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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/01/2022	11260061	ELLO-144/04US 342083-3254	9921

58249 7590 02/09/2022
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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

Michael A. GOSSELIN, Springboro, OH;
Jin-Wang LAI, Springboro, OH;
Gopi M. VENKATESH, Vandalia, OH;

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

Ellodi Pharmaceuticals, L.P., Lawrenceville, NJ

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.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet 1 of 21

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	3,705,172	12-05-1972	Buchel, et al.	
	2.	3,929,768	12-30-1975	Brattsand, et al.	
	3.	4,080,448	03-21-1978	Mirsky	
	4.	4,335,121	06-15-1982	Phillipps, et al.	
	5.	4,363,806	12-14-1982	Bergstrom, et al.	
	6.	4,472,393	09-18-1984	Shapiro	
	7.	4,985,418	01-15-1991	Richards	Change(s) applied
	8.	5,135,740	08-04-1992	Katz & Cheng	to document,
	9.	5,278,175	01-11-1994	Ray, et al.	/J.T./
	10.	5,403,893	04-04-1995	Tanaka, et al.	10/14/2021
	11.	5,446,070	08-29-1995	Mantelle, J.A.	
	12.	5,482,934	01-09-1996	Calatyud, et al.	
	13.	5,776,433	07-07-1998	Tzou, et al.	
	14.	6,171,617	01-09-2001	Gruber	
	15.	6,316,027	11-13-2001	Johnson, et al.	
	16.	6,596,298	07-22-2003	Leung, et al.	
	17.	6,596,311	07-22-2003	Dobetti	
	18.	6,740,332	05-25-2004	Zyck, et al.	
	19.	7,033,606	04-25-2006	Besse, et al.	
	20.	8,580,300	11-12-2013	Wilhelm, et al.	
	21.	8,679,545	03-25-2014	Dohil, et al.	
	22.	8,771,729	07-08-2014	Perrett, et al.	
	23.	9,387,167	07-12-2016	Perrett, et al.	
	24.	9,486,407	11-08-2016	Perrett, et al.	
	25.	9,782,347	10-10-2017	Dohil, et al.	
	26.	9,849,084	12-26-2017	Perrett, et al.	
	27.	9,867,780	~~01-16-2016~~	Greinwald, et al.	01/2018
	28.	10,105,315	10-23-2018	Meltzer, et al.	

Examiner Signature	Date Considered
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*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921
58249	7590	01/20/2022	EXAMINER	
COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			01/20/2022	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

Notice of Allowability	Application No. 17/211,119	Applicant(s) GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	AIA (FITF) Status Yes

-- 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 an internal Office communication to correct the claim dependency of claim 22.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

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

3. ☒ The allowed claim(s) is/are 1-30. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/GINA C JUSTICE/ Primary Examiner, Art Unit 1617	
---	--

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Jonathan Cousin on January 11, 2021.

The application has been amended as follows:

In Claim 22, line 1, the number "22" is changed to "19".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA JUSTICE whose telephone number is (571)272-8605. The examiner can normally be reached M-F 8:30 AM - 5 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, JOHANN RICHTER can be reached on 571-272-0646. 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.

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

Issue Classification 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

CPC						
Symbol					Type	Version
A61K	/	31	/	56	F	2013-01-01
A61K	/	9	/	0056	I	2013-01-01
A61K	/	9	/	2018	I	2013-01-01
A61K	/	9	/	2027	I	2013-01-01
A61J	/	3	/	10	I	2013-01-01
A61K	/	9	/	2009	I	2013-01-01
A61K	/	9	/	2054	I	2013-01-01
A61K	/	9	/	2081	I	2013-01-01
A61K	/	9	/	2095	I	2013-01-01
A61K	/	45	/	06	I	2013-01-01
B29C	/	43	/	003	I	2013-01-01
B29C	/	43	/	006	I	2013-01-01

CPC Combination Sets					
Symbol				Type	Set

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 30	
/GINA C JUSTICE/ Primary Examiner, Art Unit 1617 (Primary Examiner) _____ (Date) 12 January 2022		O.G. Print Claim(s) 1	O.G. Print Figure NONE

<i>Issue Classification</i> 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61K31/56	/	31	/	56	
A61K9/00	/	9	/	00	
A61K9/20	/	9	/	20	
A61J3/10	/	3	/	10	
A61K45/06	/	45	/	06	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 30	
/GINA C JUSTICE/ Primary Examiner, Art Unit 1617 (Primary Examiner) _____ (Date) 12 January 2022		O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

☒ 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: 30	
/GINA C JUSTICE/ Primary Examiner, Art Unit 1617 (Primary Examiner) _____ (Date) 12 January 2022		O.G. Print Claim(s) 1	O.G. Print Figure NONE

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

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
17211119	24-Mar-2021	Michael A. GOSSELIN	ELLO-144/04US 342083-32	9921

TITLE OF INVENTION :

CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	1617	465000	
Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
\$1200	\$0	\$1200	04-Jan-2022	\$0

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

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

2.Entity Status**Change in Entity Status**

- ☐ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
 Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
 If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27.
 Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☒ Applicant changing to regular undiscounted fee status.
 Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

3.The Following Fee(s) Are Submitted:☒ Issue Fee☐ I authorize USPTO to apply my previously paid issue fee to the current fees due☐ Publication Fee☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____☐ Advance Order - # of copies _____

☐ If in **addition** to the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____.

☐ The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed**NOTE: If no name is listed, no name will be printed**

For printing on the patent front page, list to be displayed as entered

1. COOLEY, LLP

2.

3.

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

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

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

6.Signature

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

Signature	/Jonathan M. Cousin/	Date	12-22-2021
Name	Jonathan M. Cousin	Registration Number	66418

Electronic Patent Application Fee Transmittal				
Application Number:		17211119		
Filing Date:		24-Mar-2021		
Title of Invention:		CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
First Named Inventor/Applicant Name:		Michael A. GOSSELIN		
Filer:		Jonathan M. Cousin/Carolina Pimentel		
Attorney Docket Number:		ELLO-144/04US 342083-3254		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

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

Electronic Acknowledgement Receipt

EFS ID:	44585823
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	22-DEC-2021
Filing Date:	24-MAR-2021
Time Stamp:	12:30:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 1200
RAM confirmation Number	E2021BLC30514248
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	62281	no	2
			91d6b55d0e1a72d83c062291e2c758aaefe a0616		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40250	no	2
			500d651e5f23b350083e96faf6ca4cc1c955 68ff		
Warnings:					
Information:					
Total Files Size (in bytes):			102531		
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. <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.					



UNITED STATES PATENT AND TRADEMARK OFFICE

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58249	7590	11/17/2021	EXAMINER	
COOLEY LLP			JUSTICE, GINA CHIEUN YU	
ATTN: IP Docketing Department			ART UNIT	
1299 Pennsylvania Avenue, NW			PAPER NUMBER	
Suite 700			1617	
Washington, DC 20004			NOTIFICATION DATE	
			DELIVERY MODE	
			11/17/2021	
			ELECTRONIC	

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zIPPatentDocketingMailboxUS@cooley.com

Corrected Notice of Allowability	Application No. 17/211,119	Applicant(s) GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	AIA (FITF) Status Yes

-- 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 IDS filed on 10/14/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-30. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

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

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

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
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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 _____.
--	---

/GINA C JUSTICE/
 Primary Examiner, Art Unit 1617

Docket No.: ELLO-144/04US 342083-3254
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	Gina Chieun Yu JUSTICE
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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

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

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

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

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

- ☐ 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. _____.
- ☐ In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:
- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
 - ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
 - ☐ before the mailing date of a first Office action on the merits; or
 - ☐ before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.
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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;

Application No.: 17/211,119**Docket No.:** ELLO-144/04US 342083-3254

- ☐ 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.

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

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

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

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

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

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

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

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

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

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

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

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

Application No.: 17/211,119**Docket No.:** ELLO-144/04US 342083-3254

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

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Allowed
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-162/01US	16/968,711	8/10/2020	US 2020-0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

/GINA C JUSTICE/

11/14/2021

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.

Application No.: 17/211,119**Docket No.:** ELLO-144/04US 342083-3254

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-144/04US 342083-3254.

Dated: October 14, 2021

Respectfully submitted,
COOLEY LLP**USPTO CUSTOMER NO. 58249**

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

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

Tel: (202) 842-7800

Fax: (202) 842-7899

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet

1

of

1

NON PATENT LITERATURE DOCUMENTS

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

Examiner Signature	/GINA C JUSTICE/	Date Considered	11/14/2021
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option **Dr. Falk Pharma Ex. 1056**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/ IPR Petition - USP 11,260,061

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(Use as many sheets as necessary)***Complete if Known**

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet

1

of

1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	Opposition Proceedings in European Patent No. EP 3041476 (Appln. No. 14842811.3), filed by Dr. Falk Pharma GmbH on July 22, 2020; Patentee Ellodi Pharmaceuticals, L.P.'s Written Submission in Preparation for Oral Proceedings on December 8, 2021 with new Auxiliary Requests 1-3, dated October 8, 2021, 51 pages.	
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Examiner Signature		Date Considered	
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Electronic Patent Application Fee Transmittal

Application Number:	17211119			
Filing Date:	24-Mar-2021			
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS			
First Named Inventor/Applicant Name:	Michael A. GOSSELIN			
Filer:	Jonathan M. Cousin/Sandra Laramore			
Attorney Docket Number:	ELLO-144/04US 342083-3254			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	44030020
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	14-OCT-2021
Filing Date:	24-MAR-2021
Time Stamp:	17:27:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$260
RAM confirmation Number	E20210DH27464503
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-144-04US-IDS.pdf	150431	no	6
			4b92d3b411f71b15170c7e3831bdae1bd3b4e7ab		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-144-04US-SB08.pdf	130927	no	1
			149da109ffe11d6155b2e3739445b939b38eff7		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	Oppn_3041476_Ellodis_Written_Submissions_10-08-2021_51_pages.pdf	5858302	no	51
			0a774831375642f5654c7aea93cf25b6ae9dc0b9		
Warnings:					
Information:					
4	Non Patent Literature	Oppn_2482822_EPO_Decision_revoking_EP2482822_08-25-2021_23_pgs.pdf	2777628	no	23
			06ff34943480fd9b8360ada961a557c3e6203feb		
Warnings:					
Information:					
5	Non Patent Literature	Oppn_2482822_EPOs_Comm_Minutes_of_Oral_Proceedings_08-25-2021_11_pgs.pdf	912128	no	11
			3be4cad3e24ae37e3367887cd98171853da99096		
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38218	no	2
			3913bd345b51557e23949ddc40199d0c9584a0a3		
Warnings:					

Information:	
Total Files Size (in bytes):	9867634
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. <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.	

Docket No.: ELLO-144/04US 342083-3254
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	Gina Chieun Yu JUSTICE
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

VIA EFS
Commissioner for Patents
P.O. Box 1450
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UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

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 - ☐ 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.
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- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
 - ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
 - ☐ before the mailing date of a first Office action on the merits; or
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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.

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

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

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

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

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

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

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

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

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

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

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

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

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Allowed
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-162/01US	16/968,711	8/10/2020	US 2020-0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

Remarks

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

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

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

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-144/04US 342083-3254.

Dated: October 14, 2021

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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

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

Tel: (202) 842-7800

Fax: (202) 842-7899



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921
58249	7590	10/14/2021	EXAMINER	
COOLEY LLP			JUSTICE, GINA CHIEUN YU	
ATTN: IP Docketing Department			ART UNIT	
1299 Pennsylvania Avenue, NW			PAPER NUMBER	
Suite 700			1617	
Washington, DC 20004			NOTIFICATION DATE	
			DELIVERY MODE	
			10/14/2021	
			ELECTRONIC	

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

Corrected Notice of Allowability	Application No. 17/211,119	Applicant(s) GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	AIA (FITF) Status Yes

-- 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 IDS mailed on September 29, 2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

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

3. ☒ The allowed claim(s) is/are 1-30. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/GINA C JUSTICE/ Primary Examiner, Art Unit 1617	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	1	of	2	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/03US 342083-3254

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	2021/0244660 A1	08-12-2021	Perrett, et al.	
	2.	2021/0275438 A1	09-09-2021	Meltzer, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	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
		Country Code ³ "Number" ⁴ "Kind Code" ⁵ (if known)				
	3.	WO 2021/067585 A1	04-08-2021	ADARE PHARMACEUTICALS US, L.P.		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/03US 342083-3254

Sheet

2

of

2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4.	DALEY-YATES, Peter T. "Inhaled corticosteroids: potency, dose equivalence and therapeutic index." British Journal of Clinical Pharmacology (2015); 80(3): 372-380.	
	5.	FURUTA, Glenn T., et al. "Eosinophilic esophagitis in children and adults: a systematic review and consensus recommendations for diagnosis and treatment: sponsored by the American Gastroenterological Association (AGA) Institute and North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition." Gastroenterology (2007); 133(4): 1342-1363.	
	6.	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.	
	7.	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.	
	8.	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	
	9.	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	
	10.	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.	
	11.	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	
	12.	TAFT, et al., "The adult eosinophilic esophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	
	13.	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	

Examiner Signature	/GINA C JUSTICE/	Date Considered	10/09/2021
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 480-PTO-9199 (1-800-786-9199) and select option 2.

Dr. Falk Pharma Ex. 1056
IPR Petition - USP 11,260,061
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/



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 10/04/2021
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER	
JUSTICE, GINA CHIEUN YU	
ART UNIT	PAPER NUMBER
1617	
DATE MAILED: 10/04/2021	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921

TITLE OF INVENTION: CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

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	01/04/2022

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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.

58249 7590 10/04/2021
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921

TITLE OF INVENTION: CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

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	01/04/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
JUSTICE, GINA CHIEUN YU	1617	424-465000

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

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

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

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US	9921
58249	7590	10/04/2021	342083 3254	
COOLEY LLP			EXAMINER	
ATTN: IP Docketing Department			JUSTICE, GINA CHIEUN YU	
1299 Pennsylvania Avenue, NW				
Suite 700				
Washington, DC 20004				
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 10/04/2021				

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 17/211,119	Applicant(s) GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	AIA (FITF) Status Yes

-- 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 interview on 9/8/2021 and arguments filed on 9/9/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

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

3. ☒ The allowed claim(s) is/are 1-30. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/GINA C JUSTICE/ Primary Examiner, Art Unit 1617	
---	--

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Previous claim rejection made under 35 U.S.C. 112 (b) as indicated in the Office action dated June 10, 2021 is **withdrawn** in view of amendment made to claim 22.

Previous claim rejection made under 35 U.S.C. 103 over Ramalho et al. (US 20060051414 A1) in view of Perrett et al. (US 20110081411 A1) and Milburn et al. (US 20060292099 A1) is **withdrawn** in view of applicant's remarks.

Previous claim rejection made under 35 U.S.C. 103 over Ramalho, Perrett and Milburn and further in view of Platteeuw et al. (US 2004/0265375 A1) is **withdrawn** in view of applicant's remarks.

Terminal Disclaimer

The terminal disclaimer filed on September 9, 2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 10471071 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Accordingly, the obviousness-type double patenting rejection made over the claims of the US 10471071 patent as indicated in the Office action dated June 10, 2021 is **withdrawn**.

Election/Restrictions

Claims 1-28 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 29 and 30, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on June 10, 2021 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA JUSTICE whose telephone number is (571)272-8605. The examiner can normally be reached on M-F 8:30 AM - 5 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>.

Claims 1-30 are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHANN RICHTER can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

<i>Search Notes</i> 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

CPC - Searched*		
Symbol	Date	Examiner
A61K9/0056	06/04/2021	GJ
UPDATED	09/27/2021	GJ

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
WEST, PARENTS, INVENTORS, ASSIGNEE	06/04/2021	GJ
UPDATED	09/27/2021	GJ

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
SEE SEARCH NOTE		09/27/2021	GJ

/G.C.J/ Primary Examiner, Art Unit 1617	
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Issue Classification 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	

CPC						
Symbol					Type	Version
A61K	/	31	/	56	F	2013-01-01
A61K	/	9	/	0056	I	2013-01-01
A61K	/	9	/	2018	I	2013-01-01
A61K	/	9	/	2027	I	2013-01-01
A61J	/	3	/	10	I	2013-01-01
A61K	/	9	/	2009	I	2013-01-01
A61K	/	9	/	2054	I	2013-01-01
A61K	/	9	/	2081	I	2013-01-01
A61K	/	9	/	2095	I	2013-01-01
A61K	/	45	/	06	I	2013-01-01
B29C	/	43	/	003	I	2013-01-01
B29C	/	43	/	006	I	2013-01-01

CPC Combination Sets					
Symbol				Type	Set

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 30	
/GINA C JUSTICE/ Primary Examiner, Art Unit 1617 (Primary Examiner) _____ (Date) _____		27 September 2021 O.G. Print Claim(s) 1	O.G. Print Figure NONE

<i>Issue Classification</i> 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61K31/56	/	31	/	56	
A61K9/00	/	9	/	00	
A61K9/20	/	9	/	20	
A61J3/10	/	3	/	10	
A61K45/06	/	45	/	06	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)		30	
(Date)			
/GINA C JUSTICE/		27 September 2021	
Primary Examiner, Art Unit 1617		O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)		1	NONE
(Date)			

Issue Classification 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

☒ 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: 30	
/GINA C JUSTICE/ Primary Examiner, Art Unit 1617 (Primary Examiner) _____ (Date) 27 September 2021		O.G. Print Claim(s) 1	O.G. Print Figure NONE

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet	1	of	21
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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	3,705,172	12-05-1972	Buchel, et al.	
	2.	3,929,768	12-30-1975	Brattsand, et al.	
	3.	4,080,448	03-21-1978	Mirsky	
	4.	4,335,121	06-15-1982	Phillipps, et al.	
	5.	4,363,806	12-14-1982	Bergstrom, et al.	
	6.	4,472,393	09-18-1984	Shapiro	
	7.	4,985,418	01-15-1991	Richards	
	8.	5,135,740	08-04-1992	Katz & Cheng	
	9.	5,278,175	01-11-1994	Ray, et al.	
	10.	5,403,893	04-04-1995	Tanaka, et al.	
	11.	5,446,070	08-29-1995	Mantelle, J.A.	
	12.	5,482,934	01-09-1996	Calatyud, et al.	
	13.	5,776,433	07-07-1998	Tzou, et al.	
	14.	6,171,617	01-09-2001	Gruber	
	15.	6,316,027	11-13-2001	Johnson, et al.	
	16.	6,596,298	07-22-2003	Leung, et al.	
	17.	6,596,311	07-22-2003	Dobetti	
	18.	6,740,332	05-25-2004	Zyck, et al.	
	19.	7,033,606	04-25-2006	Besse, et al.	
	20.	8,580,300	11-12-2013	Wilhelm, et al.	
	21.	8,679,545	03-25-2014	Dohil, et al.	
	22.	8,771,729	07-08-2014	Perrett, et al.	
	23.	9,387,167	07-12-2016	Perrett, et al.	
	24.	9,486,407	11-08-2016	Perrett, et al.	
	25.	9,782,347	10-10-2017	Dohil, et al.	
	26.	9,849,084	12-26-2017	Perrett, et al.	
	27.	9,867,780	01-16-2016	Greinwald, et al.	
	28.	10,105,315	10-23-2018	Meltzer, et al.	

Examiner Signature	Date Considered
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*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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

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

Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/

PTO/SB/08a (07-09)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	2	of	21	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/04US 342083-3254

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	29.	10,176,301	01-08-2019	Hill, et al.	
	30.	10,272,037	04-30-2019	Dohil, et al.	
	31.	10,632,069	04-28-2020	Perrett, et al.	
	32.	11,026,887	06-08-2021	Meltzer, et al.	
	33.	2001/0006625	07-05-2001	Bohn et al.	
	34.	2001/0014340	08-16-2001	Ohta, et al.	
	35.	2003/0050312	03-13-2003	Hjorth, et al.	
	36.	2003/0054036	03-20-2003	Liggins, et al.	
	37.	2003/0099701	05-29-2003	Takaishi, et al.	
	38.	2003/0215500	11-20-2003	Ohta, et al.	
	39.	2004/0053902	03-18-2004	Smith, Steven C.	
	40.	2004/0009212	01-15-2004	Tsai, Tsui-min	
	41.	2004/0106663	06-03-2004	Talley, et al.	
	42.	2004/0228919	11-18-2004	Houghton, et al.	
	43.	2005/0009848	01-13-2005	Brantl	
	44.	2005/0112188	05-26-2005	Elias	
	45.	2005/0232988	10-20-2005	Venkatesh, et al.	
	46.	2007/0020330	01-25-2007	Dang, et al.	
	47.	2007/0059361	03-15-2007	Rawas-Qalaji, et al.	
	48.	2007/0111978	05-17-2007	Dohil, et al.	
	49.	2009/0074862	03-19-2009	Schioppi, et al.	
	50.	2009/0123550	05-14-2009	Phillips, et al.	
	51.	2009/0123551	05-14-2009	Phillips, et al.	
	52.	2009/0131386	05-21-2009	Phillips	
	53.	2009/0149433	06-11-2009	Phillips	
	54.	2009/0155360	06-18-2009	Venkatesh, et al.	
	55.	2009/0169620	07-02-2009	Venkatesh, et al.	
	56.	2009/0181099	07-16-2009	Dohil, et al.	
	57.	2009/0191275	07-30-2009	Dohil, et al.	

