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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
58249	7590	09/27/2019		
COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004			EXAMINER JUSTICE, GINA CHIEUN YU	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 09/27/2019	DELIVERY MODE ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
14/917,125	03/07/2016	GOSSELIN et al.	ADAR-144/02US 325

COOLEY LLP ATTN: IP Docketing Department 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004		EXAMINER	
		GINA JUSTICE	
		ART UNIT	PAPER
		1617	20190923

DATE MAILED: _____

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

Commissioner for Patents

The information disclosure statement (IDS) submitted on September 16, 2019 was filed after the mailing date of the Notice of Allowance on September 16, 2019. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

Receipt date: 09/16/2019

14/917,125 - GAU: 1617

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 <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	14/917,125		
		Filing Date	March 7, 2016		
		First Named Inventor	GOSSELIN, Michael A.		
		Art Unit	1617		
		Examiner Name	JUSTICE, Gina Chieun Yu		
Sheet	1	of	1	Attorney Docket Number	ADAR-144/02US 325049-2315

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.	2009/0181099	07-16-2009	Dohil, et al.	

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

Examiner Signature	/GINA C JUSTICE/	Date Considered	09/23/2019
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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 2.

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 <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	14/917,125
				Filing Date	March 7, 2016
				First Named Inventor	GOSSELIN, Michael A.
				Art Unit	1617
				Examiner Name	JUSTICE, Gina Chieun Yu
				Attorney Docket Number	ADAR-144/02US 325049-2315
Sheet	1	of	1		

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.	2009/0181099	07-16-2009	Dohil, et al.	

Examiner Signature	Date Considered
-----------------------	--------------------

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

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

Electronic Patent Application Fee Transmittal				
Application Number:		14917125		
Filing Date:		07-Mar-2016		
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:		ADAR-144/02US 325049-2315		
Filed as Large Entity				
Filing Fees for U.S. National Stage under 35 USC 371				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
Total in USD (\$)				240

Electronic Acknowledgement Receipt	
EFS ID:	37097780
Application Number:	14917125
International Application Number:	
Confirmation Number:	1075
Title of Invention:	CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS
First Named Inventor/Applicant Name:	Michael A. GOSSELIN
Customer Number:	91543
Filer:	Jonathan M. Cousin/Sandra Laramore
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-144/02US 325049-2315
Receipt Date:	16-SEP-2019
Filing Date:	07-MAR-2016
Time Stamp:	16:06:29
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$240
RAM confirmation Number	E20199FG06583961
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	ADAR-144_02US_IDS.pdf	88101	no	4
			824a9831a2757d91ecce8760c0c606b85143b7dd		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	ADAR-144_02US_SB08.pdf	80495	no	1
			ea5bcd47c55793be902d2436afdb363023057da6		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	30712	no	2
			c3b2067f0194f5beedda4fe9050c8bf674f9f101		
Warnings:					
Information:					
Total Files Size (in bytes):			199308		
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.: ADAR-144/02US 325049-2315
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	GOSSELIN, Michael A.	Confirmation No.:	1075
Application No.:	14/917,125	Group Art Unit:	1617
Filed:	March 7, 2016	Examiner:	JUSTICE, Gina Chieun Yu
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 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.

- ☐ Enclosed is a copy of a non-English publication(s) ____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
 - ☐ Enclosed is a copy of a non-English publication(s) ____ English language publication ____ (copy enclosed) claims priority from this non-English publication.
 - ☐ Enclosed is an explanation of non-English publication(s) ____ for which an English translation is not available.
 - ☐ Enclosed is an English translation of non-English publication(s) ____ cited in the attached Form used in lieu of PTO/SB/08.
 - ☐ Enclosed is a copy of pending patent Application Serial No. ____.
- ☐ In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:
- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
 - ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
 - ☐ before the mailing date of a first office action on the merits; or
 - ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.
- ☐ In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following:
- ☐ a final action under 37 C.F.R. §1.113;
 - ☐ a notice of allowance under 37 C.F.R. §1.311; or
 - ☐ an action that otherwise closes prosecution in this application.

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

- ☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$240.00;
- ☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$120.00;
- ☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$60.00; or
- ☐ Statement as specified in 37 C.F.R. §1.97(e):
 - ☐ Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a

foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

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

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

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

- ☒ Fee under 37 C.F.R. §1.17(p) in the amount of \$240.00;
☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$120.00; or
☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$60.00;

and

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

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

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

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

Application No.: 14/917,125

Docket No.: ADAR-144/02US 325049-2315

received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

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

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

Remarks

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

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

The Director is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 50-1283, under Order No. ADAR-144/02US 325049-2315.

Dated: September 16, 2019

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 91543

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
91543	7590	09/09/2019	EXAMINER	
Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			09/09/2019	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

Corrected
Notice of Allowability

Application No.
14/917,125

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 Quick Path IDS filed on August 6, 2019.
☐ 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 1-5,8-40 and 47-48. 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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 08/07/2019
Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER

JUSTICE, GINA CHIEUN YU

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/07/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
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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
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nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	11/07/2019
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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)

91543 7590 08/07/2019
Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

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

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being 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.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075

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	\$1000	\$0.00	\$0.00	\$1000	11/07/2019

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 ☐ Government4a. 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.

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Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US	1075
91543	7590	08/07/2019	325049-2315	
Cooley LLP / Eurand			EXAMINER	
ATTN: Patent Group			JUSTICE, GINA CHIEUN YU	
1299 Pennsylvania Avenue, Suite 700				
Washington, DC 20004			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 08/07/2019				

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

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Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether 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. 14/917,125	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 RCE filed on April 25, 2019.
☐ 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 1-5,8-40 and 47-48. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617



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NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 02/28/2019
Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER

JUSTICE, GINA CHIEUN YU

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/28/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
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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
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nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	05/28/2019
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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

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(Typed or printed name)
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	05/28/2019

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).

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91543	7590	02/28/2019	~~325049-2315~~	
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ATTN: Patent Group			JUSTICE, GINA CHIEUN YU	
1299 Pennsylvania Avenue, Suite 700				
Washington, DC 20004			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 02/28/2019

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(Applications filed on or after May 29, 2000)

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public 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. 14/917,125	Applicant(s) GOSSELIN et al.	
	Examiner GINA JUSTICE	Art Unit 1617	AIA 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 amendment filed on December 20, 2018.
☐ 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 1-5,8-40 and 47-48. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/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.

Applicant's response filed on December 20, 2018 has been received and fully considered.

Claims 1-5, 8-40, 47 and 48 are now pending.

Previous claim rejections made under 35 U.S.C 112 (b) and (d) as indicated in the Office action dated September 28, 2018 are withdrawn in view of amendment made to claims 32 and 34.

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: GOSSELIN, M, et al. Confirmation No.: 1075
Serial No.: 14/917,125 Group Art Unit: 1617
Filed: March 7, 2016 Examiner: JUSTICE, Gina Yu

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

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

RESPONSE TO NON-FINAL REJECTION

This paper is filed in response to a non-final Office Action (“NFOA”), mailed September 24, 2018, setting a three-month period for reply. Accordingly, this paper is timely filed by December 24, 2018.

Claims begin on page 2 of this paper

Remarks begin on page 7 of this paper.

REMARKS

I. Status of Claims

Applicant wishes to thank the Examiner for the indication of allowed subject matter.

Upon entry of the present amendments, claims 1-5, 8-40, 47, and 48 are pending. Claims 32-35 have been amended for clarity and consistency with terminology used in the specification. Claim 32 has been further amended to delete subject matter therefrom. The status of identifiers of claims 36-40 have been changed from “Withdrawn” to “Original”, as the Examiner has indicated that the claims will be rejoined with claims 1-35, 37, and 48. Withdrawn claims 41-46 have been canceled without prejudice to, or disclaimer of, the subject matter thereof.

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

Applicant reserves the right to prosecute any cancelled subject matter in one or more divisional or continuation applications.

II. Claim Rejections under 35 U.S.C. § 112(b)

The Examiner rejected claims 32-35 under 35 U.S.C. § 112(b) as indefinite for improperly depending from a canceled claim.

To correct the dependency issues, claims 32 and 34 have been amended to depend from allowed independent claim 1. Claims 33 and 35 now properly depend from allowable claims 32 and 34, respectively. Thus, as presently amended, each of these claims either directly or indirectly refers back to allowed claim 1.

Claim 32 is further rejected under 35 U.S.C. § 112(b) for the use of the term “an additive with dual function” that allegedly renders the claim vague and indefinite. To address the alleged issues, the term “dual function additive” of claims 32 and 33 has been replaced with a “pharmaceutically acceptable additive with multi-functional activity,” which is consistent with the terminology found on p. 12, line 20 of the specification, as-filed.

In view of these amendments, Applicant believes the scope and meaning of claims 32-35 is clear. Applicant therefore requests withdrawal of the present rejection and allowance of the

pending claims.

III. Claim Rejections under 35 U.S.C. § 112(d)

The Examiner rejected claims 32 and 33 under 35 U.S.C. § 112(d) as being in improper dependent form for failing to further limit the ratio of ratio of sugar alcohol or saccharide to disintegrant recited in claim 1.

Without acquiescing to the present rejection, Applicant has further amended claim 32 by removing the ratio of components recited by the claim, thereby rendering this rejection moot.

In view of this amendment, Applicant believes claims 32 and 33 properly limit the subject matter of independent claim 1. Withdrawal of the rejection and allowance of the pending claims is respectfully requested.

CONCLUSION

In view of the amendments and remarks herein, withdrawal of the rejections is requested, and Allowance of the application is earnestly solicited. If the Examiner has any other concerns or identifies any further issues regarding the claims, Applicant respectfully requests for the Examiner to contact Applicant's representative at the telephone number provided in the signature block below.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: December 20, 2018

Respectfully submitted,
COOLEY LLP

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004

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

Tel: (202) 728-7079
Fax: (202) 842-7899

LISTING OF THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination.

1. (Previously Presented) 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 99:1wherein the corticosteroid is present in an amount of about 5% or less by weight in the composition.
2. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> method for disintegration time.
3. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds on contact with saliva in the oral cavity of a patient in need thereof.
4. (Previously Presented) The pharmaceutical composition 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.
5. (Previously Presented) The pharmaceutical composition of claim 4, wherein the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.
6. (Cancelled)

7. (Cancelled)
8. (Previously presented) The pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates, esters, and mixtures thereof.
9. (Original) The pharmaceutical composition of claim 8, wherein said corticosteroid is fluticasone.
10. (Original) The pharmaceutical composition of claim 9, wherein said corticosteroid is fluticasone propionate.
11. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3% or less by weight in the composition.
12. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5% or less by weight in the composition.
13. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1% or less by weight in the composition.
14. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 0.5% or less by weight in the composition.
15. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 4.5 mg in the composition.
16. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3 mg in the composition.
17. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5 mg in the composition.
18. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 6 mg in the composition.

19. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 0.05 to about 15 mg in the composition at a drug content of from about 0.16% to 5% by weight of the composition.
20. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 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.
21. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate 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.
22. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized with a particle size of not more than 50 microns.
23. (Previously presented) The pharmaceutical composition of claim 22, wherein the corticosteroid has a mean particle size of not more than about 10 microns.
24. (Previously presented) The pharmaceutical composition of claim 1, further comprising an adhesive agent.
25. (Original) The pharmaceutical composition of claim 24, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl ethylcellulose, sodium carboxymethylcellulose, cross-linked polyacrylic acid, cross-linked polyacrylates, aminoalkyl methacrylate copolymers, carbopol polymers, hydrophilic polysaccharide gums, maltodextrins, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
26. (Previously Presented) The pharmaceutical composition of claim 1, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.
27. (Previously Presented) The pharmaceutical composition of claim 1, wherein the sugar

alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

28. (Previously presented) The pharmaceutical composition of claim 1, further comprising a free flowing sugar alcohol or saccharide selected from the group consisting of spray-dried mannitol, spray-dried lactose, and combinations thereof.

29. (Previously presented) The pharmaceutical composition of claim 1, further comprising a lubricant selected from the group consisting of magnesium stearate, stearic acid, sodium stearyl fumarate, glyceryl behenate, and a mixture thereof.

30. (Previously presented) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.

31. (Previously presented) The pharmaceutical composition of claim 1, further comprising at least one antiviral agent.

32. (Currently Amended) The pharmaceutical composition of claim [[6]]1, wherein the rapidly dispersing microgranules further comprise a pharmaceutically acceptable additive with a dual function-multifunctional activity and wherein the ratio of sugar alcohol or saccharide to disintegrant to dual function additive is from 88:10:2 to 98:5:1.

33. (Currently Amended) The pharmaceutical composition of claim 32, wherein the ~~dual-function~~ additive with multi-functional activity is selected from the group consisting of pregelatinized starch and hydroxypropylcellulose.

34. (Currently Amended) The pharmaceutical composition of claim [[6]]1, wherein the corticosteroid has an average particle size of less than about 10 μm , the rapidly dispersing microgranules have an average 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 .

35. (Previously Presented) The pharmaceutical composition of claim 34, wherein the corticosteroid is fluticasone propionate with a particle size of less than 5 microns, the pharmaceutically acceptable carrier is silicified microcrystalline cellulose, the rapidly dispersing

microgranules comprise mannitol and crospovidone, and the composition further comprises a free-flowing sugar alcohol which is spray-dried mannitol, and a lubricant which is sodium stearyl fumarate.

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

37. (Original) The method of claim 36, wherein said condition comprises inflammation of the esophagus.

38. (Original) The method of claim 37, wherein said condition is eosinophilic esophagitis.

39. (Original) The method of claim 38, wherein said condition comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

40. (Original) The method of claim 36, wherein said condition is viral or bacterial pharyngitis, gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

41.-46. (Canceled)

47. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized.

48. (Previously presented) The pharmaceutical composition of claim 47, wherein the corticosteroid has a mean particle size of less than about 10 μm .



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
91543	7590	09/24/2018	EXAMINER	
Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			09/24/2018	ELECTRONIC

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

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

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

zIPPatentDocketingMailboxUS@cooley.com

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.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2018 has been entered.

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), as indicated in the Office action dated January 30, 2018, is withdrawn in view of amendment made to claim 1.

Previous claim rejection made under 35 U.S.C. 103 over Ramalho et al. and Perrett et al. and further in view of Platteuw et al. (US 20040265375), indicated in the same Office action, is withdrawn for the same reason.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on April 30, 2018 and June 29, 2018 was filed after the mailing date of the final Office action on January 30, 2018. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Claims 1-5, 8-33 and 47 and 48 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 36-40, directed to the process of using the 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.

Claims 41-46, directed to the invention(s) of a method of making the product of 1 require all the limitations of an allowable product claim, and has NOT been rejoined. Note that claims 41-46 recites “sweeteners”, “a disintegrant” and “a filler” which make up a preblend 2, while the rapidly dispersing microgranules are separately prepared. However, claim 1 requires the rapidly dispersing microgranules contain specific sweeteners and a disintegrant in a particular ratio relative to the disintegrant. In response to this Office action, applicant is advised that the claim 41-48 be canceled or amended to clearly include all the limitations of claim 1 and clear any issues under 35 U.S.C. 112, second paragraph, such incompleteness of claim 41, a) and omission of a proper conjunction (e.g., “and”) before the last method step of the each claim.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I and II as set forth in the Office action mailed on October 17, 2016 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.

Claim Rejections - 35 USC § 112

§ 112 (b)

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.

Claims 32-35 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 32 and 34 depend on claim 6, a canceled claim. Claims 33 and 35 are rejected for depending on the indefinite claims.

Also in claim 32, the term “an additive with dual function” renders the claim vague and indefinite. Although, the specification mentions “a pharmaceutically acceptable additive with multifunctional activity”, the term “dual function” in the claim is not consistent with the term disclosed in the specification.

§ 112 (d)

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

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

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

Subject to the following paragraph [i.e., the fifth paragraph of pre-AIA 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 32-33 are rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

In this case, claim 32 depends on claim 1 which requires the ratio of sugar alcohol or saccharide to disintegrant be no less than 90:10. However, claim 32 recites such ratio to be 88:10, which is out of the range defined by the base claim.

Claim 33 is rejected for depending on the improper dependent claim.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Conclusion

Claim 32-35 are rejected.

Claims 1-5, 8-31, 36-40, 47 and 48 are allowed.

Claims 41-46 are withdrawn from consideration.

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: GOSSELIN, M, et al. Confirmation No.: 1075
Serial No.: 14/917,125 Group Art Unit: 1617
Filed: March 7, 2016 Examiner: JUSTICE, Gina Yu

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

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

RESPONSE TO FINAL REJECTION AND
REQUEST FOR CONTINUED EXAMINATION

This paper is filed in response to a Final Office Action (“FOA”), mailed January 30, 2018, setting a three-month period for reply. Accordingly, this paper is timely filed by April 30, 2018. Filed concurrently herewith is a request for continued examination and an information disclosure statement.

Claims begin on page **2** of this paper

Remarks begin on page **10** of this paper.

LISTING OF THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination.

1. (Currently amended) 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 99:1wherein the corticosteroid is present in an amount of about 5% or less by weight in the composition.
2. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> method for disintegration time.
3. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds on contact with saliva in the oral cavity of a patient in need thereof.
4. (Currently amended) The pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable carrier ~~for adsorption of the corticosteroid~~ is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.
5. (Currently amended) The pharmaceutical composition of claim 4, wherein the pharmaceutically acceptable carrier ~~for adsorption of the corticosteroid~~ is silicified microcrystalline cellulose.
6. (Cancelled)

7. (Cancelled)
8. (Previously presented) The pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates, esters, and mixtures thereof.
9. (Original) The pharmaceutical composition of claim 8, wherein said corticosteroid is fluticasone.
10. (Original) The pharmaceutical composition of claim 9, wherein said corticosteroid is fluticasone propionate.
11. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3% or less by weight in the composition.
12. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5% or less by weight in the composition.
13. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1% or less by weight in the composition.
14. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 0.5% or less by weight in the composition.
15. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 4.5 mg in the composition.
16. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3 mg in the composition.
17. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5 mg in the composition.
18. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 6 mg in the composition.

19. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 0.05 to about 15 mg in the composition at a drug content of from about 0.16% to 5% by weight of the composition.
20. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 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.
21. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate 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.
22. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized with a particle size of not more than 50 microns.
23. (Previously presented) The pharmaceutical composition of claim 22, wherein the corticosteroid has a mean particle size of not more than about 10 microns.
24. (Previously presented) The pharmaceutical composition of claim 1, further comprising an adhesive agent.
25. (Original) The pharmaceutical composition of claim 24, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl ethylcellulose, sodium carboxymethylcellulose, cross-linked polyacrylic acid, cross-linked polyacrylates, aminoalkyl methacrylate copolymers, carbopol polymers, hydrophilic polysaccharide gums, maltodextrins, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
26. (Currently Amended) The pharmaceutical composition of claim [[6]] 1, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxypropylcellulose.
27. (Currently Amended) The pharmaceutical composition of claim [[6]] 1, wherein the sugar

alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

28. (Previously presented) The pharmaceutical composition of claim 1, further comprising a free flowing sugar alcohol or saccharide selected from the group consisting of spray-dried mannitol, spray-dried lactose, and combinations thereof.

29. (Previously presented) The pharmaceutical composition of claim 1, further comprising a lubricant selected from the group consisting of magnesium stearate, stearic acid, sodium stearyl fumarate, glyceryl behenate, and a mixture thereof.

30. (Previously presented) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.

31. (Previously presented) The pharmaceutical composition of claim 1, further comprising at least one antiviral agent.

32. (Previously presented) The pharmaceutical composition of claim 6, wherein the rapidly dispersing microgranules further comprising an additive with a dual function and wherein the ratio of sugar alcohol or saccharide to disintegrant to dual-function additive is from 88:10:2 to 98.5:1:0.5.

33. (Previously presented) The pharmaceutical composition of claim 32, wherein the dual-function additive is selected from the group consisting of pregelatinized starch and hydroxypropylcellulose.

34. (Previously presented) The pharmaceutical composition of claim 6, wherein the corticosteroid has an average particle size of less than about 10 μm , the rapidly dispersing microgranules have an average 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 .

35. (Currently amended) The pharmaceutical composition of claim 34, wherein the corticosteroid is fluticasone propionate with a particle size of less than 5 microns, the pharmaceutically acceptable carrier for adsorption of the corticosteroid is silicified

microcrystalline cellulose, the rapidly dispersing microgranules comprise mannitol and crospovidone, and the composition further comprises a free-flowing sugar alcohol which is spray-dried mannitol, and a lubricant which is sodium stearyl fumarate.

