☐
	**	244	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Official Communication - Interlocutory Notice dated January 22, 2020 (and English translation), 12 pages.	☒
	**	245	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Dr. Falk and Summons dated July 2, 2020, and English translation, 18 pages.	☒

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
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	**	246	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Response to Pleadings as filed dated October 17, 2019, and English translation, 25 pages.	☐
	**	247	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 20201 018594 U1, Submission of Dr. Falk - Pleadings dated September 13, 2019 (and English translation), 27 pages.	☒
	**	248	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Adare's Response dated April 6, 2020 to Interlocutory Decision, and English translation, 29 pages.	☐
	**	249	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Communication from Adare to German Patent Office, Auxiliary Requests 1 and 2 (clean, marked-up and English translations) as filed April 6, 2020, 23 pages.	☒
	**	250	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, Submission of Dr. Falk - response to Adare and summons, dated July 8, 2020 (and English translation), 11 pages.	☒
	**	251	German Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, submission/Response by Dr. Falk Pharma GmbH dated April 8, 2020 (and English translation), 18 pages.	☒
	**	252	HAHM and AUGSBURGER, Orally Disintegrating Tablets and Related Tablet Formulations, Pharmaceutical Dosage Forms: Tablets, Third Edition, Ch. 9, Volume 2, Herausgeber: (eds) Larry L. Augsburger, Stephen W. Hoag, CRC Press (2008), 21 pages.	☐

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	**	253	HAM, et al., "Quantitation of esophagal transit by means of 81mKr." European Journal of Nuclear Medicine (1984); 9: 362-365.	☐
	**	254	Handbook of Pharmaceutical Excipients (2009); Sixth Edition, ISBN 978 1 58212 135 2, (eds.) ROWE, et al., Cover Page, Print/Copyright and Preface Pages, 4 pages.	☐
	**	255	International Preliminary Report on Patentability for International Application No. PCT/US2017/047474, dated February 19, 2019, 8 pages.	☐
	**	256	JORVEZA (budesonide) Update by the Committee for Medicinal Products for Human Use (CHMP), Summary of opinion1 (post authorisation) dated March 26, 2020, European Medicines Agency, 1 page.	☐
	**	257	KATDARE and CHAUBAL (eds)., Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Systems, Herausg. CRC Press, Taylor & Francis Group, Boca Raton, USA, 2006; dart: Excipients for Oral Liquid Formulations, S. 155-180, 28 pages.	☐
	**	258	KHAN and ORENSTEIN, "Eosinophilic Gastroenteritis: Epidemiology, Diagnosis and Management." Paediatr Drugs. (2002); 4(9): 563-570.	☐
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	**	261	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).	☐

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	**	262	Langdon, BA and Mullamey, (2006) Handbook of Pharmaceutical Excipients. (eds.) Rowe, R.C., Sheskey, PJ and Owen, S.C., London: Pharmaceutical Press and American Pharmacists Association (extract - pages 53-55 and 742-743), 14 pages.	☐
	**	263	LEE, Geoffrey, Professor, Report of Professor Geoffrey Lee, Ph.D. on measurement of disintegration time of "Jorveza 1 mg orodispersible tablet" dated November 15, 2019, 16 pages.	☐
	**	264	LI, Xiaowei, et al., "Advances in Injectable Thermosensitive Polymers". Polymer Bulletin, No. 3, pages 109-115, June 30, 2015 (with English Abstract), 7 pages.	☒
	**	265	LIACOURAS, et al., "Primary Eosinophilic Esophagitis in Children: Successful Treatment with Oral Corticosteroids". Journal of Pediatric Gastroenterology & Nutrition (1998); 26(4): 380-385.	☐
	**	266	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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	**	268	Malaysian Application No. PI 2012001434, Search Report dated January 29, 2016, 1 page.	☐
	**	269	MARTIN, et al., "Pediatric Eosinophilic Esophagitis Symptom Scores (PEESS® v2.0) identify histologic and molecular correlates of the key clinical features of disease". J Allergy Clin Immunol. (2015 June); 135(6): 1519-1528.e8.	☐
	**	270	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).	☐

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Art Unit	1615
Examiner Name	Not Yet Assigned
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	**	271	Merck Index, "Budesonide," 14th Edition, p. 240 (2006).	☐
	**	272	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006).	☐
	**	273	Merck Index, "Clotrimazole," 14th Edition, p. 407 (2006).	☐
	**	274	Merck Index, "Mometasone Furoate," 14th Edition, pp. 1077-1078 (2006).	☐
	**	275	Merck Index, "Voriconazole," 14th Edition, p. 1728 (2006).	☐
	**	276	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.	☐
	**	277	MORETON, R. Christian, "Disintegrants in Tableting". In book: Pharmaceutical Dosage Forms: Tablets, Vol. 2, Herausgeber Augsburger & Hoag, CRC Press, Taylor and Francis Group (2008); Ch. 6, pgs. 217- 249, 33 pages.	☐
	**	278	New World Encyclopedia, "Gastrointestinal tract", https://web.archive.org/web/20090917122455/https://www.newworldencyclopedia.or..., July 8, 2019, 7 pages.	☐
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	**	280	NISHIMURA, S., et al. "Factors associated with esophageal candidiasis and its endoscopic severity in the era of antiretroviral therapy." PLoS One (2013); 8(3): e58217, 6pgs.	☐

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	**	281	Novopulmon E Novolizer, Instructions for the medical use of the medicament, [Instrukciya po medicinskomu primeneniyu preparata Novopulmon 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.	☐
	**	282	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	☐
	**	283	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated April 6, 2021, enclosing Patentee's Response to Submissions dated March 30, 2021, and English translation, 9 pages.	☐
	**	284	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Appeal No. T1954/21-3.3.01 dated January 4, 2022, 20 pages.	☐
		285	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Interlocutory Decision dated January 5, 2022, and English translation, 43 pages.	☒
		286	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Minutes of Oral Proceedings dated January 5, 2022, and English translation, 25 pages.	☒
		287	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO's Communication dated November 18, 2021 enclosing Opponent's, Dr. Falk Pharma GmbH's Further Submissions dated November 15, 2021, and English translation, 21 pages.	☒

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		288	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Interlocutory Decision dated February 14, 2022, 61 pages.	☐
		289	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Minutes of Oral Proceedings dated February 14, 2022, 15 pages.	☐
	**	290	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, D18 - Dr F's novelty table 2020, 2 pages.	☐
	**	291	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication - communication of notice of opposition dated May 13, 2019, 1 page.	☐
	**	292	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.	☐
	**	293	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated September 26, 2019, transmitting Adare's submission filed September 20, 2019, 88 pages.	☐
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	**	300	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication dated March 25, 2020 transmitting communication from Dr. Falk Pharma GmbH dated March 20, 2020, and English translation, 34 pages.	☐
	**	301	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Adare Development, I, L.P on November 6, 2019, EPO Communication re Summons to Attend Oral Proceedings and Preliminary Opinion, dated July 2, 2020, and English translation, 18 pages.	☐

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	**	302	Opposition Proceedings in European Patent No. 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Adare's Written Submissions in Preparation for Oral Proceedings on April 23, 2021, dated February 23, 2021, 25 pages.	☐
	**	303	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 2, 2019, transmitting Notice of Opposition filed June 26, 2019, 43 pages.	☒
	**	304	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated July 22, 2020 regarding date of oral proceedings, 3 pages.	☒
	**	305	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication dated November 19, 2019, with Patentee's response to Opposition dated November 8, 2019, and English translation, 22 pages.	☒
	**	306	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, EPO Communication to Adare regarding oral proceedings dated March 2, 2020, and English translation, 14 pages.	☒
	**	307	Opposition Proceedings in European Patent No. 3086782 (Appln. No. 14814872.9), filed by Adare Development, I, L.P on June 26, 2019, Patentee, Dr. Falk's Written Submissions, Auxiliary Request I and Test Report Jorveza® 1 mg (dated August 18, 2020, produced by Patentee, Dr. Falk Pharma), filed September 10, 2020, and English translation, 22 pages.	☐
		308	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; communication from the European Patent Office (EPO) dated May 18, 2022 enclosing Opponent's response to appeal dated May 12, 2022 and D27, and English translation, 44 pages.	☒

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Art Unit	1615
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Attorney Docket Number	ELLO-119/08US 342083-2017

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		309	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Ellodi's Withdrawal of Appeal dated July 11, 2022, 3 pages.	☐
	**	310	Opposition Proceedings in European Patent No. EP 2482822, Appeal No. T1954/21-3.3.01 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication - Minutes of Oral Proceeding, dated August 25, 2021, and English translation, 11 pages.	☐
	**	311	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare - Letter to EPO re Oral Proceedings dated July 17, 2020, 5 pages.	☐
	**	312	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Adare's Communication to the EPO re oral proceedings, dated August 11, 2020, 4 pages.	☐
	**	313	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Written Submission from Adare (Proprietor) dated July 17, 2020, 126 pages.	☐
	**	314	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated March 8, 2019 regarding notice of opposition, 1 page.	☐
	**	315	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication re oral proceedings, dated August 5, 2020, 1 page.	☐
	**	316	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication re Oral Proceedings dated July 13, 2020, 3 pages.	☐

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	**	317	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's consolidated list of cited opposition documents, July 18, 2020, 1 page.	☐
	**	318	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to Attend Oral Hearing and Preliminary Opinion in opposition dated February 13, 2020, 15 pages.	☐
	**	319	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019, Summons to attend oral proceedings dated February 13, 2020, 13 pages.	☐
	**	320	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 1082123205), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Patentee in Preparation for Oral Proceedings on March 8, 2021, dated January 8, 2021, with Auxiliary Requests 1-14, 52 pages.	☐
	**	321	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharm a GmbH on March 1, 2019; EPO's Decision revoking European Patent No. 2482822, dated August 25, 2021, 23 pages.	☐
	**	322	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication in connection with Summons to attend oral proceedings, dated November 20, 2020, 12 pages.	☐
	**	323	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Falk's Communication to the EPO re oral proceedings, dated August 12, 2020, 3 pages.	☒

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	**	324	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Opponent's response to Summons dated July 17, 2020, and English translation, 15 pages.	☒
	**	325	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Opponent's submissions dated March 1, 2021, and English translation, 11 pages.	☐
	**	326	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Opponent in response to the Summons to attend Oral Proceedings, dated and filed December 8, 2020, and English translation, 37 pages.	☐
		327	Opposition Proceedings in European Patent No. EP 2886108, Appeal No. T0611/22-3.3.07 (Appln. No. 13199278.6), (in the name of Dr. Falk Pharma GmbH) filed by Ellodi Pharmaceuticals, L.P. on November 6, 2019; EPO Communication dated May 27, 2022 confirming Termination of Appeal Proceedings filed May 16, 2022, 4 pages.	☐
		328	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Adare Development I, L.P., on November 6, 2019, Dr. Falk Pharma's Response to Summons and Adare's Written Submissions and clean and marked versions of Auxiliary Requests I and II, dated December 18, 2020, and English translation, 26 pages.	☒
		329	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Datasheet for the decision of 14 October 2019, Case Number T 1621/16 - 3.3.06, Application No. 09163237.2, 28 pages.	☐
		330	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Ellodi's Notice of Appeal against decision filed March 4, 2022, 5 pages.	☐

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		331	Opposition Proceedings in European Patent No. EP 2886108 (Appln. No. 13199278.6), filed by Ellodi Pharmaceuticals, L.P., on November 6, 2019, Ellodi's Withdrawal of Appeal filed May 16, 2022, 3 pages.	☐
		332	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 22, 2022 confirming withdrawal of appeal as filed July 14, 2022 by Opponent, 4 pages.	☐
		333	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated June 20, 2022 enclosing Opponent's Grounds of Appeal dated June 10, 2022, and English translation, 27 pages.	☒
		334	Opposition Proceedings in European Patent No. EP 3041476, Appeal No. T1007/22-3.3.07 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Withdrawal of Appeal filed by Ellodi Pharmaceuticals, L.P. dated June 14, 2022, 3 pages.	☐
	**	335	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated February 22, 2021 enclosing Opponent's Submissions (and English translation), dated February 16, 2021, 11 pages.	☐
	**	336	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; EPO Communication dated July 29, 2020 advising of and enclosing Notice of Opposition filed by Dr. Falk Pharma GmbH on July 22, 2020, 82 pages.	☐
		337	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Appeal filed by Ellodi Pharmaceuticals, L.P. dated April 22, 2022, 5 pages.	☐