Examiner Signature	Date Considered
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*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/

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(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
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IPR Petition - USP 11,260,061

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PTO/SB/08a (07-09)

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**INFORMATION DISCLOSURE
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Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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		Country Code ³ "Number" "Kind Code ⁵ (if known)				
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	166.	European Application No. EP 14184844.0, Extended European Search Report dated February 9, 2015, 7 pages.	
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	170.	European Application No. EP 17842162.4, Extended European Search Report dated April 1, 2020, 8 pages.	
	171.	European Application No. EP 19207287.4, Extended European Search Report dated April 6, 2020, 9 pages.	
	172.	FALCOZ, et al., "Bioavailability of Orally Administered Micronised Fluticasone Propionate." Clinical Pharmacokinetics (2000); 39 Suppl. 1: 9-15.	
	173.	Forum of the National Formulary of Japan, compilation, Drugs in Japan, 2009 edition, published 2008, p. 2161-2165 (and English translation/summary of pertinent paragraphs), 8 pages.	
	174.	Georgia Application No. AP 2010012674, Search Report (with English translation) dated November 28, 2013, 11 pages.	
	175.	HAM, et al., "Quantitation of esophageal transit by means of ^{81m} Kr." European Journal of Nuclear Medicine (1984); 9: 362-365.	
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	178.	KHAN and ORENSTEIN, "Eosinophilic Gastroenteritis: Epidemiology, Diagnosis and Management." Paediatr Drugs. (2002); 4(9): 563-570.	
	179.	KRISHNA, et al., "Treatment of Eosinophilic Esophagitis Is Oral Viscous Budesonide Superior to Swallowed Fluticasone Spray?" Gastroenterol Hepatol (2011 Jan); 7(1): 55-59.	
	180.	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).	
	181.	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.	

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First Named Inventor	Michael A. GOSSELIN
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Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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	182.	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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	187.	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).	
	188.	Merck Index, "Budesonide," 14th Edition, p. 240 (2006)	
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	194.	Novopulmon E Novolizer®, Instructions for the medical use of the medicament, [Instrukciya po medicinskomu primeneniyu preparata Novopulmon E Novolizer (international nonproprietary name: budesonide), registracionniy nomer N LS-002405-231211, 23.12.2011], MEDA Manufacturing, GmbH Registration No. LS-002405, Date of Registration December 23, 2011 (with English summary of relevant portions), 9 pages.	
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	197.	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.	
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	201.	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.	
	202.	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.	
	203.	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis – Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	
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	207.	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.	
	208.	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.	
	209.	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.	
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	211.	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.	
	212.	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.	
	213.	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.	
	214.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), 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.	
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	217.	Declaration of Stephen Perrett, MBA, Ph.D. dated July 16, 2020, 6 pages.	
	218.	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	
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	225.	FURUTA, et al., "Review article: the pathogenesis and management of eosinophilic oesophagitis". Alimentary Pharmacology & Therapeutics (2006); 24: 172-182.	
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	228.	FURUTA, Glenn T., "Eosinophils in the Esophagus: Acid is Not the Only Cause". Journal of Pediatric Gastroenterology & Nutrition (April 1998); 26(4): 468-471.	
	229.	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.	
	230.	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.	
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	232.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), 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.	
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	235.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), 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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	239.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Submission filed by Adare Development I, L.P., on September 20, 2019, 91 pages.	
	240.	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.	
	241.	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.	
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	243.	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.	
	244.	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.	
	245.	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.	
	246.	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.	
	247.	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.	
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	249.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	

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First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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	250.	PCT Application No. PCT/US2010/050860, Written Opinion of the International Search Authority dated February 10, 2011.	
	251.	PCT Application No. PCT/US2014/052073, International Preliminary Report on Patentability dated March 8, 2016.	
	252.	PCT Application No. PCT/US2014/052073, International Search Report dated November 20, 2014.	
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	257.	PCT Application No. PCT/US2019/019040, International Preliminary Report on Patentability, dated August 27, 2020, 8 pages.	
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	272.	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.	
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	279.	DOHIL, et al., "Oral Viscous Budesonide Is Effective in Children With Eosinophilic Esophagitis in a Randomized, Placebo-Controlled Trial". Gastroenterol. (2010 August); 139(2): 418-429.	
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	284.	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.	
	285.	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.	
	286.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 12, 2020, and English translation, 5 pages.	
	287.	German Patent Complaint Proceedings in the Regional Court, Mannheim, Germany, Adare Development I, L.P. vs. Dr. Falk Pharma GmbH, Docket No. 7 O 75/19, Official Order dated February 13, 2020, and English translation, 5 pages.	

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	291.	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 BB17 - Current EPA register extract on D5 dated 27 November 2020, 117 pages.	
	292.	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.	
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	294.	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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	298.	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.	
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	300.	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.	
	301.	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.	
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	310.	EPO Communication dated April 25, 2019 in connection with Application No. EP 08848597.4, 13 pages.	
	311.	Budesonid, https://www.chemie.de/lexikon/Budesonid.html , July 12, 2019, and English version, September 10, 2020, 3 pages.	
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	313.	New World Encyclopedia, "Gastrointestinal tract", https://web.archive.org/web/20090917122455/https://www.newworldencyclopedia.org/... , July 8, 2019, 7 pages.	
	314.	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, 2020, and English translation, 16 pages.	
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	317.	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.	
	318.	Supplementary European Search Report in European Patent Application No. EP 20192973.4, dated November 18, 2020, 5 pages.	

Examiner Signature	/GINA C JUSTICE/	Date Considered	09/27/2021
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2. Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C.J/

Docket No.: ELLO-144/04US 342083-3254
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	Gina Chieun Yu JUSTICE
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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

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

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

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

[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 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in **prior Applications Serial Nos. 16/578,568 and/or 14/917,125 (U.S. Patent No. 10,471,071)**, to which the above-identified application claims priority under 35 U.S.C. §120.

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

- ☒ 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. _____.

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

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☐ before the mailing date of a first Office action on the merits; or
- ☐ before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

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

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

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

Application No.: 17/211,119**Docket No.:** ELLO-144/04US 342083-3254

- ☐ 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.

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

☐ 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).

Application No.: 17/211,119**Docket No.:** ELLO-144/04US 342083-3254

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

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed

/GINA C JUSTICE/

09/27/2021

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-144/04US 342083-3254.

Dated: July 29, 2021

Respectfully submitted,
COOLEY LLP**USPTO CUSTOMER NO. 58249**

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

By: /Jonathan M. Cousin/
Jonathan M. Cousin
Reg. No. 66,418
Matthew Scheideman
Reg. No. 76,605

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

WEST Search History

DATE: Tuesday, September 28, 2021

Hide?	<u>Set Name</u>	<u>Query</u>	<u>Hit Count</u>
		<i>DB=PGPB,USPT; PLUR=YES; OP=OR</i>	
☐	L21	L20 and @pd > 20210605	2
☐	L20	(rapidly adj dispersing adj microgranule) with (mannitol sugar saccharide sucrose) with (crospovidone hydroxylpropylcellulose hpc)	69
☐	L19	(rapidly adj dispersing adj microgranule) with (mannitol sugar saccharide sucrose) with (crospovidone starch cellulose hydroxylpropylcellulose hpc)	75
		<i>DB=USPT; PLUR=YES; OP=OR</i>	
☐	L18	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) and ((reduc\$ micronis\$ micronize\$) with (active drug) with (particle adj size) with uniform\$)	0
		<i>DB=PGPB,USPT; PLUR=YES; OP=OR</i>	
☐	L17	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) and ((reduc\$ micronis\$ micronize\$) with (active drug) with (particle adj size) with uniform\$)	3
		<i>DB=USPT; PLUR=YES; OP=OR</i>	
☐	L16	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) and ((reduc\$ micronis\$ micronize\$) near10 (active drug) nears10 (particle adj size) near10 uniform\$)	359
		<i>DB=PGPB,USPT,USOC,EPAB,JPAB,DWPI; PLUR=YES; OP=OR</i>	
☐	L15	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)).AB. and ((micronis\$ micronize\$) near10 (active drug))	44
☐	L14	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)).AB. and (microni\$ near10 (active drug))	57
☐	L13	L12 not L11	15
☐	L12	((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)).AB. and (micron\$ near5 (active drug))	64
☐	L11	L10	49
☐	L10	L9 and tablet	49
☐	L9	((A61K9/0056)).CPC. AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))).AB. and (micron\$ near5 (active drug))	52
☐	L8	((A61K9/0056)).CPC. AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))).AB. and (micron\$ with (active drug))	91
☐	L7	L6 AND (MICRON\$)	27
☐	L6	((A61K9/0056)).CPC. AND (CORE NEAR5 (DRUG ACTIVE) NEAR5 (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))).AB.	83

☐	L5	((A61K9/0056)).CPC. AND (CORE NEAR10(DRUG ACTIVE) NEAR10 (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEGR\$))).AB.	102
☐	L4	((A61K9/0056)).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEGR\$))).AB.	116
☐	L3	((A61K9/0056)).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) ODT)	219
☐	L2	((A61K9/0056)).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$)) AND (DISINTEGR\$ ODT)	369
☐	L1	((A61K9/0056)).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$))	424

END OF SEARCH HISTORY

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	1	of	2	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/03US 342083-3254

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	2021/0244660 A1	08-12-2021	Perrett, et al.	
	2.	2021/0275438 A1	09-09-2021	Meltzer, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	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
		Country Code ³ "Number" ⁴ "Kind Code" ⁵ (if known)				
	3.	WO 2021/067585 A1	04-08-2021	ADARE PHARMACEUTICALS US, L.P.		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2Dr. Falk Pharma Ex. 1056

IPR Petition - USP 11,260,061

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/03US 342083-3254

Sheet

2

of

2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4.	DALEY-YATES, Peter T. "Inhaled corticosteroids: potency, dose equivalence and therapeutic index." British Journal of Clinical Pharmacology (2015); 80(3): 372-380.	
	5.	FURUTA, Glenn T., et al. "Eosinophilic esophagitis in children and adults: a systematic review and consensus recommendations for diagnosis and treatment: sponsored by the American Gastroenterological Association (AGA) Institute and North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition." Gastroenterology (2007); 133(4): 1342-1363.	
	6.	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.	
	7.	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.	
	8.	PCT/US2020/053778, International Search Report and Written Opinion mailed January 8, 2021, 9 pages.	
	9.	RATNAPARKHI, et al., "Review On: Fast Dissolving Tablet", Journal of Pharmacy Research. (January 2009); 2(1): 5-12.	
	10.	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.	
	11.	SINGH, Arun, et al. "Oral candidiasis: An overview." Journal of Oral and Maxillofacial Pathology: JOMFP (2014); 18.Suppl 1: S81.	
	12.	TAFT, et al., "The adult eosinophilic esophagitis quality of life questionnaire: a new measure of health-related quality of life". Alimentary Pharmacology & Therapeutics (2011 Oct); 34(7): 790-798.	
	13.	WECHSLER, Joshua B., et al. "Eosinophilic esophagitis reference score accurately identifies disease activity and treatment effects in children." Clinical Gastroenterology and Hepatology (2018); 16(7): 1056-1063.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Patent Application Fee Transmittal				
Application Number:		17211119		
Filing Date:		24-Mar-2021		
Title of Invention:		CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
First Named Inventor/Applicant Name:		Michael A. GOSSELIN		
Filer:		Jonathan M. Cousin/Sandra Laramore		
Attorney Docket Number:		ELLO-144/04US 342083-3254		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	43904794
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Donna Doyle
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	29-SEP-2021
Filing Date:	24-MAR-2021
Time Stamp:	17:37:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$260
RAM confirmation Number	E20219SH37572493
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-144-04US-IDS.pdf	150455	no	6
			1b46aedcb2ad883a3af322bed7e0b9149df06a59		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-144-04US-SB08.pdf	195520	no	2
			1149d876e5e3dac58ce3c73304399806e5d9f765		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2021067585A1.pdf	1212506	no	81
			1e216ff2f58b6e67b996b781951cbb9d8287813		
Warnings:					
Information:					
4	Non Patent Literature	DALEY-YATES_2015.pdf	10183523	no	9
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Warnings:					
Information:					
5	Non Patent Literature	FURUTA_2007.pdf	25612279	no	22
			8d5bb5a2de4f4c2db819f3d15dd68fbdcd0d639e		
Warnings:					
Information:					
6	Non Patent Literature	MARTIN- J_Allergy_Clin_Immunol_2015. pdf	17240224	no	22
			285c613ab6765a583b4bae87d4e8d2ca0c3d939c		
Warnings:					

Information:					
7	Non Patent Literature	NISHIMURA_2013.pdf	6582107	no	6
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Information:					
8	Non Patent Literature	PCTUS2020053778_ISR-and-WO.pdf	1177818	no	9
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Warnings:					
Information:					
9	Non Patent Literature	RATNAPARKHI-Review_On_Fast_Dissolving_Tablet-J_Pharm_Res_2009.pdf	7853067	no	8
			e52e7d0bb04337e5d172bbcdc733b933f8397bf0		
Warnings:					
Information:					
10	Non Patent Literature	SCHOEPFER-Gastroenterology_2014.pdf	7608370	no	33
			ece122a0887077e55d731684a573ff73f0207e15		
Warnings:					
Information:					
11	Non Patent Literature	SINGH_2014.pdf	4454480	no	5
			207a19ee5977d82ed45b67bf7c3ab43b7f45d2e7		
Warnings:					
Information:					
12	Non Patent Literature	TAFT_Alimentary_Pharmacology_Therapeutics_2011.pdf	9329781	no	9
			5e3b2476a41f2763b1c1a0013cde0e430d3c5171		
Warnings:					
Information:					
13	Non Patent Literature	WECHSLER_2018.pdf	9644486	no	15
			103dfe0dc96d2748f64dfc442435e53825aacbd6		
Warnings:					
Information:					

14	Fee Worksheet (SB06)	fee-info.pdf	38219	no	2
			53a1f752a62f996d92bcde3d2f799c1627e738ab		
Warnings:					
Information:					
Total Files Size (in bytes):				101282835	
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. <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.					

Docket No.: ELLO-144/04US 342083-3254
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	Gina Chieun Yu JUSTICE
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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

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

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

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

- ☒ No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- ☐ Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) _____ cited 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. _____.

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

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☐ before the mailing date of a first Office action on the merits; or
- ☐ before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

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

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

- ☒ Fee under 37 C.F.R. §1.17(p) in the amount of \$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).

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

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-119/06US	16/821,464	3/17/2020	US 2020-0214979 A1	7/9/2020			Pending
ELLO-162/01US	16/968,711	8/10/2020	US 2020 - 0381097 A1	12/3/2020			Pending
ELLO-150/05US	16/992,671	8/13/2020	US 2020-0368147 A1	11/26/2020			Pending
ELLO-119/07US	17/236,295	4/21/2021	US 2021-0244660 A1	8/12/2021			Pending
ELLO-150/06US	17/306,458	5/3/2021	US 2021-0275438 A1	9/9/2021			Pending
ELLO-150/07US	17/376,996	7/15/2021					Pending
ELLO-119/01US	12/896,005	10/1/2010	US 2011-0081411 A1	4/7/2011	8,771,729	7/8/2014	Registered
ELLO-119/03US	14/311,732	6/23/2014	US 2014-0303131 A1	10/9/2014	9,387,167	7/12/2016	Registered
ELLO-119/02US	14/294,660	6/3/2014	US 2014-0287051 A1	9/25/2014	9,486,407	11/8/2016	Registered
ELLO-119/04US	15/205,390	7/8/2016	US 2017-0071855 A1	3/16/2017	9,849,084	12/26/2017	Registered
ELLO-150/03US	15/680,301	8/18/2017	US 2018-0133145 A1	5/17/2018	10,105,315	10/23/2018	Registered
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-119/05US	15/816,154	11/17/2017	US 2018-0153802 A1	6/7/2018	10,632,069	4/28/2020	Registered
ELLO-150/04US	16/131,812	9/14/2018	US 2019-0008760 A1	10/10/2019	11,026,887	6/8/2021	Registered

Remarks

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

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

Application No.: 17/211,119

Docket No.: ELLO-144/04US 342083-3254

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-144/04US 342083-3254.

Dated: September 29, 2021

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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

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

Tel: (202) 842-7800

Fax: (202) 842-7899

Application Number * 17/211,119 *	Application/Control No. 17/211,119	Applicant(s)/Patent under Reexamination GOSSELIN et al.	
	Examiner JUSTICE, GINA CHIEUN YU	Art Unit 1617	
Document Code - DISQ		Internal Document - DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed: <u>09 September 2021</u>	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
/FELICIA D ROBERTS/ Technology Center: <u>OPLC</u> Telephone: <u>(571)272-0550</u> <u>10471071</u>

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	17211119	
Filing Date	24-Mar-2021	
First Named Inventor	Michael GOSSELIN	
Attorney Docket Number	ELLO-144/04US 342083-3254	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
ELLODI PHARMACEUTICALS, L.P.	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 10471071 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.		

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☐ Small Entity ☐ Micro Entity ☒ Regular Undiscounted	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>66418</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/Jonathan M. Cousin/
Name	Jonathan M. Cousin

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

Electronic Patent Application Fee Transmittal

Application Number:	17211119			
Filing Date:	24-Mar-2021			
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS			
First Named Inventor/Applicant Name:	Michael A. GOSSELIN			
Filer:	Jonathan M. Cousin/Carolina Pimentel			
Attorney Docket Number:	ELLO-144/04US 342083-3254			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

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

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17211119

Filing Date: 24-Mar-2021

Applicant/Patent under Reexamination: GOSSELIN

Electronic Terminal Disclaimer filed on September 9, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

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

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	43722997
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	09-SEP-2021
Filing Date:	24-MAR-2021
Time Stamp:	15:17:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 170
RAM confirmation Number	E202199F17461912
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	41202	no	2
			2884ec3188e30d961b245852a6208744c401cd25		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37976	no	2
			ece8eabff80a1445798ce349e8a62036f48f3a45		
Warnings:					
Information:					
Total Files Size (in bytes):			79178		
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. <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.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	G. C. Y. Justice
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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

AMENDMENT/RESPONSE TO OFFICE ACTION

This paper is filed in response to the non-final Office Action dated June 10, 2021, to which the deadline for responding is September 10, 2021. 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/Arguments begin on page 8 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:
 - a. a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and
 - b. at least one disintegrant;wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg, and the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm~~100 µm~~ to about 100 µm~~100 nm~~; and
wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.
2. (Original) The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.
3. (Original) The orally disintegrating tablet of claim 2, wherein the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.
4. (Currently Amended) The orally disintegrating tablet of claim 2, wherein said topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, or a pharmaceutically salt or ester thereof.

5. (Currently Amended) The orally disintegrating tablet of claim 4, wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 3 mg.

6. (Currently Amended) The orally disintegrating tablet of claim 4, wherein said topically acting corticosteroid is fluticasone or an ester thereof.

7. (Currently Amended) The orally disintegrating tablet of claim ~~[[5]]~~4, wherein said topically acting corticosteroid is fluticasone propionate.

8. (Original) The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 3 mg in the orally disintegrating tablet.

9. (Original) The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 1.5 mg in the orally disintegrating tablet.

10. (Currently Amended) The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size of ranging from about ~~10- μ m~~ 100 nm to about ~~100- μ m~~ 10 μ m.

11. (Currently Amended) The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size ranging from about 100 nm~~4- μ m~~ to about ~~100- μ m~~ 4 μ m.

12. (Original) The orally disintegrating tablet of claim 1, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.

13. (Original) The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.

14. (Original) The orally disintegrating tablet of claim 12, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.

15. (Original) The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

16. (Original) The orally disintegrating tablet of claim 12, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .

17. (Original) The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is present at an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.

18. (Original) The orally disintegrating tablet of claim 1, wherein the total weight of the tablet is in the range of from about 300 to about 900 mg.

19. (Currently Amended) An orally disintegrating tablet comprising:
a. fluticasone propionate adsorbed onto microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, amorphous magnesium aluminum silicate, or combinations thereof; and
b. at least one disintegrant,
wherein:

the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg, and

the fluticasone propionate has a mean particle size ranging from about 100 nm~~10 µm~~ to about 10 µm~~100 nm~~; and

wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration test.

20. (Original) The orally disintegrating tablet of claim 19, wherein the microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate, or a combination thereof, is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.

21. (Original) The orally disintegrating tablet of claim 19, comprising silicified microcrystalline cellulose in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.

22. (Original) The orally disintegrating tablet of claim 22, wherein fluticasone propionate has a mean particle size of about 4 µm or less.

23. (Original) The orally disintegrating tablet of claim 21, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.

24. (Original) The orally disintegrating tablet of claim 20, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.

25. (Original) The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.

26. (Original) The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

27. (Original) The orally disintegrating tablet of claim 24, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .

28. (Currently Amended) The orally disintegrating tablet of claim 19, wherein the silicified microcrystalline cellulose is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet, fluticasone propionate is present in an amount ranging from about 1 mg to about 3 mg, and fluticasone propionate has a mean particle size of ranging from about 4 μm to about 100 μm ~~of ranging from about 4 μm to about 100 μm~~ to about 100 μm to about 4 μm .

29. (Withdrawn) A method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1.

30. (Withdrawn) A method of preparing the orally disintegrating tablet of claim 1, comprising the steps of:

- (a) micronizing the corticosteroid;
- (b) preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is microcrystalline cellulose, silicified microcrystalline

cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate;

(c) preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener;

(d) preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c);

(e) compressing the blend of step (d) to form a tablet.

REMARKS

Upon entry to these amendments, claims 1-30 are pending in the present application. Claims 29-30 were previously withdrawn from consideration. In this response, claims 1, 4-7, 10, 11, 19, and 28 have been amended, without prejudice or disclaimer. Specifically, claims 1, 10, 11, 19 and 28 were amended to address the claim objection, and claims 1 and 4-7 were amended for clarity and consistency. Support for the claim amendments can be found throughout the application as originally filed. No new matter is added.