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

37. (Withdrawn) The method of claim 36, wherein said condition comprises inflammation of the esophagus.

38. (Withdrawn) The method of claim 37, wherein said condition is eosinophilic esophagitis.

39. (Withdrawn) The method of claim 38, wherein said condition comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

40. (Withdrawn) The method of claim 36, wherein said condition is viral or bacterial pharyngitis, gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

41. (Withdrawn – currently amended) A method of preparing the pharmaceutical composition of claim 1, comprising the steps of:

- a) preparing the rapidly dispersing;
- b) preparing a preblend 1 by blending the pharmaceutically acceptable carrier ~~for~~ ~~adsorption of the corticosteroid~~, the corticosteroid, and a glidant;
- c) preparing a preblend 2 by blending a filler, the preblend 1 of step b), a disintegrant, and sweetener;
- d) preparing a final compressible blend, by blending the rapidly dispersing granules of step a), a lubricant, the preblend 2 of step c), and a filler;
- e) preparing the orally disintegrating tablet by compressing the blend of step d).

42. (Withdrawn) The method of claim 41, comprising the steps of:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by blending silicified microcrystalline cellulose,

micronized fluticasone propionate and colloidal silicon dioxide;

- c) preparing the preblend 2 by blending mannitol, the preblend 1 of step a, crospovidone, and sucralose powder;
- d) preparing the final compressible blend, by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), sugar alcohol, or rinsed mannitol;
- e) preparing the orally disintegrating tablet by compressing the blend of step d).

43. (Withdrawn – currently amended) The method of claim 41 wherein:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by charging a blender with one quarter of the total amount of pharmaceutically acceptable carrier ~~for adsorption of the corticosteroid~~, the corticosteroid, the glidant, and another quarter of the total amount of pharmaceutically acceptable carrier ~~for adsorption of the corticosteroid~~ and blending the resulting combination;
- c) preparing the preblend 2 by charging a high shear granulator with a free flowing filler, preblend 1, a remaining half of the total amount of pharmaceutically acceptable ~~carrier for adsorption of the corticosteroid~~, the disintegrant, and the sweetener and blending the resulting combination; and
- d) preparing the final compressible blend by charging a blender with one half of the total amount of rapidly dispersing granules of step a), the lubricant, the preblend 2 of step c), and the remaining half of the total amount of rapidly dispersing granules of step a) and blending the resulting combination to provide a compressible blend;
- e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

44. (Withdrawn) The method of claim 43 comprising the steps of:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by charging a blender with one quarter of the total amount of silicified microcrystalline cellulose (SMCC), micronized fluticasone propionate, colloidal silicon dioxide and another quarter of the total amount of SMCC and blending the resulting combination;

c) preparing the preblend 2 by charging a high shear granulator with spray dried mannitol), preblend 1, the remaining half of the total amount of SMCC, crospovidone, and sucralose powder and blending the resulting combination;

d) preparing the final compressible blend comprising charging a V-blender with one half of the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), and remaining half of the rapidly dispersing granules of step a and blending the resulting combination;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

45. (Withdrawn – currently amended) The method of claim 41 comprising the steps of:

a) preparing the rapidly dispersing microgranules 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 in presence of water or an alcohol-water mixture and then drying the granulate;

b) preparing the milled preblend 1 by blending the pharmaceutically acceptable carrier ~~for adsorption of the corticosteroid~~, corticosteroid, and glidant in a blender and then milling the resulting mixture through a comminuting mill equipped with a screen with a 30 Mesh opening;

c) preparing the milled preblend 2 by blending half of the total amount of a filler which is free flowing mannitol, the preblend 1 from step b), the disintegrant, and the sweetener in a blender and then milling the resulting mixture through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;

d) preparing the compressible blend by blending the rapidly dispersing granules of step a), the lubricant, the milled preblend 2 of step c), and the rinsed free flowing mannitol;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

46. (Withdrawn – currently amended) The method of claim 45 comprising the steps of:

a) 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 crospovidone in presence of water or an alcohol-water mixture and then drying the granulate;

b) preparing a milled preblend 1 by blending silicified microcrystalline cellulose, micronized fluticasone propionate and colloidal silicon dioxide in a blender and then milling through a comminuting mill equipped with a screen with a 30 Mesh opening;

c) preparing the milled preblend 2 by blending half of the total amount of free flowing mannitol, the preblend 1 from step b), crospovidone, and sucralose powder in a blender and then milling through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;

d) preparing the compressible blend by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the milled preblend 2 of step c), and the rinsed free flowing mannitol;

[[i]] e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

47. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized.

48. (Previously presented) The pharmaceutical composition of claim 47, wherein the corticosteroid has a mean particle size of less than about 10 μm .

REMARKS

I. Status of Claims

Upon entry of the present amendments, claims 1-5, 8-35, 47, and 48 are pending. Claims 36-46 have been withdrawn. Claims 1, 4, 5, 26, 27, 35, 41, 43, and 45 have been amended. Claims 6 and 7 have been cancelled.

Claim 1 has been amended to incorporate the limitations of claim 7 (which has been cancelled). Thus, currently amended claim 1 is effectively claim 7 rewritten in independent form. Because the Examiner indicated that claim 7 was allowable, and currently amended claim 1 is effectively claim 7 rewritten in independent form, Applicant respectfully submits that claim 1 and the claims depending thereon (i.e., claims 2-6, 8-35, 47, and 48) are allowable.

Claims 4, 5, 35, 41, 43, and 45 have been amended to cancel the phrase “for the adsorption of the corticosteroid” for consistency with claim 1. Claims 26 and 27 have been amended to depend on claim 1. Claim 46 has been amended to correct a typographical error.

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

Applicant reserves the right to prosecute any cancelled subject matter in one or more divisional or continuation applications.

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

The Examiner rejected claims 1-4, 6, 8-25, 27-31, 47 and 48 under 35 U.S.C. § 103 as allegedly unpatentable over US Pub. No. 2006/0051414 (“Ramalho”) in view of US Pub. No. 2011/0081411 (“Perrett”). The Examiner also rejected claim 5 under 35 U.S.C. § 103 as allegedly unpatentable over Ramalho and Perrett further in view of 2004/0265375 (hereinafter “Platteeuw”).

Applicant does not agree with the Examiner’s allegation that claims 1-4, 6, 8-25, 27-31, 47 and 48 are obvious over Ramalho, Perrett, and Platteeuw. However, solely in the interest of expediting prosecution, and without acquiescing to the propriety the rejection, Applicant has amended claim 1 to include the limitations of claim 7, which was not rejected as allegedly

obvious over Ramalho, Perrett, and Platteeuw. Because currently amended claim 1 is effectively claim 7 rewritten in independent form, Applicant respectfully submits that the currently pending claims are allowable over the cited references.

Accordingly, Applicants request withdrawal of the present rejection and allowance of the pending claims.

III. Rejoinder of Withdrawn Claims

Applicant respectfully requests rejoinder of withdrawn claims 36-46, which are directed to methods of using and making the pharmaceutical composition recited in claim 1. According to MPEP 821.04, when claims directed to the elected product claims are in condition for allowance, the nonelected method of use and making claims that require all the limitations of the allowable product claims should be considered for rejoinder. In response to the restriction requirement mailed October 17, 2016, Applicant elected product claims 1-35. Because nonelected method of use claims 36-40 and nonelected method of making claims 41-46 depend on claim 1 and therefore require all limitations of claim 1, and claim 1 is now in condition for allowance, Applicant respectfully requests rejoinder of withdrawn claims 36-46.

CONCLUSION

In view of the amendments and remarks herein, withdrawal of the rejections are requested, and Allowance of the application are earnestly solicited.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: April 30, 2018

Respectfully submitted,
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
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Please find below and/or attached an Office communication concerning this application or proceeding.

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

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

zpatdcdocketing@cooley.com

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.

DETAILED ACTION

Applicant's response filed on October 6, 2017 has been received and reviewed. Claims 1-48 are now pending, of which claims 36-46 are withdrawn from consideration.

Previous claim rejection made under 35 U.S.C. 112 (b) as indicated in the previous Office action dated April 6, 2017 is withdrawn in view of amendment made to claim 1 that adds "and" in line 5.

Previous claim rejections made under 35 U.S.C. 102 (a)(1) and 103 over Perrett et al. (US 20110081411 A1) are withdrawn in view of amendment made to claim 1 that requires the corticosteroid drug "adsorbed onto a pharmaceutically acceptable carrier".

Previous obviousness-type double patenting rejections made under the claims of U.S. Pat. Nos. 9486407 and 8771729 are also withdrawn in view of amendment made to claim 1 that requires the corticosteroid drug "adsorbed onto a pharmaceutically acceptable carrier".

Claim Rejections - 35 USC § 103

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.

Claims 1-4, 6, 8-25, 27-31, 47 and 48 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, cited in IDS)(“Perrett” 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]. The premix is then blended with “auxiliary” granulates which can comprise mannitol granules, which meet the “rapidly dispersible microgranules” of instant claims 1 and 6. Ramalho further teaches using maize starch gum, which is a hydrophilic polysaccharide gum and meets instant claims 24 and 25. Using lubricants such as magnesium stearate and stearic acid is disclosed. See [0054]; instant claim 29. The reference further teaches that prior art composition is able to disperse in water most preferably in 1 minute. See instant claim 3.

Ramalho fails to teach corticosteroid.

Perrett discloses an ODT comprising fluticasone propionate microgranules. See Example 1. The reference teaches that the orodispersible tablet is used for treating a condition associated with inflammation of the gastrointestinal tract in an individual. Perrett 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] and claim 28; See instant claims 15-18. Example 1 teaches a 100 mg orodispersible tablet comprising 4 mg of a corticosteroid, meeting 19 and 21. The reference also teaches that the corticosteroid crystals can have an average particle size ranging from about 1-50 microns. See instant claims 22, 23, new claims 47 and 48.

Regarding claim 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 substituted 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 an expected therapeutic result (i.e., effective in treating inflammation of the gastrointestinal tract of a subject).

Regarding claim 2, Ramalho teaches the tablet in Example 10 disintegrates between 30 and 55 seconds.

Regarding claims 11-14 and 20, Perrett teaches that the amount of the corticosteroid-containing granules in the composition can be as low as 5 wt %. The reference also teaches that such granules can contain up to about 80 wt % of pharmaceutically acceptable ingredients such as fillers and diluents and up to about 10 % of film-forming binders. See [0069-0070]. Thus the actual amount of the

corticosteroid in the total weight of an orodispersible tablet can be as low as 0.5 wt % based on the total weight of the composition.