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	**	338	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Notice of Opposition and Statement of Grounds of Opposition (with English translation of Statement of Grounds of Opposition), and Consolidated List of references relied upon, filed July 22, 2020, 513 pages.	☐
	**	339	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Adare's Response to Opposition dated .January 11, 2021, 15 pages.	☐
	**	340	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Ellodi Pharmaceuticals, L.P.'s Written Submission in Preparation for Oral Proceedings on December 8, 2021 with new Auxiliary Requests 1-3, dated October 8, 2021, 51 pages.	☐
	**	341	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Adare's Response to the Grounds of Opposition, filed November 2, 2020, 78 pages.	☐
	**	342	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Consolidated List of References dated and filed December 8, 2020, 1 page.	☐
	**	343	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated June 22, 2020, 1 page.	☐
	**	344	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; EPO Communication of a notice of opposition dated May 8, 2020, 1 page.	☐

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	**	345	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Further Written Submissions dated and filed December 8, 2020, and English translation, 30 pages.	☐
		346	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Opponent's Submission/Withdrawal of Opposition dated July 20, 2022, and English translation, 2 pages.	☒
	**	347	Opposition Proceedings in European Patent No. EP 3403654 (Appln. No. 18178891.0), filed by Dr. Falk Pharma GmbH; Statement of Grounds of Opposition filed on April 28, 2020, and English translation, 38 pages.	☐
	**	348	Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Decision (and English translation) dated October 26, 2020, pronounced in the oral hearing of 21 July 2020, 45 pages.	☐
	**	349	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	☐
	**	350	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	☐
	**	351	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	☐
	**	352	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	☐
	**	353	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	☐

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	**	354	PCT Application No. PCT/US2014/052073, Written Opinion of the International Searching Authority dated November 20, 2014.	☐
	**	355	PCT Application No. PCT/US2014/054203, International Preliminary Report on Patentability dated March 8, 2016.	☐
	**	356	PCT Application No. PCT/US2014/054203, International Search Report dated December 23, 2014.	☐
	**	357	PCT Application No. PCT/US2014/054203, Written Opinion of the International Searching Authority dated December 23, 2014.	☐
	**	358	PCT Application No. PCT/US2019/019040, International Preliminary Report on Patentability, dated August 27, 2020, 8 pages.	☐
	**	359	PCT Application No. PCT/US2019/019040, International Search Report and Written Opinion, mailed June 25, 2019, 12 pages.	☐
	**	360	PCT Application No. PCT/US2019/019040, Invitation To Pay Additional Fees, mailed April 25, 2019, 2 pages.	☐
		361	PCT/US2020/053778, International Preliminary Report on Patentability mailed April 5, 2022, 7 pages.	☐
	**	362	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	☐
		363	PCT/US2021/042566, International Search Report and Written Opinion, mailed November 5, 2021, 9 pages.	☐
	**	364	PELLE, et al., "Using defined daily doses to study the use of antibacterials in UK hospitals". Hosp Pharm (2006); 13: 133-136.	☐

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	**	365	PONCHEL, Gilles, "Formulation of oral mucosal drug delivery systems for the systemic delivery of bioactive materials". Advanced Drug Delivery Reviews, Volume 13, Issues 1-2, January-February 1994, Pages 75-87.	☐
	**	366	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	☐
	**	367	REMEDIOS, et al., "Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate". Gastrointestinal Endoscopy (2006); 63(1): 3-12.	☐
	**	368	ROBERTSON, et al., "Oesophageal transit of small tablets", J. Pharm. Pharmacol. (1988); 40: 595-596.	☐
	**	369	SCHAEFER, et al., "Comparison of Oral Prednisone and Topical Fluticasone in the Treatment of Eosinophilic Esophagitis: A Randomized Trial in Children". Clinical Gastroenterology and Hepatology (2008); 6: 165-173.	☐
	**	370	SCHOEPFER, et al., "Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis". Gastroenterology (2014 Dec 1); 147(6): 1255-1266.	☐
	**	371	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	☐
		372	SJOSTROM and CAIRNCROSS, "What Makes Flavor Leadership." Food Technology (1953); (7) 2: 56-58.	☐
	**	373	Supplementary European Search Report in European Patent Application No. EP 20192973.4, dated November 18, 2020, 5 pages.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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LLO-119_08US - _342083.2017_ Ellodi Pharmaceuticals_ Inc. -

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

(Use as many sheets as necessary)

Sheet 37 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

****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]
	**	374	TAFT, et al., "The adult eosinophilic oesophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	☐
	**	375	Taiwanese Application No. TW 099133628, Search Report (English translation) dated November 16, 2014, 9 pages.	☒
	**	376	Taiwanese Application No. TW 104107443, Search Report (English translation) dated May 29, 2015,1 page.	☐
	**	377	TAKAKU, Fumimaro, et al. Manual of Therapeutic Agents 2007, Published 2007, p. 617-619 (and English translation/summary of pertinent paragraphs), 5 pages.	☒
	**	378	TAYEBI and MORTAZAVI, "Formulation and Evaluation of a Novel Matrix-Type Orally Disintegrating Ibuprofen Tablet". Iran J Pharm Res. (2011 Summer); 10(3): 469-479.	☐
	**	379	TEITELBAUM et al. "Eosinophilic esophagitis in children: immunopathological analysis and response to fluticasone propionate." Gastroenterology (2002), 122(5): 1216-1225.	☒
	**	380	THORBURN and FERGUSON, "Topical corticosteroids and lesions of the oral mucosa". Advanced Drug Delivery Reviews, Volume 13, Issues 1-2, January-February 1994, Pages 135-149.	☐
	**	381	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Replica dated July 19, 2019, and English translation, 25 pages.	☒
	**	382	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Complaint dated July 3, 2019, and English translation, 34 pages.	☐

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.

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LLO-119_08US - _342083.2017_ Ellodi Pharmaceuticals_ Inc. -

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 38 of 39

Complete if Known	
Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

****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]
	**	383	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, submission by Dr. Falk Pharma GmbH - statement of defense, dated May 24, 2019, and English translation, 16 pages.	☒
	**	384	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Submission of Dr. Falk - Rejoinder dated September 13, 2019 (English translation), 8 pages.	☒
		385	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Defendant's Consent to Withdrawal filed July 15, 2022, and English translation, 2 pages.	☒
		386	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Order concerning value under dispute dated July 20, 2022, and English translation, 2 pages.	☒
		387	UM Complaint Proceedings in the Regional Court, Mannheim, Germany, Ellodi Pharmaceuticals, L.P. (formerly Adare Development I, L.P.) vs. Dr. Falk Pharma GmbH, Reference No. 4c O 10/2019, Withdrawal Submission filed by Ellodi Pharmaceuticals, L.P., dated July 11, 2022, and English translation, 2 pages.	☒
	**	388	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB1 "Breakdown of Features", and English translation, 2 pages.	☒
	**	389	Utility Model Cancellation Proceedings, Dr. Falk Pharma GmbH (Plaintiff) vs. Adare Development I, L.P. (Patentee), Utility model DE 202010018594 U1, July 12, 2019 - Exhibit BB4 - Letter from Lederer & Keller dated September 27, 2018 regarding European Patent No. 2211896, and Machine English translation, 28 pages.	☒

Examiner Signature		Date Considered	

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LLO-119_08US - _342083.2017_ Ellodi Pharmaceuticals_ Inc. -

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 39 of 39

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Application Number	17/569,047
Filing Date	01-05-2022
First Named Inventor	Stephen PERRETT
Art Unit	1615
Examiner Name	Not Yet Assigned
Attorney Docket Number	ELLO-119/08US 342083-2017

****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]
	**	390	VOGT et al., "Biowaiver monographs for immediate release solid oral dosage forms: Prednisolone," Journal of Pharmaceutical Sciences, 96(1): 27-37 (2007).	☐
	**	391	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis - Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	☐
	**	392	WEBB, Paul A., "Surface Area, Porosity, and Related Physical Characteristics". In book: Pharmaceutical Dosage Forms: Tablets, 3rd Edition, Vol. 3, CRC Press, Taylor and Francis Group, Boca Raton, London, New York (2008); Chapter 11, pgs. 277-302.	☐
	**	393	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	☐
	**	394	WEI et al., "Efficacy of Single-Dose Dexamethasone as Adjuvant Therapy for Acute Pharyngitis" The Laryngoscope, 112(1):87-93 (2002).	☐
	**	395	WEN, Hong, (ed. SWARBICK, James) "Adsorption at Solid Surfaces: Pharmaceutical Applications". Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1 (2007); pgs. 34-38, 7 pages.	☐
	**	396	Wikipedia, "Retard", https://de.wikipedia.org/wiki/Retard, June 13, 2019, and Google machine translation, 7 pages.	☐
	**	397	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.

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Electronic Acknowledgement Receipt	
EFS ID:	46395591
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Matthew H. Scheideman/Haruka Kanesaka
Filer Authorized By:	Matthew H. Scheideman
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	11-AUG-2022
Filing Date:	05-JAN-2022
Time Stamp:	18:19:19
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.)
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36	Non Patent Literature	UM_complaint_proceedings_4c_O_10_2019_Def_Consent-to-Withdrawal_07-15-2022_2_pgs.pdf	553906 e59241005b87ce52f53b512dfc1e626e27c91be5	no	2
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37	Non Patent Literature	UM_Complaint_Proceedings-4c-10-2019_Order-valuedispute__07-20-2022_2_pgs.pdf	502758 c2b5377aa5b378ffde7e2009b5b115d5821afbe6	no	2
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		Total Files Size (in bytes):	135058499		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION TREATY)

(PCT Rule 44bis.1(c))

To:

COUSIN, Jonathan A.
Cooley LLP
1299 Pennsylvania Avenue, N.W., Suite 700
Washington, District of Columbia 20004
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing *(day/month/year)* 14 April 2022 (14.04.2022)	
Applicant's or agent's file reference ELLO-16702WO	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2020/053778	01 October 2020 (01.10.2020)	01 October 2019 (01.10.2019)

Applicant
ELLODI PHARMACEUTICALS, L.P.

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne e-mail pct.team4@wipo.int Telephone No. +41 22 338 74 04

Form PCT/IB/326 (revised January 2020)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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 ELLO-16702WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2020/053778	International filing date *(day/month/year)* 01 October 2020 (01.10.2020)	Priority date *(day/month/year)* 01 October 2019 (01.10.2019)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ELLODI PHARMACEUTICALS, L.P.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 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 05 April 2022 (05.04.2022)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne e-mail pct.team4@wipo.int

Form PCT/IB/373 (revised January 2020)

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	08 JAN 2021

Applicant's or agent's file reference	FOR FURTHER ACTION
ADAR-16702WO	See paragraph 2 below

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

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

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

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

Applicant ADARE PHARMACEUTICALS US, L.P.

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

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

2. **FURTHER ACTION**

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

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

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

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

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Additional comments:

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

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

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

☐ the entire international application.

☒ claims Nos. 4-51, 55-102

because:

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

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

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

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

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

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

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

☐ See Supplemental Box for further details.

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

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

1. Statement

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

2. Citations and explanations:

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

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

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

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

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

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/53778

Supplemental Box

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

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

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

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

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

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
ELLO16602WO		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2021/042566	21 July 2021	21 July 2020
Applicant		
ELLODI PHARMACEUTICALS, L.P.		

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

☒ the text is approved as submitted by the applicant.

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

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

☒ the text is approved as submitted by the applicant.