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

Applicant-Initiated Interview Summary

Applicant thanks Examiner Justice for the courtesy extended to Applicant and Applicant's representative, Jon Cousin, on September 2, 2021. During the interview, Applicant's representative discussed the rejection and cited prior art. As noted in the Examiner's Interview Summary, Ramalho is limited to formulations for systemic drugs, and does not provide guidance on formulating orally disintegrating tablets of topically active corticosteroids in order to improve exposure of the topically active drug to the esophagus. Applicant thanks the Examiner for acknowledging some of the differences between the presently claimed invention and Ramalho.

Applicant disagrees that Milburn teaches general advantages of micronized drug particles. Miburn is directed to ophthalmic compositions and provides no guidance on how to extrapolate ophthalmic compositions to oral compositions, let alone oral compositions with topically active drugs.

Claim Objections

Claims 1, 10, 11, 19 and 28 are objected to because of informalities. Without acquiescing and solely to expedite prosecution, Applicant has amended the claims such that the particle size ranges are arranged from lowest to highest. Applicant respectfully requests that the objection of claims 1, 10, 11, 19 and 28 be withdrawn.

Claim Rejections – 35 USC §112

Claim 22 is rejected under 35 U.S.C. 112 as allegedly being indefinite. Claim 22 has been amended to depend on claim 19. Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – 35 USC §103

Claims 1-12, 14-24, and 26-28 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over combinations of U.S. Publication No. 2006/0051414 A1 (hereinafter “Ramalho”) in view of U.S. Publication No. 2011/0081411 A1 (hereinafter “Perrett”), U.S. Publication No. 2006/0292099 A1 (hereinafter “Milburn”), and U.S. Publication No. 2004/0265375 A1 (hereinafter “Platteeuw”).

Independent claims 1 and 19 are directed to, *inter alia*, an orally disintegrating tablet (ODT) comprising a **topically acting** corticosteroid (e.g., fluticasone propionate) adsorbed onto a pharmaceutically acceptable carrier. As discussed in Applicant’s Specification, Applicant discovered that adsorbing the **topically acting** corticosteroid onto the pharmaceutically acceptable carrier **enhances the probability that corticosteroid is exposed to inflamed esophageal tissue** (*see, e.g.*, Specification, ¶[0055]). Thus, the claimed ODT is used to topically (not systemically) treat inflammatory diseases of the esophagus, such as eosinophilic esophagitis, because the formulation exposes the topically acting corticosteroid to the inflamed esophageal tissue. When the corticosteroid is not adsorbed to a pharmaceutically acceptable carrier, agglomerated particles are formed and the topically acting corticosteroid is not readily exposed to the inflamed tissue.

Ramalho is directed to an ODT containing a systemically active drug that “exerts its gastrokinetic action by acting on the peripheral dopamine₂ receptors in the stomach” (i.e., not the esophagus). (Ramalho, ¶[0004]). While Ramalho teaches a “[p]re-mixture of domperidone and a half part of disintegrating agent (i.e., microcrystalline cellulose) and calibration 0.7 mm diameter mesh size sieve,” domperidone was not micronized and there’s no indication that the domperidone was adsorbed to the disintegrating agent (which the Examiner equates with the pharmaceutically acceptable carrier), as required by the pending claims. Moreover, because

Ramalho is directed to an ODT containing a systemically active drug, Ramalho does not teach or suggest an ODT in order to enhance exposure of a **topically active drug** (such as a corticosteroid) to inflamed esophageal tissue.

Perrett, Milburn, and Platteeuw do not cure the deficiencies, because these references provide no guidance on formulating an ODT in order to enhance exposure of a topically active drug (such as a corticosteroid) to inflamed **esophageal tissue**. Therefore, these references do not cure the deficiencies in Ramalho.

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

Double Patenting

Claims 1-28 are rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-40 of U.S. Patent No. 10,471,071 B2. Filed herewith is a terminal disclaimer over U.S. Patent No. 10,471,071, thereby obviating the rejection.

CONCLUSION

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

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283 **referencing Docket No.** ELLO-144/04US 342083-3254.

Dated: September 9, 2021

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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Jonathan M. Cousin
Reg. No. 66,418
Matthew Scheideman
Reg. No. 76,605

Electronic Acknowledgement Receipt

EFS ID:	43720446
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	09-SEP-2021
Filing Date:	24-MAR-2021
Time Stamp:	15:16:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ELLO-144-04US_Track_1_Amen dment.pdf	226265 1f93f5f6802114381a58ed09416117773107 8068	yes	11

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Amendment/Req. Reconsideration-After Non-Final Reject	1	1	
Claims	2	7	
Applicant Arguments/Remarks Made in an Amendment	8	11	

Warnings:

Information:

Total Files Size (in bytes):	226265
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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/211,119		Filing Date 03/24/2021		☒ To be Mailed			
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)	(Column 2)								
FOR		NUMBER FILED	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	09/09/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x \$100 =		0		
	Independent (37 CFR 1.16(h))	* 2	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		0		
		(Column 1)	(Column 2)		(Column 3)						
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=		x \$0 =				
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x \$0 =				
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
							TOTAL ADD'L FEE				
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.							LIE				
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".							/ANGELA D JOHNSON/				
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921
58249	7590	09/08/2021	EXAMINER	
COOLEY LLP			JUSTICE, GINA CHIEUN YU	
ATTN: IP Docketing Department			ART UNIT	
1299 Pennsylvania Avenue, NW			PAPER NUMBER	
Suite 700			1617	
Washington, DC 20004			NOTIFICATION DATE	
			DELIVERY MODE	
			09/08/2021	
			ELECTRONIC	

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/211,119	Applicant(s) GOSSELIN et al.		
	Examiner GINA JUSTICE	Art Unit 1617	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
GINA JUSTICE	Primary Examiner	Telephonic
JONATHAN COUSIN	Attorney of Record	

Date of Interview: 02 September 2021

Issues Discussed:

35 U.S.C. 103

Applicant's representative argued that Ramalho is limited to teach tablets for systemically active drug rather than a topically active drug, and Milburn fails to teach treating esophageal tissue. Examiner indicated that the Milburn teachings on advantages of micronized drug particles may have a broad application, but agreed with applicant's representative that Ramalho may not necessarily suggest premixing drugs with excipients to form an intimate mixture for topically active drugs. Applicant's representative indicated that a response with arguments will be filed in due time.

☒ Attachment

/GINA C JUSTICE/ Primary Examiner, Art Unit 1617	
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

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

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

Agenda for Telephonic Interview of Appl. Nos. 17/211,119
(Attorney Docket Nos. ELLO-144/04US)
September 2, 2021 at 10:00 AM ET

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

- I. PTO Representative – Examiner Justice
- II. Applicant’s Representatives – Jonathan Cousin (Reg. No. 66,418), Cooley LLP
- III. Pending Claims:
 - a. Independent claims 1 and 19 are directed to, *inter alia*, an orally disintegrating tablet in which a **topically acting** corticosteroid (e.g., fluticasone propionate) is adsorbed onto a pharmaceutically carrier, and the topically acting corticosteroid (e.g., fluticasone propionate) has a specific diameter.
 - b. As discussed in Applicant’s response filed on October 6, 2017, Applicant discovered that adsorbing the corticosteroid onto the pharmaceutically acceptable carrier **enhance the probability that corticosteroid is exposed to inflamed esophageal tissue** (*see, e.g.*, the as-filed application, [0055]) .
- IV. Discussion Points:
 - a. **Claim Objection.** Applicant believes the claim scope is clear since the upper and lower limits are stated in the claim, and a skilled artisan would understand the meets and bounds of the claims. However, Applicant can amend the claims in order to expedite prosecution.
 - b. **112(b) Rejection.** Applicant will amend claim 22 to depend on claim 19.
 - c. **103 Rejection**
 - i. Ramalho is directed to an orally disintegrating tablet containing a systemically active drug that “exerts its gastrokinetic action by acting on the peripheral dopamine₂ receptors in the stomach” (i.e., not the esophagus). Ramalho does not provide any guidance on enhancing exposure of a **topically active drug** (such as a corticosteroid) to inflamed esophageal tissue.
 - ii. Milburn is directed to ophthalmic treatments and compositions. Milburn does not provide any guidance on enhancing exposure of a topically active drug (such as a corticosteroid) to inflamed **esophageal tissue**.

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet 1 of 21

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	3,705,172	12-05-1972	Buchel, et al.	
	2.	3,929,768	12-30-1975	Brattsand, et al.	
	3.	4,080,448	03-21-1978	Mirsky	
	4.	4,335,121	06-15-1982	Phillipps, et al.	
	5.	4,363,806	12-14-1982	Bergstrom, et al.	
	6.	4,472,393	09-18-1984	Shapiro	
	7.	4,985,418	01-15-1991	Richards	
	8.	5,135,740	08-04-1992	Katz & Cheng	
	9.	5,278,175	01-11-1994	Ray, et al.	
	10.	5,403,893	04-04-1995	Tanaka, et al.	
	11.	5,446,070	08-29-1995	Mantelle, J.A.	
	12.	5,482,934	01-09-1996	Calatyud, et al.	
	13.	5,776,433	07-07-1998	Tzou, et al.	
	14.	6,171,617	01-09-2001	Gruber	
	15.	6,316,027	11-13-2001	Johnson, et al.	
	16.	6,596,298	07-22-2003	Leung, et al.	
	17.	6,596,311	07-22-2003	Dobetti	
	18.	6,740,332	05-25-2004	Zyck, et al.	
	19.	7,033,606	04-25-2006	Besse, et al.	
	20.	8,580,300	11-12-2013	Wilhelm, et al.	
	21.	8,679,545	03-25-2014	Dohil, et al.	
	22.	8,771,729	07-08-2014	Perrett, et al.	
	23.	9,387,167	07-12-2016	Perrett, et al.	
	24.	9,486,407	11-08-2016	Perrett, et al.	
	25.	9,782,347	10-10-2017	Dohil, et al.	
	26.	9,849,084	12-26-2017	Perrett, et al.	
	27.	9,867,780	01-16-2016	Greinwald, et al.	
	28.	10,105,315	10-23-2018	Meltzer, et al.	

Examiner Signature	Date Considered
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*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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Dr. Falk Pharma Ex. 1056
IPR Petition - USP 11,260,061

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	2	of	21	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/04US 342083-3254

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	29.	10,176,301	01-08-2019	Hill, et al.	
	30.	10,272,037	04-30-2019	Dohil, et al.	
	31.	10,632,069	04-28-2020	Perrett, et al.	
	32.	11,026,887	06-08-2021	Meltzer, et al.	
	33.	2001/0006625	07-05-2001	Bohn et al.	
	34.	2001/0014340	08-16-2001	Ohta, et al.	
	35.	2003/0050312	03-13-2003	Hjorth, et al.	
	36.	2003/0054036	03-20-2003	Liggins, et al.	
	37.	2003/0099701	05-29-2003	Takaishi, et al.	
	38.	2003/0215500	11-20-2003	Ohta, et al.	
	39.	2004/0053902	03-18-2004	Smith, Steven C.	
	40.	2004/0009212	01-15-2004	Tsai, Tsui-min	
	41.	2004/0106663	06-03-2004	Talley, et al.	
	42.	2004/0228919	11-18-2004	Houghton, et al.	
	43.	2005/0009848	01-13-2005	Brantl	
	44.	2005/0112188	05-26-2005	Elias	
	45.	2005/0232988	10-20-2005	Venkatesh, et al.	
	46.	2007/0020330	01-25-2007	Dang, et al.	
	47.	2007/0059361	03-15-2007	Rawas-Qalaji, et al.	
	48.	2007/0111978	05-17-2007	Dohil, et al.	
	49.	2009/0074862	03-19-2009	Schioppi, et al.	
	50.	2009/0123550	05-14-2009	Phillips, et al.	
	51.	2009/0123551	05-14-2009	Phillips, et al.	
	52.	2009/0131386	05-21-2009	Phillips	
	53.	2009/0149433	06-11-2009	Phillips	
	54.	2009/0155360	06-18-2009	Venkatesh, et al.	
	55.	2009/0169620	07-02-2009	Venkatesh, et al.	
	56.	2009/0181099	07-16-2009	Dohil, et al.	
	57.	2009/0191275	07-30-2009	Dohil, et al.	

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

Sheet

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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	58.	2010/0034894	02-11-2010	Szymczak, et al.	
	59.	2010/0215753	08-26-2010	Sherwood, et al.	
	60.	2010/0216754	08-26-2010	Phillips, et al.	
	61.	2011/0097401	04-28-2011	Phillips, et al.	
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	68.	2014/0328861	11-06-2014	Payton, et al.	
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	73.	2018/0133145	05-17-2018	Meltzer, et al.	
	74.	2017/0071855	03-16-2017	Perrett, et al.	
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	82.	2020/0368147	11-26-2020	Meltzer, et al.	
	83.	2020/0381097	12-03-2020	Meltzer, et al.	

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Sheet	4	of	21	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/04US 342083-3254

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	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
		Country Code ³ "Number" "Kind Code ⁵ (if known)				
	84.	CA 2430481 A1	06-13-2002	SAMYANG CORPORATION		
	85.	CA 2704946 A1	05-22-2019	MERITAGE PHARMA, INC.		
	86.	CA 2776164 A1	04-07-2011	APTALIS PHARMATECH, INC.		
	87.	CL 3827-2008	12-21-2007	EURAND, INC.		
	88.	DE 202010018594 U1 (and English Abstract)	02-16-2018	ADARE PHARMACEUTICALS INC.		
	89.	DE 2323215 A1	11-29-1973	AP Bofors		
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	95.	EP 1323417 A1	07-02-2003	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
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	98.	EP 2214679 B1	03-27-2019	Meritage Pharma, Inc.		
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	103.	JP H11-511162 A (English Abstract)	09-28-1999			
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	105.	JP 2001-524094 A	11-27-2001			

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Sheet	5	of	21	Application Number	17/211,119
				Filing Date	March 24, 2021
				First Named Inventor	Michael A. GOSSELIN
				Art Unit	1617
				Examiner Name	Gina Chieun Yu JUSTICE
				Attorney Docket Number	ELLO-144/04US 342083-3254

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		Country Code ³ "Number" Kind Code ⁵ (if known)				
	106.	JP 2002-521321 A	07-16-2002			
	107.	JP 2003-292459 A (with English Abstract, and English translation)	10-15-2003	PHARMA POWER BIOTEC CO LTD		
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	114.	KR 10-2012-0104975 (and English Abstract)	09-24-2012	APTALIS PHARMATECH INC.		
	115.	WO 1997/006786 A1	02-27-1997	R.P. SCHERER LIMITED		
	116.	WO 1998/047535 A1	10-29-1998	WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED		
	117.	WO 2000/064450 A1	11-02-2000	LEO PHARM PROD LTD.		
	118.	WO 2003/093344 A1	11-13-2003	JANSSSEN PHARMACEUTICAL N.V.		
	119.	WO 2001/019342 A2	03-22-2001	GLAXO GROUP LIMITED		
	120.	WO 2003/039520 A1 (with English Abstract)	05-18-2003	ETHYPHARM		
	121.	WO 2004/064810 A1 (with English Abstract)	08-05-2004	NIPPON SHINYAKU CO., LTD.		
	122.	WO 2002/092057 A1 (with English Abstract)	11-21-2002	YAMANOUCHI PHARMACEUTICAL CO., LTD.		
	123.	WO 2004/067004 A1	08-12-2004	OREXO AB		

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				Filing Date	March 24, 2021
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		Country Code ³ "Number" Kind Code ⁵ (if known)				
	124.	WO 2004/069225 A1	08-19-2004	ELAN PHARMA INTERNATIONAL LTD.		
	125.	WO 2004/091585 A1	10-28-2004	SYNTHON B.V.		
	126.	WO 2005/087194 A1	09-22-2005	SCHERING AKTIENGESELLSCHAFT		
	127.	WO 2007/071179 A1 (with English Abstract)	06-28-2007	QUANTUM HI-TECH (BEIJING) RESEARCH INSTITUTE		
	128.	WO 2007/074472 A2	07-05-2007	JUBILANT ORGANOSYS LIMITED		
	129.	WO 2008/098634 A1	08-21-2008	POLICHEM S.A.		
	130.	JP 2011-503073 A (and English Abstract)	01-27-2011			
	131.	WO 2009/064457 A2	05-22-2009	MERITAGE PHARMA, INC.		
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	133.	WO 2009/064819 A2	05-22-2009	MERITAGE PHARMA, INC.		
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	135.	WO 2009/098595 A2	08-13-2009	FOAMIX LTD.		
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	137.	WO 2010/144865 A2	12-16-2010	MERITAGE PHARMA, INC.		
	138.	WO 2011/041509 A1	04-07-2011	EURAND, INC.		
	139.	WO 2015/034678 A2	03-12-2015	APTALIS PHARMATECH, INC.		
	140.	WO 2015/035114 A1	03-12-2015	APTALIS PHARMATECH, INC.		
	141.	WO 2018/035393 A1	02-22-2018	ADARE PHARMACEUTICALS, INC.		
	142.	WO 2019/165138 A1	08-29-2019	ADARE DEVELOPMENT I, L.P.		
	143.	ZA 6805392	06-04-1969	Farbenfabriken Bayer AG		

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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
	144.	German Utility Model Cancellation Action filed by Dr. Falk Pharma GmbH on March 1, 2019 with the German Patent Office, in connection with DE Patent No. 202010018594 U1 in the name of Adare Pharmaceuticals, Inc., and English translation, 21 pages.	
	145.	[Author Unknown] Definition of sustained-release (downloaded from Merriam-Webster online at https://www.merriam-webster.com/dictionary/sustainedrelease#medicalDictionary); accessed 7/31/2019, 1 page.	
	146.	[Author Unknown] Jorveza® package leaflet (downloaded from the European Medicines Agency at www.ema.europa.eu/en/medicines/human/EPAR/jorveza#product-informationsection); accessed 8/1/2019, 8 pages.	
	147.	[Author Unknown] Jorveza® package leaflet, Jorveza 1mg orodispersible tablets, tablets package leaflet (PIL) for United Kingdom-Ireland, Mat-No: 1147370 (Losan Pharma), Dated March 15, 2018, Date Code Falk: GB-IE/03.18, 2 pages.	
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	156.	BOWER et al., "Manifestations and Treatment of Laryngeal Sarcoidosis". Am. Rev. Respir. Dis., 122(2): 325-332 (1980).	
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	158.	BRUNNER, et al., "Gastrointestinal transit, release and plasma pharmacokinetics of a new oral budesonide formulation." British Journal of Clinical Pharmacology (2005); 61(1): 31-38.	
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	160.	CAMPIERIA et al., "Oral budesonide is as effective as oral prednisolone in active Crohn's disease," Gut, 41: 209-214 (1997).	
	161.	JORVEZA (budesonide) Update by the Committee for Medicinal Products for Human Use (CHMP), Summary of opinion ¹ (post authorisation) dated March 26, 2020, European Medicines Agency, 1 page.	
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	163.	DILGER, K., et al. "Active eosinophilic esophagitis is associated with impaired elimination of budesonide by cytochrome P450 3A enzymes." Digestion (2013); 87(2):110-117. Epub 2013 Jan 25.	
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	166.	European Application No. EP 14184844.0, Extended European Search Report dated February 9, 2015, 7 pages.	
	167.	European Application No. EP 14842811.3, Extended European Search Report dated March 23, 2017, 6 pages.	
	168.	European Application No. EP 18178891.0, Extended European Search Report dated August 13, 2018, 3 pages.	

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Application Number	17/211,119
Filing Date	March 24, 2021
First Named Inventor	Michael A. GOSSELIN
Art Unit	1617
Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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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
	169.	European Application No. EP 19189185.2, Extended European Search Report dated August 29, 2019, 9 pages.	
	170.	European Application No. EP 17842162.4, Extended European Search Report dated April 1, 2020, 8 pages.	
	171.	European Application No. EP 19207287.4, Extended European Search Report dated April 6, 2020, 9 pages.	
	172.	FALCOZ, et al., "Bioavailability of Orally Administered Micronised Fluticasone Propionate." Clinical Pharmacokinetics (2000); 39 Suppl. 1: 9-15.	
	173.	Forum of the National Formulary of Japan, compilation, Drugs in Japan, 2009 edition, published 2008, p. 2161-2165 (and English translation/summary of pertinent paragraphs), 8 pages.	
	174.	Georgia Application No. AP 2010012674, Search Report (with English translation) dated November 28, 2013, 11 pages.	
	175.	HAM, et al., "Quantitation of esophageal transit by means of ^{81m} Kr." European Journal of Nuclear Medicine (1984); 9: 362-365.	
	176.	International Preliminary Report on Patentability for International Application No. PCT/US2017/047474, dated February 19, 2019, 8 pages.	
	177.	International Search Report and Written Opinion for International Application No. PCT/US2017/047474, mailed December 26, 2017, 11 pages.	
	178.	KHAN and ORENSTEIN, "Eosinophilic Gastroenteritis: Epidemiology, Diagnosis and Management." Paediatr Drugs. (2002); 4(9): 563-570.	
	179.	KRISHNA, et al., "Treatment of Eosinophilic Esophagitis Is Oral Viscous Budesonide Superior to Swallowed Fluticasone Spray?" Gastroenterol Hepatol (2011 Jan); 7(1): 55-59.	
	180.	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).	
	181.	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.	