Regarding claims 22, 23, 47 and 48, although Perrett does not specifically teach to micronize the active ingredient, the reference teaches that microscale crystals of fluticasone propionate are provided.

Regarding claims 30 and 31, Perrett teaches combining the corticosteroid actives with antifungal agents or antiviral agent. See Perrett claims 9-14.

Claim 5 is rejected under 35 U.S.C. 103 as being unpatentable over Ramalho and Perrett as applied to claims 1-4, 6, 8-25, 27-31, 47 and 48 as above, and further in view of Platteeuw et al. (US 2004/0265375, published on December 30, 2004).

Ramalho and Perrett fail to teach silicified microcrystalline cellulose of instant claims 5.

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.

Allowable Subject Matter

Claims 7, 26 and 32-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed on October 6, 2017 have been fully considered but they are moot in view of the new grounds of rejection as indicated above.

Conclusion

No claims are allowed.

Claims 7, 26 and 32-35 are objected to.

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

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

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

/GINA C JUSTICE/
Primary Examiner, Art Unit 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: GOSSELIN, M, et al. Confirmation No.: 1075
Serial No.: 14/917,125 Group Art Unit: 1617
Filed: March 7, 2016 Examiner: JUSTICE, Gina Yu

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

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RESPONSE TO NON-FINAL REJECTION UNDER 37 C.F.R. § 1.111

This paper is filed in response to a Non-Final Office Action (“NFOA”), April 6, 2017, setting a three-month period for reply. Filed herewith is a petition for a 3-month extension of time. Accordingly, this paper is timely filed.

Claims begin on page **2** of this paper

Remarks begin on page **10** of this paper.

LISTING OF THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination.

1. (Currently amended) 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 in an amount of about 5% or less by weight in the composition; and
 - b. ~~a pharmaceutically acceptable carrier for adsorption of the corticosteroid;~~
b. [[c.]] rapidly dispersing microgranules,
wherein the corticosteroid is present in an amount of about 5% or less by weight in the composition.
2. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> method for disintegration time.
3. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds on contact with saliva in the oral cavity of a patient in need thereof.
4. (Previously presented) The pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable carrier for adsorption of the corticosteroid is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.
5. (Previously presented) The pharmaceutical composition of claim 4, wherein the pharmaceutically acceptable carrier for adsorption of the corticosteroid is silicified microcrystalline cellulose.
6. (Previously presented) The pharmaceutical composition of claim 1, wherein the rapidly dispersing microgranules comprise a sugar alcohol, or a saccharide, or a mixture thereof and at

least one disintegrant.

7. (Previously presented) The pharmaceutical composition of claim 6, 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.
8. (Previously presented) The pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates, esters, and mixtures thereof.
9. (Original) The pharmaceutical composition of claim 8, wherein said corticosteroid is fluticasone.
10. (Original) The pharmaceutical composition of claim 9, wherein said corticosteroid is fluticasone propionate.
11. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3% or less by weight in the composition.
12. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5% or less by weight in the composition.
13. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1% or less by weight in the composition.
14. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 0.5% or less by weight in the composition.
15. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 4.5 mg in the composition.
16. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 3 mg in the composition.
17. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 1.5 mg in the composition.

18. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is present in an amount of about 6 mg in the composition.
19. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 0.05 to about 15 mg in the composition at a drug content of from about 0.16% to 5% by weight of the composition.
20. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate in the range of 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.
21. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is fluticasone propionate 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.
22. (Previously presented) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized with a particle size of not more than 50 microns.
23. (Previously presented) The pharmaceutical composition of claim 22, wherein the corticosteroid has a mean particle size of not more than about 10 microns.
24. (Previously presented) The pharmaceutical composition of claim 1, further comprising an adhesive agent.
25. (Original) The pharmaceutical composition of claim 24, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl ethylcellulose, sodium carboxymethylcellulose, cross-linked polyacrylic acid, cross-linked polyacrylates, aminoalkyl methacrylate copolymers, carbopol polymers, hydrophilic polysaccharide gums, maltodextrins, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
26. (Previously presented) The pharmaceutical composition of claim 6, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate,

crosslinked carboxymethyl cellulose, and low-substituted hydroxypropylcellulose.

27. (Previously presented) The pharmaceutical composition of claim 6, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.
28. (Previously presented) The pharmaceutical composition of claim 1, further comprising a free flowing sugar alcohol or saccharide selected from the group consisting of spray-dried mannitol, spray-dried lactose, and combinations thereof.
29. (Previously presented) The pharmaceutical composition of claim 1, further comprising a lubricant selected from the group consisting of magnesium stearate, stearic acid, sodium stearyl fumarate, glyceryl behenate, and a mixture thereof.
30. (Previously presented) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.
31. (Previously presented) The pharmaceutical composition of claim 1, further comprising at least one antiviral agent.
32. (Previously presented) The pharmaceutical composition of claim 6, wherein the rapidly dispersing microgranules further comprising an additive with a dual function and wherein the ratio of sugar alcohol or saccharide to disintegrant to dual-function additive is from 88:10:2 to 98.5:1:0.5.
33. (Previously presented) The pharmaceutical composition of claim 32, wherein the dual-function additive is selected from the group consisting of pregelatinized starch and hydroxypropylcellulose.
34. (Previously presented) The pharmaceutical composition of claim 6, wherein the corticosteroid has an average particle size of less than about 10 μm , the rapidly dispersing microgranules have an average 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 .
35. (Previously presented) The pharmaceutical composition of claim 34, wherein the

corticosteroid is fluticasone propionate with a particle size of less than 5 microns, the pharmaceutically acceptable carrier for adsorption of the corticosteroid is silicified microcrystalline cellulose, the rapidly dispersing microgranules comprise mannitol and crospovidone, and the composition further comprises a free-flowing sugar alcohol which is spray-dried mannitol, and a lubricant which is sodium stearyl fumarate.

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

37. (Withdrawn) The method of claim 36, wherein said condition comprises inflammation of the esophagus.

38. (Withdrawn) The method of claim 37, wherein said condition is eosinophilic esophagitis.

39. (Withdrawn) The method of claim 38, wherein said condition comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

40. (Withdrawn) The method of claim 36, wherein said condition is viral or bacterial pharyngitis, gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

41. (Withdrawn) A method of preparing the pharmaceutical composition of claim 1, comprising the steps of:

- a) preparing the rapidly dispersing microgranules;
- b) preparing a preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, and a glidant;
- c) preparing a preblend 2 by blending a filler, the preblend 1 of step b), a disintegrant, and sweetener;
- d) preparing a final compressible blend, by blending the rapidly dispersing granules of step a), a lubricant, the preblend 2 of step c), and a filler;
- e) preparing the orally disintegrating tablet by compressing the blend of step d).

42. (Withdrawn) The method of claim 41, comprising the steps of:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by blending silicified microcrystalline cellulose, micronized fluticasone propionate and colloidal silicon dioxide;
- c) preparing the preblend 2 by blending mannitol, the preblend 1 of step a, crospovidone, and sucralose powder;
- d) preparing the final compressible blend, by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), sugar alcohol, or rinsed mannitol;
- e) preparing the orally disintegrating tablet by compressing the blend of step d).

43. (Withdrawn) The method of claim 41 wherein:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by charging a blender with one quarter of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, the glidant, and another quarter of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid and blending the resulting combination;
- c) preparing the preblend 2 by charging a high shear granulator with a free flowing filler, preblend 1, a remaining half of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid, the disintegrant, and the sweetener and blending the resulting combination; and
- d) preparing the final compressible blend by charging a blender with one half of the total amount of rapidly dispersing granules of step a), the lubricant, the preblend 2 of step c), and the remaining half of the total amount of rapidly dispersing granules of step a) and blending the resulting combination to provide a compressible blend;
- e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

44. (Withdrawn) The method of claim 43 comprising the steps of:

- a) preparing the rapidly dispersing microgranules;
- b) preparing the preblend 1 by charging a blender with one quarter of the total amount of silicified microcrystalline cellulose (SMCC), micronized fluticasone propionate, colloidal silicon

dioxide and another quarter of the total amount of SMCC and blending the resulting combination;

c) preparing the preblend 2 by charging a high shear granulator with spray dried mannitol), preblend 1, the remaining half of the total amount of SMCC, crospovidone, and sucralose powder and blending the resulting combination;

d) preparing the final compressible blend comprising charging a V-blender with one half of the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), and remaining half of the rapidly dispersing granules of step a and blending the resulting combination;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

45. (Withdrawn) The method of claim 41 comprising the steps of:

a) preparing the rapidly dispersing microgranules 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 in presence of water or an alcohol-water mixture and then drying the granulate;

b) preparing the milled preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, corticosteroid, and glidant in a blender and then milling the resulting mixture through a comminuting mill equipped with a screen with a 30 Mesh opening;

c) preparing the milled preblend 2 by blending half of the total amount of a filler which is free flowing mannitol, the preblend 1 from step b), the disintegrant, and the sweetener in a blender and then milling the resulting mixture through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;

d) preparing the compressible blend by blending the rapidly dispersing granules of step a), the lubricant, the milled preblend 2 of step c), and the rinsed free flowing mannitol;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

46. (Withdrawn) The method of claim 45 comprising the steps of:
- a) 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 crospovidone in presence of water or an alcohol-water mixture and then drying the granulate;
 - b) preparing a milled preblend 1 by blending silicified microcrystalline cellulose, micronized fluticasone propionate and colloidal silicon dioxide in a blender and then milling through a comminuting mill equipped with a screen with a 30 Mesh opening;
 - c) preparing the milled preblend 2 by blending half of the total amount of free flowing mannitol, the preblend 1 from step b), crospovidone, and sucralose powder in a blender and then milling through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;
 - d) preparing the compressible blend by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the milled preblend 2 of step c), and the rinsed free flowing mannitol;
 - i) preparing the orally disintegrating tablets by compressing the compressible blend of step d).
47. (New) The pharmaceutical composition of claim 1, wherein the corticosteroid is micronized.
48. (New) The pharmaceutical composition of claim 47, wherein the corticosteroid has a mean particle size of less than about 10 μm .

REMARKS

I. Status of Claims

Claims 1-35 are pending. Claims 36-46 have been withdrawn. Claim 1 has been amended to address the rejection under 35 U.S.C. § 112(b), and to clarify that the corticosteroid is adsorbed onto the pharmaceutically acceptable carrier in the pharmaceutical composition.