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

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

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

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

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/042566

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

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

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

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

3. ☒ Claims Nos.: 4-29, 33-57, 60, 61
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/042566

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 9/24; A61K 9/26; A61K 9/36; A61K 31/4439; A61P 1/00; A61P 37/02 (2021.01)
CPC - A61K 9/0056; A61K 9/2009; A61K 9/2086; A61K 9/2866; A61K 31/4439; A61P 1/00; A61P 37/02 (2021.08)

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/0209432 A1 (LUPIN LIMITED) 30 July 2015 (30.07.2015) entire document	1-3
X	US 2012/0128764 A1 (VENKATESH et al) 24 May 2012 (24.05.2012) entire document	30-32
X --- Y	US 2014/0328861 A1 (ATOPIX THERAPEUTICS LIMITED) 06 November 2014 (06.11.2014) entire document	58 --- 59
Y	US 8,932,596 B2 (BENHAMOU et al) 13 January 2015 (13.01.2015) entire document	59

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2021	NOV 05 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Harry Kim Telephone No. PCT Helpdesk: 571-272-4300

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

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MICHAEL S. TUSCAN
COOLEY LLP
1299 PENNSYLVANIA AVE.
SUITE 700
WASHINGTON, DC 20004

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	NOV 05 2021

Applicant's or agent's file reference	FOR FURTHER ACTION
ELLO16602WO	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2021/042566	21 July 2021	21 July 2020

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61K 9/24; A61K 9/26; A61K 9/36; A61K 31/4439; A61P 1/00; A61P 37/02 (2021.01)
CPC - A61K 9/0056; A61K 9/2009; A61K 9/2086; A61K 9/2866; A61K 31/4439; A61P 1/00; A61P 37/02 (2021.08)

Applicant ELLODI PHARMACEUTICALS, L.P.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	11 October 2021	Harry Kim PCT Helpdesk: 571-272-4300 Telephone No. 571-272-4300

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2021/042566

Box No. I Basis of this opinion

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Additional comments:

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2021/042566

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

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

☐ the entire international application.

☒ claims Nos. 4-29, 33-57, 60, 61

because:

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

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4-29, 33-57, 60, 61 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 4-29, 33-57, 60 and 61 are multiple dependent claims not drafted in accordance with the second and third sentences of Rule 6.4 (a).

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

☒ no international search report has been established for said claims Nos. 4-29, 33-57, 60, 61

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

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

☐ See Supplemental Box for further details.

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2021/042566

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

1. Statement

Novelty (N)	Claims	59	YES
	Claims	1-3, 30-32, 58	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-3, 30-32, 58, 59	NO
Industrial applicability (IA)	Claims	1-3, 30-32, 58, 59	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by US 2015/0209432 to Lupin Limited (hereinafter, "Lupin").

Regarding claim 1, Lupin discloses a delayed release pharmaceutical composition (Para. [0020], pharmaceutical composition according to the invention comprises but is not limited to ... modified release tablets; Para. [0077], pharmaceutical composition comprises granules, wherein the granules comprising an active layer comprising Proton Pump Inhibitor, Crospovidone and basic inorganic salt; an intermediate coating layer formed on active layer, and an enteric coating layer which is formed on the intermediate coating layer ... the Proton Pump Inhibitor is released in the pH range of no less than 5.0 to no more than 6.0) comprising at least one proton pump inhibitor (PPI), or a pharmaceutically acceptable salt thereof (Para. [0077], pharmaceutical composition comprises granules, wherein the granules comprising an active layer comprising Proton Pump Inhibitor), magnesium oxide (Para. [0077], pharmaceutical composition comprises granules, wherein the granules comprising an active layer comprising Proton Pump Inhibitor, Crospovidone and basic inorganic salt; Para. [0023], Examples of the basic inorganic salt of magnesium include ground magnesium carbonate, magnesium carbonate, magnesium oxide), and one or more enteric polymers (Para. [0077], an enteric coating layer which is formed on the intermediate coating layer; Para. [0038], "Enteric coating layer" comprises one or more enteric polymers and one more pharmaceutically acceptable excipients comprise but not limited to sustained release agents), wherein the PPI, or pharmaceutically acceptable salt thereof, and the magnesium oxide are present as a mixture (Para. [0077], active layer comprising Proton Pump Inhibitor, Crospovidone and basic inorganic salt; Para. [0023], Examples of the basic inorganic salt of magnesium include ground magnesium carbonate, magnesium carbonate, magnesium oxide), and wherein the amount of PPI, or pharmaceutically salt thereof in the mixture is greater than or equal to the amount of magnesium oxide (MgO) in the mixture (Para. [0077], wherein basic inorganic salt is present in an amount less than 0.2 part by weight based on one part by weight of Proton Pump Inhibitor; Para. [0023], Examples of the basic inorganic salt of magnesium include ground magnesium carbonate, magnesium carbonate, magnesium oxide).

Regarding claim 2, Lupin discloses the pharmaceutical composition of claim 1, comprising an inert core, wherein the mixture of the PPI, or the pharmaceutically acceptable salt thereof, and MgO is disposed over the inert core (Para. [0033], active layer is formed by coating cores or inert pellets. Cores or inert pellets are composed of one or more materials selected from sucrose, starch, lactose and microcrystalline cellulose; Para. [0077], active layer comprising Proton Pump Inhibitor, Crospovidone and basic inorganic salt; Para. [0023], Examples of the basic inorganic salt of magnesium include ground magnesium carbonate, magnesium carbonate, magnesium oxide).

Regarding claim 3, Lupin discloses the pharmaceutical composition of claim 1, wherein the one or more enteric polymers are disposed over the mixture of the PPI, or the pharmaceutically acceptable salt thereof, and MgO (Para. [0077], pharmaceutical composition comprises granules, wherein the granules comprising an active layer comprising Proton Pump Inhibitor, Crospovidone and basic inorganic salt; an intermediate coating layer formed on active layer, and an enteric coating layer which is formed on the intermediate coating layer; Para. [0038], "Enteric coating layer" comprises one or more enteric polymers and one more pharmaceutically acceptable excipients comprise but not limited to sustained release agents).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2021/042566

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 7-10, 30, 31, 37, 39-41, 46-49, 52-55 and 60 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s):

Regarding claims 7-10, 30, 31, 37, 39-41, 46, and 47, the claims contain ratios with no basis for the ratios, which is improper. For the purposes of the Written Opinion proposed and herein, the basis for the ratios is analyzed as 'weight ratio', as best interpreted.

Regarding claim 48 and 49, the claim depends from any one of the preceding claims, but claims 30-47 fail to provide sufficient antecedent basis for " ... the PPI ... ". Herein, claims 48 and 49 have both been analyzed as depending from any one of claims 1-29 to provide sufficient antecedent basis, as best interpreted.

Regarding claims 52 and 53, the claims contain percentages with no basis for the percentages, which is improper. Herein, the basis for the percentages is analyzed as '% by weight', as best interpreted.

Regarding claims 54 and 55, claim 54 depends from any one of the preceding claims and claim 55 depends from claims 1-53, but claims 30-47 fail to provide sufficient antecedent basis for " ... the pharmaceutical composition ... ". Herein, claims 54 and 55 have both been analyzed as depending from any one of claims 1-29 to provide sufficient antecedent basis, as best interpreted.

Regarding claim 60, the claim depends from claim 58 or 59 which fail to provide sufficient antecedent basis for " ... the patient ... ". Herein, claim 60 has been analyzed as depending from claim 55 to provide sufficient antecedent basis, as best interpreted.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2021/042566

Supplemental Box

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

Claims 30-32 lack novelty under PCT Article 33(2) as being anticipated by US 2012/0128764 to Venkatesh et al. (hereinafter, "Venkatesh").

Regarding claim 30 (as best interpreted), Venkatesh discloses an orally disintegrating tablet (ODT) (Abstract, orally disintegrating tablets) comprising delayed release particles and rapidly dispersing granules (Para. [0009], pharmaceutical dosage form comprising: (i) a first population of controlled-release particles, wherein the controlled release particles of the first population comprise: a core comprising a proton pump inhibitor or a pharmaceutically acceptable salt, solvate, and/or ester thereof a first coating disposed over the core, comprising an enteric polymer, and a second coating disposed over the core, comprising an enteric polymer and a water-insoluble polymer, wherein the first coating is substantially free of water-insoluble polymers; and (ii) rapidly dispersing granules), wherein the delayed release particles comprise a mixture of esomeprazole, or a pharmaceutically acceptable salt thereof, magnesium oxide (MgO), and a delayed release coating disposed over the mixture, and wherein the weight ratio of esomeprazole to magnesium oxide ranges from about 2:1 to about 10:1 (Para. [0009], a first population of controlled-release particles, wherein the controlled release particles of the first population comprise: a core comprising a proton pump inhibitor or a pharmaceutically acceptable salt, solvate, and/or ester thereof a first coating disposed over the core, comprising an enteric polymer, and a second coating disposed over the core, comprising an enteric polymer and a water-insoluble polymer; Para. [0065], the core comprises an alkaline agent (in addition to a proton pump inhibitor). Non-limiting examples of suitable alkaline agents include ... magnesium oxide ... the ratio of the proton pump inhibitor to the alkaline agent in the core ranges from about 7:1 to about 1:3; Para. [0049], A non-limiting list of PPIs suitable for use in the compositions of the present invention include ... esomeprazole).

Regarding claim 31 (as best interpreted), Venkatesh discloses the ODT of claim 30, wherein the weight ratio of esomeprazole to magnesium oxide is in the range from about 5:1 to about 7:1 (Para. [0065], the core comprises an alkaline agent (in addition to a proton pump inhibitor). Non-limiting examples of suitable alkaline agents include ... magnesium oxide ... the ratio of the proton pump inhibitor to the alkaline agent in the core ranges from about 7:1 to about 1:3; Para. [0049], A non-limiting list of PPIs suitable for use in the compositions of the present invention include ... esomeprazole).

Regarding claim 32, Venkatesh discloses the ODT of claim 30, comprising a binder, wherein the binder is optionally hydroxypropyl cellulose (Para. [0069], the drug layer comprises a polymeric binder; Para. [0068], The polymeric binder can be any of those disclosed herein, for example hydroxypropylcellulose).

Claim 58 lacks novelty under PCT Article 33(2) as being anticipated by US 2014/0328861 to Atopix Therapeutics Limited (hereinafter, "Atopix").

Regarding claim 58, Atopix discloses a method of treating eosinophilic esophagitis (EoE) with a pharmaceutical composition that disintegrates or disperses in the mouth or in a solution (Abstract, methods and compositions for preventing, treating, or ameliorating eosinophilic esophagitis (EoE) in an individual; Para. [0439], Formulations for oral administration in the present invention may be presented as: ... chewable tablets, or lozenges) comprising esomeprazole or a salt thereof (Para. [0175], compositions comprising a CRTH2 antagonist and/or a PPI for use in preventing, treating, or ameliorating EoE in an individual; Para. [0160], the PPI is selected from the group consisting of ... esomeprazole).

Claim 59 lacks an inventive step under PCT Article 33(3) as being obvious over US 2014/0328861 to Atopix Therapeutics Limited (hereinafter, "Atopix") in view of US 8,932,596 to Benhamou et al. (hereinafter, "Benhamou").

Regarding claim 59, Atopix discloses the method of treating EoE of claim 58, but fails to explicitly disclose wherein the EoE is an early inflammatory stages of the disease, variant of EoE, or allergic variant of EoE.
Benhamou is also in the field of methods of treating EoE (Benhamou, Abstract) and teaches wherein the EoE is an early inflammatory stages of the disease, variant of EoE, or allergic variant of EoE (Benhamou Col. 4, Ln. 34, method of treating EE in a subject; Col. 6, Lns. 25-27, Such a preventive treatment generally comprises the repeated application of the device before symptoms of EE, or at early stage thereof; Col. 8, Lns. 65-66, controlling the inflammatory reaction).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Atopix to include early inflammatory stages of the disease as taught by Benhamou. The motivation for doing so would have been to provide preventative measures and thereby reduce development of the disease (Benhamou Col. 6, Lns. 20-27).

Claims 1-3, 30-32, 58, and 59 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Docket No.: ELLO-119/08US 342083-2017
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Stephen PERRETT	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	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 documents, Cite Numbers 142, 144, 145, 146, 170, 174, 181, 188, 195, 214, 228, 229, 230, 285, 286, 287, 288, 289, 308, 309, 327, 328, 329, 330, 331, 332, 333, 334, 337, 346, 361, 363, 372, 385, 386, and 387 on the attached Form used in lieu of PTO/SB/08 is enclosed.