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	182.	LI, Xiaowei, et al., "Advances in Injectable Thermosensitive Polymers". Polymer Bulletin, No. 3, pages 109-115, June 30, 2015 (with English Abstract), 7 pages.	
	183.	LIPKA, et al., "The natural history of steroid-naïve eosinophilic esophagitis in adults treated with endoscopic dilation and proton pump inhibitor therapy over a mean duration of nearly 14 years." Gastrointest Endosc. (2014); 80(4): 592-598.	
	184.	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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	186.	Malaysian Application No. PI 2012001434, Search Report dated January 29, 2016, 1 page.	
	187.	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).	
	188.	Merck Index, "Budesonide," 14th Edition, p. 240 (2006)	
	189.	Merck Index, "Ciclesonide," 14th Edition, p. 376 (2006)	
	190.	Merck Index, "Clotrimazole," 14th Edition, p. 407 (2006)	
	191.	Merck Index, "Mometasone Furoate," 14th Edition, pp. 1077-1078 (2006)	
	192.	Merck Index, "Voriconazole," 14th Edition, p. 1728 (2006)	
	193.	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.	

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	194.	Novopulmon E Novolizer®, Instructions for the medical use of the medicament, [Instrukciya po medicinskomu primeneniyu preparata Novopulmon E Novolizer (international nonproprietary name: budesonide), registracionniy nomer N LS-002405-231211, 23.12.2011], MEDA Manufacturing, GmbH Registration No. LS-002405, Date of Registration December 23, 2011 (with English summary of relevant portions), 9 pages.	
	195.	DELLON, et al., "Efficacy of Budesonide vs Fluticasone for Initial Treatment of Eosinophilic Esophagitis in a Randomized Controlled Trial". Gastroenterology (2019); 157: 65-73.	
	196.	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.	
	197.	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.	
	198.	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.	
	199.	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.	
	200.	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.	
	201.	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.	
	202.	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.	
	203.	von ARNIM and MALFERTHEINER, "Eosinophilic Esophagitis – Treatment of Eosinophilic Esophagitis with Drugs: Corticosteroids", Digestive Diseases (2014); 32: 126-129.	
	204.	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.	

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	205.	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.	
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	207.	MORETON, R. Christian, "Disintegrants in Tableting". In book: Pharmaceutical Dosage Forms: Tablets, Vol. 2, Herausgeber Augsburg & Hoag, CRC Press, Taylor and Francis Group (2008); Ch. 6, pgs. 217-249, 33 pages.	
	208.	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.	
	209.	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.	
	210.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; Written Submissions of the Patentee in Preparation for Oral Proceedings on March 8, 2021, dated January 8, 2021, with Auxiliary Requests 1-14, 52 pages.	
	211.	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.	
	212.	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.	
	213.	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.	
	214.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), 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.	
	215.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO's Communication re oral proceedings, dated August 5, 2020, 1 page.	
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	216.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019; EPO Communication dated July 23, 2020, with Adare's Written Submissions in Preparation for Oral Proceedings, Auxiliary Requests 1-7 (clean and marked-up), and supporting evidence, as filed July 17, 2020, 126 pages.	
	217.	Declaration of Stephen Perrett, MBA, Ph.D. dated July 16, 2020, 6 pages.	
	218.	"NUROFEN" tablet package insert, 200 MG Tablets and Capsules, Date of revision: February 2018, Reference ID 3039860, and English version, 2 pages.	
	219.	Dolo-Dobendan®, 1.4 mg/10 mg lozenges package insert, Reference ID 3030657, Revised: January 2015, with English translation, 7 pages.	
	220.	PELLE, et al., "Using defined daily doses to study the use of antibacterials in UK hospitals". Hosp Pharm (2006); 13: 133-136.	
	221.	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.	
	222.	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.	
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	224.	LIACOURAS, et al., "Primary Eosinophilic Esophagitis in Children: Successful Treatment with Oral Corticosteroids". Journal of Pediatric Gastroenterology & Nutrition (1998); 26(4): 380-385.	
	225.	FURUTA, et al., "Review article: the pathogenesis and management of eosinophilic oesophagitis". Alimentary Pharmacology & Therapeutics (2006); 24: 172-182.	
	226.	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.	
	227.	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.	

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	228.	FURUTA, Glenn T., "Eosinophils in the Esophagus: Acid is Not the Only Cause". Journal of Pediatric Gastroenterology & Nutrition (April 1998); 26(4): 468-471.	
	229.	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.	
	230.	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.	
	231.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, Adare - Letter to EPO re Oral Proceedings dated July 17, 2020, 5 pages.	
	232.	Opposition Proceedings in European Patent No. EP 2482822 (Appln. No. 10821232.5), 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.	
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	234.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), 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.	
	235.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), 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.	
	236.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), filed by Dr. Falk Pharma GmbH on March 1, 2019, EPO Communication dated November 5, 2019, forwarding Letter from Opponent dated October 29, 2019, 247 pages.	
	237.	Opposition Proceedings in European Patent No. 2482822 (Appln. No. 10821232.5), 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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	240.	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.	
	241.	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.	
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	245.	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.	
	246.	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.	
	247.	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.	
	248.	PCT Application No. PCT/US2010/050860, International Preliminary Report on Patentability dated April 3, 2012.	
	249.	PCT Application No. PCT/US2010/050860, International Search Report dated February 10, 2011.	

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Examiner Name	Gina Chieun Yu JUSTICE
Attorney Docket Number	ELLO-144/04US 342083-3254

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	288.	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.	
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	294.	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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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Patent Application Fee Transmittal

Application Number:	17211119			
Filing Date:	24-Mar-2021			
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS			
First Named Inventor/Applicant Name:	Michael A. GOSSELIN			
Filer:	Jonathan M. Cousin/Sandra Laramore			
Attorney Docket Number:	ELLO-144/04US 342083-3254			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	43373969
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	29-JUL-2021
Filing Date:	24-MAR-2021
Time Stamp:	11:57:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$260
RAM confirmation Number	E20217SB57402473
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ELLO-144-04US-IDS.pdf	146886	no	5
			92fb5afa802064086d3893526400fa6deb89a403		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ELLO-144-04US-SB08.pdf	402124	no	21
			5171723c021a405450886b8968b61ee55de72637		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	38219	no	2
			b9eccca42bae4e57d80fd85554f4e3ef5466105b5		
Warnings:					
Information:					
Total Files Size (in bytes):			587229		
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. <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.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Michael A. GOSSELIN	Confirmation No.:	9921
Application No.:	17/211,119	Group Art Unit:	1617
Filed:	March 24, 2021	Examiner:	Gina Chieun Yu JUSTICE
For:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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

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

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

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

[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 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in **prior Applications Serial Nos. 16/578,568 and/or 14/917,125 (U.S. Patent No. 10,471,071)**, to which the above-identified application claims priority under 35 U.S.C. §120.

- ☒ No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- ☐ Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) _____ cited 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. _____.

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

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☐ before the mailing date of a first Office action on the merits; or
- ☐ before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

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

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

- ☒ Fee under 37 C.F.R. §1.17(p) in the amount of \$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).

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

Cooley Docket No.	Application No.	Application Date	Publication No.	Publication Date	Registration No.	Registration Date	Case Status
ELLO-144/02US	14/917,125	9/5/2014	US 2016-0206627 A1	7/21/2016	10,471,071	11/12/2019	Registered
ELLO-144/03US	16/578,568	9/5/2014	US 2020-0016171 A1	1/16/2020			Allowed

Remarks

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

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

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-144/04US 342083-3254.

Dated: July 29, 2021

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

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

By: /Jonathan M. Cousin/
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254

CONFIRMATION NO. 9921

PUBLICATION NOTICE



OC000000126826298

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

Title:CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

Publication No.US-2021-0205328-A1

Publication Date:07/08/2021

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 Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921
58249	7590	06/10/2021	EXAMINER	
COOLEY LLP			JUSTICE, GINA CHIEUN YU	
ATTN: IP Docketing Department			ART UNIT	
1299 Pennsylvania Avenue, NW			PAPER NUMBER	
Suite 700			1617	
Washington, DC 20004			NOTIFICATION DATE	
			DELIVERY MODE	
			06/10/2021	
			ELECTRONIC	

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

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

I. Claims 1-28, drawn to an orally disintegrating tablet comprising: a. a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and b. at least one disintegrant; wherein the corticosteroid is present in an amount ranging from about 0.5 mg to about 10 mg, and the corticosteroid has a mean particle size of ranging from about 100 μ m to about 100 nm; and wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time., classified in CPC A61K31/56 {Medicinal preparations containing steroids}.

II. Claim 29, drawn to a method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1, classified in CPC A61P 1/04 {Drugs for esophagitis}.

III. Claim 30, drawn to a method of preparing the orally disintegrating tablet of claim 1, comprising the steps of: (a) micronizing the corticosteroid; (b) preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate; (c) preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener; (d) preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c); (e) compressing the blend of step (d) to form a tablet., classified in CPC A61J 3/10 {Methods specially adapted for bringing pharmaceutical products into compressed tablets}.

The inventions are independent or distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, a method of treating eosinophilic esophagitis can be practiced with materially different products known in the art.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, an orally disintegrable tablet as defined in Invention I can be made with a process materially different from the process of Invention III which requires specific components not recited in claim 1.

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

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above

and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

- the inventions have acquired a separate status in the art in view of their different classification
- the inventions have acquired a separate status in the art due to their recognized divergent subject matter
- the inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).

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

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

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Telephone Election

During a telephone conversation with Jonathan Cousin on May 25, 2021 a provisional election was made to prosecute the invention of **Group I, claims 1-28**. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29 and 30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Joint Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must

include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

Claims 1, 10, 11, 19 and 28 are objected to because of the following informalities: The claims recite particle size ranges from the highest length to the lowest, which is not the typical way of expressing a numerical range. For example, in

claim 1, the range “from about 100 μm to about 100 nm” should be written “from about 100 nm to about 100 μm ”. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

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.

Claim 22 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 22 depends on itself. For prior art consideration only, it is assumed that claim 22 depends on claim 19 for the purpose of prior art consideration for the sake of compact prosecution.

An appropriate correction is required to overcome this rejection.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of

rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1, 2, 4-12, 14-20, 22-24, 26 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over Ramalho et al. (US 20060051414 A1, published on March 9, 2006) (“Ramalho” hereunder) in view of Perrett et al. (US 20110081411 A1, published April 7, 2011)(“Perrett” hereunder) and Milburn et al. (US 20060292099 A1, published December 28, 2006) (“Milburn” hereunder).

Ramalho discloses fast water-dispersible tablets, or orally disintegrating tablets (ODT), containing domperidone “premixed or associated with” with a half part of a

disintegrating agent (i.e., microcrystalline cellulose); due to the intimate contacts between the drug and the excipient, it is viewed that this pre-blending results in the active agent adsorbed onto the disintegrating agent. See [0034]; instant claims 1a, 2 and 19a. The reference teaches that rapidly dispersing microgranules including mannitol and starch gum (auxiliary granulate) as well as disintegrating agents are used. See [0048]. See instant claim 1b and 19b. The reference further teaches that prior art composition is able to disperse in water most preferably in 1 minute. See instant claim 1.

Ramalho fails to teach corticosteroid.

Perrett discloses an ODT comprising fluticasone propionate microgranules. See Example 1. The reference teaches that the ODT is used for treating a condition associated with inflammation of the gastrointestinal tract in an individual. The reference also teaches that the corticosteroid crystals can have an average particle size ranging from about 1-50 microns.

Regarding claims 1, it would have been obvious to one of ordinary skill in the art before the filing of the present invention to modify the teachings of Ramalho and substitute the drug with a corticosteroid such as fluticasone propionate as motivated by Perrett. The skilled artisan would have been motivated to do so, as 1) both references are directed to ODTs that rapidly integrate upon contact with moisture; and 2) Perrett teaches that the medical utility of the corticosteroid in such formulation is old and well known. In substituting the active ingredients with another that is commonly formulated in a rapidly integrating tablet, the skilled artisan would have had a reasonable expectation of successfully producing a stable ODT with expected therapeutic results

(i.e., effective in treating inflammation of the gastrointestinal tract of a subject). See also instant claim 4.

In claims 1, 10, 11 and 22, Ramalho teaches that the active drug in the invention is not micronized. However, micronized drug particles in orally disintegrable tablets is well known in the art. For example, Milburn teaches, “a micronized drug form promotes better and more uniform absorption than forms having a larger average size and wider distribution of particle sizes.” See [1172]. There, “micronized” means reducing the average particle size to less than about 30 microns in diameter. See *Id.* Thus, using the corticosteroid crystals of the micronized size as suggested in Parrett for better and more uniform absorption of the drug as motivated by Milburn would have been obvious.

Regarding claims 4-9, Parrett Example 1 teaches a 100 mg orodispersible tablet comprising 4 mg of a corticosteroid. Parrett also teaches that the solid composition according to the invention can contain about 0.5 mg to about 20 mg of the corticosteroid, and particularly discloses subranges and an embodiment comprising 0.25 mg of fluticasone. See Parrett [0040-41].

Regarding claims 12, 14-16, 23, 24, 26 and 27, Parrett teaches rapidly dispersing microgranules comprising one or more sugar alcohols and/or saccharides crospovidone. See [0089]. The average particle size of the microgranules are not more than about 400 microns; the average particle diameter of the sugar/ saccharides is not more than about 30 microns. See *Id.*

Regarding claim 17 and 20, Ramalho teaches that microcrystalline cellulose (pharmaceutically acceptable carrier) is used in an amount ranging from about 10-30 wt % of the total weight of the orally disintegrating tablet. See abstract.

Regarding claim 18, Ramalho teaches that the total weight of the tablet sample is about 260 mg, which overlaps with “about 300 mg” of the present claim. It is viewed that designing the tablet of the size and weight suitable for oral administration would only take ordinary skill in the art.

Regarding claim 19, Ramalho teaches that the disclosed formulation has a disintegration time between 30-55 seconds. See [0101]. The reference teaches that hardness has effects on the disintegration time. See Fig. 1.

Regarding the amount of fluticasone propionate, Parrett teaches that corticosteroids be used at “a sufficiently low dose” and discloses a tablet comprising 4 mg of the active. See [0040, 0041]; Example 1.

Claims 3, 21 and 28 are rejected under 35 U.S.C. 103 as being unpatentable over Ramalho, Perrett and Milburn as applied to claims 1, 2, 4-12, 14-20, 22-24, 26 and 27 as above, and further in view of Platteeuw et al. (US 2004/0265375, published on December 30, 2004) (“Platteeuw” hereunder).

Ramalho and Perrett fail to teach silicified microcrystalline cellulose.

Platteeuw teaches using silicified microcrystalline cellulose in an ODT is well known in the art. The reference teaches that silicified microcrystalline cellulose is

formed by coprocessing with silicon dioxide and has enhanced compressibility properties in wet granulation conditions and an attractive choice as a binder or diluent. See [0011]. The reference teaches that silicified microcrystalline cellulose has been known to provide good tablet strength, friability and higher loading of an active ingredient, and also useful as a stabilizer that improves homogeneity of solids in oral dosage forms. See [0013]. The reference teaches that, when formulated in an ODT, this modified microcrystalline cellulose provides adequate disintegratability (in 30 seconds) and solubility in the oral cavity while also providing sufficient mechanical strength to resist destruction in the course of manufacture, storage, transport and/or use. See [0014]; Examples.

It would have been obvious to one of ordinary skill in the art at the time before the present invention to modify the teachings of Perrett and use silicified microcrystalline cellulose as the disintegrating agent in the Ramalho formulation as motivated by Platteeuw. The skilled artisan would have been motivated to do so, as 1) Perrett teaches that ODTs formulated with the modified microcrystalline cellulose have sufficient durability to withstand handling, shipping and or packing in [0047]; and 2) Platteeuw teaches that silicified microcrystalline cellulose is useful in making an ODT with an improved disintegratability and tablet strength and stability during storage, transport and/or use.

Furthermore, since the reference teaches and suggest that both the silicified microcrystalline cellulose and microcrystalline cellulose are used as a binder, filler and disintegrating agent, substituting one for the other or combining them for the same purposes is prima facie obvious. See MPEP 2144.06. Since Ramalho teaches using

10-30 wt % of microcrystalline cellulose, replacing such with the about the same amount of silicified microcrystalline cellulose or optimizing the concentration thereof would have been well within the skill in the art.

In claim 28, Perrett Example 1 teaches a 100 mg orodispersible tablet comprising 4 mg of a corticosteroid, which is close or overlap with “about 3 mg”. See also Parrett [0040-41]. Regarding the particle size of corticosteroid, using the corticosteroid crystals of the micronized size as suggested in Parrett for better and more uniform absorption of the drug as motivated by Milburn would have been obvious.

Double Patenting

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 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 §§ 706.02(l)(1) - 706.02(l)(3) 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 USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The 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/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-28 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 10471071 B2.

Reference claim 1 is directed to a pharmaceutical composition in the form of an orally disintegrating tablet comprising: a. a topically acting corticosteroid or pharmaceutically acceptable salt, ester, or polymorph adsorbed onto a pharmaceutically acceptable carrier; and b. rapidly dispersing microgranules comprising a sugar alcohol, or a saccharide, or a mixture thereof and at least one disintegrant, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1; wherein the corticosteroid is present in an amount of about 5% or less by weight in the composition. Reference claim 20 and 21 further teaches that the particle size of the corticosteroid is not more than 50 microns or about 10 microns. Reference claim 2 further discloses that the tablet of claim 1 disintegrates within 30 seconds when tested using the USP < 701> method for disintegration time.

Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of the claims disclose orally disintegrating tablets with overlapping limitations.

The pharmaceutically acceptable carriers, the type of corticosteroids, dose thereof, the rapidly dispersing microgranule as described in the present claims are disclosed in the reference claims.

Regarding claim 18, since the corticosteroid is present in the composition of the reference claim 1 at an amount of at most about 5 wt %, and the dose of the drug can be up to 18 mg, the total weight of the tablet can be about 360 mg.

Conclusion

No claims are allowed.

Claims 13 and 25 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA JUSTICE whose telephone number is (571)272-8605. The examiner can normally be reached on M-F 8:30 AM - 5 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, JOHANN RICHTER can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

<i>Notice of References Cited</i>	Application/Control No. 17/211,119		Applicant(s)/Patent Under Reexamination GOSSELIN et al.	
	Examiner GINA JUSTICE		Art Unit 1617	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20110081411-A1	04-2011	Perrett; Stephen	A61P31/12	424/451
*	B	US-20060292099-A1	12-2006	Milburn; Michael	A61K31/724	424/70.1
*	C	US-20060051414-A1	03-2006	Ramalho; Maria Julia Caeiro	A61K9/0095	424/464
*	D	US-20040265375-A1	12-2004	Platteeuw, Johannes J.	A61K9/2009	424/464
*	E	US-10471071-B2	11-2019	Gosselin; Michael A.	A61K9/2009	1/1
	F					
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FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

<i>Search Notes</i> 	Application/Control No. 17/211,119	Applicant(s)/Patent Under Reexamination GOSSELIN et al.
	Examiner GINA JUSTICE	Art Unit 1617

CPC - Searched*		
Symbol	Date	Examiner
A61K9/0056	06/04/2021	GJ

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
WEST, PARENTS, INVENTORS, ASSIGNEE	06/04/2021	GJ

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

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WEST Search History

DATE: Tuesday, June 01, 2021

Hide?	<u>Set Name</u>	<u>Query</u>	<u>Hit Count</u>
		<i>DB=PGPB,USPT,USOC,EPAB,JPAB,DWPI; PLUR=YES; OP=OR</i>	
☐	L14	L13 AND (\$STEROID)	7
☐	L13	L10 NOT (ADARE ELLOI).AS. AND ((MINUTE SECONDS) WITH (DISSOLV\$ DISINTEGR\$))	19
☐	L12	L10 NOT (ADARE ELLOI).AS. AND (MINUTE SECONDS)	21
☐	L11	L10 NOT (ADARE ELLOI).AS.	21
☐	L10	(A61K9/0056).CPC. AND ((MEAN ADJ PARTICLE ADJ SIZE) NEAR10 MICRONIZED) AND TABLET	22
☐	L9	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) NEAR10 MICRONIZED) AND TABLET	152
☐	L8	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) NEAR10 MICRONIZED) AND (A61J3/10).CPC.	3
☐	L7	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) WITH2 MICRONIZED) AND (A61J3/10).CPC.	105
☐	L6	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) WITH5 MICRONIZED) AND (A61J3/10).CPC.	105
☐	L5	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) WITH MICRONIZED) AND (A61J3/10).CPC.	3
☐	L4	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) NEAR10 MICRONIZED) AND (A61J3/10).CPC.	3
☐	L3	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) NEAR10 MICRONIZED)	158
☐	L2	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) NEAR20 MICRON\$)	1099
☐	L1	(A61K9/0056).CPC. AND ((PARTICLE ADJ SIZE) WITH MICRON\$)	1104

END OF SEARCH HISTORY

Bibliographic Data

Application No: 17/211,119

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /GINA C JUSTICE/

Examiner's Signature

Initials

Title:

CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING
TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/24/2021	424	1617	ELLO-144/04US 342083-3254
RULE			

APPLICANTS

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

INVENTORS

Michael A. GOSSELIN, Springboro, OH, UNITED STATES

Jin-Wang LAI, Springboro, OH, UNITED STATES

Gopi M. VENKATESH, Vandalia, OH, UNITED STATES

CONTINUING DATA

This application is a CON of 16578568 09/23/2019

16578568 is a DIV of 14917125 03/07/2016 PAT 10471071

14917125 is a 371 of PCT/US2014/054203 09/05/2014

PCT/US2014/054203 has PRO of 61874450 09/06/2013

FOREIGN APPLICATIONS

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03/31/2021

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Search Results

Terms	Documents
((A61K9/0056)).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) and ((reduc\$ micronis\$ micronize\$) with (active drug) with (particle adj size) with uniform\$)	2

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Prior Art Searches

DB=PGPB,USPT; PLUR=YES; OP=OR

Date

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(A61K9/0056).CPC. AND ((ORALLY rapid\$)
 ADJ (DISINTEGR\$ DISSOL\$)) and ((reduc\$
 micronis\$ micronize\$) with (active drug) with
 (particle adj size) with uniform\$)