Claims 47 and 48 are newly added. Support new claims 47 and 48 can be found throughout the application as originally filed, for example in the paragraph bridging pages 13-14.

II. Interview Summary

Applicant's representatives, Tom Blinka and Jon Cousin, thank Examiner Justice for the courtesy of holding a telephonic interview on July 26, 2017, in which the presently claimed invention and the prior art of record were discussed. Applicant does not disagree with the Examiner's summary of the content of the interview. However, Applicant does not acquiesce to the Examiner's statement regarding the key difference between the presently claimed invention and Perrett's invention, as there are other distinctions between the present claims and Perrett.

III. Claim Rejections under 35 U.S.C. § 112(b)

The Examiner rejected claims 1-35, because "[c]laim 1 recites components a, b, and c which are not connected by a coordinating conjunction (i.e., "and" or "or")." Claim 1 has been amended to add the coordinating conjunction "and" between components a and b (component c has been incorporated into component a).

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

The Examiner rejected claims 1, 3, 4, 6-10, 15-19, 21-31, and 34 under 35 U.S.C. §102(a)(1) as allegedly anticipated by U.S. Patent Application Publication 2011/0081411 (hereinafter "Perrett").

Currently amended claim 1 is directed to an orally disintegrating tablet (ODT) comprising a corticosteroid adsorbed onto a pharmaceutically acceptable carrier. Adsorption of the corticosteroid onto the pharmaceutically acceptable carrier occurs by first blending and comminuting corticosteroid particles with the pharmaceutically acceptable carrier, prior

compressing the mixture into an ODT (*see* the as-filed application, paragraph bridging pages 13-14.)

The Examiner cites to Perrett and alleges Perrett teaches an ODT comprising “4 wt % fluticasone propionate” and “magnesium stearate [that is] used as a processing aid and lubricant, which also serves as an excipient and a carrier” (*see* NFOA, page 4). However, Perrett does not teach or suggest a corticosteroid adsorbed onto a pharmaceutically acceptable carrier as required by the present claims. Indeed, Perrett cannot teach a corticosteroid adsorbed onto magnesium stearate, because Perrett uses magnesium stearate as a lubricant which is added after the ODT is manufactured to “externally lubricate the punch and die surfaces and was therefore present in only trace amounts *on* the tablet.” (emphasis added) (*see* Perrett at paragraph [0088] in Example 1). Thus, Perrett’s corticosteroid is not adsorbed onto a pharmaceutically acceptable carrier as required by the presently claimed invention.

Therefore, the presently claimed invention is not anticipated by Perrett, because Perrett does not teach each and every element of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the present rejection.

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

The Examiner rejected claims 2, 11-14, 20, 32, and 33 under 35 U.S.C. § 103 as allegedly unpatentable over Perrett. The Examiner also rejected claims 5 and 35 under 35 U.S.C. § 103 as allegedly unpatentable over Perrett in view of 2004/0265375 (hereinafter “Platteeuw”).

As discussed above, currently amended claim 1 is directed to an orally disintegrating tablet (ODT) comprising a corticosteroid adsorbed onto a pharmaceutically acceptable carrier. Applicant discovered that adsorbing the corticosteroid onto the pharmaceutically acceptable carrier, prior to blending other excipients, prevents the corticosteroid from aggregating during manufacturing (*see*, the as-filed application at page 4, last paragraph, and page 9, last paragraph). As a result, the presently claimed ODT achieves corticosteroid content uniformity and the corticosteroid is readily exposed to inflamed esophageal tissue (*see, e.g.*, the as-filed application, last paragraph on 3 to second paragraph on page 4, and page 9, last paragraph).

Perrett is directed to an ODT containing a low dose of corticosteroid, e.g., “4 wt %

fluticasone propionate ...” (see NFOA, page 4). Solid dosage forms having a drug content of $\leq 5\%$ by weight, such as those taught by Perrett, suffer from non-uniform blends which result in inhomogeneous drug content within a batch – at drug content levels ≤ 5 wt %, drug particles tend to aggregate and form larger particles (see, the as-filed application, paragraph bridging at pages 2-3). As a result, the ODT disclosed in Perrett will consist of agglomerated corticosteroid granules that are not uniformly dispersed in the ODT and are not readily exposed to the inflamed tissue to the esophagus (see, the as-filed application at pages 3-4).

Perrett did not recognize any advantage of adsorbing a corticosteroid onto a pharmaceutically acceptable carrier, much less improving drug content uniformity and exposure of the corticosteroid to the inflamed tissue to the esophagus to treat eosinophilic esophagitis.

A. The Examiner has Failed to Satisfy the Burden of Proof for *Prima Facie* Obviousness

In order to establish *prima facie* obviousness, the Examiner must show, *inter alia*, that each element of the presently claimed invention was taught in the cited prior art. However, as discussed above, Perrett does not, and cannot, teach or suggest a corticosteroid adsorbed onto a pharmaceutically acceptable carrier.

Further, Platteeuw does not cure the deficiencies in Perrett. Platteeuw is directed to orally disintegrating compositions comprising silicified microcrystalline cellulose (SMCC). As discussed throughout Platteeuw, SMCC functions as the disintegrating agent, not as a carrier onto which a drug is adsorbed (see Abstract and paragraph [0015]). Moreover, all of the exemplified compositions have a drug dose of about 8% wt to about 20%, not $\leq 5\%$ as required by the present claims (see Examples 1-21). Further, Platteeuw does not even mention a corticosteroid in the laundry list of drugs provided in paragraph [0054].

Thus, Platteeuw does not cure the deficiencies in Perrett, because Platteeuw does not teach or suggest a low dose drug adsorbed onto pharmaceutically acceptable, let alone a corticosteroid. Therefore the Examiner has failed to establish *prima facie* obviousness because the combination of Perrett and Platteeuw does not teach or suggest all of the elements of the claimed invention, in particular a corticosteroid adsorbed onto a pharmaceutically acceptable carrier.

Accordingly, Applicants request withdrawal of the present rejection.

B. The Skilled Artisan Would Not Combine Platteeuw with Perrett as Alleged by the Examiner

As discussed above, both of the cited references are directed to different orally disintegrating technologies – Perrett employs rapidly dispersing microgranules to achieve oral disintegration, whereas Platteeuw employs SMCC to achieve oral disintegration. There simply is no reason to combine two different oral disintegrating technologies, since each technology already achieves oral disintegration.

Accordingly, Applicants request withdrawal of the present rejection.

CONCLUSION

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

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: October 6, 2017

Respectfully submitted,
COOLEY LLP

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
91543	7590	07/31/2017	EXAMINER	
Cooley LLP / Eurand ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			07/31/2017	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):

zpatcdocketing@cooley.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 14/917,125	Applicant(s) GOSSELIN ET AL.		
	Examiner GINA YU JUSTICE	Art Unit 1617	AIA (First Inventor to File) Status Yes	Page 1 of 2

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

1. GINA YU JUSTICE (Primary Examiner); Telephonic
2. Thomas Blinka (Attorney of Record); Telephonic
3. John Cousin (Attorney of Record); Telephonic

Date of Interview: 26 July 2017

Claim(s) discussed: Claim 1

Identification of prior art discussed: Perrett et al. (US 20110081411) and Platteuw et al.(US 20040265375), both cited in the pending rejections.

Amendment Proposed: Applicant's representatives proposed amending claim 1 to specify that the corticosteroid is "adsorbed onto the carrier" to apparently to overcome the pending 102 and 103 rejections over Perrett.

Brief Description of main topic of discussion: Applicant's representatives explained that the key difference between applicant's invention and the Perrett invention is that in the present invention, micronized, milled drug particles adsorbed onto the carrier results in better content uniformity and presentation of drug to the substrate, whereas the formulation made by the prior art method results in agglomeration of particles.

Issues Discussed:

Proposed Amendments:

Agreement was reached that the proposed amendment would remove the pending rejections, as the amendment introduces a new structural limitation. Examiner indicated that a new search would be necessary to address the limitation, which would result in a final Office action unless the claims are allowed at that stage.

Claim Interpretation and/or scope:

Examiner indicated that the definition of adsorption would be critical in this case to determine patentability in this case. No agreement was reached on the definition.

/GINA YU JUSTICE/ Primary Examiner, Art Unit 1617	
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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 time limit 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.

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 applicant's 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**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
91543	7590	04/06/2017	EXAMINER	
Cooley LLP ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
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Office Action Summary	Application No. 14/917,125	Applicant(s) GOSSELIN ET AL.	
	Examiner GINA YU JUSTICE	Art Unit 1617	AIA (First Inventor to File) Status Yes

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

Period for Reply

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

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

Status

1) ☒ Responsive to communication(s) filed on March 7, 2017.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

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

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

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

Disposition of Claims*

5) ☒ Claim(s) 1-46 is/are pending in the application.
5a) Of the above claim(s) 36-46 is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-35 is/are rejected.

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

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

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

Application Papers

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

11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: ____.

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

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-35) in the reply filed on February 17, 2017 is acknowledged. The traversal is on the ground(s) that examiner allegedly provided no sufficient reason for lack of a special technical feature which makes a contribution over the prior art. Specifically, applicant asserts that the examiner did not mention "a pharmaceutically acceptable carrier for adsorption of the corticosteroid" in the discussion of WO 2011/041509. However, the reference in fact teaches that a pharmaceutical excipients, namely magnesium stearate, is included in the example formulation, and further discloses that the carriers of the present invention (e.g., microcrystalline cellulose, etc.) are old and well known excipients used in orally disintegrating tablets. See rejections below.

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

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.

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

Claim 1 recites components a, b and c which are not connected by a coordinating conjunction (i.e., "and" or "or"). Since it is not clear whether all of a-c are required in the claimed invention, the metes and bounds of the scope of claim 1 is unclear and claim 1 is vague and indefinite. The remaining claims are rejected for depending on the indefinite base claim. For the sake of compact prosecution and prior art consideration only, examiner assumes that the components a, b and c are all required in the composition of claim 1. An appropriate correction is required to overcome this rejection under 35 U.S.C.112 (b).

Claim Rejections - 35 USC § 102

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 the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1, 3, 4, 6-10, 15-19, 21-31 and 34 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Perrett et al. (US 20110081411 A1, published April 7, 2011, cited in IDS)(“Perrett” hereunder).