[X] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 except for Cite Numbers 142, 144, 145, 146, 170, 174, 181, 188, 195, 214, 228, 229, 230, 285, 286, 287, 288, 289, 308, 309, 327, 328, 329, 330, 331, 332, 333, 334, 337, 346, 361, 363, 372, 385, 386, and 387, referred to above are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). 16/821,464 (U.S. Patent No. 11,246,828), 15/816,154 (U.S. Patent No. 10,632,069), 15/205,390

(U.S. Patent No. 9,849,084), 14/311,732 (U.S. Patent No. 9,387,167) and/or 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 on the attached Form used in lieu of PTO/SB/08.

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

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

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

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

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

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

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

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

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

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

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

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

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

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

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

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

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

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

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

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

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

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

and

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

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

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

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

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

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

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

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

Remarks

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

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

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ELLO-119/08US 342083-2017.

Dated: August 11, 2022

Respectfully submitted,
COOLEY LLP

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/569,047

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	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 480 =	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	1820

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	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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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
17/569,047	01/05/2022	1615	1980	ELLO-119/08US 342083-2017	20	1

CONFIRMATION NO. 8616

UPDATED FILING RECEIPT

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

OC000000135254210

Date Mailed: 07/21/2022

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

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

Applicant(s)

Ellodi Pharmaceuticals, L.P., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 58249

Domestic Priority data as claimed by applicant

This application is a CON of 16/821,464 03/17/2020 PAT 11246828
which is a CON of 15/816,154 11/17/2017 PAT 10632069
which is a CON of 15/205,390 07/08/2016 PAT 9849084
which is a CON of 14/311,732 06/23/2014 PAT 9387167
which is a DIV of 12/896,005 10/01/2010 PAT 8771729
which claims benefit of 61/247,642 10/01/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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: 01/18/2022
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/569,047**
Projected Publication Date: 10/27/2022
Non-Publication Request: No
Early Publication Request: No
Title

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	PERRETT, et al.	Confirmation No.:	8616
Application No.:	17/569,047	Group Art Unit:	1615
Filed:	January 5, 2022	Examiner:	To Be Assigned

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

BY EFS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-145

RESPONSE TO NOTICE TO FILE MISSING PARTS AND PRELIMINARY AMENDMENT

Dear Commissioner:

This paper is submitted in response to the Notice to File Missing Parts of Nonprovisional Application mailed on January 19, 2022. Submitted herewith is a four-month extension of time to extend the period for filing a response to July 19, 2022. Thus, this response is timely filed.

Prior to Examination on the merits, please amend the above-identified U.S. Patent Application as follows:

Amendments to the Claims begin on page **2** of this paper.
Remarks begin on page **5** of this paper.

IN THE CLAIMS:

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

1. (Original) An orally disintegrating tablet comprising:

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

(ii) at least one disintegrant;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20-27. (Cancelled)

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

29-30. (Cancelled)

REMARKS

Claims 1-30 were pending at the time the Notice was mailed on January 19, 2022. By this paper, claims 20-27, and 29-30 are cancelled, without prejudice or disclaimer. Applicant reserves its right to prosecute in this or in another application any subject matter no longer being claimed.

Upon entry of the amendments, claims 1-19 and 28 are pending. There are total of 20 claims with 1 independent claim. Applicant believes the payment $2,980 requested by the Notice has been changed as shown below.

Basic filing fee	$320.00
Surcharge fee	$160.00
Search fee	$700.00
Examination fee	$800.00
Excess claim fee over 20 (none)	$0.00
Four-month extension fee	$2,320.00
Total	**$4,300.00**

Accordingly, Applicant submits payment of $4,300.00 in response to the Notice.

CONCLUSION

Entry and consideration of the foregoing amendments is respectfully requested. The above-noted amendments are supported by the application as originally filed and do not introduce any new matter.

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.

Dated: July 18, 2022
Customer No. 58249

Respectfully submitted,
COOLEY LLP

COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004
Tel: (202) 728-7139
Fax: (202) 842-7899

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

Electronic Patent Application Fee Transmittal

Application Number:	17569047
Filing Date:	05-Jan-2022
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Filer:	Jonathan M. Cousin/Samantha Cerami
Attorney Docket Number:	ELLO-119/08US 342083-2017

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	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
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 - 4 months with $0 paid	1254	1	2320	2320
Miscellaneous:				
		Total in USD ($)		**4300**

Electronic Acknowledgement Receipt	
EFS ID:	46207749
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Samantha Cerami
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	18-JUL-2022
Filing Date:	05-JAN-2022
Time Stamp:	10:05:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$4300
RAM confirmation Number	E20227HA06211383
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	Applicant Response to Pre-Exam Formalities Notice	ELLO_119_08US_Response_to_NTFMP.pdf	1764457 f5bd651d98215cbbd18a2ceafb4c3600c1ab29bc	no	2
Warnings:					
Information:					
2		ELLO_119_08US_Prelim_Amendment.pdf	160836 954d00d0188b8659ba017a560a64846ec53a8d91	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	6

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	49022 476aca0e9bf533704d8e106177771de82cff2043	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1974315		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017

CONFIRMATION NO. 8616

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

FORMALITIES LETTER

OC000000131160081

Date Mailed: 01/19/2022

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

- $ **320** basic filing fee.
- $ **160** surcharge.
- $ **700** search fee.
- $ **800** examination fee.
- $ **1000** for **10** total claims over 20.

- $(0) previous unapplied payment amount.
- $ **2980** 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.

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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**.

/tlulu/

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

Courtesy Reminder for
Application Serial No: 17/569,047

Attorney Docket No: ELLO-119/08US
342083-2017
Customer Number: 58249
Date of Electronic Notification: 01/20/2022

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:
zIPPatentDocketingMailboxUS@cooley.com

To view your correspondence online or update your email addresses, please visit us anytime at **https://ppair-my.uspto.gov/pair/PrivatePair.**
If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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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
17/569,047	01/05/2022	1615	0.00	ELLO-119/08US 342083-2017	30	2

CONFIRMATION NO. 8616

FILING RECEIPT

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

OC000000131180080

Date Mailed: 01/19/2022

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

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

Applicant(s)

Ellodi Pharmaceuticals, L.P., Lawrenceville, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 58249

Domestic Priority data as claimed by applicant

This application is a CON of 16/821,464 03/17/2020
which is a CON of 15/816,154 11/17/2017 PAT 10632069
which is a CON of 15/205,390 07/08/2016 PAT 9849084
which is a CON of 14/311,732 06/23/2014 PAT 9387167
which is a DIV of 12/896,005 10/01/2010 PAT 8771729
which claims benefit of 61/247,642 10/01/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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: 01/18/2022
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/569,047**
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

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

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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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/569,047

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	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 =	* 10			OR	x 100 =	1000
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 480 =	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	2820

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	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
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.

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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
17/569,047	01/05/2022	Stephen PERRETT	ELLO-119/08US 342083-2017

CONFIRMATION NO. 8616

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

FORMALITIES LETTER

OC000000131160081

Date Mailed: 01/19/2022

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

- $ **320** basic filing fee.
- $ **160** surcharge.
- $ **700** search fee.
- $ **800** examination fee.
- $ **1000** for **10** total claims over 20.

- $(**0**) previous unapplied payment amount.
- $ **2980** 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**.

/tlulu/

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

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

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	TBD (Continuation of U.S. Patent Application No. 16/821,464, filed March 17, 2020)
Filing Date	Concurrent Herewith
First Named Inventor	Stephen PERRETT
Title	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	ELLO-119/08US 342083-2017

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.**

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

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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):

ELLODI PHARMACEUTICALS, L.P.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	*Troy Hamilton*	Date (Optional)	3/14/2021
Name	Troy Hamilton		
Title	CEO		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

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Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Electronic Acknowledgement Receipt

EFS ID:	44671680
Application Number:	17569047
International Application Number:	
Confirmation Number:	8616
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-119/08US 342083-2017
Receipt Date:	05-JAN-2022
Filing Date:	
Time Stamp:	14:59:40
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	Oath or Declaration filed	ELLO-119-08US_Inventors_Oaths_FULLY-EXECUTED.pdf	3928488 e9c7695ead45a910a2a78de62b9481a473e3831e	no	3

Warnings:

Dr. Falk Pharma Ex. 1096
PGR Petition - USP 12,290,598

Information:					
2		ELLO-119-08US_Specification_Continuation.pdf	205697 6efb573bc872401a8c4a43f17508ac78bb004046	yes	30
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	25	
	Claims		26	29	
	Abstract		30	30	
Warnings:					
Information:					
3	Application Data Sheet	ELLO-119-08US_Application_Data_Sheet.pdf	1304136 250204591e55f06ff2ccdd3afdc4f0b5ec790169	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4	Power of Attorney	ELLO-119-08US_POAtransmittal_POAsigned.pdf	759198 8697aef7b83a5e78090edee62d33b2814eb76234	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	6197519		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14/311,732

filed on June 23, 2014.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2036 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Stephen PERRETT Date (Optional): 10 May 2016

Signature: S. Perrett

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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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.

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LEGAL NAME OF INVENTOR

Inventor: Fredric Jay COHEN Date (Optional): 11 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.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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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Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

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☐ 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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WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Gopi VENKATESH Date (Optional): Aug 20, 2014

Signature: G. M Venkatesh

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.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation application of U.S. Patent Application No. 16/821,464, filed March 17, 2020, which is a continuation application of U.S. Patent Application No. 15/816,154, filed November 17, 2017 (U.S. Patent No. 10,632,069, issued April 28, 2020), which is a continuation of U.S. Patent Application No. 15/205,390, filed July 8, 2016 (U.S. Patent No. 9,849,084, issued December 26, 2017), which is a continuation application of U.S. Patent Application No. 14/311,732, filed June 23, 2014 (U.S. Patent 9,387,167, issued July 12, 2016), which is a divisional application of U.S. Patent Application No. 12/896,005, filed October 1, 2010 (U.S. Patent No. 8,771,729, issued July 8, 2014), and claims the benefit of priority to U.S. Provisional Patent Application No. 61/247,642, filed October 1, 2009, the disclosures of each of which are herein incorporated by reference in its entirety for all purposes.

TECHNICAL FIELD OF THE INVENTIONS

[0002] This invention relates to orally administered corticosteroid compositions, useful for the treatment of conditions associated with inflammation of the gastrointestinal tract.

BACKGROUND OF THE INVENTION

[0003] There are currently no approved topically administered anti-inflammatory medications for the treatment of conditions associated with inflammation of the upper portion of the gastrointestinal tract. One such condition, eosinophilic esophagitis (EE), is an inflammatory condition of the esophagus. It is characterized histologically by a proliferation of eosinophils. The disease is painful, leads to difficulty swallowing and predisposes patients to food impaction and other complications.

[0004] Experimental and "off-label" treatments for EE include directing steroid medications formulated and approved for inhalation to the back of the throat such that they are not appreciably inhaled, and instructing the patient to rinse their mouth immediately after administration and not to swallow food or water for two hours after administration. Rinsing is recommended because residual drug in the mouth and throat can lead to candiasis infection, and swallowing is contraindicated because it may wash drug away from the esophagus. Aqueous corticosteroid

preparations intended for oral inhalation through nebulization are also mixed with sugars to produce a thickened and sweetened liquid for administration.

[0005] Off-label treatments for EE also include administration of corticosteroid tablets containing steroids such as prednisolone. However, systemic administration of corticosteroids is associated with a number of known and undesirable side-effects. For example, oral prednisolone can produce generalized suppression of immune function, and in children, particularly troubling side-effects from long term systemic exposure include growth retardation, which may lead to a reduction in adult height.

[0006] There is therefore a need in the art for orally administered corticosteroid formulations which provide topical (rather than systemic) treatment of inflammation of the gastrointestinal tract, particularly inflammation of the upper gastrointestinal tract, such as EE.

SUMMARY OF THE INVENTION

[0007] In one embodiment, the present invention is directed to a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test, and/or which disintegrates within 60 seconds when placed in the oral cavity of a human.

[0008] In another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, and a pharmaceutically acceptable substantially non-aqueous liquid.