2

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Date	L16	micronis\$ micronize\$) near10 (active drug) nears10 (particle adj size) near10 uniform\$)	356	L16	L16	L16
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Date	L14	(A61K9/0056).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) .AB. and (microni\$ near10 (active drug))	58	L14	L14	L14
Date	L13	L12 not l11	12	L13	L13	L13
Date	L12	(A61K9/0056).CPC. AND ((ORALLY rapid\$) ADJ (DISINTEGR\$ DISSOL\$)) .AB. and (micron\$ near5 (active drug))	65	L12	L12	L12
Date	L11	L10	53	L11	L11	L11
Date	L10	L9 and tablet	53	L10	L10	L10
Date	L9	(A61K9/0056).CPC. AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))) .AB. and (micron\$ near5 (active drug))	53	L9	L9	L9
Date	L8	(A61K9/0056).CPC. AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))) .AB. and (micron\$ with (active drug))	92	L8	L8	L8
Date	L7	L6 AND (MICRON\$)	30	L7	L7	L7
Date	L6	(A61K9/0056).CPC. AND (CORE NEAR5 (DRUG ACTIVE) NEAR5 (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))) .AB.	82	L6	L6	L6
Date	L5	(A61K9/0056).CPC. AND (CORE NEAR10 (DRUG ACTIVE) NEAR10 (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))) .AB.	101	L5	L5	L5
Date	L4	(A61K9/0056).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) (RAPIDLY ADJ (DISSOL\$ DISINTEG\$))) .AB.	117	L4	L4	L4
Date	L3	(A61K9/0056).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSOR\$)) AND ((ORALLY ADJ DISINTEGR\$) ODT)	214	L3	L3	L3

Date	<u>L2</u>	(A61K9/0056).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSORS\$)) AND (DISINTEGR\$ ODT)	363	<u>L2</u>	<u>L2</u>	<u>L2</u>
Date	<u>L1</u>	(A61K9/0056).CPC. AND (CORE WITH (DRUG ACTIVE) WITH (COATED ADSORS\$))	417	<u>L1</u>	<u>L1</u>	<u>L1</u>

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**Courtesy Reminder for
Application Serial No: 17/211,119**

Attorney Docket No: ELLO-144/04US
342083-3254

Customer Number: 58249

Date of Electronic Notification: 05/05/2021

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/211,119	03/24/2021	Michael A. GOSSELIN	ELLO-144/04US 342083-3254	9921
58249	7590	05/03/2021	EXAMINER	
COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			05/03/2021	ELECTRONIC

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

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

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<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 17/211,119	Applicant(s) GOSSELIN et al.	
	Examiner CHERYL P GIBSON BAYLOR	Art Unit OPET	AIA (FITF) Status Yes
1. THE REQUEST FILED <u>24 March 2021</u> IS GRANTED . The above-identified application has met the requirements for prioritized examination A. ☒ for an original nonprovisional application (Track I). B. ☐ for an application undergoing continued examination (RCE). 2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs: A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u> ; D. filing a notice of appeal; E. filing a request for suspension of action; F. mailing of a notice of allowance; G. mailing of a final Office action; H. completion of examination as defined in 37 CFR 41.102; or I. abandonment of the application. Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.			
/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET			



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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
17/211,119	03/24/2021	1629	2820	ELLO-144/04US 342083-3254	30	2

CONFIRMATION NO. 9921

FILING RECEIPT



0000000124519113

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

Date Mailed: 04/01/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

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Jin-Wang LAI, Springboro, OH;
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Applicant(s)

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Power of Attorney: The patent practitioners associated with Customer Number 58249

Domestic Priority data as claimed by applicant

This application is a CON of 16/578,568 09/23/2019
which is a DIV of 14/917,125 03/07/2016 PAT 10471071
which is a 371 of PCT/US2014/054203 09/05/2014
which claims benefit of 61/874,450 09/06/2013

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.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/211,119**

Projected Publication Date: 07/08/2021

Non-Publication Request: No

Early Publication Request: No

Title

CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/211,119			
APPLICATION AS FILED - PART I									
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	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), (l), 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(j))	30	minus 20 = *	10			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		
				TOTAL		TOTAL	2820		
* If the difference in column 1 is less than zero, enter "0" in column 2.									
APPLICATION AS AMENDED - PART II									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		x =		
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		x =		
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
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Application Number	TBD (Continuation of U.S. Patent Application No. 16/578,568, filed September 23, 2019)
Filing Date	Concurrent Herewith
First Named Inventor	Michael A. GOSSELIN
Title	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	ELLO-144/04US 342083-3254

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.



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58249

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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)
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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		

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Dr. Falk Pharma Ex. 1056
IPR Petition - USP 11,260,061

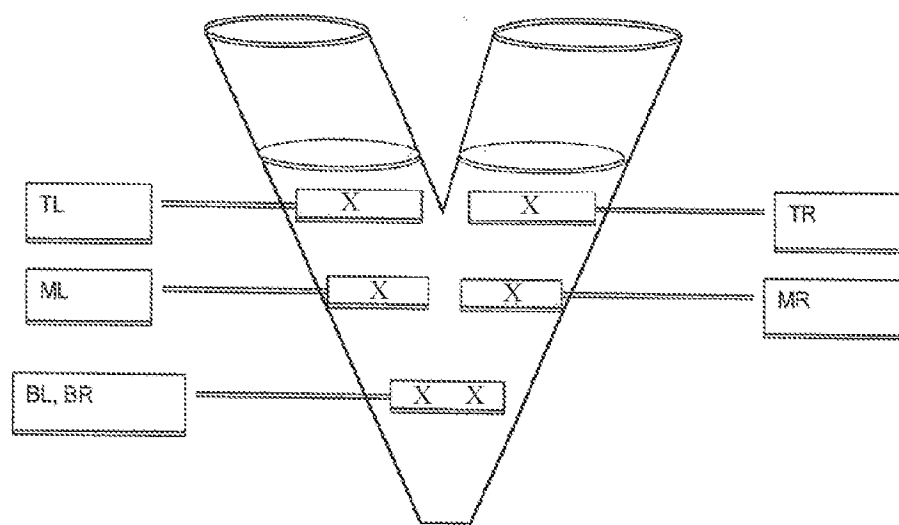


FIG. 1

**CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET
COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS**

CROSS-RELATED APPLICATIONS

[0001] This application is a Continuation of U.S. Patent Application No. 16/578,568, filed September 23, 2019, which is a Divisional of U.S. Patent Application No. 14/917,125, filed March 7, 2016, which is the U.S. National Stage of International Patent Application No. PCT/US2014/054203, filed September 5, 2014, which claims the benefit of priority under 35 USC §119(e) of U.S. Provisional Patent Application No. 61/874,450, filed September 6, 2013, disclosures of which are herein incorporated by reference in their entireties for all purposes.

FIELD OF THE INVENTION

[0002] This invention relates to orally administered low dose, topically acting corticosteroid compositions, useful for the treatment of conditions associated with inflammation of the esophagus.

BACKGROUND OF THE INVENTION

[0003] Esophageal inflammation disorders such as eosinophilic esophagitis (EoE) characterized by high levels of eosinophils in the esophagus, as well as basal zonal hyperplasia, are gaining increased recognition in children and adults. Many aspects of the disease remain unclear including its etiology, natural history, and optimal therapy. EoE affects all age groups but most frequently individuals between 20 and 50 years of age. Symptoms of EoE often mimic those of gastroesophageal reflux disease (GERD) and include vomiting, dysphagia, pain and food impaction. The common occurrence regarding misdiagnosis of EoE for GERD often results in delayed treatment in patients with EoE. 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, particularly the inflammatory conditions of the esophagus, *i.e.*, EoE. The disease is painful, leads to difficulty swallowing and predisposes patients to food impaction and other complications. Although systemic treatments with corticosteroids such as prednisolone are effective, they are associated with significant adverse effects such as suppression of the hypothalamo-pituitary—adrenal (HPA) axis as reflected in salivary cortisol

levels, generalized suppression of immune function, and particularly in children, troubling side-effects from long term systemic exposure include growth retardation, which may lead to a reduction in adult height.

[0004] In contrast, twice-daily treatments of EoE include directing steroid medications through a metered dose inhaler (MDI) to the back of the throat such that they are not appreciably inhaled, and instructing the patient to keep the mouth closed during the “puff and swallow” treatment and rinse the 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 candidiasis infection, and swallowing is contraindicated because it may wash drug away from the esophagus. In another study, 50% of fluticasone propionate (FP)-treated patients achieved histologic remission compared with 9% of patients receiving placebo ($P = 0.047$), FP decreased esophageal eosinophil levels, with a more pronounced effect in non-allergic individuals. However, this therapy is particularly problematic for younger children and those with developmental delay, who are unlikely to utilize this puff and swallow technique effectively.

[0005] In another randomized, double blind, placebo controlled trial performed to evaluate the effect of oral 1 mg budesonide viscous solution (0.5-mg respule dissolved along with five 1-g packets of sucralose in 10-15 mL fluid) dosed twice daily vs. placebo in adolescent and adult patients with active EoE for 15 days, the pretreatment and post treatment disease activities were assessed clinically, endoscopically, and histologically. The primary end point was reduced mean numbers of eosinophils in the esophageal epithelium (number per high-power field [hpf] = esophageal eosinophil load). A 15-day course of treatment with budesonide is well tolerated and highly effective in inducing a histologic and clinical remission in adolescent and adult patients with active EoE. A 15-day course of therapy significantly decreased the number of eosinophils in the esophageal epithelium in patients given budesonide (from 68.2 to 5.5 eosinophils/hpf; $P < 0.0001$); but not in the placebo group (from 62.3 to 56.5 eosinophils/hpf; $P = 0.48$). Dysphagia scores significantly improved among patients given budesonide compared with those given placebo (5.61 vs 2.22; $P < 0.0001$). White exudates and red furrows were reversed in patients given budesonide, based on endoscopy examination. This dosage form has not been FDA approved for commercial use, and the oral administration is going to be messy and likely to produce inconsistent results.

[0006] When oral solid dosage forms with a drug load of $\leq 5\%$ by weight are required, the drug is either micronized and co-processed by blending with at least one carrier excipient or granulating in a fluid bed or high shear granulator by spraying preferably a solution of the drug to achieve blend uniformity/homogeneity of the blend and subsequently, content uniformity in the finished dosage units per regulatory requirements (FDA's Draft Guidance for Industry "Powder blend and finished dosage units - stratified in-process dosage unit sampling and assessment" October 2003). Many micronized drugs show a tendency to segregate and form larger particles in the blend in order to reduce their high surface energy, resultant segregation and agglomeration could cause resurfacing of the blend non-uniformity/inhomogeneity issues set out to resolve in the first place. Segregation and agglomeration in the blends containing especially poorly water soluble, low-dose drugs must be avoided not only during powder blending but also until processed into finished dosage forms, capsules or tablets, to achieve and maintain desired blend uniformity/homogeneity and/or to avoid high dissolution variability. Segregation of drug particles, especially in direct compression blends, is equipment and material dependent. It is thus very challenging to achieve acceptable blend homogeneity during direct compression blending of a low-dose drug with suitable pharmaceutically acceptable excipients (*i.e.*, at a drug content of $< 5\%$ by weight in the blend) and maintain the blend homogeneity until processing into finished dosage forms (e.g., tablets or capsules) (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 1985; 11(4): 891-900; Yalkowsky S.H. and Bolton S. Particle size and content uniformity, Pharmaceutical Research, 1990; 7(9): 962-966; Ahmad H. and Shah N. Formulation of low dose medicines-Theory and Practice, *Amer. Pharm. Rev.* 2000; 3 (3): 1-5; Mahmoudi Z. N. et al. The influence of filler in blend uniformity of micronized drugs. Contributed poster, AAPS Annual Meeting (USA) 2010; Mahmoudi Z. N. et al. Effect of drug particle size on blend segregation and content uniformity. Contributed poster, AAPS Annual Meeting (USA) 2011).

[0007] WO2011041509 discloses the preparation of an orally administrable pharmaceutical composition containing a topically acting corticosteroid in an amount of less than 20 mg. Although there is no specific discussion of how to achieve acceptable blend uniformity in the working example of the compression blend which contains fluticasone propionate at only 4% by weight, which will be translated into achieving acceptable content uniformity of the ODTs, the fact that fluticasone is granulated with suitable pregranulated excipients, such as rapidly dispersing

microgranules comprising mannitol and crospovidone, suggests that the granulation of fluticasone has been performed for the purpose of achieving acceptable content uniformity in the finished tablets. However, the micronized topically acting corticosteroid particles may be present in the agglomerated granules and as such may not be readily exposed to the inflamed EoE tissues upon oral administration for rapid induction of remission of EoE.

[0008] There is therefore a need for low-dose corticosteroid compositions having acceptable blend uniformity/homogeneity during blending of a topically acting corticosteroid with suitable pharmaceutically acceptable excipients as a carrier (*i.e.*, at a drug content of < 5%, especially at <3% by weight in the blend) and maintain the blend homogeneity until processing into finished unit dosage forms (e.g., tablets or capsules), which while exhibiting high content uniformity are suitable for oral administration in patients to provide topical (rather than systemic) treatment of inflammation of the of the upper gastrointestinal tract, particularly eosinophilic esophagitis (EoE) since the micronized, topically acting corticosteroid particles having been adsorbed largely on the surface of the carrier are capable of rapidly inducing remission of EoE.

SUMMARY OF THE INVENTION

[0009] The present invention is directed to an oral solid pharmaceutical composition comprising a low-dose topically acting corticosteroid and at least one pharmaceutically acceptable carrier for adsorption of the drug, wherein the drug is in an amount of less than about 5% (weight of drug/weight of composition), particularly less than 3% by weight and the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration in humans. The blend of a corticosteroid with the carrier has high blend uniformity/drug homogeneity which is translated into content uniformity of finished unit tablets.

[0010] The composition of the invention which can be formulated as an orally disintegrating tablet (hereafter referred to as an ODT) that disintegrates within 30 seconds when tested using the USP <701> Disintegration Test, and/or disintegrates within 60 seconds when placed in the oral cavity of a human.

[0011] The present invention is also directed to a process for making low dose pharmaceutical compositions comprising adsorbing a topically acting corticosteroid optionally micronized onto at least one pharmaceutically acceptable carrier such as silicified microcrystalline cellulose by blending for a sufficiently long time and passing through a de-segregating/comminuting mill at

least once before blending with other pharmaceutically acceptable excipients, and then formulating the resulting blend into a suitable unit dose presentation, e.g., tableting.

[0012] The present invention discloses a method of preparing pharmaceutical compositions comprising especially poorly water soluble, low-dose, micronized drugs and at least one pharmaceutically acceptable carrier which must be blended for a sufficiently long time using a suitable blender-comminuting mill combination, thereby avoiding segregation-agglomeration of the drug particles in the blend not only during powder blending but also until processed into finished dosage forms, capsules or tablets, to achieve and maintain desired high blend uniformity / homogeneity and/or to achieve high content uniformity of the finished dosage units and also to avoid high dissolution variability.

[0013] The compositions of the present invention are useful for treatment of various conditions including the inflammatory conditions of the gastrointestinal tract. Accordingly, the present invention also provides a method for treating inflammatory conditions of the upper gastrointestinal tract in an individual particularly in the esophagus (eosinophilic esophagitis) via topical action with minimal systemic absorption and concomitant corticosteroid related side-effects. The method comprises administering to an individual to treat eosinophilic esophagitis a pharmaceutical composition of the present invention comprising topically acting optionally micronized corticosteroid particles adsorbed onto silicified microcrystalline cellulose. Alternatively, the compositions of the present invention may comprise a water soluble or water-swellaable pharmaceutically acceptable excipient, such as bio-gelling or bioadhesive polymer that will enhance bioadherence of the corticosteroid to the inflamed esophageal mucosa.

DETAILED DESCRIPTION OF THE FIGURES

[0014] FIG. 1 shows the sampling locations in a blender for taking representative samples as per draft FDA Guidance (FDA's Draft Guidance for Industry "Powder blend and finished dosage units - stratified in-process dosage unit sampling and assessment" October 2003).

DETAILED DESCRIPTION OF THE INVENTION

[0015] The invention is directed to a solid pharmaceutical composition which comprises a corticosteroid in an amount of less than about 5% (weight of drug/weight of composition) and at least one pharmaceutically acceptable carrier for adsorption of the drug, wherein the composition

has no significant systemic glucocorticoid or mineralocorticoid activity, and wherein the solid pharmaceutical composition disintegrates within 30 seconds when tested using the USP <701> disintegration method. The composition disintegrates in about 60 seconds or less on contact with saliva in the oral cavity of a subject or patient in need thereof.

[0016] The solid pharmaceutical composition of the present invention provides a therapeutically effective amount of a topical corticosteroid to inflamed tissues of the upper gastrointestinal tract, particularly to the esophageal inflamed tissues.

[0017] As used above, and throughout the description of the invention, the following terms, unless otherwise indicated, shall have the following meanings.

[0018] The term “drug”, “active” or “active pharmaceutical ingredient” as used herein includes a pharmaceutically acceptable and topically acting corticosteroid, pharmaceutically acceptable salts, esters, solvates (including hydrates), polymorphs, stereoisomers, and/or prodrugs, and mixtures thereof. The terms “salts” refers to the product formed by the reaction of a suitable inorganic or organic acid with the “free base” form of the drug. Suitable acids include those having sufficient acidity to form a stable salt, for example acids with low toxicity such as the salt approved for use in humans or animals. Non-limiting examples of acids that may be used to form salts of a orally active drug, include inorganic acids, e.g., HCl, H₃PO₄ H₂SO₄. Non-limiting examples of organic acids include alkyl sulfonic acids and propionic acid.

[0019] 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.

[0020] The term “about”, as used herein to refer to a numerical quantity, includes “exactly”. For example, “about 30 seconds” includes 30 seconds, exactly, as well as values close to 30 seconds (e.g., 25 seconds, 29 seconds, 31 seconds, 35 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 μ m” means “about 1 μ m to about 50 μ m”).

[0021] 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.

[0022] 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.

[0023] 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., aldosterone). Corticosteroids which typically have systemic glucocorticoid or mineralocorticoid activity when administered orally can also be used in the diluted compositions of the present invention, wherein the systemic uptake of the corticosteroid is reduced or suppressed.

[0024] Suitable topically acting corticosteroids which may be included in the pharmaceutical composition of the present invention include budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, triamcinolone and salts, or esters and mixtures thereof.

[0025] In a particular embodiment, the composition of the present invention comprises fluticasone. In other embodiments, the composition of the present invention comprises budesonide. In certain other embodiments, the composition of the present invention comprises ciclesonide.

[0026] In one embodiment, the corticosteroid may be in the form of crystals having a mean particle size of about 100 μm or less, about 75 μm or less, about 50 μm or less, more particularly about 25 μm or less, or about 15 μm or less. A particular embodiment of the invention is where the corticosteroid is micronized in order to achieve a mean particle size of less than about 10 μm , less than about 8 μm or less, less than about 6 μm , or particularly, less than about 4 μm . Alternatively, such crystals may have an average size in the sub-micron range (e.g., average particle size of about $<1 \mu\text{m}$), *i.e.*, may be as nanoparticles (e.g., average particle size in the range of about 1-100 nm).

[0027] In another embodiment, the corticosteroid may be present in an amorphous form, for example in association with a stabilizing agent which limits drug recrystallization, e.g., polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose,

hydroxyethylcellulose; SOLUPLUS[®], KOLLIDON[®] VA64, sodium lauryl sulphate, Tween surfactants, EUDRAGIT[®] EPO polymer, and mixtures thereof.

[0028] The amount of corticosteroid present in the pharmaceutical compositions of the present invention is selected so as to maximize the therapeutic benefit from topical administration while minimizing side effects from systemic absorption. In the case of solid pharmaceutical compositions of the present invention, the amount of corticosteroid in the composition is less than about 5% w/w (weight of drug/ weight of composition). In one embodiment the amount of corticosteroid in the pharmaceutical composition is less than about 4%. In another embodiment it is less than about 3%. In yet another embodiment it is less than about 2%, less than about 1.5%, less than about 1%, less than about 0.5% by weight or less. In one embodiment the amount of corticosteroid in the pharmaceutical composition is between about 0.50 mg and about 18 mg. In still another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 0.75 mg and about 12 mg. In yet another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 1.5 mg and about 9 mg. In still other embodiments, the amount of corticosteroid is about 0.01 mg, about 0.05 mg, about 0.1 mg, about 0.15 mg, about 0.1 mg, about 0.2 mg, about 0.25 mg, about 0.3 mg, about 0.35 mg, about 0.4 mg, about 0.45 mg, about 0.5 mg, about 0.6 mg, about 0.7 mg, about 0.75 mg, about 0.8 mg, about 1 mg, about 1.5 mg, about 2 mg, about 3 mg, about 4 mg, about 4.5 mg, about 5 mg, about 6 mg, about 7 mg, about 8 mg, about 9 mg, about 10 mg, about 12 mg, about 18 mg, inclusive of all ranges and sub-ranges there between.

[0029] In the embodiment of the invention the rapidly disintegrating composition of the invention may comprise pharmaceutically acceptable excipients which swell, dissolve or otherwise facilitate disintegration of the ODT composition forming a smooth viscous suspension containing micronized corticosteroid particles to coat inflammatory esophageal mucosa to treat eosinophilic esophagitis. In certain embodiments of the present invention the total weight of the dosage form is kept in the range of from 300 to 900 mg to incorporate as much rapidly dispersing microgranules comprising at least one sugar alcohol in combination with at least one disintegrant, as possible to maximize eosinophilic esophagitis surface coating with micronized corticosteroid. In another embodiment, the rapidly dispersing microgranules comprise at least one disintegrant in combination with a sugar alcohol and/or 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 sub-ranges there between. In one embodiment, the average particle size of a sugar alcohol and/or saccharide is about 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 .