Perrett discloses an orally disintegrating tablet (ODT) comprising fluticasone propionate microgranules. See Example 1. The composition comprises microgranules comprising 91.2% mannitol and 4.8 wt % crospovidone which is blended with 4 wt % fluticasone propionate and magnesium stearate used as a processing aid and lubricant, which also serves as an excipient and a carrier. See instant claims 1, 6-10, 26 and 29. The sugar alcohol: disintegrant ratio is 95:5, meeting instant claim 7. The tablet is said to disintegrate in about 60 seconds or less in the simulated saliva using the USP <701> Disintegration test, which indicates the disintegration time within 60 seconds when placed in the oral cavity of a human. See [0007]; instant claim 2. Regarding claim 4, Perrett also discloses an embodiment comprising microcrystalline cellulose, which is the pharmaceutically acceptable carrier in present claim 4.

Perrett 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 Perrett [0040-41] and claim 28; See instant claims 15-18. Example 1 teaches an 100 mg ODT comprising 4 mg of a corticosteroid, meeting 19 and 21. The reference also teaches that the corticosteroid crystals can have an average particle size ranging from about 1-50 microns. See instant claim 22 and 23. Using the adhesive agent of instant claims 24 and 25 is disclosed in the Perrett claims 4 and 5. The reference further teaches that

spray dried mannitol is used in the disintegrating tablet formulation as a compressible diluent. See instant claim 28. Further incorporating to the composition antifungal agents or antiviral agent is disclosed in the Perrett claims 9-14. See instant claim 30 and 31. The reference also teaches that the average particle size of the drug particles can be about 4 microns, the rapidly dispersing granules have an average particle size of less than about 300 microns, and the sugar alcohol and/or saccharide has an average particle size of less than about 30 microns. See Perrett claim 18; instant claim 34.

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 2, 11-14, 20, 32 and 33 is rejected under 35 U.S.C. 103 as being unpatentable over Perrett as applied to claims 1, 3, 4, 6-10, 15-19, 21-31 and 34 as above, and further in view of the teachings of the same reference.

Regarding claim 2, Perrett teaches that the solid pharmaceutical composition according to the prior art teaching disintegrates within 30 seconds in the simulated test or in the oral cavity of a patient. See [0030].

Regarding claims 11-14 and 20, the reference further teaches that the amount of the corticosteroid-containing granules in the composition can be as low as 5 wt %. The reference also teaches that such granules can contain up to about 80 wt % of pharmaceutically acceptable ingredients such as fillers and diluents and up to about 10 % of film-forming binders. See [0069-0070]. Thus the actual amount of the corticosteroid in the total weight of the ODT composition can be as low as 0.5 wt % based on the total weight of the composition.

Regarding claims 32 and 33, although Perrett does not specifically mention "a dual function additive" in the rapidly dispersing microgranules, the reference teaches that pregelatinized starch is a suitable diluent like sugars and sugar alcohols, and also can be used as a disintegrants [0052-0053]. In paragraph [0047], Perrett specifically discloses hydroxypropylcellulose (HPC) as one of the disintegrants to be used in the

range of about 1 to about 10 % by weight. The reference also teaches that HPC functions as a stabilizing agent for corticosteroid crystals and used as a film-forming binder in the corticosteroid-containing granules in the amount of from about 0.5 to about 10 %. See Perrett, [0069].

It is well settled in patent law that the idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). As shown by the recited teachings, present claim 32 and 33 define nothing more than the concomitant use of conventional disintegrants known to be suitable to make the rapidly dispersing microgranules, to make another rapidly dispersing microgranules for the same purposes. Thus, it would be prima facie obvious to make rapidly dispersing microgranules comprising a sugar alcohol/saccharide such as mannitol, a disintegrant such as crospovidone, as exemplified in Example 1, and an additional disintegrant such as HPC. See MPEP 2144.06.

Thus, the presently claimed ratio of “sugar alcohol or saccharide to disintegrant to dual function additive” would be no different than a ratio of the sugar/saccharide to a first disintegrant to a second disintegrant. Regarding the weight ratio of the sugar/saccharide to these disintegrants, the range of the sugar alcohol/saccharide and disintegrant in Example 1 is 95:5. It is well settled in patent law that changes of proportions will not support the patentability of subject matter encompassed by the prior

art unless there is evidence indicating such change is critical. See *In re Williams*, 36 F.2d 436, 438 (CCPA 1929) ("It is a settled principle of law that a mere carrying forward of an original patented conception involving only change of form, proportions, or degree, or the substitution of equivalents doing the same thing as the original invention, by substantially the same means, is not such an invention as will sustain a patent, even though the changes of the kind may produce better results than prior inventions."). In this case, Perrett teaches that the amount of a disintegrant portion in the rapidly dispersing microgranules should be about 1 to about 10 %, and the amount of sugar alcohol and/or saccharide in the granules can range from about 99-90 % of the total weight of the disintegrant-containing granules. Since combining the two art-recognized functionally equivalent disintegrants is an obvious matter, manipulation of the weight amount of the two disintegrants, depending on the desired disintegration speed and properties, to make up the total amount of the disintegrant concentration of about 1 to about 10 wt % of the rapidly dispersing microgranules would have been well within the skill in the art.

Claim 5 and 35 are rejected under 35 U.S.C. 103 as being unpatentable over Perrett as applied to claims 1-4 and 6-34 as above, and further in view of Platteeuw et al. (US 2004/0265375, published on December 30, 2004).

Regarding claim 35, the reference teaches that spray dried mannitol and sodium stearyl fumarate are used as a compressible diluent and a lubricant, respectively. See

[0046]. Perrett fails to teach silicified microcrystalline cellulose of instant claims 5 and 35.

Platteeuw teaches using silicified microcrystalline cellulose in an ODT is well known in the art and provides an enabling disclosure of how to make such tablets. 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; instant claim 2.

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 to make an oral disintegrating tablet comprising corticosteroids as motivated by Platteeuw. The skilled artisan would have been motivated to do so, as 1) Perrett teaches that the disintegrating tablet should 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 adequate disintegrability and tablet strength and stability during storage, transport and/or use. Since the reference also provides an enabling disclosure of how to make such tablet, the skilled artisan would have had a reasonable expectation of successfully producing an ODT with good disintegrability and improved strength.

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(I)(1) - 706.02(I)(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.

1. US PAT. NO. 9486407 B2

**Claims 1-4, 6-34 are rejected on the ground of nonstatutory double
patenting as being unpatentable over claims 1-42 of U.S. Patent No. 9486407 B2.**

Present claim 1 is directed to a pharmaceutical composition in the form of an ODT comprising: (a) a topically acting corticosteroid or pharmaceutically acceptable salt, ester, or polymorph in an amount of about 5% or less by weight in the composition; (b) a pharmaceutically acceptable carrier for adsorption of the corticosteroid; (c) rapidly dispersing microgranules.

The '660 claims 1 and 5 disclose an orally disintegrating solid tablet comprising a) less than or equal to about 20 mg of a topical corticosteroid; b) at least one excipient which can be sugar alcohols; and c) rapidly dispersing granules comprising a disintegrant.

The excipient of the '660 claims are defined to include microcrystalline cellulose, which is "a pharmaceutically acceptable carrier for adsorption of the corticosteroid" in instant claim 1 b and 4.

Patented claims 1 and 2 teaches that the composition disintegrates within 60 or 30 seconds when tested using USP <701> Disintegration test. See instant claim 2.

The rapidly dispersing granules are defined to include microgranules made with a sugar alcohol and/or saccharide having an average particle size of not more than about

30 microns and the disintegrant. See '660, col. 8, lines 7 – 25, col. 13, lines 18 – 29; instant claims 6.

The ratio of the disintegrant: sugar alcohol/saccharide is defined in spec. 8, lines 26 - 35; instant claim 7.

The corticosteroids of instant claims 8-10 are disclosed in patented claim 3.

The amount of the corticosteroid as claimed in present claims 11-21 are disclosed in claims 35 and 42 and further defined in '660, col. 7, line 31 - col. 8, line 6.

Patented claim 6 teaches that the drug particles have an average particle size of less than about 400 microns, which is defined to include 1-50 microns and nanoparticles. See col. 11, line 53 - col. 12, line 13; instant claims 22 and 23.

Patented claims 16-17 disclose the adhesive agents of instant claims 24 and 25.

The disintegrants of the '660 claims are defined to include crospovidone, sodium starch glycoate, cross-linked sodium carboxymethylcellulose, calcium silicate, and low-substituted hydroxypropyl cellulose. See '660, spec., col. 8, line 44 - col. 9, line 3; instant claim 26.

The specific sugars of instant claim 27 are claimed in patented claim 10.

The excipient of the '660 claims further include spray dried mannitol, crospovidone, optionally magnesium stearate or sodium stearyl fumarate as lubricant. See '660, spec., col. 3, lines 46-54; instant claims 28 and 29.

Patented claims 27-32 disclose antifungal and antiviral agents. See instant claims 30 and 31.

Regarding claims 32 and 33, although the '660 claims do not specifically mention "a dual function additive" such as HPC in the rapidly dispersing microgranules, such composition is no more than incorporation of an additional disintegrant that is disclosed in patented claim 12. It is well settled in patent law that the idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). As shown by the recited teachings, present claim 32 and 33 define nothing more than the concomitant use of conventional disintegrants suitable for the rapidly dispersing microgranules to make another rapidly dispersing microgranules used for the same purpose. It would follow that making rapidly dispersing microgranules comprising a sugar alcohol/saccharide such as mannitol, a disintegrant such as crospovidone, as exemplified in Example 1, with an additional disintegrant such as HPC is prima facie obvious. See MPEP 2144.06.

Thus, the presently claimed ratio of "sugar alcohol or saccharide to disintegrant to dual function additive" would be no different than a ratio of the sugar/saccharide to a first disintegrant to a second disintegrant. Regarding the weight ratio of the sugar/saccharide to these disintegrants, the prior art microgranules are defined to have the sugar alcohol/saccharide and disintegrant ratio of 95:5. See '407, Example 1. It is well settled in patent law that changes of proportions will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

change is critical. See *In re Williams*, 36 F.2d 436, 438 (CCPA 1929) ("It is a settled principle of law that a mere carrying forward of an original patented conception involving only change of form, proportions, or degree, or the substitution of equivalents doing the same thing as the original invention, by substantially the same means, is not such an invention as will sustain a patent, even though the changes of the kind may produce better results than prior inventions."). In this case, Perrett teaches that the amount of a disintegrant portion in the rapidly dispersing microgranules should be about 1 to about 10 %, and the amount of sugar alcohol and/or saccharide in the granules can range from about 99-90 % of the total weight of the disintegrant-containing granules. Since combining the two art-recognized functionally equivalent disintegrants is an obvious matter, manipulation of the weight amount of the two disintegrants, depending on the desired disintegration speed and properties, to make up the total amount of the disintegrant concentration of about 1 to about 10 wt % of the rapidly dispersing microgranules would have been well within the skill in the art.