[0009] In another embodiment, the present invention is directed to a method for treating an inflammatory condition of the gastrointestinal tract. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

[0010] In yet another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, a pharmaceutically acceptable aqueous or substantially non-aqueous liquid, and a pharmaceutically acceptable phase change agent dissolved or suspended in the liquid, wherein after administration to a patient, the composition undergoes a change in physical properties upon contact with the gastrointestinal tract of the patient.

[0011] In yet another embodiment, the present invention is direction to a composition in solid or liquid form additionally comprising cyclodextrins.

[0012] The compositions of the present invention are useful for various conditions including the treatment of inflammatory conditions of the gastrointestinal tract. Accordingly, the present invention also provides a method for treating inflammatory conditions of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0013] All documents (e.g., patents, patent publication, journal articles, etc.) cited in the present application are incorporated by reference in their entirety for all purposes.

[0014] The term "drug", "active" or "active pharmaceutical ingredient" as used herein includes a pharmaceutically acceptable and therapeutically effective compound (e.g., corticosteroid), pharmaceutically acceptable salts, stereoisomers and mixtures of stereoisomers, solvates (including hydrates), and/or esters thereof (e.g., of corticosteroid).

[0015] The terms "orally disintegrating tablet", "orally dispersing tablet", or "ODT" refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing. The rate of oral disintegration can vary, but is significantly faster than the rate of oral disintegration of conventional solid dosage forms or chewable solid dosage forms (i.e., tablets or capsules) which are intended to be swallowed immediately after administration. ODT compositions of the present invention can contain pharmaceutically acceptable ingredients which swell, dissolve or otherwise facilitating the disintegration or dissolution of the ODT composition. Such ingredients can include pharmaceutical a disintegrant, a sugar alcohol, a saccharide, or a mixture thereof, a water-soluble binder, a meltable solid (e.g., a wax), which can release the corticosteroid upon entering the stomach, etc.

[0016] The term "about", as used herein to refer to a numerical quantity, includes "exactly". For example, "about 60 seconds" includes 60 seconds, exactly, as well as values close to 60 seconds (e.g., 50 seconds, 55 seconds, 59 seconds, 61 seconds, 65 seconds, 70 seconds, etc.). When the term "about" is used in reference to a range of values, the term "about" refers to both the minimum and maximum value of the range (e.g., "about 1-50 μm" means "about 1 μm to about 50 μm").

[0017] The term "adhesive agent", as used herein refers to agents which promote adhesion of the corticosteroid to biological surfaces, and includes, but is not limited to bio-adhesive agents. Adhesive agents can include compounds which adhere to the oropharyngeal mucosa, as well as compounds which increase the residence time of the compositions of the present invention on the oropharyngeal mucosa of a patient.

[0018] The term "intimately associated", as used herein to describe the spatial relationship between two or more components of a composition refers to components that are intimately mixed, such as for example in mixtures, coatings and matrices.

[0019] The term "having no significant systemic glucocorticoid or mineralocorticoid activity", as used herein refers to corticosteroid compositions which do not provide a generalized effect in the body through absorption into the circulation, but do provide local effects through topical contact with a diseased tissue. Corticosteroids which have high systemic glucocorticoid potencies when administered orally include e.g., hydrocortisone, prednisone, prednisolone, methylprednisolone, dexamethasone, betamethasone, etc.) or mineralocorticoid potencies (e.g., alsosterone). These corticosteroids may be suitable for use in the compositions of the present invention if they are used at a sufficiently low dose, or are otherwise formulated such that they do not have significant systemic glucocorticoid or mineralcorticoid activity. Exemplary corticosteroids suitable for use in the compositions of the present invention include, but are not limited to budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone and tixocortol.

[0020] The term "bio-gelling polymer" as used herein refers to a polymer forms a gel under GI tract physiological conditions, for example, upon contact with physiological fluids or at physiological temperature.

[0021] The term "substantially non-aqueous liquid" refers to liquids which are completely anhydrous, or include only small amounts of water (e.g. less than about 10% water, for example less than about 9%, less than about 8%, less than about 7%, less than about 6%, less than about 5%, less than about 4%, less than about 3%, less than about 2%, or less than about 1% water).

[0022] The term "phase change agent" refers to an agent which, upon dissolution or suspension in the substantially non-aqueous liquids of the present invention, causes the liquid pharmaceutical compositions of the present invention to undergo a change in physical properties after administration to a patient. For example, such changes in physical properties include precipitation of the dissolved or suspended components of the composition (e.g. the corticosteroid, optional

excipients, and the phase change agent); gelation of the composition (e.g., formation of a hydrogel of the phase change agent and optionally excipients, wherein the hydrogel comprises at least a portion of the corticosteroid); or an increase in viscosity of the composition. These changes in physical properties have the effect of increasing or enhancing contact of the corticosteroid to the mucosa of the gastrointestinal tract of the patient.

[0023] Unless indicated otherwise, all percentages and ratios are calculated by weight. Unless indicated otherwise, all percentages and ratios are calculated based on the total composition.

[0024] The solid and liquid pharmaceutical compositions of the present invention are suitable for topical administration of a corticosteroid to the gastrointestinal tract, for example the upper gastrointestinal tract such as the esophagus. Topical administration of a corticosteroid for conditions associated with inflammation of the gastrointestinal tract is desirable because it results in fewer side-effects than systemic corticosteroid administration. Such side-effects are reduced still further with the use of corticosteroids which do not have significant systemic glucocorticoid or mineralocorticoid activity because of their reduced systemic exposure.

[0025] The pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract, for example inflammatory conditions of the upper gastrointestinal tract such as the esophagus. Thus, the present invention includes treating inflammatory conditions of the gastrointestinal tract by administering to a patient in need thereof a solid or liquid pharmaceutical composition of the present invention. Inflammatory conditions of the gastrointestinal tract which may be treated according to the present invention include inflammation of the esophagus, inflammation of the glottis, inflammation of the epiglottis, inflammation of the tonsils, inflammation of the oropharynx, eosinophilic esophagitis, gastroesophageal reflux disease (GERD), non-erosive reflux disease (NERD), erosive esophagitis, Barrett's esophagus, eosinophilic gastroenteritis, hypereosinophilic syndrome, corrosive (caustic) chemical esophagitis, radiation-induced esophagitis, chemotherapy-induced esophagitis, transient drug-induced esophagitis (also known as medication esophagitis), persistent drug-induced esophagitis, Crohn's disease of the esophagus, scleroderma, and scleroderma sine scleroderma, systemic lupus erythematosus, systemic vasculitides, leukocytoclastic vasculitis, polyarteritis nodosa, Churg-Strauss syndrome, rheumatoid vasculitis, and pseudomembranous esophagitis.

[0026] In other embodiments, the pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract such as an autoimmune

disease, Behcet's syndrome, Kawasaki disease, X-linked lymphoproliferative syndrome; an infectious viral disease caused by one or more of the following viruses: Adenoviridae, Coronaviridae, Coxsackie virus, Herpes simplex, HIV, Influenza (Type A), Lassa virus, Epstein-Barr virus, Parainfluenza, or Respiratory syncytial virus; an infectious bacterial disease caused by one or more of the following bacteria: Arcanobacterium hemolyticum, Chlamydia (Chlamydophila), Corynebacterium, Francisella tularensis, Group A, C, G Streptococcus, S. pneumoniae, S. pyogenes, Haemophilus influenza type B, Mycoplasma pneumonia, Neisseria gonorrhea, Multiple (e.g. peritonsillar cellulitis/abscess); an infectious fungal disease caused by Candida (e.g. Candida albicans) or Histoplasma (e.g. H capsulatum); inflammation caused by injury or an irritant selected from the group consisting of an airway foreign body, chloroacetophenone, chlorobenzylidene malononitrile, chronic smoke exposure, morpholine, sulfuryl fluoride, and scalded throat; lepidopterism, Seasonal allergic pharyngitis, and Stevens-Johnson syndrome; or periodic fever; etc.

[0027] In one embodiment, the present invention includes a method for treating inflammation of the esophagus comprising administering to a patient in need thereof a pharmaceutical composition of the present invention. In one such embodiment, the present invention includes a method for treating eosinophilic esophagitis comprising administering to a patient in need thereof a pharmaceutical composition of the present invention.

[0028] In another embodiment, the present invention includes a method for treating gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis comprising administering to an individual in need thereof a pharmaceutical composition of the present invention.

[0029] In another embodiment, the present invention includes a method for treating a food allergy with an identified allergen, e.g., "atopic IBS", and "atopic bowel".

[0030] In one embodiment, the present invention provides a solid pharmaceutical composition which comprises less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity, and wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test. In another embodiment, the solid pharmaceutical compositions of the present invention disintegrate within 60 seconds in the oral cavity of the patient, e.g. human. In still other embodiments, the solid pharmaceutical compositions of the

present invention disintegrate within 30 seconds in simulated saliva (using the USP <701> Disintegration Test), or in the oral cavity of a patient. In still other embodiments, the solid or liquid pharmaceutical compositions of the present invention topically provide a therapeutically effective amount of a corticosteroid to inflamed tissues of the gastrointestinal tract, after oral administration to a patient in need thereof.

[0031] Solid pharmaceutical compositions of the present invention can include, for example, an ODT (as described herein), a wafer, a film, or other solid dosage form which disintegrates or dissolves rapidly in the mouth to form a solution or dispersion of a corticosteroid, which can readily be swallowed.

[0032] In another embodiment, the present invention provides a liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable solvent, wherein the liquid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity. In one such embodiment the composition also includes a pharmaceutically acceptable bio-gelling polymer dissolved in the solvent, and the composition increases in viscosity upon contact with the gastrointestinal tract of an individual. In other embodiments, the liquid compositions of the present invention comprise a corticosteroid complex with a cyclodextrin, typically suspended or dissolved in a liquid carrier. The liquid compositions of the present invention may be in the form of a solution or a suspension. Liquid pharmaceutical compositions according to the present invention are compositions which are liquids at standard temperature and pressure conditions.

[0033] Suitable pharmaceutically acceptable liquids which may be used in the liquid pharmaceutical compositions of the present invention include, for example, alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone (NMP), 2-pyrrolidone, glycerol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, ethyl butyrate, dibutyl malonate, tributyl citrate, tri-n-hexyl acetylcitrate, diethyl succinate, diethyl glutarate, diethyl malonate, triethyl citrate, triacetin, tributyrin, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, caprolactam, N,N-diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, 1,3-dimethyl-3,4,5,6-tetrohydro-2(1H)-pyrimidinone, and combinations thereof. In one embodiment, the liquid is selected from the group of alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, glycerol and combinations thereof. In one such embodiment, the liquid is selected from the group of ethanol,

glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof. In other embodiments, the liquid pharmaceutical compositions of the present invention can comprise aqueous suspensions or solutions of a corticosteroid.

[0034] In one embodiment the bio-gelling polymer is a thermosensitive polymer. Suitable thermosensitive polymers include polyacrylamides, such as poly(N-isopropylacrylamide), as well as poly(ether-ester) copolymers, such as poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol). Such thermosensitive polymers can precipitate or cause an increase in viscosity of the liquid compositions of the present invention upon administration to a patient, and subsequent warming in the gastrointestinal tract. Thus, the compositions of the invention precipitate on or have a longer residence time on the gastrointestinal mucosa the patient, thereby increasing the topical contact of the corticosteroid on the gastrointestinal mucosa. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0035] In another embodiment, the compositions of the present invention include a bioadhesive agent, which is a lipid or a mixture of lipids. Such lipids or lipid mixtures may undergo a phase transition on contact with wetted biological surfaces to form an adhesive film. Examples of such lipids include mixtures of so-called membrane and non-membrane lipids which will typically form lamellar and non-lamellar structures, such as hexagonal or cubic phases, respectively. Examples of such lipids are glycerphospholipids such as phosphatidyl choline, and diacyl glycerols such as glycerol dioleate. Such self-organizing structures demonstrate superior spreading and adhesion to biological surfaces and have the advantage or being pharmaceutically acceptable materials. Advantageously the active agent, e.g. a corticosteroid may be dissolved in the lipid component.