[0030] In one embodiment of the invention the dosage form has total weight of 300 mg and contain about 0.05 mg (0.16%), about 0.75 mg (0.25% w/w), about 1.5 mg (0.5% w/w), about 3 mg (1% w/w), about 4.5 mg (1.5%), about 6 mg (2% w/w), about 9 mg (3% w/w), about 12 mg (4% w/w), about 16 mg (5%) of the corticosteroid.

[0031] In another embodiment of the invention the dosage forms has total weight of 600 mg and contain about 0.75 mg (0.125% w/w), about 1.5 mg (0.25% w/w), about 3 mg (0.5% w/w), about 4.5 mg (0.75%), about 6 mg (0.1% w/w), about 9 mg (1.5% w/w), about 12 mg (2% w/w), about 18 mg (3% w/w) of the corticosteroid. In one embodiment of the invention the topically acting corticosteroid is fluticasone propionate and it is in the range of about 0.05 to about 15 mg in the pharmaceutical composition at a drug content of from about 0.16% to 5% by weight of the composition.

[0032] In another embodiment the fluticasone propionate is in the range of about 0.75 to about 4.5 mg in the composition at a drug content of from about 0.25% to 1.5% by weight in the composition.

[0033] In another embodiment the fluticasone propionate is in the range of 0.05 to about 18 mg in the composition at a drug content of from about 0.125% to 5% by weight in the composition.

[0034] The pharmaceutically acceptable carrier used in the mixture of the present invention is suitable for adsorption of the drug, it should have the properties of an excellent carrier for dry blends providing blend flowability and workability and preventing the segregation. It may concur in providing corticosteroid content uniformity. It is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate (commercially available as VEEGUM™ or NEUSILIN™). It is preferably silicified microcrystalline cellulose which is composed of intimately associated microcrystalline cellulose and colloidal silicon dioxide particles, (PROSOLV® SMCC; MCC, 98% and CSD, 2%). The use of this ingredient in the composition of the invention improves the flow and blending properties of the corticosteroid

mixture; improved blend uniformity/homogeneity and physical stability of the formulations during storage until their final processing into finished dosage forms such as tablets or capsules, *i.e.*, to avoid or minimize potential de-mixing and segregation of corticosteroid microparticles is also achieved. The presence of this carrier in admixture with the active also ensures reproducibility of preparations of the composition of the invention (in particular with the applied technology of direct tableting). In one embodiment of the present invention a low dose corticosteroid blend with the carrier showing high blend uniformity, low segregation potential and excellent flowability is disclosed. This blend is particularly suitable for producing a rapidly disintegrating diluted corticosteroid composition. In one embodiment of the invention the blend comprises fluticasone propionate adsorbed on silicified microcrystalline cellulose, and rapidly dispersing microgranules.

[0035] 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.

[0036] The rate of disintegration of the solid pharmaceutical compositions of the present invention measured using the USP <701> Disintegration Test 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.

[0037] In addition to the corticosteroid and the carrier, the blend of the compositions or the oral dosage forms of the present invention may contain further pharmaceutically acceptable ingredients which swell, dissolve or otherwise facilitate disintegration. Such ingredients can include disintegrant, a sugar alcohol, a saccharide, or a mixture thereof, a water-soluble polymeric binder, a bio-gelling or a bioadhesive polymer, which can retain the corticosteroid particle adhered onto the inflamed esophageal tissues longer than in its absence.

[0038] In one embodiment, the present invention provides a solid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable bio-gelling polymer which enables longer retention of the corticosteroid at the inflamed esophageal tissues. The ingredient herein called “bio-gelling polymer” or “bio-adhesive agent” is an agent which promote adhesion of the corticosteroid to biological surfaces, especially the inflamed mucosa through gelling under GI tract physiological conditions, for example, upon contact with physiological fluids and/or at physiological temperature, and includes, but is not limited to the bio-gelling polymers listed below.

[0039] The bio-gelling polymer may be 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 partially or fully cover the inflamed esophageal tissues while keeping the corticosteroid particle(s) close or in intimate contact with the inflamed tissues, thereby increasing the topical contact of the corticosteroid with the inflamed tissues.

[0040] In one embodiment, the composition of the present invention includes a bioadhesive agent such as a lipid or a polymer. Examples of such lipids are glycerphospholipids such as phosphatidyl choline, and diacyl glycerols such as glycerol dioleate. Examples of bioadhesive polymers include chitosan, polyorthoesters, and copolymers, terpolymers and mixtures thereof.

[0041] In another embodiment, the solid pharmaceutical compositions of the present invention include an adhesive agent. Suitable adhesive agents include sucrose aluminum sulfate complex, chitosan and derivatives such as trimethylchitosan, polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, cross-linked polyacrylic acid copolymers, polyvinylpyrrolidone, vinylpyrrolidone-polyvinyl acetate copolymer (*e.g.*, KOLLIDON[®] VA 64 from BASF), SOLUPLUS[®], poly(ethylene glycol 6000 – vinylcaprolactam – vinyl acetate) (13:57:30) copolymer from BASF), polyvinyl alcohol, polyethylene oxide, polyamide, alginic acid and its salts, carrageenan, xanthan gum, ammoniomethacrylate copolymers, CARBOPOL polymers, maltodextrins, pectins, sucralose, and combinations thereof.

[0042] 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.

[0043] In certain embodiments of the present invention, the solid pharmaceutical composition includes any solid dosage form which disintegrates rapidly in the mouth to form a suspension of powdered corticosteroid, which is hypothesized to coat or adhere onto the inflamed esophageal mucosa when swallowed.

[0044] In one embodiment, the composition of the present invention is in the form of an ODT. The ODT comprises the drug is in amount less than about 5% (weight of drug/weight of composition) and a pharmaceutically acceptable carrier, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration in

humans. The drug particles, (e.g., a corticosteroid as described herein optionally coated or optionally combined with an adhesive agent as described herein) are combined with rapidly dispersing microgranules. Rapidly dispersing microgranules comprise a sugar alcohol, a saccharide, or a mixture thereof and a disintegrant alone or a disintegrant in combination with a pharmaceutically acceptable additive with multi-functional activity (e.g., pregelatinized starch, hydroxypropylcellulose or the like).

[0045] 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.

[0046] The amount of disintegrant in the ODT is typically in the range of about 1% to about 10% by weight.

[0047] 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.

[0048] 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 sub-ranges there between.

[0049] The amount of sugar alcohol and/or saccharide in the ODT ranges from about 30% to about 70% by weight.

[0050] 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.

[0051] 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 sub-ranges there between.

[0052] The corticosteroid particles are typically adsorbed onto the carrier. The process for the preparation includes repeatedly mixing corticosteroid and carrier so that the blend is adsorbed onto the carrier. Corticosteroid is typically micronized (mean particle size of less than 10 μm) for the following reasons. Firstly, the finished dosage form (such as the ODT) is designed to rapidly disintegrate on contact with saliva in the oral cavity. In order to accomplish this, the dosage form (ODT) should have preferably a minimum of 100 mg of rapidly dispersing microgranules, irrespective of the dose of corticosteroid (for example, 0.1 mg, 1 mg, 10 mg or 20 mg). Secondly, in order to achieve blend uniformity/homogeneity in the blend and content uniformity of the finished unit dosage forms, a homogeneous distribution could be achieved by incorporating the micronized drug particles in silicified microcrystalline cellulose alone or in combination with rapidly dispersing microgranules by at least once blending and milling as described in examples of different embodiments of the present invention. The first option of incorporating the drug in the silicified microcrystalline cellulose will largely prevent segregation of corticosteroid microparticles during transient storage until final processing into finished dosage forms, capsules or tablets exhibiting high content uniformity and/or low dissolution variability.

[0053] Rapidly dispersing granules or granulate can be prepared as described in U.S. 2005/0232988 or U.S. 2003/0215500 by granulating a disintegrant 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). Rapidly dispersing microgranules can alternatively be prepared as described in U.S. 13/310,632 by granulating a sugar alcohol, a saccharide, or a mixture thereof and a disintegrant in combination

with a pharmaceutically acceptable additive with multi-functional activity (e.g., starch, hydroxypropylcellulose or the like) at a low level of 0.5-3.0% by weight in a fluid bed granulator.

[0054] The rapidly dispersing microgranules present in the ODT help rapid disintegration of the tablet when placed in the oral cavity, creating a smooth suspension containing the corticosteroid drug particles. It is desirable to incorporate sufficient amount of rapidly dispersing microgranules to coat extensively the esophageal mucosa. This creates a content uniformity problem in these low-dose ODTs (for example, 300 mg ODT containing 12 mg or less of a corticosteroid). Typically, this problem is overcome by granulation, which involves spraying a dilute solution of the corticosteroid on to an excipient powder bed. The drug particles are embedded in the granules and consequently may not become exposed to the inflamed mucosa, resulting in being poorly efficacious. It has been surprisingly observed possible not only to achieve desired content uniformity but also enhance the probability of largely keeping the corticosteroid drug particles exposed to the inflamed mucosa by adsorbing micronized topically acting corticosteroid drug particles onto the pharmaceutically acceptable carrier (such as silicified microcrystalline cellulose) prior to blending with rapidly dispersing microgranules and other excipients and compressing into ODTs.

[0055] The dosage form as described herein may also include pharmaceutically acceptable excipients typically used in disintegrating tablet formulations such as fillers, diluents, glidants, disintegrants, binders and lubricants.

[0056] Examples of suitable fillers, diluents and/or binders include lactose (e.g. spray-dried lactose, such as FAST-FLO[®]), microcrystalline cellulose (various grades of AVICEL[®], CEOLUS[®]), hydroxypropylcellulose, L-hydroxypropylcellulose (low substituted), low molecular weight hydroxypropyl methylcellulose (HPMC) (e.g., METHOCEL[™] E, F and K from Dow Chemical, MetholoseE SH from Shin-Etsu, Ltd), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylhydroxyethylcellulose and other cellulose derivatives, sucrose, agarose, sorbitol, mannitol, dextrans, 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. The preferred filler for the composition of the invention is mannitol such as spray dried mannitol.

[0057] Examples of suitable disintegrants include crospovidone (cross-linked PVP), sodium starch glycolate, cross-linked sodium carboxymethylcellulose, calcium silicate, and low substituted hydroxypropyl cellulose. The preferred disintegrant for the composition of the invention is crospovidone.

[0058] Specific examples of glidants and lubricants include stearic acid, magnesium stearate, calcium stearate or other metallic stearates, talc, glyceryl behenate, colloidal silica, corn starch, and optionally magnesium stearate or sodium stearyl fumarate (lubricant intragranularly mixed or used externally to lubricate die and punch surfaces). The preferred glidant for the composition of the invention is colloidal silica and preferred lubricant is sodium stearyl fumarate.

[0059] The solid pharmaceutical compositions of the present invention can include other dosage forms besides an ODT, a wafer, a film, or other solid dosage form which disintegrates rapidly in the mouth to form a suspension or dispersion of a corticosteroid, which can readily be swallowed to coat the mucosal surface of eosinophilic esophagitis.

[0060] 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. Pat. No. 6,316,027), containing a corticosteroid as the active pharmaceutical ingredient. Film dosage forms can include edible films such as those described in U.S. Pat No. 6,596,298 or U.S. Pat No. 6,740,332, containing a corticosteroid as the active pharmaceutical ingredient. In one embodiment of the present invention the solid composition comprises a lyophilized matrix, wherein the lyophilized matrix comprises corticosteroid, the carrier and excipient. Suitable excipients include mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

[0061] Topical administration of a corticosteroid to the oral cavity of individuals has been associated with candidiasis infection. While the invention is designed so as to be less prone to promoting such an infection, however in another embodiment of the invention, the pharmaceutical composition may 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, isavuconazole, isoconazole, itraconazole, ketoconazole, micafungin, miconazole, miconazole nitrate, naftifine, natamycin, nystatin, oxiconazole, posaconazole, pramiconazole, ravuconazole, rimocidin, setaconazole, sulconazole, terbafine, terconazole, tioconazole, tolnaftate, undecylenic acid, and voriconazole.

[0062] In another embodiment, pharmaceutical compositions of the present invention include an antiviral agent. Antiviral agents which may be included in the solid pharmaceutical compositions of the present invention include interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, guanosine analogs, puridine analogs, pyrimidine analogs, and other “uncategorized” antiviral drugs recognized in the art which do not fall within any of the above classes (e.g., foscarnet and miltefosine). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abacavir, aciclovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, durunavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate, etravirine, famciclovir, fosamprenavir, ganciclovir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, lovirode, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon alpha-2a, pegylated interferon alpha-2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegravir, ritonavir, ribavirin, rimantadine, rilpivirine, saquinavir, stampidine, stavudine, tenofovir, tipranavir, TNX-355, trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

[0063] Tablet dosage forms, including ODT dosage forms, comprising the low dosage strength of a topically acting corticosteroid and a pharmaceutically acceptable carrier, wherein the drug is in amount less than about 5% (weight drug/weight of composition), have no significant systemic glucocorticoid or mineralocorticoid activity after oral administration in humans, disintegrate in less than about 30 sec (USP method), and have a low friability in order to have sufficient durability to withstand handling, shipping, and/or packaging in push-through blister packaging. Friability is

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 sub-ranges there between).

[0064] Different preparation processes can be applied to prepare blends of a corticosteroid with suitable carrier having blend homogeneity, *i.e.*, acceptable blend uniformity and also content uniformity suitable for tableting. Blending the above ingredients can be achieved both by dry mixing or by granulation.

[0065] The present invention further discloses the method of manufacturing oral composition, such as compression or compressible blend at a drug load of from about 0.50 to about 3% by weight wherein it is challenging to achieve and maintain acceptable blend uniformity until the compression or compressible blend is processed into final unit dosage forms (e.g., orally disintegrating tablets) exhibiting acceptable content uniformity. The method comprises the following steps:

- 1) preparing the rapidly dispersing microgranules or granulate;
- 2) preparing the preblend 1 comprising charging a V-blender with one quarter of silicified microcrystalline cellulose (SMCC, a pharmaceutically acceptable carrier), micronized corticosteroid, colloidal silicon dioxide (a glidant) and another quarter of SMCC and blending the contents for 10 minutes;
- 3) preparing the preblend 2 comprising charging a high shear granulator with a free flowing filler (such as spray dried mannitol), preblend 1, remaining half of SMCC, disintegrant (such as crospovidone), and sweetener (sucralose powder) and blending the contents for 10 minutes at an impeller speed of 300 ± 50 rpm and a chopper speed of 1500 ± 50 rpm;
- 4) preparing the final compressible blend comprising charging a V-blender with one half of the rapidly dispersing granules of step 1, lubricant (such as sodium stearyl fumarate), the pre-blend 2 of step 3, and remaining half of rapidly dispersing granules of step 1 and blending for 30 minutes, sampled and further blended for 10 ± 1 minutes to achieve acceptable blend uniformity/homogeneity as per regulatory requirements;
- 5) preparing the orally disintegrating tablets comprising the compressible blend of step 4, which exhibit acceptable content uniformity as per regulatory requirements.

[0066] In one embodiment, the method of manufacturing orally disintegrating tablets is performed by repeated dry blending and milling. The method comprises the following steps:

1) preparing the rapidly dispersing microgranules or granulate with an average particle size of not more than about 400 μm by 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) in presence of water or an alcohol-water mixture and then drying the granulate (fluid-bed equipment or a conventional oven);

2) preparing the milled preblend 1 by blending the pharmaceutically acceptable carrier (such as silicified microcrystalline cellulose), micronized corticosteroid and glidant (such as colloidal silicon dioxide) in a V-blender for 10 minutes at 25 ± 1 rpm and then milling through a comminuting mill equipped with a 024R screen (30 Mesh opening) at approximately 2400 ± 100 rpm;

3) preparing the milled preblend 2 by blending half of free flowing mannitol, preblend 1 from step 2, disintegrant (crospovidone), and sweetener (sucralose powder) in a V-blender for 10 minutes at 25 ± 1 rpm and then milling through a comminuting mill equipped with a 024R screen at a speed of 2400 ± 100 rpm, and rinsing the mill with remaining half of free flowing mannitol;

4) preparing the compressible blend by blending the rapidly dispersing granules of step 1, lubricant (such as sodium stearyl fumarate), the milled preblend 2 of step 3, rinsed free flowing mannitol) for total time of 40 minutes;

5) preparing the tablets by compressing the compressible blend of step 4.

[0067] The repeated dry blending and milling process is the preferred process for the preparation of the compositions of the invention.

[0068] In the process of the invention the different steps and the order of addition of individual components is important to achieve as acceptable blend uniformity/homogeneity in the compressible blend, as well as acceptable content uniformity of the finished dosage units as per regulatory requirements. The tablets obtained with the above process have the appearance, disintegration time, hardness and friability appropriate and suitable for ODTs to withstand attrition during transport in bulk containers, commercial packaging in blisters or bottles, and transport of primary/secondary packaged products for commercial distribution and end use and the purpose of the invention. Moreover, the tablets manufactured and then packaged in blisters are highly stable at accelerated and long-term ICH stability conditions.

[0069] The solid pharmaceutical compositions of the present invention are suitable for oral administration of a topically acting corticosteroid to treat inflamed tissues of the upper

gastrointestinal tract, for example the esophagus. The use of a topically acting corticosteroid for treating conditions associated with inflammation of the gastrointestinal tract is desirable because it results in fewer side-effects than a highly systemically acting corticosteroid.

[0070] 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, and pseudomembranous esophagitis.

[0071] In one specific embodiment, the pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the upper gastrointestinal tract, particularly eosinophilic esophagitis.

[0072] Thus, the present invention includes pharmaceutical composition for use as medicaments in the treatment of inflammatory conditions of the gastrointestinal tract.

[0073] The invention also includes the method of administering to a patient in need thereof a solid pharmaceutical composition of the present invention. In one 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. Upon administration of a solid pharmaceutical composition of the present invention to an individual, the composition disintegrates in the patient's oral cavity. In another embodiment, the present invention includes a method for treating gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis comprising administering to an individual in need thereof a pharmaceutical composition of the present invention. In another embodiment, the present invention includes a method for treating a food allergy with an identified allergen, e.g., "atopic IBS", and "atopic bowel".

[0074] From the foregoing description and the experimental part, it can be seen that the present invention provides several important advantages. The described invention provides low dose oral compositions comprising a corticosteroid and a pharmaceutical carrier characterized by high

content uniformity and stability, the composition and dosage forms wherein the corticosteroid microparticles are present largely at or near the surface of the carrier and are therefore likely to be suitably positioned for the topical treatment of inflammation of gastroenteric tract, particularly EoE, upon disintegration of the corticosteroid ODT in the oral cavity of a patient and swallowing of the resultant viscous suspension.

EXPERIMENTS

METHODS

[0075] *Bulk/tapped density* is measured according to USP <616> method 1.

[0076] *Particle size distribution* (PSD) is measured on samples of 5-10 mg with ATM sonic sifter.

[0077] *Flowability* is tested using Sotax flow tester on about 110 g of materials employing standard six pre-vibration/vibration mode; the flow property is expressed as a flow index (α'/α_{ref}) and as Carr's index.

[0078] *Water content* is determined using Karl Fisher titration or LOD is measured according to USP<921> 1a method.

[0079] *Blend Uniformity Testing*: Blend uniformity testing is carried out by withdrawing 6 random samples using a sampling thief from different locations of the final direct compression blend contained in the V- or twin shell blender as shown in FIG. 1. Samples collected are tested for their drug contents using an HPLC stability-indicating method.

[0080] *Content Uniformity of ODTs*: Orally disintegrating tablets are randomly sampled at the beginning, middle and end of each compression run, 10 tablets are tested for their content uniformity using the HPLC stability-indicating method.

[0081] *Disintegration* is performed according to USP<701> method. *Friability* is measured according to USP<1216> method.

EXAMPLES

Example 1: Rapidly Dispersing Microgranules

[0082] Rapidly dispersing microgranules are prepared following the procedure disclosed in US Patent Application Publication No. U.S. 2003/0215500 published November 20, 2003, the contents of which are hereby incorporated by reference in its entirety for all purposes. Specifically, D-mannitol (152 kg) with an average particle size of approximately 20 μm or less (PEARLITOL[®]

25 from Roquette, France) is blended with 8 kg of cross-linked povidone (CROSPVIDONE[®] XL-10 from ISP) in a high shear granulator (GMX 600 from Vector), granulated with purified water (approximately 32 kg), wet-milled using a Comil from Quadro, and finally tray-dried to provide microgranules having an LOD (loss on drying) of less than about 1.0%. Alternatively, the wet milled granules are dried in a fluid-bed dryer to provide microgranules having an LOD of less than 1.0% by weight. The dried granules are sieved and oversize material is again milled to produce rapidly dispersing microgranules with an average particle size in the range of approximately 175-300 microns.

[0083] D-mannitol with a median particle size of < 20 µm (93parts) and Crospovidone (5 parts) are granulated by spraying the starch solution (2 parts of STARCH 1500[®] from Colorcon) in a top spray fluid-bed granulator and dried for a loss on drying of <1.0%. The dried granules are sieved through a 20 mesh sieve, and oversized granules are milled and sieved, if needed to produce alternate rapidly dispersing granules.