Claims 5 and 35 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 9486407 B2 as applied to claims 1-4, 6-34 as above, and further in view of Platteeuw.

Regarding claim 35, the ODT in the 407 claims are defined to include spray dried mannitol and sodium stearyl fumarate are used as a compressible diluent and a lubricant, respectively. The '407 claims fail to teach silicified microcrystalline cellulose of instant claims 5 and 35.

Platteeuw teaches using silicified microcrystalline cellulose in an oral disintegrating tablet is well known in the art and provides an enabling disclosure of how to make such tablets. 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 ODT composition of the '407 claims and use silicified microcrystalline cellulose to make an oral disintegrating tablet comprising corticosteroids as motivated by Platteeuw. The skilled artisan would have been motivated to do so, as 1) both inventions are directed to ODTs having adequate disintegratability; and 2) Platteeuw teaches that silicified microcrystalline cellulose is useful in making an ODT with such disintegratability and improved tablet strength and stability during storage, transport and/or use. Since the reference also provides an enabling disclosure of how to make such tablet, the skilled artisan would have had a

reasonable expectation of successfully producing an ODT with good disintegratability and improved strength.

2. US PAT. NO. 8771729 B2

Claims 1-4, 6-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 8771729 B2.

The '729 claims are directed to an orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid, an excipient and rapidly dispersing granules comprising a disintegrant and a sugar alcohol and/or saccharide, wherein the solid pharmaceutical composition disintegrates within 60 or 30 seconds when tested using the USP <701> Disintegration Test, and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract. The excipients of the '729 claims are defined to include fillers, diluents such as microcrystalline cellulose of instant claim 4. Although the claims at issue are not identical, they are not patentably distinct from each other because the presently claimed limitations are either disclosed in the patented claims or defined in the specification. Claims 32 and 33 are rendered obvious for an analogous reasons stated in the rejection made over the claims of the '729 patent.

Claims 5 and 35 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 8771729 B2 as applied to claims 1-4, 6-34 as above, and further in view of Platteeuw.

Regarding claim 35, the ODT in the '729 claims are defined to include spray dried mannitol and sodium stearyl fumarate are used as a compressible diluent and a lubricant, respectively. The '729 claims fail to teach silicified microcrystalline cellulose of instant claims 5 and 35.

Platteeuw is relied upon as discussed above.

It would have been obvious to one of ordinary skill in the art at the time before the present invention to modify the ODT composition of the '729 claims and use silicified microcrystalline cellulose to make an oral disintegrating tablet comprising corticosteroids as motivated by Platteeuw. The skilled artisan would have been motivated to do so, as 1) both inventions are directed to ODTs having adequate disintegratability; and 2) Platteeuw teaches that silicified microcrystalline cellulose is useful in making an ODT with such disintegratability and improved tablet strength and stability during storage, transport and/or use. Since the reference also provides an enabling disclosure of how to make such tablet, the skilled artisan would have had a reasonable expectation of successfully producing an ODT with good disintegratability and improved strength.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA YU JUSTICE whose telephone number is

(571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:00 PM.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, 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 <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA YU JUSTICE/
Primary Examiner, Art Unit 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	GOSSELIN, M, et al.	Confirmation No.:	1075
Serial No.:	14/917,125	Group Art Unit:	1617
Filed:	March 7, 2016	Examiner:	JUSTICE, Gina Yu

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

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

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sirs:

This paper is a response to a Restriction Requirement mailed on October 17, 2016, setting a two-month period for reply. Filed herewith is a petition for a 2-month extension of time. Accordingly, this paper is timely filed. Applicants discuss below their election, with traverse, of Group I, which Applicants believe encompasses claims 1-35.

Remarks begin on page **2** of this paper.

REMARKS

I. Response to Restriction Requirement

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

The October 17, 2016, Office Action required restriction to one of the following inventions under 35 U.S.C. § 121:

Group I: Claims 1-35, drawn 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 in an amount of about 5% or less by weight in the composition; b. a pharmaceutically acceptable carrier for adsorption of the corticosteroid; c. rapidly dispersing microgranules.

Group II: Claims 36-40, drawn to a method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.

Group III: Claims 41-46, drawn to a method of preparing the pharmaceutical composition of claim 1 comprising the steps of: a) preparing the rapidly dispersing microgranules; b) preparing a preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, and a glidant; c) preparing a preblend 2 by blending a filler, the preblend 1 of step b), a disintegrant, and a sweetener; d) preparing a final compressible blend, by blending the rapidly dispersing granules of step a), a lubricant, the preblend 2 of step c), and a filler; e) preparing the orally disintegrating tablet by compressing the blend of step d).

More specifically, the Examiner bases the restriction on the inventions lacking a single general concept as follows:

Groups I-III lack unity of invention because even though the inventions of these groups require the technical feature of the composition of Group I, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of WO 2011/041509 A1 (cited in IDS) which teaches an orally disintegrating tablet comprising a topically acting corticosteroid at 4% and rapidly dispersing microgranules.

Applicants traverse the Examiner's restriction requirement and request reconsideration. Applicants submit that the Examiner has not satisfied the requirements for the restriction between Groups I-III. 37 CFR § 1.475 states that:

“[w]here a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, *considered as a whole*, makes over the prior art.” (Emphasis added).

Thus, the Examiner has to prove with specificity that the inventions in the instant application, considered as a whole, lack a special technical feature which defines a contribution over the cited prior art to issue a Restriction Requirement in a National Stage Application. However, in the Office Action, the Examiner only proffers some (but not all) of the claim elements are taught by the cited prior art, and provides not a scintilla of rationale regarding why the pharmaceutically acceptable carrier for absorption of a corticosteroid (which is not taught in WO 2011/041509 A1) is not a special technical feature. Indeed, the only explanation that the Examiner provides regarding the restriction is that “WO 2011/041509 A1 (cited in IDS) ... teaches an orally disintegrating tablet comprising a topically acting corticosteroid at 4% and rapidly dispersing microgranules.” Non-Final Office Action, mailed October 17, 2016, pg. 4. The Examiner’s explanation fails to state any reason why the claims, considered as a whole, lack a special technical feature which makes a contribution over the prior art.

Consequently, as 37 CFR § 1.475 requires that the claims, *considered as a whole*, share technical features that define a contribution over the prior art, and the Examiner has failed to show that claimed pharmaceutically acceptable excipient for the absorption of a corticosteroid is not a special technical feature, the Restriction Requirement is improper. In view of the aforesaid, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement.

A. Provisional Group Election

To comply with the Examiner's Restriction Requirement, Applicants provisionally elect, with traverse, Group I, which includes claims 1-35. Applicants also affirm their right to file one or more divisional applications with respect to any other non-elected subject matter.

B. Rejoinder

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

CONCLUSION

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

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: February 17, 2017

Respectfully submitted,
COOLEY LLP

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/917,125	03/07/2016	Michael A. GOSSELIN	ADAR-144/02US 325049-2315	1075
91543	7590	10/17/2016	EXAMINER	
Cooley LLP ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			JUSTICE, GINA CHIEUN YU	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
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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):

zpatcdocketing@cooley.com

Office Action Summary	Application No. 14/917,125	Applicant(s) GOSSELIN ET AL.	
	Examiner GINA YU JUSTICE	Art Unit 1617	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1) ☐ Responsive to communication(s) filed on ____.

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

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

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

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

Disposition of Claims*

5) ☒ Claim(s) 1-46 is/are pending in the application.

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

6) ☐ Claim(s) ____ is/are allowed.

7) ☐ Claim(s) ____ is/are rejected.

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

9) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: ____.

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

DETAILED ACTION

Election/Restrictions

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF
INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-35, drawn 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 in an amount of about 5% or less by weight in the composition; b. a pharmaceutically acceptable carrier for adsorption of the corticosteroid; c. rapidly dispersing microgranules.

Group II, claims 36-40, drawn to a method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claims 1.

Group III, claims 41-46, drawn to a method of preparing the pharmaceutical composition of claims 1 comprising the steps of: a) preparing the rapidly dispersing microgranules; b) preparing a preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, and a glidant; c) preparing a preblend 2 by blending a filler, the preblend 1 of step b), a disintegrant, and a sweetener; d) preparing a final compressible blend, by blending the rapidly dispersing granules of step a), a lubricant, the preblend 2 of step c), and a filler; e) preparing the orally disintegrating tablet by compressing the blend of step d).

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-III lack unity of invention because even though the inventions of these groups require the technical feature of the composition of Group I, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of WO 2011/041509 A1 (cited in IDS) which teaches an orally disintegrating tablet comprising a topically acting corticosteroid at 4 % and rapidly dispersing microgranules.

A telephone call was made to Thomas Blinka on September 9, 2016 to request an oral election to the above restriction requirement, but did not result in an election being made.

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

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may 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. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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).

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA YU JUSTICE whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:00 PM.

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

/GINA YU JUSTICE/
Primary Examiner, Art Unit 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: LAI, Jin-Wang, et al. Confirmation No.: *To Be Assigned*

Application No.: *To Be Assigned* Group Art Unit: *To Be Assigned*

Filed: March 7, 2016 Examiner: *To Be Assigned*

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

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, please amend the application as follows.

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

Remarks begin on page 11 of this paper.

LISTING OF THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination.

1. (Currently amended) A pharmaceutical composition in the form of an orally disintegrating tablet ~~for oral administration~~ comprising:
 - a. a topically acting corticosteroid or pharmaceutically acceptable salt, ester, or polymorph in an amount of about 5% or less by weight in the composition;
 - b. a pharmaceutically acceptable carrier for adsorption of the corticosteroid ~~drug~~ particles;
 - c. rapidly dispersing microgranules.
2. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> method for disintegration time.
3. (Original) The pharmaceutical composition of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds on contact with saliva in the oral cavity of a patient in need thereof.
4. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, or 3~~, wherein the pharmaceutically acceptable carrier for adsorption of the corticosteroid ~~drug particles~~ is ~~chosen~~ selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, ~~or and~~ amorphous magnesium aluminum silicate.
5. (Currently amended) The pharmaceutical composition of claim 4, wherein the pharmaceutically acceptable carrier for adsorption of the corticosteroid is silicified microcrystalline cellulose.
6. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, or 5~~, wherein the rapidly dispersing microgranules comprise a sugar alcohol, or a saccharide, or a

mixture thereof and at least one disintegrant.