[0036] Suitable non-aqueous solvents which may be included in the liquid pharmaceutical compositions of the present invention include pharmaceutically acceptable non-aqueous solvents in which the particular bio-gelling polymer is soluble. For example, the solvent may be an alcohol (e.g., ethanol), N-methyl-pyrrolidone (NMP), glycerol, propylene glycol, liquid polyethylene glycol, diethylene glycol monoethyl ether and mixtures thereof. In certain embodiments the solvent is water-miscible and the bio-gelling polymer is water-insoluble, so that upon administration the solvent mixes rapidly with the water from the digestive tract of the patient, causing the bio-gelling polymer and corticosteroid to precipitate on the gastrointestinal mucosa of

the patient. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0037] Other bio-gelling polymers which may be included within the liquid pharmaceutical compositions of the present invention include cellulose derivatives (e.g., esters and/or ethers, crosslinked cellulose esters and/or ethers) cellulose esters, methacrylic acid and methacrylate polymers, polylactides, polyglycolides, polycaprolactones, polydioxannones, polycarbonates, polyhydroxybutyrates, polyalkyene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, and copolymers, terpolymers and mixtures thereof. Bio-gelling polymers swell, and/or form hydrogels upon contact with moisture in the gastrointestinal tract, thereby adhering or increasing the viscosity of the compositions of the present invention on the mucosa of the gastrointestinal tract. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

[0038] In certain embodiments, the liquid pharmaceutical compositions of the present invention increase in viscosity upon contact with the gastrointestinal tract of an individual. In one embodiment, the increase in viscosity is at least 50% (relative to the viscosity prior to administration). In another such embodiment, the increase in viscosity is at least 100%. In yet another such embodiment, the increase in viscosity is at least 200%. The viscosity of the compositions before contact with the gastrointestinal tract of an individual may be measured using a viscometer. The change in viscosity of the compositions upon contact with the gastrointestinal tract of an individual may be determined by measuring the viscosity of the composition under simulated physiological conditions. For example, the viscosity of a given composition may be measured in simulated saliva.

[0039] Suitable corticosteroids which may be included in the pharmaceutical compositions of the present invention include budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, tixocortol and salts, solvates, and esters thereof. In a particular embodiment, the compositions of the present invention comprise fluticasone. In other embodiments, the compositions of the present invention comprise budesonide. Corticosteroids which typically have systemic glucocorticoid or mineralocorticoid activity when administered orally can also be used

in the compositions of the present invention, if the composition is modified to reduce or suppress systemic uptake of the corticosteroid.

[0040] The amount of corticosteroid present in the pharmaceutical compositions of the present invention will depend upon the particular corticosteroid utilized. In general, however, the amount will be selected so as to maximize the therapeutic benefit from topical administration while minimizing systemic absorption. In the case of solid pharmaceutical compositions of the present invention, the amount of corticosteroid in the composition typically is less than or equal to 20 mg. In one embodiment the amount of corticosteroid in the pharmaceutical composition is between about 0.01 mg and about 20 mg. In another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 1 mg and about 15 mg. In still another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 10 mg. In yet another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 5 mg. In still other embodiments, the amount of corticosteroid is about 0.01 mg, about 0.02 mg, about 0.03 mg, about 0.04 mg, about 0.05 mg, about 0.06 mg, about 0.07 mg, about 0.08 mg, about 0.09 mg, about 0.1 mg, about 0.2 mg, about 0.3 mg, about 0.4 mg, about 0.5 mg, about 1 mg, about 2 mg, about 3 mg, about 4 mg, about 5 mg, about 6 mg, about 7 mg, about 8 mg, about 9 mg, about 10 mg, about 11 mg, about 12 mg, about 13 mg, about 14 mg, about 15 mg, about 16 mg, about 17 mg, about 18 mg, about 90 mg, or about 20 mg, inclusive of all ranges and subranges therebetween.

[0041] Typical amounts of corticosteroid in the solid pharmaceutical compositions of the present invention include about 0.25 mg, about 0.5 mg, about 1 mg, about 1.5 mg, about 2 mg, about 2.5 mg, about 3 mg, about 3.5 mg, about 4 mg, about 4.5 mg and about 5 mg. In the case of liquid pharmaceutical compositions of the present invention, the concentration of corticosteroid in the composition typically is such that an amount of corticosteroid consistent with the amounts described above (i.e., 0.01 mg to 20 mg) may be conveniently administered to an individual. For example, the concentration of corticosteroid may be such that a single pump from a spray pump device delivers about 0.05 mg, or any other therapeutically effective pre-selected amount, of corticosteroid to the oral cavity of an individual. In a particular embodiment, the compositions of the present invention comprise about 0.25 mg of fluticasone.

[0042] Upon administration of a solid pharmaceutical composition of the present invention to an individual, the composition disintegrates in the patient's oral cavity. In one embodiment, the

composition of the present invention is in the form of an ODT. An ODT comprises drug containing particles (e.g., a corticosteroid as described herein optionally coated or combined with an adhesive agent as described herein), combined with rapidly dispersing microgranules. Rapidly dispersing microgranules can be prepared as described in US 2005/0232988 or US 20010014340 by granulating a disintegrant having an average particle size of not more than about 30 μm with a sugar alcohol and/or saccharide having an average particle size of not more than about 30 μm. The granulation can be carried out, for example, in a high shear granulator with approximately 20-25% water as the granulating fluid, and if needed wet milled and dried to produce rapidly dispersing microgranules having an average particle size of not more than about 300 μm (e.g., about 175-300 μm).

[0043] The ratio of the disintegrant to the sugar alcohol, saccharide, or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01, for example about 90/10, about 91/9, about 92/8, about 93/7, about 94/6, about 95/5, about 96/4, about 97/3, about 98/2, about 99/1, inclusive of all values, ranges, and subranges therebetween.

[0044] The ratio of the rapidly dispersing microgranules to drug-containing particles ranges from about 5/1 to about 1/1, including about 5/1, 4/1, 3/1, 2/1, 1/1, inclusive of all values, ranges, and subranges therebetween.

[0045] The corticosteroid containing particles of the ODT dosage form should also have a small enough particle size such that after disintegration of the ODT in the oral cavity of the patient, a smooth, easy-to-swallow suspension results. In most embodiments in which the pharmaceutical compositions of the present invention is provided as an ODT dosage form, the average particle size of the taste-masked non-opioid analgesic/opioid analgesic drug-containing microparticles is not more than about 400 μm, or in some embodiments not more than about 300 μm.

[0046] The ODT dosage form as described herein may also include pharmaceutically acceptable excipients typically used in disintegrating tablet formulations such as microcrystalline cellulose and spray dried mannitol (compressible diluents), croscarmellose sodium or crospovidone (super disintegrant), coloring agents, and optionally magnesium stearate or sodium stearyl fumarate (lubricant intragranularly mixed or used externally to lubricate die and punch surfaces).

[0047] Tablet dosage forms, including ODT dosage forms, comprising the pharmaceutical composition of the present invention have a low friability, e.g., less than about 1%, (e.g., less than about 0.9%, less than about 0.8%, less than about 0.7%, less than about 0.6%, less than about

0.5%, less than about 0.4%, less than about 0.3%, etc., inclusive of all ranges and subranges therebetween) in order to have sufficient durability to withstand handling, shipping, and/or packaging in push-through blister packaging.

[0048] A non-limiting list of suitable disintegrants for the rapidly dispersing microgranules includes crospovidone (cross-linked PVP), sodium starch glycolate, cross-linked sodium carboxymethylcellulose, calcium silicate, and low substituted hydroxypropyl cellulose. The amount of disintegrant in the ODT is typically in the range of about 1% to about 10% by weight.

[0049] A non-limiting list of suitable sugar alcohols includes mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol and combinations thereof. A non-limiting list of suitable saccharides includes lactose, sucrose, maltose, and combinations thereof. The amount of sugar alcohol and/or saccharide in the ODT ranges from about 30% to about 70% by weight.

[0050] Pharmaceutically acceptable excipients include fillers, diluents, glidants, disintegrants, binders and lubricants. Other pharmaceutically acceptable excipients include acidifying agents, alkalizing agents, preservatives, antioxidants, buffering agents, chelating agents, coloring agents, complexing agents, emulsifying and/or solubilizing agents, flavors, perfumes, humectants, sweetening agents and wetting agents.

[0051] Examples of suitable fillers, diluents and/or binders include lactose (e.g. spray-dried lactose, α-lactose, β-lactose, TABLETOSE®, various grades of PHARMATOSE®, MICROTOSE® or FAST-FLO®), microcrystalline cellulose (various grades of AVICEL®, CEOLUS®, ELCEMA®, VIVACEL®, MING TAI® or SOLKA-FLOC®), hydroxypropylcellulose, L-hydroxypropylcellulose (low substituted), low molecular weight hydroxypropyl methylcellulose (HPMC) (e.g. Methocel E, F and K from Dow Chemical, Metolose SH from Shin-Etsu, Ltd), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylhydroxyethylcellulose and other cellulose derivatives, sucrose, agarose, sorbitol, mannitol, dextrins, maltodextrins, starches or modified starches (including potato starch, maize starch and rice starch), calcium phosphate (e.g. basic calcium phosphate, calcium hydrogen phosphate, dicalcium phosphate hydrate), calcium sulfate, calcium carbonate, sodium alginate and collagen.

[0052] Examples of suitable diluents include e.g. calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose,

dextrans, dextrin, dextrose, fructose, kaolin, lactose, mannitol, sorbitol, starch, pregelatinized starch, sucrose and sugar.

[0053] Examples of suitable disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrillin potassium, sodium starch glycolate, starch, pregelatinized starch, and carboxymethyl starch (e.g. PRIMOGEL® and EXPLOTAB®).

[0054] Specific examples of glidants and lubricants include stearic acid, magnesium stearate, calcium stearate or other metallic stearates, talc, waxes and glycerides, light mineral oil, PEG, glyceryl behenate, colloidal silica, hydrogenated vegetable oils, corn starch, sodium stearyl fumarate, polyethylene glycols, alkyl sulfates, sodium benzoate and sodium acetate.

[0055] Other excipients include e.g. flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and agents for modified release.

[0056] Other functional excipients such as cyclodextrins may be used, for example as taste-masking agents (e.g., by means of their complexation with the corticosteroid). Cyclodextrins may also be used as a carrier and/or a dispersant to facilitate delivery and distribution of the corticosteroid at the intended site of therapeutic activity.

[0057] Compositions of the present invention in the form of an ODT disintegrate into corticosteroid containing particles while sugar alcohol/saccharide-containing granules included within the composition rapidly dissolve, thereby forming a smooth suspension that can be readily swallowed.

[0058] Other corticosteroid-containing orally disintegrating or orally dissolving dosage forms such as wafers or films can also be used. For example, wafers can include dried or lyophilized compositions such as orally disintegrating or dissolving dosage forms prepared using ZYDIS® lyophilization technology (e.g., as described in U.S. Patent No. 6,316,027), containing a corticosteroid as the active pharmaceutical ingredient. Film dosage forms can include edible films such as those described in US 6,596,298 or US 6,740,332, containing a corticosteroid as the active pharmaceutical ingredient.

[0059] The rate of disintegration of the compositions of the present invention in the oral cavity of an individual can be on the order of about 60 seconds or less, about 50 seconds or less, about 40 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

[0060] The rate of disintegration of the solid pharmaceutical compositions of the present invention can be measured using various in vitro test methods, for example the USP <701> Disintegration Test. When using the USP <701> Disintegration Test, the rate of disintegration of the compositions of the present invention typically is about 60 seconds or less, about 45 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

[0061] In other embodiments, the solid pharmaceutical compositions of the present invention can have any rate of disintegration or dissolution in the oral cavity of a patient which provides a therapeutically effective amount of corticosteroid to the inflamed tissues of the gastrointestinal tract. For example, in some embodiments, solid pharmaceutical compositions according to the present invention include compositions that provide about 0.5 mg to about 20 mg of the corticosteroid to the inflamed tissues of the gastrointestinal tract after oral administration.