Example 2: Blend preparation by high shear process for 1.5 mg fluticasone ODT; batch 1

[0084] A preblend 1 is first prepared by blending one quarter of silicified microcrystalline cellulose (SMCC commercially available as PROSOLV[®] HD90), micronized fluticasone propionate, colloidal silicon dioxide, and another quarter of SMCC in a 1 quart V-blender for 10 ± 1 minutes (see Table 1 for weights of individual components of compressible blends of ODTs, 1.5 and 3 mg). A second preblend (preblend 2) is prepared: 10 L granulation bowl of a high shear granulator, PMA 1 is charged with spray-dried mannitol (PARTECK[®] M200), preblend 1, remaining half of SMCC, crospovidone and sucralose powder. Blending is performed for 10 ± 1 minutes at an impeller speed of 300±50 rpm and a chopper speed of 1500±50 rpm to produce preblend 2. One half of rapidly dispersing microgranules, sodium stearyl fumarate, preblend 2 and the remaining half of rapidly dispersing microgranules are blended in a 8 qt V shell blender and sampled for blend uniformity at 30 and 40 minutes. The final blend is sampled for bulk/tapped density, particle size distribution (PSD), flowability and moisture testing.

Table 1: Compositions of compressible blends of Fluticasone ODT's, 1.5 and 3 mg

Ingredients (mg)	Fluticasone ODTs							
	1.5 mg batch 1		1.5 mg batch 2	1.5 mg batch 3	1.5 mg batch 4	3 mg batch 5		3 mg batch 6
	(%/tablet)	(mg/tablet)	(mg/tablet)	(mg/tablet)	(mg/tablet)	(%/tablet)	(mg/tablet)	(mg/tablet)
Micronized Fluticasone Propionate USP	0.50	1.50	1.50	1.50	1.50	1.0	3.00	3.00
Colloidal Silicon Dioxide NF	0.30	0.90	0.90	0.90	0.90	0.30	0.90	0.90
Colloidal Microcrystalline Cellulose NF	10.00	30.00	30.00	30.00	30.00	10.00	30.00	30.00
Crospovidone NF	7.50	22.50	22.50	22.50	22.50	7.50	22.50	22.50
Sucralose NF	0.40	1.20	1.20	1.20	1.20	0.40	1.20	1.20
Spray-dried Mannitol USP	30.30	90.90	90.90	90.90	89.40	29.80	89.40	87.90
Rapidly Dispersing Granules	50.00	150.00	150.0	150.0	150.0	50.00	150.0	150.0
Sodium Stearyl Fumarate NF	1.00	3.00	3.00	3.00	4.50	1.00	3.00	4.50
Total	100.00	300.0	300.0	300.0	300.0	100.0	300.0	300.0

Example 3: Blends preparation by repeated blending and milling for 1.5 and 3 mg
fluticasone ODT; batch 2, 3 5

[0085] A preblend 1 (see Table 1 for weights of individual components of compressible blends of ODTs, 1.5 and 3 mg) is prepared by charging a 2 quart V-blender sequentially with half of SMCC, micronized fluticasone propionate, colloidal silicon dioxide and the remaining half of SMCC and blending for 10 ± 1 minutes. The preblend 1 is passed through a QUADRO Comil fitted with a 024R screen (30 mesh opening) at approximately 2400 ± 100 rpm. Preblend 2 is prepared: half of spray-dried mannitol, milled preblend 1, crospovidone, and sucralose powder are blended in a 4 quart V-blender for 10 ± 1 minutes and milled through the 024R screen. The Comil is rinsed by passing the remaining half of spray-dried mannitol through a 024R screen. Half of rapidly dispersing microgranules, sodium stearyl fumarate, milled preblend 1, rinsed mannitol and the remaining half of rapidly dispersing granules are blended and sampled for blend uniformity at 30 and 40 minutes. The final blends are sampled for testing of bulk/tapped density, particle size distribution (PSD), flowability, and moisture content.

Example 4: Blend uniformity results of blends of examples 2 and 3

[0086] Test results for the compressible blends of Examples 2 and 3 are presented in Table 2. The compression blends, ODT 1.5 mg (batch 1) and ODT 1.5 mg (batch 2), which have been processed using two different combinations of equipment – V -blender-high shear granulator and V-blender-comminuting mill- show similar blend physical (powder) properties such as bulk and tapped densities, particle size distributions, flow properties, and blend uniformity values, excepting that the 30-minute blended batch shows a slightly higher %RSD.

Table 2: Physical/Blend uniformity test results for Fluticasone ODT, 1.5 and 3 mg Compressible Blends

Test	Parameters		Blend Batch#											
			1.5 mg batch 1		1.5 mg batch 2		1.5 mg batch 3		3 mg batch 5		1.5 mg batch 4		3 mg batch 6	
Bulk/Tap Density USP <616> Method I	Bulk Density		0.57		0.57		0.57		0.57		0.57		0.58	
	Tapped Density		0.71		0.71		0.72		0.70		0.78		0.77	
Particle Size Analysis	Sieve #	Particle Size (µm)	% Retained		% Retained		% Retained		% Retained		% Retained		% Retained	
	20	840	0.62		0.39		0.36		0.61		0.6		0.4	
	40	425	16.08		14.05		17.32		18.08		18.9		20.2	
	60	250	13.37		12.00		14.57		14.62		13.8		14.8	
	80	180	9.70		10.33		10.07		10.21		10.7		12.0	
	100	150	6.60		5.84		7.90		8.37		6.2		5.5	
	200	75	22.61		24.62		19.83		21.24		20.0		20.0	
	Pan	20	31.01		32.77		29.95		26.86		29.8		27.1	
LOD USP <921> 1a			1.0		1.0		1.0		0.9		1.0		1.1	
Flow Results	Parameters													
	Flow Angle		67.9		69		55.7		55.9		68.5		67.3	
	Flow Index		0.83		0.84		0.68		0.68		0.84		0.82	
	Flow Quality		Good		Good		Medium		Medium		Good		Good	
Blend Uniformity	Blending time		30 min	40 min	30 min	40 min		30 min	40 min	40 min	40 min			
	Minimum, %		94.8	94.5	93.2	93.4		95.8	101.0	94.7	97.3			
	Maximum, %		105.1	100.4	98.6	99.9		102.8	104.8	99.4	101.1			
	Mean, %		99.3	97.2	95.7	97.0		98.9	102.0	97.4	99.5			
	%RSD		3.6	2.2	2.0	2.9		2.7	1.4	1.0	1.5			
Content Uniformity	Mean						101.5		101.1		100.6		100.7	
	±SD						3.7		1.5		2.0		1.0	
	AV						8.8		3.7		4.7		2.4	

Table 3: Stratified Blend uniformity results for Fluticasone ODT Compression Blends

Sampling Location	Label Claim (%)							
	1.5 mg 101		1.5 mg 201		1.5 mg301	3 mg 101		3 mg 201
	30 min	40 min	30 min	40 min	40 min	30 min	40 min	40 min
Top Left	98.9	96.0	95.9	99.9	94.7	100.6	101.5	98.0
Middle Left	105.1	94.5	93.2	93.4	98.2	100.0	101.6	99.9
Bottom Left	101.2	97.8	95.5	99.0	95.5	102.8	104.8	97.3
Top Right	94.8	95.9	94.1	93.6	98.5	96.4	101.7	101.1
Middle Right	98.3	100.4	98.6	98.2	99.4	95.8	101.0	99.5
Bottom Right	97.4	98.7	96.8	97.6	97.8	98.0	101.6	100.9
Maximum	105.1	100.4	98.6	99.9	99.4	102.8	104.8	101.1
Minimum	94.8	94.5	93.2	93.4	94.7	95.8	101.0	97.3
Mean	99.3	97.2	95.7	97.0	97.4	98.9	102.0	99.5
RSD	3.6%	2.2%	2.0%	2.9%	1.9%	2.7%	1.4%	1.5%

Example 5: Compression of ODTs of Examples 2 and 3

[0087] The compression blends of Examples 2 and 3 are compressed using a rotary tablet press, Manesty Beta Press equipped with 8 punch die sets of 9.5 mm round, plain, flat-faced radius edge tooling. The average tablet weight is about 300 mg. The main compression force used is maintained at 5-6 kN, with a pre-compression force set at 2 ± 0.2 kN for compression runs (except where noted). During the compression, the tablet press instrumentation by SMI is used to measure press speed and compression force. During tableting, tablets are periodically sampled for visual inspection of ‘appearance’, in-process measurements of weight, thickness, hardness and friability. Additional tablets are also samples as ‘composite samples’ for analytical testing. Details of compression parameters and tablet properties are shown in Table 4. Tablets appears as round tablets they are also

tested for assay, potency, content uniformity, dissolution (greater than 90% release after 45 minutes for all batches); they have friability not more than 0.4%, hardness of about 4 kP, disintegration time less than 30 sec.

Example 6: Confirmatory compression blend and ODT batches
(ODT 1.5 mg: batch 3, 3 mg: batch 5)

[0088] Blend batches preparation by a twice repeated blending and milling process (repeated process of blending in the V-shell blender in conjunction with the milling using the Comil) for 1.5 and 3.0 mg fluticasone ODTs compression blends (see Table 1 for compositions, and Tables 2 and 3 for Physical/Blend uniformity test results and Stratified Blend uniformity results, respectively). Although bulk and tapped density values, particle size distributions blend uniformity values for the confirmatory compression blends are similar to those of the corresponding attributes of the ODT compression blend batch, ODT 1.5 mg (batch 2), the estimated flow properties of both ODT 1.5 mg (batch 3) and ODT 3 mg (batch 5) are not very good. Both compression blend batches are compressed using the same Beta Press equipped with the same set of tooling, and under comparable compression parameters. During compression of both compression blends, some picking and/or sticking to the punches is observed. Details of compression parameters and tablet properties are shown in Table 4.

Example 7: Blends preparation by repeated blending and milling for 1.5 and 3 mg fluticasone ODT, Lubricant at 1.5% by weight, batches 4 and 6

[0089] Fluticasone compression blend batches are prepared by first preparing preblend 1 and preblend 2 as disclosed in Example 3, then blending the components of the final blend without incorporating the lubricant for 35 minutes and further blending for 5 minutes following the addition of the lubricant (sodium stearyl fumarate at 1.5% by weight). The final blends are sampled for testing of bulk and tapped density, particle size distribution (PSD), flowability, moisture content, blend uniformity, and stratified blend uniformity of both batches. Results are reported in Tables 2 and 3.

Example 8: Compression of ODTs of Example 7

[0090] Both batches are compressed using the same rotary tablet press, same set of tooling and under similar compression conditions as disclosed above.

Table 4: Compaction process conditions chemical/physical test results for Fluticasone ODTs

	1.5 mg tablet				3 mg tablet	
Compression parameters	1.5 mg batch 1	1.5 mg batch 2	1.5 mg batch 3	1.5 mg batch 4	3.mg batch 5	3 mg batch 6
Compression force (kN)	5.1-5.5	5.1-6.0	5.3-5.8	5.5-6.0	5.1	4.7-6.0
Precompression force (kN)	2.1-2.2	2.2	2.0-2.2	0	2.0	0
Results						
Average weight (mg)	304.3±3.2	305.4±3.4	303.8±0.7	304.7±3.3	307±2.1	301.8±2.1
Hardness min-max (kp)	3.23-4.01	3.0-3.9	2.67-4.12	3.8-3.6	3.00-3.85	3.0-4.2
Thickness min-max (mm)	4.059-4.149	4.02-4.23	4.09-4.21	4.13-4.19	4.28-4.33	3.99-4.15
Friability (%)	0.29	0.24	0.63	0.64	0.52	0.27
Disintegration – Start (sec)	12	13	12	12	10	14
Disintegration – End (sec)	14	14	12	24	16	15
Assay % label claim	n.p.	100.0	n.p.	99.2	103.8	101.6
Related Substances (%)	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Unknown	n.p.	n.p.	n.p.	<0.10	<0.10	<0.10
Unknown	n.p.	0.11	n.p.	n.p.	n.p.	n.p.
Total	n.p.	0.11	n.p.	<0.10	<0.10	<0.10
Dissolution (% at x minutes)						
10	63	52	69	67	54	54
20	79	81	86	83	73	73
30	87	91	93	89	84	82
45	92	95	96	93	91	88
60	95	96	98	94	94	90

N.P. --> not performed

Example 9: Stability testing

[0091] Fluticasone ODT batches 2 (1.5 mg) and 5 (3 mg) are packaged in 30 cc (30 tablets per bottle) HDPE bottles, with rayon coil and 0.5 g pouch dessicant (Sorb-it ½ g packet) included. All ODTs are stable at accelerated conditions (40°C/75% RH) for a period of 6 months, as well as at long-term stability conditions (25°C/60% RH) for a period of 9 months as shown in Tables 5 and 6. The physical properties, such as appearance, hardness, friability, and disintegration time at all stability conditions are also comparable to the initial values of Fluticasone ODTs, 1.5 and 3 mg.

Table 5: Stability data for Fluticasone ODT batch 2 (1.5 mg)

Test/Method	Batch 2, 1.5 mg														
	Time = Initial					Time = 6 months 40°C/75%RH					Time = 9 months 25°C/60%RH				
Physical Appearance/ Visual	White round tablets					White round tablets					White round tablets				
Moisture	1.0%					1.9%					1.8%				
Disintegration	16 sec					25 sec					18 sec				
Friability	0.3%					0.6%					0.1%				
Hardness (kP)	Min: 2.2 Max: 3.6 Mean: 3.0					Min: 1.4 Max: 3.3 Mean: 2.5					Min: 2.7 Max: 4.3 Mean: 3.4				
Potency (%)	1: 100.0 2: 100.0 Mean: 100.0					1: 100.0 2: 100.2 Mean: 100.1					1: 99.5 2: 98.3 Mean: 98.9				
Related Substances,	RRT		%RS			RRT		%RS			RRT		%RS		
Unknown	-		-			0.89		0.14			1.66		0.10		
Unknown	0.75		0.11			0.90		0.13			-		-		
Total (%)	0.11					0.27					0.10				
Dissolution															
Minutes	10	20	30	45	60	10	20	30	45	60	10	20	30	45	60
Minimum (%)	61	82	90	93	95	66	84	92	96	97	66	83	90	93	94
Maximum (%)	67	86	94	97	99	68	86	93	97	99	69	85	91	95	96
Mean (%)	64	85	92	95	97	67	85	92	96	98	67	84	91	94	95
%RSD	3.3	2.1	1.7	1.7	1.7	1.0	0.7	0.7	0.8	0.8	1.8	0.9	0.8	0.8	0.8

Table 6: Stability data for Fluticasone ODT batch 5 (3 mg)

Test/Method	Batch 5, 3 mg														
	Time = Initial					Time = 6 months 40°C/75%RH					Time = 9 months 25°C/60%RH				
Physical Appearance/ Visual	White round tablets					White round tablets					White round tablets				
Moisture Content	0.9%					1.3%					1.8%				
Disintegration Time	17 sec					17 sec					15 sec				
Friability	1.2%					1.6%					1.1%				
Hardness (kP)	Min: 1.9 Max: 3.5 Mean: 2.6					Min: 1.3 Max: 3.7 Mean: 2.5					Min: 1.7 Max: 3.0 Mean: 2.4				
Potency (%)	1: 103.6 2: 103.9 Mean: 103.8					1: 99.8 2: 97.4 Mean: 98.6					1: 100.7 2: 100.1 Mean: 100.4				
Related Substances,	RRT		%RS			RRT		%RS			RRT		%RS		
Unknown	0.89		<0.1			0.89		0.14			1.66		0.13		
Unknown	-		-			0.90		0.13			-		-		
Total (%)	< 0.1					0.27					0.10				
Dissolution															
Minutes	10	20	30	45	60	10	20	30	45	60	10	20	30	45	60
Minimum (%)	57	78	87	92	94	47	64	72	78	80	56	76	85	91	93
Maximum (%)	61	81	90	95	97	56	76	89	97	101	59	78	89	96	99
Mean (%)	59	79	88	94	96	53	73	84	91	94	58	77	86	93	95
%RSD	3.1	1.7	1.4	1.4	1.3	6.1	6.4	7.0	7.4	7.6	1.5	1.2	1.7	2.0	2.2

Example 10: Preparation of Clinical Trial Materials, batches C1, C2

[0092] Clinical trial batches (Fluticasone propionate ODTs, 1.5 and 3 mg with 1.5% by weight of sodium stearyl fumarate) are prepared by a repeated blending - milling -blending process followed by compression as disclosed in Examples 7 and 8. The in-process testing results and the analytical results of the clinical batches are presented in Table 7 and Table 8, respectively. The compression blend batches show physical (powder) properties similar to that of the feasibility batches, except that the clinical batches have more finer particles passing through 100 mesh sieve (67-76% particles are < 150 µm in size) as compared to 47-57% finer particles in the feasibility batches. However, this has not affected the

tableting properties of the clinical batches significantly; in batch C-2 (3 mg) a slightly higher %RSD in content uniformity and excellent blend uniformity results are observed.

Table 7: Physical/Blend uniformity test results for Clinical Trial Batches 1.5 and 3 mg

Test/Method	Test Parameter		1.5 mg Blend		3 mg Blend	
			1.5001	1.5002	3.0001	3.0002
Bulk/ Tap Density USP <616> Method 1	Bulk Density (g/cc)		0.56	0.56	0.56	0.56
	Tapped Density (g/cc)		0.75	0.75	0.75	0.74
	Hausner Ratio		1.34	1.34	1.34	1.32
	Carr's Index		25.14	25.41	25.56	24.44
Particle Size Analysis	Size/	Particle Size (µm)	% Retained	% Retained	% Retained	% Retained
	20	840	0.50	0.80	0.20	0.70
	40	425	2.90	3.30	7.30	3.40
	60	250	6.00	10.60	5.10	9.90
	80	180	8.90	11.40	9.30	10.80
	100	150	5.50	6.00	6.10	5.70
	200	75	23.20	23.40	24.40	21.40
	Pan	< 75	53.00	44.50	52.60	48.10
LOD (USP <921>1a)			1.3	1.2	1.6	1.2
Blend Uniformity	Minimum (%)		97.4	94.0	96.4	94.1
	Maximum (%)		98.1	97.0	99.1	96.2
	Mean (%)		97.9	96.1	98.1	95.8
	% RSD		0.3	1.2	0.9	0.9

Table 8: Physical/Blend uniformity test results for Clinical Trial Batches of Fluticasone ODTs, 1.5 and 3 mg

Parameter	ODT 1.5 mg C1	ODT 1.5 mg C2	ODT 3 mg C1	ODT 3 mg C2
Physical Appearance/ Visual	White round tablets	White round tablets	White round tablets	White round tablets
Moisture Content	1.9%	1.2%	1.8%	1.3%
Disintegration Time	15 sec	18 sec	16 sec	19 sec
Friability	0.1%	0.0%	0.4%	0.3%
Hardness, kP	Min: 3.1 Max: 5.1 Mean: 3.9	Minimum: 3.9 Maximum: 5.4 Mean: 4.6	Minimum: 2.8 Maximum: 4.3 Mean: 3.4	Minimum: 3.5 Maximum: 4.9 Mean: 4.3
Potency (%)	1: 98.3 2: 99.2 Mean: 98.8	1: 95.4 2: 96.1 Mean: 95.8	1: 98.3 2: 99.6 Mean: 99.0	1: 98.1 2: 97.9 Mean: 98.0
Related Substance (%)	%RS at RRT	%RS at RRT	%RS at RRT	%RS at RRT
Individual Impurity (NMT 0.5%)	<0.1% at 0.89	<0.10	<0.10	<0.10
Total (NMT 1.5%)	<0.1% at 0.90	<0.10	<0.10	<0.10
Content Uniformity of Dosage units – Minimum (%)	97.0	93.2	98.3	96.1
- Maximum	99.3	97.9	100.4	98.5
- Mean	98.1	96.3	99.2	97.5
- % RSD	2.3	6.1	1.7	3.7
% Mean Dissolved / 60 min	96%	95%	94%	93%

Example 11: Stability data for Clinical Trial Batches, Fluticasone ODTs, 1.5 and 3 mg

[0093] Fluticasone ODT batches, 1.5 mg and 3 mg are packaged in 30 c't (30 tablets per bottle) HDPE bottles, with rayon coil and 0.5 g pouch dessicant (Sorb-it ½ g packet) included. All ODTs are stable at accelerated conditions (40°C/75% RH) for a period of 9 months, as well as at long-term stability conditions (25°C/60% RH) for a period of 24 months as shown in Table 9. The physical properties, such as appearance, hardness, friability, and disintegration time at all stability conditions are also comparable to the initial values of Fluticasone ODTs, 1.5 and 3 mg.

Table 9: Stability data for Clinical Trial Batches Fluticasone ODTs, 1.5 and 3 mg

ODT Batch #	ODTs, 1.5 mg		ODTs, 3 mg	
Parameter	Time: Initial	Time: 24 months at 25°C/60%RH	Time: Initial	Time: 24 months at 25°C/60%RH
Physical Appearance/ Visual	White round tablets	White round tablets	White round tablets	White round tablets
Moisture Content	2.2%	2.1%	2.4%	2.0%
Disintegration Time	0-5 sec	0-5 sec	0-5 sec	0-5 sec
Friability	0.03%	0.12%	0.02%	0.50%
Hardness, kP	Min: 3.6 Max: 6.1 Mean: 4.8	Min: 3.8 Max: 5.9 Mean: 5.0	Min: 4.0 Max: 5.9 Mean: 4.7	Min: 3.3 Max: 6.2 Mean: 4.8
Potency (%)	1: 100.8 2: 100.3 Mean: 100.6	1: 99.7 2: 99.8 Mean: 99.7	1: 100.3 2: 101.3 Mean: 100.8	1: 100.0 2: 100.0 Mean: 100.0
Related Substances	%RS at RRT	%RS at RRT	%RS at RRT	%RS at RRT
Unknown	<0.1% at 0.89	-	<0.1% at 0.89	-
Unknown	<0.1% at 0.90	-	<0.1% at 0.90	-
Total	<0.1	<QL	<0.1	<QL
% Mean Dissolved / 60 min	96%	95%	94%	93%

Example 12: Clinical tests

[0094] A proof of concept study is conducted for clinical batches ODT-FT 1.5 mg and 3 mg dose strengths in patients with a diagnosis of EoE aged 12 years to 55 years.