7. (Currently amended) The pharmaceutical composition of claim 6, 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.

8. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, or 8,~~ wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates, esters, and mixtures thereof.

9. (Original) The pharmaceutical composition of claim 8, wherein said corticosteroid is fluticasone.

10. (Original) The pharmaceutical composition of claim 9, wherein said corticosteroid is fluticasone propionate.

11. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, or 10,~~ wherein the ~~topically acting~~ corticosteroid is present in an amount of about 3% or less by weight in the composition.

12. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, or 10,~~ wherein the ~~topically acting~~ corticosteroid is present in an amount of about 1.5% or less by weight in the composition.

13. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, or 10,~~ wherein the ~~topically acting~~ corticosteroid is present in an amount of about 1% or less by weight in the composition.

14. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, or 10,~~ wherein the ~~topically acting~~ corticosteroid is present in an amount of about 0.5% or less by weight in the composition.

15. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, or 10,~~ wherein the ~~topically acting~~ corticosteroid is present in an amount of about 4.5 mg in the

composition.

16. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, or 8~~, wherein the ~~topically acting~~ corticosteroid is present in an amount of about 3 mg in the composition.

17. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, or 8~~, wherein the ~~topically acting~~ corticosteroid is present in an amount of about 1.5 mg in the composition.

18. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, 8, 9, or 10~~, wherein the ~~topically acting~~ corticosteroid is present in an amount of about 6 mg in the composition.

19. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, or 8~~, wherein the ~~topically acting~~ corticosteroid is fluticasone propionate in the range of 0.05 to about 15 mg in the composition at a drug content of from about 0.16% to 5% by weight of the composition.

20. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, or 8~~, wherein the ~~topically acting~~ corticosteroid is fluticasone propionate in the range of 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.

21. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, or 8~~, wherein the ~~topically acting~~ corticosteroid is fluticasone propionate 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.

22. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21~~, wherein the corticosteroid is micronized with a particle size of not more than 50 microns.

23. (Currently Amended) The pharmaceutical composition of claim 22, wherein the corticosteroid has a mean particle size of not more than about 10 microns.

24. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, or 23~~, wherein the composition further comprising an adhesive agent.

25. (Original) The pharmaceutical composition of claim 24, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl ethylcellulose, sodium carboxymethylcellulose, cross-linked polyacrylic acid, cross-linked polyacrylates, aminoalkyl methacrylate copolymers, carbopol polymers, hydrophilic polysaccharide gums, maltodextrins, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

26. (Currently amended) The pharmaceutical composition of claim[[s]] ~~6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, or 25~~ wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.

27. (Currently amended) The pharmaceutical composition of claim[[s]] ~~6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, or 26~~, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

28. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, or 27~~, further comprising a free flowing sugar alcohol or saccharide selected from the group consisting of spray-dried mannitol, spray-dried lactose, and combinations thereof.

29. (Currently amended) The pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, or 28~~, further comprising a lubricant selected from the group consisting of magnesium stearate, stearic acid, sodium stearyl fumarate, glyceryl behenate, and a mixture thereof.

30. (Currently amended) The solid pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, or 29~~, further

comprising at least one antifungal agent.

31. (Currently amended) The pharmaceutical composition of claim[[s]] 1, ~~2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, or 29~~, further comprising at least one antiviral agent.

32. (Currently amended) The pharmaceutical composition of claim[[s]] ~~6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31~~, wherein the rapidly dispersing microgranules further comprising an additive with a dual function and wherein the ratio of sugar alcohol or saccharide to disintegrant to dual-function additive is from 88:10:2 to 98.5:1:0.5.

33. (Currently amended) The pharmaceutical composition of claim 32, wherein the dual-function additive is selected from the group consisting of pregelatinized starch; and hydroxypropylcellulose ~~and the like~~.

34. (Currently amended) The pharmaceutical composition of claim[[s]] ~~6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, or 33~~, wherein the corticosteroid has an average particle size of less than about 10 μm , the rapidly dispersing microgranules have an average 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 .

35. (Currently amended) The pharmaceutical composition of claim 34, wherein the corticosteroid is fluticasone propionate with a particle size of less than 5 microns, the pharmaceutically acceptable carrier for adsorption of the corticosteroid is silicified microcrystalline cellulose, the rapidly dispersing microgranules ~~consist of~~ comprise mannitol and crospovidone, and the composition further comprises a ~~the~~ free-flowing sugar alcohol which is spray-dried mannitol, and ~~the a~~ a lubricant which is sodium stearyl fumarate.

36. (Currently amended) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35~~.

37. (Currently amended) The method of claim 36, wherein said condition ~~of the gastrointestinal tract~~ comprises inflammation of the esophagus.
38. (Original) The method of claim 37, wherein said condition is eosinophilic esophagitis.
39. (Original) The method of claim 38, wherein said condition comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.
40. (Currently amended) The method of claim ~~32~~ 36, wherein said condition is viral or bacterial pharyngitis, gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.
41. (Currently amended) A method of preparing the pharmaceutical composition of claim[[s]] ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35~~ comprising the steps of:
- a) preparing the rapidly dispersing microgranules;
 - b) preparing a preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, and a glidant;
 - c) preparing ~~the~~ a preblend 2 by blending a filler, the preblend 1 of step a b), a disintegrant, and a sweetener[[s]];
 - d) preparing ~~the~~ a final compressible blend, by blending the rapidly dispersing granules of step a), a lubricant, the preblend 2 of step c), and a filler;
 - e) preparing the orally disintegrating tablet by compressing the blend of step d).
42. (Currently amended) The method of claim 41, comprising the steps of:
- a) preparing the rapidly dispersing microgranules;
 - b) preparing ~~a~~ the preblend 1 by blending ~~the~~ silicified microcrystalline cellulose, micronized fluticasone propionate and colloidal silicon dioxide;
 - c) preparing the preblend 2 by blending mannitol, the preblend 1 of step a, crospovidone, and sucralose powder;
 - d) preparing the final compressible blend, by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), sugar alcohol, or rinsed mannitol;

e) preparing the orally disintegrating tablet by compressing the blend of step d).

43. (Currently amended) The method of claim 41 wherein:

a) preparing the rapidly dispersing microgranules;

b) preparing the preblend 1 by charging a blender with one quarter of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid, the corticosteroid, the glidant, and another quarter of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid and blending the ~~contents~~ resulting combination;

c) preparing the preblend 2 by charging a high shear granulator with a free flowing filler, preblend 1, a remaining half of the total amount of pharmaceutically acceptable carrier for adsorption of the corticosteroid, the disintegrant, and the sweetener and blending the ~~contents~~ resulting combination; and

d) preparing the final compressible blend ~~comprising~~ by charging a blender with one half of the total amount of rapidly dispersing granules of step a), the lubricant, the preblend 2 of step c), and the remaining half of the total amount of rapidly dispersing granules of step a) and blending the resulting combination to provide a compressible blend;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

44. (Currently amended) The method of claim 43 comprising the steps of:

a) preparing the rapidly dispersing microgranules;

b) preparing the preblend 1 ~~comprising~~ by charging a blender with one quarter of the total amount of silicified microcrystalline cellulose (SMCC), micronized fluticasone propionate, colloidal silicon dioxide and another quarter of the total amount of [(())SMCC((())] and blending the resulting combination;

c) preparing the preblend 2 ~~comprising~~ by charging a high shear granulator with spray dried mannitol), preblend 1, the remaining half of the total amount of SMCC, crospovidone), and sucralose powder and blending the resulting combination;

d) preparing the final compressible blend comprising charging a V-blender with one half of the rapidly dispersing granules of step a), sodium stearyl fumarate, the preblend 2 of step c), and the remaining half of the rapidly dispersing granules of step a and blending the resulting

combination;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

45. (Currently amended) The method of claim 41 comprising the steps of:

a) 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 in presence of water or an alcohol-water mixture and then drying the granulate;

b) preparing ~~a~~ the milled preblend 1 by blending the pharmaceutically acceptable carrier for adsorption of the corticosteroid, corticosteroid, and glidant in a blender and then milling the resulting mixture through a comminuting mill equipped with a[[n]] screen with a 30 Mesh opening;

c) preparing the milled preblend 2 by blending half of the total amount of a filler which is free flowing mannitol, the preblend 1 from step b), the disintegrant, and the sweetener in a blender and then milling the resulting mixture through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;

d) preparing the compressible blend by blending the rapidly dispersing granules of step a), the lubricant, the milled preblend 2 of step c), and the rinsed free flowing mannitol;

e) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

46. (Currently amended) The method of claim 45 comprising the steps of:

a) 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 crospovidone in presence of water or an alcohol-water mixture and then drying the granulate;

~~fb)~~ preparing a milled preblend 1 by blending silicified microcrystalline cellulose, micronized fluticasone propionate and colloidal silicon dioxide in a blender and then milling through a comminuting mill equipped with a[[n]] screen with a 30 Mesh opening;

g~~c~~) preparing the milled preblend 2 by blending half of the total amount of free flowing mannitol, the preblend 1 from step b), crospovidone, and sucralose powder in a blender and then milling through a comminuting mill equipped with a screen with a 30 Mesh opening, and rinsing the mill with the remaining half of the total amount of free flowing mannitol;

h~~d~~) preparing the compressible blend by blending the rapidly dispersing granules of step a), sodium stearyl fumarate, the milled preblend 2 of step c), and the rinsed free flowing mannitol;

i) preparing the orally disintegrating tablets by compressing the compressible blend of step d).

REMARKS

After entry of this amendment, claims 1- 46 are pending. Claims 1 and 4 are amended for clarity. Support for currently amended claim 1 is found throughout the specification, particularly page 5.

Various claims have been amended to remove multiple dependencies, correct typographical errors, and for clarity.

Entry and consideration of these amendments is respectfully requested. No new matter is believed to have been added by way of these amendments

CONCLUSION

An action on the merits is respectfully requested. If any outstanding issues remain, the Examiner is invited to phone the undersigned.

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.

Dated: March 7, 2016

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Respectfully submitted,
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