[0062] In one embodiment, the solid pharmaceutical compositions of the present invention include an adhesive agent. Suitable adhesive agents include sucrose aluminum sulfate complex, chitosan and derivatives thereof (e.g., trimethylchitosan, chitosan salts), polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, Eudragit® polymers (E, L, S, NE, RL, and RS grades), carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

[0063] In certain embodiments of the solid pharmaceutical compositions of the present invention, the corticosteroid and the adhesive agent are intimately associated. In one such embodiment the solid pharmaceutical composition comprises corticosteroid surrounded or encapsulated by the adhesive agent. In another such embodiment the solid pharmaceutical composition comprises corticosteroid disposed on the surface of the adhesive agent. In still other embodiments, the solid pharmaceutical composition comprises corticosteroid mixed or granulated with the adhesive agent.

[0064] Topical administration of a corticosteroid to the oral cavity of individuals has been associated with candidiasis infection. Consequently, in one embodiment pharmaceutical compositions of the present invention include an antifungal agent. Suitable antifungal agents include, but are not limited to mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and other "uncategorized" antifungals recognized in the art that do not fall within any of the above categories (e.g., tolnaflate and ciclopirox). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abafungin, amorolfine, anidulafungin, bifonazole, butenafine, butoconazole, candicin, caspofungin, ciclopirox, clotrimazole, econazole, fenticonazole, filipin, fluconazole, flucytosine, griseofulvin, isavuconizole, isoconazole, itraconazole, ketoconazole, micafungin, miconazole, miconazole nitrate, naftifine, natamycin, nystatin, oxiconazole, posaconazole, pramiconazole, ravuconazole, rimocidin, setaconizole, sulconazole, terbafine, terconazole, tioconazole, tolnaftate, undecylenic acid, and voriconazole.

[0065] In another embodiment, pharmaceutical compositions of the present invention include an antiviral agent. Antiviral agents which may be included in the solid pharmaceutical compositions of the present invention include interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, guanosine analogs, purine analogs, pyrimidine analogs, and other "uncategorized" antiviral drugs recognized in the art which do not fall within any of the above classes (e.g. foscarnet and miltefosine). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abacavir, aciclovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, durunavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate, etravirine, famciclovir, fosamprenavir, ganciclocvir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, loviride, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon α-2a, pegylated interferon α-2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegrvir, ritonavir, ribavirin, rimantadine, rlipivirine, saquinavir, stampidine, stavudine, tenofovir, tipranavir, TNX-355,

trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

[0066] In one embodiment, the solid pharmaceutical compositions of the present invention comprise corticosteroid-containing granules. The corticosteroid-containing granules may be granules comprising corticosteroid crystals and a film-forming binder, e.g., prepared by granulation. The corticosteroid crystals can have an average particle size ranging from about 1-300 μm, for example about 1-50 μm, about 1-100 μm, about 1-150 μm, about 1-200 μm, about 1-250 μm, about 50-100 μm, about 50-150 μm, about 50-200 μm, about 50-250 μm, about 50-300 μm, about 100-150 μm, about 100-200 μm, about 150-200 μm, about 150-250 μm, about 150-300 μm, about 200-250 μm, about 200-300 μm, or about 250-300 μm.

[0067] In another embodiment, the corticosteroid may be in the form of crystals. Such crystals may have an average size in the sub-micron range (e.g., average particle size of about < 1 μm), or may be nanoparticles (e.g., average particle size in the range of about 1-100 nm).

[0068] In yet another embodiment, the corticosteroid may be present in amorphous form, for example in association with a stabilizing agent which limits drug recrystallization, e.g., polyvinylpyrrolidone (PVP) (including homo- and copolymers of polyvinylpyrrolidone and homopolymers or copolymers of N-vinylpyrrolidone); crospovidone; gums; cellulose derivatives (including hydroxypropyl methylcellulose (HPMC), hydroxypropyl methylcellulose phthalate, hydroxypropyl cellulose, ethyl cellulose, hydroxyethylcellulose, sodium carboxymethyl cellulose, calcium carboxymethyl cellulose, sodium carboxymethyl cellulose, and others); dextran; acacia; homo- and copolymers of vinyllactam, and mixtures thereof, cyclodextrins; gelatins; hypromellose phthalate; sugars; polyhydric alcohols; polyethylene glycol (PEG); polyethylene oxides; polyoxyethylene derivatives; polyvinyl alcohol; propylene glycol derivatives and the like, sodium lauryl sulphate, TWEEN® surfactants, EUDRAGIT® polymers; and combinations thereof.

[0069] The film-forming binder may comprise any suitable binder used in granulation. Non-limiting examples of suitable film-forming binders include water-soluble, alcohol-soluble or acetone/water soluble binders, e.g. polyvinylpyrrolidone (PVP), corn starch, polyethylene oxide, polyethylene glycol, hydroxypropyl methylcellulose (HPMC), methylcellulose, or hydroxypropylcellulose (HPC). The amount of film-forming binder in the corticosteroid-containing granules can range from about 0.5% to about 10%, including about 0.5%-1%, about 0.5%-2%, about 0.5%-5%, about 0.5%-7%, about 1%-2%, about 1%-5%, about 1%-7%, about

1%-10%, about 2%-5%, about 2%-7%, about 2%-10%, about 5%-7%, about 5%-10%, and about 7%-10%.

[0070] The corticosteroid-containing granules of the present invention may also include other pharmaceutically acceptable ingredients, for example, fillers or diluents. Non-limiting examples of other pharmaceutically acceptable ingredients for the corticosteroid-containing granules include, for example, mannitol, lactose, microcrystalline cellulose, potassium sulfate, calcium phosphate, modified starch, and mixtures thereof. The amount of other pharmaceutically acceptable ingredients (e.g. fillers or diluents) in the corticosteroid-containing granules can range from about 5%-80%, including about 5%-70%, about 5%-60%, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, about 5%-15%, about 5%-10%, about 10%-70%, about 10%-60%, about 10%-50%, about 10%-40%, about 10%-30%, about 10%-20%, about 10%-15%, about 20%-70%, about 20%-60%, about 20%-50%, about 20%-40%, about 20%-30%, about 20%-25%, about 30%-70%, about 30%-60%, about 30%-50%, about 30%-40%, about 30%-35%, about 40%-70%, about 40%-60%, about 40%-50%, about 40%-45%, about 50%-70%, about 50%-60%, about 50%-55%, about 60%-70%, or about 60%-65%.

[0071] In another embodiment, the corticosteroid-containing granules of the present invention can be in the form of corticosteroid-layered beads. Corticosteroid-layered beads comprise a core, e.g. a pharmaceutically acceptable sugar bead, coated with a corticosteroid layer. Such corticosteroid-layered beads can be prepared, for example, by dissolving or suspending corticosteroid in a polymeric binder solution, which is then sprayed or coated onto inert particles (e.g., sugar spheres or cellulose spheres (CELPHERE®)). Suitable polymeric binders include any of those disclosed herein, for example starches, modified celluloses (e.g., hydroxypropylcellulose, carboxymethylcellulose sodium), alginic acid, polyvinyl pyrrolidone (povidone), and mixtures thereof. The amount of corticosteroid in the corticosteroid layer, and the thickness of the corticosteroid layer can be modified to provide a therapeutically effective dose of corticosteroid. The corticosteroid-containing layer comprises about 90%-99% corticosteroid, and about 1% to about 10% binder.

[0072] The corticosteroid-containing granules of the present invention can be prepared by any suitable method. For example, the corticosteroid-containing granules can be prepared by granulation of corticosteroid crystals, one or more disintegrants, and one or more fillers (e.g., sugar alcohol, saccharide and/or microcrystalline cellulose) in a high shear granulator or a fluid-bed

granulator using a solution of one or more polymeric binders, and dried in fluid bed equipment or on trays in a conventional oven to produce the corticosteroid-containing granules.

[0073] The solid pharmaceutical compositions of the present invention may include rapidly dispersing granules comprising a disintegrant and a sugar alcohol and/or a saccharide. The disintegrant-containing granules can include disintegrants or so-called super-disintegrants, e.g. crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethyl cellulose, low substituted hydroxypropylcellulose, and mixtures thereof. The amount of disintegrant in the rapidly dispersing granules can range from about 1%-10%, or about 5%-10% of the total weight of the rapidly dispersing granules, including all ranges and subranges therebetween.

[0074] Sugar alcohols are hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group. Non-limiting examples of suitable sugar alcohols for the rapidly dispersing granules of the pharmaceutical compositions of the present invention include e.g. arabitol, isomalt, erythritol, glycerol, lactitol, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof. The term "saccharide" is synonymous with the term "sugars" includes monosaccharides such as glucose, fructose, the lactose, and ribose; and disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose. In one embodiment, non-limiting examples of suitable saccharides for use in the compositions of the present invention include e.g. lactose, sucrose, maltose, and mixtures thereof. In another embodiment, the rapidly dispersing granules comprise at least one disintegrant in combination with a sugar alcohol. In another embodiment, the rapidly dispersing granules comprise at least one disintegrant in combination with a saccharide. In yet another embodiment, the disintegrant-containing granules comprise at least one disintegrant in combination with a sugar alcohol and a saccharide. The amount of sugar alcohol and/or saccharide in the rapidly dispersing granules ranges from about 99%-90%, or about 95%-90% of the total weight of the disintegrant-containing granules, including all ranges and subranges therebetween. In one embodiment, the average particle size of a sugar alcohol and/or saccharide is 30 μm or less, for example about 1-30 μm, about 5-30 μm, about 5-25 μm, about 5-20 μm, about 5-15 μm, about 5-10 μm, about 10-30 μm, about 10-25 μm, about 10-20 μm, about 10-15 μm, about 15-30 μm, about 15-25 μm, about 15-20 μm, about 20-30 μm, about 20-25 μm, or about 25-30 μm.

[0075] The corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) of the solid pharmaceutical compositions of the present invention can also be coated with a taste-masking layer to improve the palatability of the composition. The corticosteroid-containing particles can be taste-masked by coating the corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) with a water-insoluble polymer. Non-limiting examples of suitable water-insoluble polymers for the taste-masking layer include ethylcellulose, polyvinyl acetate (PVA), cellulose acetate (CA), cellulose acetate butyrate (CAB), methacrylate copolymers, such as those available under the tradename "EUDRAGIT" (e.g., type RL, RS, and NE30D), and combinations thereof.

[0076] In one embodiment, the water-insoluble polymer is ethylcellulose having a viscosity of about 90-110 cps when tested in an Ubbelohde viscometer as a 5 weight % 80:20 toluene/ethanol solution at 25°C.

[0077] In one embodiment, the solid pharmaceutical compositions of the present invention comprise about 25-35% of corticosteroid crystals, microencapsulated with a taste-masking layer comprising a water-insoluble polymer (e.g., ethylcellulose); about 60-70% of rapidly-dispersing granules (e.g., comprising crospovidone and mannitol); about 5% of additional disintegrant (e.g., crospovidone); about 1% of one or more flavors, and about 0.5%-1% of a sweetener (e.g., sucralose).

[0078] The method of producing drug-layered beads in one embodiment of the invention comprises dissolving or suspending corticosteroid in a polymeric binder solution and layering onto inert particles (50-100 mesh or 150-300 μm in diameter) such as sugar spheres or cellulose spheres (e.g., CELPHERE® CP-203) using a fluid-bed coater equipped with a bottom-spray Wurster insert. These corticosteroid-coated beads can then be taste-masked by fluid-bed coating or by solvent coacervation as described herein.

[0079] In another embodiment, the compositions of the present invention can comprise corticosteroid particles (e.g., crystals), coated with a taste-masking layer. The taste-masking layer (as described herein) can be applied to the corticosteroid particles by any suitable method, for example coacervation or fluidized bed coating methods. Alternatively, the compositions of the present invention can comprise a corticosteroid complexed with a cyclodextrin.