[0095] The doses utilized are 1.5 mg administered twice daily and 3.0mg administered once daily. The study also included a placebo arm. Each arm enrolls 8 subjects. Findings of efficacy analyses demonstrate a positive signal for efficacy with the greatest response seen histologically in the decrease of peak eosinophil count per high power field (a hallmark of the disease and indicator of treatment response). Both 1.5 mg and 3 mg treatment groups are clearly more efficacious than placebo histologically. The percent of subjects with at least 30% decrease in the overall EoE symptom severity, as measured by patient questionnaire, also shows numerical superiority of the two FT-ODTs over placebo. Endoscopic improvements are also seen with changes in furrowing and vascularity showing the greatest differentiation of FT-ODTs from placebo, indicating a positive anti-inflammatory effect of the formulations.

[0096] Overall, the FT-ODTs of the invention demonstrate improvements in histology, overall symptoms and overall endoscopic activity.

Example 13: Preparation of Blends for 0.75, 4.5 and
6 mg Fluticasone ODTs - Batches 7 to 9

[0097] Fluticasone compression blend batches at a drug load of 0.25% by weight are prepared by first preparing preblend 1 and pre blend 2 as disclosed in Example 3. A preblend 1 (see Table 10 for weights of individual components of compression blends of ODTs, 0.75mg, 4.5mg and 6mg) is prepared by charging a 2 quart V-blender sequentially with half of SMCC, micronized fluticasone propionate, colloidal silicon dioxide and the remaining half of SMCC and blending at 25 rpm for 10 ± 1 minutes. The preblend 1 is passed through a QUADRO Comil fitted with a 024R screen (30 mesh opening) at approximately 2400 ± 100 rpm. Preblend 2 is prepared: half of spray-dried mannitol, milled preblend 1, crospovidone, and sucralose powder are blended in a 32 quart V-blender at 25 rpm for 10 ± 1 minutes and milled through the 024R screen. The Comil is rinsed by passing the remaining half of spray dried mannitol through a 024R screen. Half of rapidly dispersing microgranules, milled preblend 1, rinsed mannitol and the remaining half of

rapidly dispersing granules are blended in a 32 quarts V-blender at 25 rpm, without incorporating the lubricant, for 35 minutes and further blended for 5 minutes following the addition of the lubricant (sodium stearyl fumarate at 1.5% by weight).

Example 14: Preparation of Blends for 1.5mg Fluticasone ODTs at
Batch Size: 30 kgs; batch 10

[0098] The manufacturing process for the fluticasone compression blend batch at a lower drug load of 0.5% by weight is scaled up to a semi-industrial scale of 30 kgs. The process essentially consists of first preparing preblend 1 and preblend 2 as disclosed in Example 3. A preblend 1 (see Table 10 for weights of individual components of compressible blends of ODTs, 1.5mg) is prepared by charging a 32 quart V-blender sequentially with half of SMCC, micronized fluticasone propionate, colloidal silicon dioxide and the remaining half of SMCC and blending at 25 rpm for 10 ± 1 minutes. The preblend 1 is passed through a QUADRO Comil fitted with a 024R screen (30 mesh opening) at approximately 2400 ± 100 rpm. Preblend 2 is prepared: half of spray-dried mannitol, milled preblend 1, crospovidone, and sucralose powder are blended in a Galley blender with 113L tote at 12 rpm for 20 ± 1 minutes and milled through the 024R screen. The Comil is rinsed by passing the remaining half of spray-dried mannitol through a 024R screen. Half of rapidly dispersing microgranules, milled preblend 1, rinsed mannitol and the remaining half of rapidly dispersing granules are blended at 12 rpm for up to 40 minutes.

[0099] The final blends in Example 13 and 14 are sampled and subjected to in-process testing as per United States Pharmacopeia requirements and analytical testing of bulk and tapped density, particle size distribution (PSD), flowability, blend uniformity and moisture content. This is the first time, a direct compression ODT blend batch at a drug load of 0.25 % by weight is manufactured using the procedure established for the blend at a drug load of 0.5% by weight. No technical issues have been encountered during the manufacture. The results reported in Table 11 show acceptable physical characteristics. Although the blend uniformity data indicate a uniform distribution of the active, a low potency is evident in Batch 7 with the lowest drug load, probably due to a loss of the active during blending/milling. During the semi-industrial scale compression blending process prior to

incorporating the lubricant, the blends sampled at 20, 30 and 40 minutes show acceptable blend uniformity values as shown below.

Blend Uniformity (% Label Claim)	Sampling Time	20 min	30 min	40 min
	Mean (%)	101.4	99.1	98.3
	Minimum (%)	99.3	97.2	95.9
	Maximum (%)	104.3	100.6	100.1
	RSD (%)	1.4	1.4	1.3

Example 15: Compression of ODTs of Example 13 and 14

[0100] Batches of ODTs, 0.75mg, 4.5mg and 6mg are compressed using the same rotary tablet press (Beta Press) equipped with the same force feeder and same set of tooling (B-size tooling, 9.5 mm round flat faced radius edge) and under similar compression conditions as disclosed previously for ODTs, 1.5mg or 3mg. The compressed tablets of 0.75mg, 4.5mg and 6mg meet the specifications for tablet weight, disintegration time, friability, hardness and thickness. The physical properties of the tablets are similar and comparable to the other dose strengths. The potency and content uniformity results for the 0.75mg ODTs indicate a low potency confirming the low blend uniformity results reported above.

[0101] ODTs, 1.5mg are compressed using the industrial tablet press, Korsch XL 400 equipped with D tooling, 9.5 mm round, flat faced radius edge, operated at 1015 tablets per minutes. The compressed tablets are observed to meet all specifications for tablet weight, disintegration time, friability, hardness and tablet thickness. The physical properties of the tablets are similar and comparable to the same dose strength or other dose strengths produced at small scale. The potency and content uniformity results confirm the blend uniformity results, resulting ODTs meeting all product specifications. The results of the scale up batch have shown that the current small-scale process at a drug load of 0.5% by weight or higher, is scalable. The comparable /similar results obtained between dose

strengths and consistency in results between batch sizes at least at a drug load of 0.5% by weight or higher, indicate a robust, suitable direct compression manufacturing process for ODT dose strengths ranging from 1.5mg to 6mg or at a drug load of from 0.5%, to 2% by weight. This low-end drug load has been possible in the past only by spray granulation, by spraying the drug solution while granulating tablet components excepting the lubricant.

Table 10: Compositions of compression blends of Fluticasone ODTs, 0.75mg (Batch 7), 4.5mg (Batch 8), 6mg (Batch 9) and 1.5mg (Batch 10)

Ingredients (mg)	Fluticasone ODTs				
ODT Batch #	0.75 mg batch 7		4.5 mg batch 8	6.0 mg batch 9	1.5 mg batch 10
	(%/tablet)	(mg/tablet)	(mg/tablet)	(mg/tablet)	(mg/tablet)
Micronized Fluticasone Propionate USP	0.25	0.75	4.50	6.00	1.50
Colloidal Silicon Dioxide NF	0.30	0.90	0.90	0.90	0.90
Silicified Microcrystalline Cellulose NF	10.00	30.0	30.00	30.00	30.00
Crospovidone NF	7.50	22.50	22.50	22.50	22.50
Sucralose NF	0.40	1.20	1.20	1.20	1.20
Spray-dried Mannitol USP	30.05	90.15	86.40	84.90	89.40
Rapidly Dispersing Granules	50.00	150.00	150.00	150.0	150.0
Sodium Stearyl Fumarate NF	1.50	4.50	4.50	4.50	4.50
Total	100.00	300.00	300.00	300.00	300.00

Table 11: Physical/Blend uniformity test results for Fluticasone ODT, 0.75mg, 4.5mg and 6mg Compression Blends

Test	Parameters		Blend Batch #		
			0.75 mg batch 7	4.5 mg batch 8	6.0 mg batch 9
Bulk/Tap Density USP <616> Method I	Bulk Density		0.56	0.55	0.55
	Tapped Density		0.75	0.73	0.75
	Hausner Ratio		1.33	1.33	1.33
Particle Size Analysis	Sieve #	Particle Size (µm)	% Retained	% Retained	% Retained
	20	840	0.6	0.6	0.6
	40	425	10.0	9.8	7.6
	60	250	16.9	16.7	15.1
	80	180	20.2	19.2	18.5
	100	150	9.3	9.3	9.4
	200	75	25.2	26.9	28.4
	Pan	20	17.8	17.5	20.5
LOD USP <921> (KF)			1.4	1.8	1.5
Flow Results	Flow Angle		82.6	83.9	83.2
	Flow Index		1.01	1.02	1.01
	Flow Quality		Very Good	Very Good	Medium
Blend Uniformity	Blending Time		Blend (40 min) After Lubrication		
	Mean, %		91.3	97.1	98.7
	Minimum, %		88.5	94.7	94.7
	Maximum, %		94.1	98.7	100.4
	%RSD		2.2	1.3	2.1

Table 12: Compaction process conditions and chemical/physical test results for Fluticasone ODTs

	ODTs			
Compression parameters	0.75 mg batch 7	4.5 mg batch 8	6.0 mg batch 9	1.5 mg batch 10
Compression force (kN)	5.3-5.6	5.0-5.2	5.2-5.3	4.8-5.1
Precompression force (kN)	2.0	1.5-1.7	1.5	1.3-1.4
Average weight, mg (%RSD)*	302.3 (0.56)	301.9 (0.84)	300.6 (0.54)	301.2 (0.76)
	297.3 (0.58)	301.7 (0.94)	303.6 (0.42)	302.2 (0.40)
	296.4 (0.40)	303.2 (0.77)	299.6 (0.76)	302.1 (0.33)
Hardness min-max (kp)*	3.70 (2.4-5.9)	3.35 (3.0-3.9)	4.34 (3.8-4.8)	4.45 (4.9-5.8)
	3.57 (2.4-5.9)	3.72 (2.8-4.4)	3.13 (2.3-3.4)	4.92 (3.8-5.5)
	2.95 (2.8-3.2)	3.75 (3.1-4.6)	3.14 (2.1-4.0)	4.91 (4.6-5.4)
Thickness min-max (mm)	4.15-4.41	4.01-4.12	4.01-4.19	4.01-4.04
Friability (%) Start/Middle/End	0.2/0.2/0.3	0.5/0.2/0.3	0.5/0.5//0.3	0.0/0.1/0.0
Disintegration – Start (sec)	10	15	15	12
Disintegration – End (sec)	10	14	16	14
Assay % label claim	95.5-95.6	98.6	99.3-100.1	97.2-99.3
Related Substances (%) - RRT				
Unknown 0.79		ND	ND	0.18
Unknown 0.89/0.90		ND/0.10	ND/ND	<0.10/ 0.11
Unknown 1.58 / 1.84		ND/ND	ND/ND	<0.10/ <0.10
Total		0.10	<0.10	0.29
Time	% Dissolved			
10 Min	58 (1.9)	46 (2.6)	46 (3.1)	64 (2.5)
20 Min	72 (1.1)	74 (15.2)	66 (1.1)	82 (0.9)
30 Min	79 (0.9)	85 (8.8)	77 (1.2)	90 (1.2)
45 Min	84 (0.8)	89 (2.8)	86 (1.5)	93 (1.0)
60 Min	86 (0.6)	92 (1.0)	91 (1.4)	95 (1.0)

* --> Tested at Start, Middle and End of compression; ND --> not detected

[0102] Stability of Fluticasone ODTs batch 7 (0.75 mg), batch 8 (4.5) and batch 9 (6 mg) is testes; these batches are packaged in 30 cc (30 tablets per bottle) HDPE bottles, with rayon coil and 0.5 g silica pouch dessicant (Sorb-it ½ g packet) included. All ODTs are stable at accelerated conditions (40°C/75% RH) for a period of 6 months, as well as at long-term stability conditions (25°C/60% RH) for a period of 9 months; all values measured at given time points (T= 0, 1 month, 2 months, 3 months, 6 months, 9 months) are within the acceptance criteria (disintegration: NMT 30 sec, assay: NLT 90.0% and NMT 110.0%, each impurity: NMT 0.5%, total impurity: NMT 1.5%). The physical properties, such as appearance, hardness, friability, and disintegration time at all stability conditions are also comparable to the initial values of the corresponding Fluticasone ODTs.

[0103] While the invention has been described in connection with the specific embodiments herein, it will be understood that it is capable of further modifications and this application is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice within the art to that the invention pertains and as may be applied to the essential features hereinbefore set forth and as follows in the scope of the appended claims.

CLAIMS

What is claimed is:

1. An orally disintegrating tablet comprising:
 - a. a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and
 - b. at least one disintegrant;wherein the corticosteroid is present in an amount ranging from about 0.5 mg to about 10 mg, and the corticosteroid has a mean particle size of ranging from about 100 μ m to about 100 nm; and
wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.
2. The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.
3. The orally disintegrating tablet of claim 2, wherein the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.
4. The orally disintegrating tablet of claim 2, wherein said corticosteroid is budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, or a pharmaceutically salt or ester thereof.
5. The orally disintegrating tablet of claim 4, wherein the corticosteroid is present in an amount ranging from about 0.5 mg to about 3 mg.
6. The orally disintegrating tablet of claim 4, wherein said corticosteroid is fluticasone or an ester thereof.

7. The orally disintegrating tablet of claim 5, wherein said corticosteroid is fluticasone propionate.
8. The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 3 mg in the orally disintegrating tablet.
9. The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 1.5 mg in the orally disintegrating tablet.
10. The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size of ranging from about 10 μ m to about 100 nm.
11. The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size ranging from about 4 μ m to about 100 nm.
12. The orally disintegrating tablet of claim 1, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.
13. The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.
14. The orally disintegrating tablet of claim 12, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.
15. The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

16. The orally disintegrating tablet of claim 12, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .

17. The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is present at an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.

18. The orally disintegrating tablet of claim 1, wherein the total weight of the tablet is in the range of from about 300 to about 900 mg.

19. An orally disintegrating tablet comprising:

a. fluticasone propionate adsorbed onto microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, amorphous magnesium aluminum silicate, or combinations thereof; and

b. at least one disintegrant,

wherein:

the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg, and

the fluticasone propionate has a mean particle size ranging from about 10 μm to about 100 nm; and

wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration test.

20. The orally disintegrating tablet of claim 19, wherein the microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate, or a combination thereof, is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.

21. The orally disintegrating tablet of claim 19, comprising silicified microcrystalline cellulose in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.
22. The orally disintegrating tablet of claim 22, wherein fluticasone propionate has a mean particle size of about 4 μm or less.
23. The orally disintegrating tablet of claim 21, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.
24. The orally disintegrating tablet of claim 20, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.
25. The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.
26. The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.
27. The orally disintegrating tablet of claim 24, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .
28. The orally disintegrating tablet of claim 19, wherein the silicified microcrystalline cellulose is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet, fluticasone propionate is present in an amount ranging from about 1

mg to about 3 mg, and fluticasone propionate has a mean particle size of about 4 μ m to about 100 nm.

29. A method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1.

30. A method of preparing the orally disintegrating tablet of claim 1, comprising the steps of:

(a) micronizing the corticosteroid;

(b) preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate;

(c) preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener;

(d) preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c);

(e) compressing the blend of step (d) to form a tablet.

Abstract

The present invention is directed to orally administered compositions of topically acting corticosteroids for the treatment of inflammation of the gastrointestinal tracts such as eosinophilic esophagitis. The present invention also provides a method for treating conditions 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 as orally disintegrating tablets comprising a topically active corticosteroid adsorbed onto a pharmaceutically acceptable carrier such as silicified microcrystalline cellulose.

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
First Named Inventor/Applicant Name:		Michael A. GOSSELIN		
Filer:		Jonathan M. Cousin/Carolina Pimentel		
Attorney Docket Number:		ELLO-144/04US 342083-3254		
Filed as Large Entity				
Filing Fees for Track I Prioritized Examination - Nonprovisional Application 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
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	10	100	1000
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				7160

Electronic Acknowledgement Receipt

EFS ID:	42254243
Application Number:	17211119
International Application Number:	
Confirmation Number:	9921
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	58249
Filer:	Jonathan M. Cousin/Carolina Pimentel
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ELLO-144/04US 342083-3254
Receipt Date:	24-MAR-2021
Filing Date:	
Time Stamp:	15:14:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$7160
RAM confirmation Number	E20213NF14262522
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	TrackOne Request	ELLO-144-04US_Track_1_Requ est_Form.pdf	139047	no	1
			c550b18e14e791fa3b4155b86d31daaccb13d8b0		
Warnings:					
Information:					
2	Application Data Sheet	ELLO-144-04US_Applicaton_Da ta_Sheet_Continuation_Track_1.pdf	118956	no	7
			b65dfa4a158ba40e2246c5dbedd1a15dee2d6439		
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Oath or Declaration filed	ELLO-144-04US_Inventors_Oat hs_parent_executed.pdf	5696272	no	3
			24c769a4372721703e2a1fdc942cae9e9c8d95b5		
Warnings:					
Information:					
4	Power of Attorney	ELLO-144-04US_POAtrans_PO Assigned.pdf	176050	no	2
			103608137a9297fcd2fa495b6ed9b08e4422028e		
Warnings:					
Information:					
5	Drawings-other than black and white line drawings	ELLO-144-04US_Figures_Conti nuation_Track_1.pdf	70902	no	1
			770b8ca86a27b669696df8428114aac8369aa925		
Warnings:					
Information:					
6		ELLO-144-04US_Specification_ Continuation_Track_1.pdf	308430	yes	45
			e5efae356e6f1f23b206442236bde75c84506b4		

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	39	
	Claims		40	44	
	Abstract		45	45	
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	41574	no	2
			4aed66a758dc625913849472f63f7098d7fd436a		
Warnings:					
Information:					
Total Files Size (in bytes):			6551231		
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. <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.					

Doc Code: TRACK1.REQ

Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Michael A. GOSSELIN	Nonprovisional Application Number (if known):	TBD
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature / Jonathan M. Cousin /	Date March 24, 2021
Name (Print/Typed) Jonathan M. Cousin	Practitioner Registration Number 66,418

Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*

☒ *Total of 1 forms are submitted.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Michael	A.	GOSSELIN		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Springboro	State/Province	OH	Country of Residence	US
Mailing Address of Inventor:					
Address 1	c/o Adare Pharmaceuticals, Inc.				
Address 2	1200 Lenox Drive				
City	Lawrenceville	State/Province	NJ		
Postal Code	08648	Country i	US		
Inventor 2					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Jin-Wang		LAI		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Springboro	State/Province	OH	Country of Residence	US
Mailing Address of Inventor:					
Address 1	c/o Adare Pharmaceuticals, Inc.				
Address 2	1200 Lenox Drive				
City	Lawrenceville	State/Province	NJ		
Postal Code	08648	Country i	US		
Inventor 3					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Gopi	M.	VENKATESH		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254		
		Application Number			
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS				
City	Vandalia	State/Province	OH	Country of Residence	US
Mailing Address of Inventor:					
Address 1	c/o Adare Pharmaceuticals, Inc.				
Address 2	1200 Lenox Drive				
City	Lawrenceville	State/Province	NJ		
Postal Code	08648	Country i	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	zIPatentDocketingMailboxUS@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
Attorney Docket Number	ELLO-144/04US 342083-3254	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	1	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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	16/578568	2019-09-23		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/578568	Division of	14/917125	2016-03-07	10471071	2019-11-12
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14/917125	a 371 of international	PCT/US2014/054203	2014-09-05		
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
PCT/US2014/054203	Claims benefit of provisional	61/874450	2013-09-06		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
			Remove
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. ☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.
--

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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.

☐ 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		
Address 2			
City	Lawrenceville	State/Province	NJ
Country	US	Postal Code	08648
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	ELLO-144/04US 342083-3254
		Application Number	
Title of Invention	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		

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 ¹		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Jonathan M. Cousin/		Date (YYYY-MM-DD)	2021-03-24
First Name	Jonathan	Last Name	Cousin	Registration Number
				66418

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

PTO/AIA/01 (08-12)

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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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	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
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 <u>PCT/US14/54203</u>			
filed on <u>September 5, 2014</u>			
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-2038 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: <u>Michael A. GOSSELIN</u>		Date (Optional): <u>SEPT 19, 2014</u>	
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.

If you need assistance in completing the form, call 1-800-PTO-9198 and select option 2.

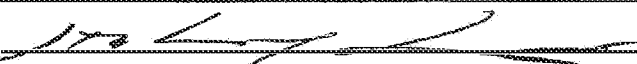
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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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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	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS	
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 <u>PCT/US14/54203</u> filed on <u>September 5, 2014</u>
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-2038 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:	<u>Jin-Wang LAI</u>	Date (Optional): _____
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.

If you need assistance in completing the form, call 1-800-PTO-9198 and select option 2.

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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	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS		
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 <u>PCT/US14/54203</u> filed on <u>September 5, 2014</u> 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 identify 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-2038 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: <u>Gopi M. VENKATESH</u>		Date (Optional): <u>Sept 19, 2014</u>	
Signature: <u>[Signature]</u>			
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 1.62. 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 this 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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SCORE Placeholder Sheet for IFW Content

Application Number: 17211119

Document Date: 03/24/2021

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- Drawing

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