[0080] In one embodiment, the method of preparing the compositions of the present invention includes a taste-masking step. The taste-masked corticosteroid-containing particles of the

compositions of the present invention (e.g., corticosteroid crystals, corticosteroid-containing microgranules or drug-layered beads) of the present invention can be prepared by various methods, including solvent coacervation with a water-insoluble polymer such as ethylcellulose. The water-insoluble polymer (e.g., ethylcellulose), a phase-inducer (e.g., polyethylene), and corticosteroid are loaded into a coacervation tank containing cyclohexane. The mixture in the tank is heated to about 80°C to dissolve the ethylcellulose, and then slowly cooled under controlled conditions thereby causing phase-induced microencapsulation of corticosteroid particles by the ethylcellulose. Microencapsulation or coacervation refers to the process of applying a membrane by phase separation for imparting taste-masking (or sustained release) properties. Upon reaching ambient temperature, the suspension of microencapsulated corticosteroid particles are filtered, washed with fresh cyclohexane and dried to reduce residual solvent levels within acceptable limits (e.g., <4,000 ppm), in one embodiment less than 1,000 ppm. The coating weight of the microencapsulated corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. Examples of such a coacervation process are disclosed in U.S. Pat. Nos. 5,252,337, 5,639,475, 6,139,865 and 6,495,160.

[0081] Alternatively, the coacervation solution can comprise a mixture of the water-insoluble polymer (e.g., ethylcellulose) and a water-insoluble or gastrosoluble pore-former (e.g., calcium carbonate). The ratio of water-insoluble polymer to pore-former can range from about 50/50 to 95/05, including about 55/45, about 60/40, about 65/35, about 70/30, about 75/25, about 80/20, about 85/15, and about 90/10, including all ranges and subranges therebetween. The coating weight of the microencapsulated corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. In one embodiment, the coacervation step comprises suspending the drug-containing particles in a solution of water-insoluble ethylcellulose at 80°C in the coacervation tank. During the cooling cycle, the micronized pore-former is introduced into the tank at a temperature of about 58°C, while constantly stirring the suspension to uniformly distribute the pore-former in the microcapsule-membrane, at the forming/hardening phase. Examples of such a coacervation process are disclosed in U.S. Patent Publication No. US 2006/0105038.

[0082] In one embodiment, the solid pharmaceutical composition of the present invention is in the form of an orally disintegrating tablet (ODT). In one such embodiment the ODT comprises drug

particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol and/or saccharide. The drug particles may comprise, for example, corticosteroid crystals with or without a coating, corticosteroid-layered beads or granulates of corticosteroid with one more additional components. In certain embodiments the ODT is in the form of a wafer or film (for example those described in US 6,534,549, US 7,125,564, etc.).

[0083] In one embodiment of the present invention the solid composition comprises a lyophilized matrix, wherein the lyophilized matrix comprises corticosteroid and an excipient. Suitable excipients include mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

[0084] The amount of corticosteroid-containing granules in the solid compositions of the present invention can range from about 5% to about 50%, including about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, and about 50%, inclusive of all values, ranges, and sub-ranges therebetween. In one embodiment, the composition of the present invention is an ODT comprising about 30% by weight of corticosteroid-containing granules.

[0085] One embodiment of a method for producing pleasant tasting corticosteroid ODT formulations of the present invention, comprising corticosteroid microparticles with a mean particle size of about 100-400 μm, comprises (i) preparing drug-containing cores having corticosteroid crystals with a desired mean particle size, e.g., as microgranules, corticosteroid particles (e.g., crystals), or as drug-layered beads, (ii) preparing granules comprising a disintegrant, a sugar alcohol and/or a saccharide, and (iii) compressing a blend comprising the corticosteroid microparticles and the disintegrant granules, optionally with pharmaceutically acceptable flavorant(s), sweetener(s), other disintegrant(s), colorant(s) and/or compression aides such as microcrystalline cellulose in sufficient quantities into the ODT form using a tablet press, such as a rotary tablet press equipped with an external lubrication system to lubricate the punches and dies prior to compression. These ODT tablets rapidly disintegrate upon exposure to the saliva in the mouth into a smooth, easy-to-swallow suspension with no gritty aftertaste.

[0086] In another embodiment, the method for preparing ODT formulations of the present invention comprising corticosteroid microparticles with a mean particle size of about 100-400 μm can also include a unit process for taste-masking the corticosteroid-containing particles (e.g.,

corticosteroid crystals, corticosteroid-containing granules or drug-layered beads) by coacervation or fluid bed coating prior to blending and compression into ODT tablets. For example, corticosteroid crystalline material with an average particle size range of about 1-200 μm, more particularly about 50-150 μm can be coated with a taste-masking layer by either fluid-bed coating or solvent coacervation in accordance with other aspects of the invention. Corticosteroid crystalline material with a mean particle size of about 5-50 μm can also be taste-masked by solvent coacervation as described herein.

[0087] In another embodiment, the compositions of the present invention can be orally disintegrating tablets prepared by mixing corticosteroid microgranules or taste-masked corticosteroid microparticles, one or more flavoring agents, a sweetener, rapidly-dispersing microgranules, microcrystalline cellulose, and an additional disintegrant, and compressing this mixture into orally disintegrating tablets. The orally disintegrating tablets formed thereby rapidly disintegrate on contact with saliva in the buccal cavity, and have a pleasant taste (good creamy mouth feel) and provide rapid, substantially-complete release of the dose in the stomach.

[0088] In yet another embodiment, the compositions of the present invention may be orally disintegrating tablets formed by compressing a composition comprising corticosteroid-containing particles, rapidly-dispersing granules, and optionally flavoring agents, sweeteners, and other pharmaceutically acceptable excipients in a tablet press equipped with an externally lubricating system to pre-lubricate dies and punches, thereby providing a tablet formulation otherwise free of lubricant. The orally disintegrating tablets thus produced typically exhibit sufficient hardness and sufficiently low friability to be suitable for packaging in HDPE bottles and push-through film backed or peel-off paper backed blister packs using conventional equipment for storage, transportation and commercial distribution.

[0089] In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: (a) preparing corticosteroid-containing microgranules by granulating crystalline corticosteroid material having an average particle size of about 5-50 μm and one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and mixtures thereof, with a polymeric binder in a high-shear granulator or a fluid-bed coater; (b) granulating one or more sugar alcohols and/or saccharides, each having an average particle diameter of not more than about 30 μm, with a disintegrant such as crospovidone, using water or an alcohol-water mixture in a conventional granulator, and drying the granulate in fluid-bed

equipment or a conventional oven to produce rapidly-dispersing microgranules with an average particle size of not more than about 400 μm, as described in U.S. Patent Publication No. US 20050232988; filed Apr. 19, 2004; (c) blending the corticosteroid microgranules of step (a) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and the rapidly-dispersing microgranules of step (b); and (d) compressing the blend of step (c) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

[0090] In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: a) preparing a drug-containing core particle (e.g., corticosteroid crystals, drug-layered beads, or corticosteroid-containing microgranules) by granulating the drug and optionally one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and mixtures thereof with a polymeric binder in a high-shear granulator or a fluid-bed coater, or drug-layering on an inert particle (60-100 mesh sugar sphere or cellulose sphere, e.g., CELPHERE® CP-203) from a solution/suspension comprising a polymeric binder and the drug in a fluid-bed coater and optionally applying a seal-coat (e.g., OPADRY® Clear); b) taste-masking core particles by microencapsulation, e.g. by solvent coacervation or fluid-bed coating with a water-insoluble polymer such as ethylcellulose, or with a mixture of a water-insoluble functional polymer and a water-soluble/gastrosoluble pore-former (e.g., ethylcellulose and sodium chloride or calcium carbonate at a ratio ranging from about 50/50 to 95/5) to produce pleasant-tasting microparticles with a desired particle size distribution (e.g., an average particle size of not more than about 400 μm, or an average particle size of not more than about 300 μm); c) granulating one or more sugar alcohols and/or saccharides, each of which has an average particle diameter of not more than about 30 μm, with a disintegrant such as crospovidone, as disclosed herein; d) blending the taste-masked microparticles of step (b) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and rapidly-dispersing microgranules of step (c); and e) compressing the blend of step (d) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

EXAMPLE 1

[0091] Fluticasone Propionate Microgranules A: Mannitol 25 (91.2% w/w) and Crospovidone XL-10 (4.8% w/w) at a ratio of 95/5 are co-milled individually by passing the mixture through a

COMIL® milling apparatus, equipped with 0.225'' spacers, at a speed of about 1400-1500 rpm. The mannitol, crospovidone, and fluticasone propionate (4% w/w) crystalline material are blended for about 3-5 minutes to mix the ingredients. A Glatt GPCG-3 fluid-bed apparatus equipped with a top spray granulation chamber and a granulation bowl is charged with the pre-blend of mannitol, crospovidone, and fluticasone propionate (batch size: 1500 g) and granulated by spraying purified water (nozzle: 1.2 mm tip) at an atomization pressure of about 1.25 bar and at a spray rate of 30-50 mL/min and an outlet temperature of >70°C and at a product temperature of >33°C. The wet mass is dried until the moisture level (the percent loss on drying) is less than about 1%.

[0092] Tableting: A Hata production tablet press equipped with a vacuum transfer system, tablet de-duster, a metal detector, and a Matsui Ex-lube system were set up according to standard operating procedures. Magnesium stearate was used as a processing aid, i.e., to externally lubricate the punch and die surfaces and was therefore present in only trace amounts on the tablets. The weight range for the tablets was typically ±5% of the target tablet weight. The Ex-lube system was started to ensure that the lubricant was spraying properly when the tablet press was running. The tableting parameters, such as fill depth (mm), pre-compression position (mm or kN) and main compression position (mm or kN) were adjusted on the press in order to produce 4 mg tablets that meet the exemplary specifications listed below:

TABLE:

Tablet Parameters		
Parameter	Target	Range
Weight (mg)	100	95-105
Thickness (mm)	2.4	2.0-2.8
Hardness (N)	28	8-48
Friability	NMT 0.6%	1.0%
Weight 10 tablets (g)	1.0g	0.96-1.04

[0093] Following the successful set-up, the press was run in `Automatic Mode` until completion. During the run, tablets were sampled periodically to ensure that the tablets produced would meet the specifications listed above.

[0094] The tablets are tested in the USP <701> Disintegration test and disintegrate in about 60 seconds or less.

EXAMPLE 2

[0095] A liquid is prepared by mixing 89.8% of 95% ethanol, by weight 5% ethylcellulose, 0.2% by weight oleic acid and 5% fluticasone propionate. Upon dabbing on to a mucosal surface a film is formed which adheres readily to skin or mucosal tissues.

[0096] An ethyl alcohol based gel is prepared by mixing the following components: 67% by weight of 95% ethyl alcohol; 8% by weight ethylcellulose; 2% by weight hydroxypropylcellulose; 2% by weight polyacrylic acid; 14% by weight menthol; 5% by weight water USP; and 2% by weight fluticasone propionate. A smooth, slightly opaque and sticky gel is formed.

[0097] The film, resulting from the application of this gel to a mucosal surface adheres to the surface and requires mechanical effort for its removal.

[0098] It will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without departing from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

WHAT IS CLAIMED IS:

1. An orally disintegrating tablet comprising:

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

(ii) at least one disintegrant;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20. An orally disintegrating tablet comprising:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ELLO-119/08US 342083-2017
	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.
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	ELLO-119/08US 342083-2017
	Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	

City	Vandalia	State/Province	OH	Country of Residence	US

Mailing Address of Inventor:

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City	Lawrenceville	**State/Province**	NJ
Postal Code	08648	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	58249		
Email Address	zIPPatentDocketingMailboxUS@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	ELLO-119/08US 342083-2017	**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.

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Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(●) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	58249		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16/821464	2020-03-17

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/821464	Continuation of	15/816154	2017-11-17	10632069	2020-04-28

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/816154	Continuation of	15/205390	2016-07-08	9849084	2017-12-26

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/205390	Continuation of	14/311732	2014-06-23	9387167	2016-07-12

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/311732	Division of	12/896005	2010-10-01	8771729	2014-07-08

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Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
12/896005	Claims benefit of provisional	61/247642	2009-10-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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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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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	Ellodi Pharmaceuticals, L.P.		
Mailing Address Information For Applicant:			
Address 1	1200 Lenox Drive, Suite 100		
Address 2			
City	Lawrenceville	**State/Province**	NJ
Country	US	Postal Code	08648
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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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)	2022-01-05
First Name	Jonathan	Last Name	Cousin	Registration Number	66,418

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