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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/980,639	12/28/2015	Brian AULT	POZN.P0026US.C1	1980
108197 7590 04/04/2016 Parker Highlander PLLC 1120 South Capital of Texas Highway Bldg. 1, Suite 200 Austin, TX 78746			EXAMINER JUSTICE, GINA CHIEUN YU	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 04/04/2016	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):

docket@phiplaw.com

# Office Action Summary

Application No.  
14/980,639

Applicant(s)  
AULT ET AL.

Examiner  
GINA YU JUSTICE

Art Unit  
1617

AIA (First Inventor to File)  
Status  
No

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

## Period for Reply

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

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

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.  
☐ 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) 19,29,33,34,40,42 and 45 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) 19,29,33,34,40,42 and 45 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](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto: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 is being examined under the pre-AIA first to invent provisions.

## **DETAILED ACTION**

### ***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 claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions

of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/forms/](http://www.uspto.gov/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 <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

**Claims 19, 29, 33, 34, 40, 42 and 45 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 9220698 B2.**

Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of delivering a pharmaceutical composition a patient in need thereof, comprising orally administering to the patient an AM unit dose form and, 10 hours ( $\pm 20\%$ ) later, a PM unit dose form, wherein: the AM and PM unit dose forms each comprises: i) naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and ii) esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole; said esomeprazole, or pharmaceutically acceptable

salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater. The pharmacokinetic profile of the naproxen and esomeprazole in the present claims are also disclosed in the patented claims. It is noted that the unit "hr\*ng/mL" in the present claims are disclosed in certificate of correction for the '698 patent issued on January 14, 2016.

### ***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.

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

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* Application of: Brian AULT *et al.*

Group Art Unit: 1617

Serial No.: 14/980,639

Examiner: Gina C.Y. Justice

Filing Date: December 28, 2015

Attorney Docket No.: POZN.P0026US.C1

Title: METHOD FOR DELIVERING A  
PHARMACEUTICAL COMPOSITION  
TO PATIENT IN NEED THEREOF

Confirmation No.: 1980

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the  
United States Patent and Trademark Office via EFS-Web on the date below:

April 22, 2016

Date

/Steven L. Highlander/

Steven L. Highlander

**AMENDMENT AND REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.111**

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

Commissioner:

This is in response to the office action mailed on April 4, 2016, to which a response is due on July 5, 2016 (July 4<sup>th</sup> being a federal holiday). No fees are believed due in connection with this response; however, should any fees be due, applicants authorize the Commissioner to debit Parker Highlander PLLC Deposit Acct. No. 50-5902/POZN.P0026US.C1.

A **Listing of Claims** begin on page 2 of this response; **Remarks** begin on page 5.

## LISTING OF CLAIMS

The following listing of claims replaces all previous listings or versions thereof:

1-18. (Canceled)

19. (Previously presented) A method for delivering a pharmaceutical composition to a patient in need thereof, comprising:

orally administering to the patient an AM unit dose form and, 10 hours ( $\pm 20\%$ ) later, a PM unit dose form, wherein:

the AM and PM unit dose forms each comprises:

- i) naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and
- ii) esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole;

said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,

the AM and PM unit dose forms target:

- i) a pharmacokinetic (pk) profile for naproxen where:
  - a) for the AM dose of naproxen, the mean  $C_{\max}$  is 86.2  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{\max}$  is 3.0 hours ( $\pm 20\%$ ); and
  - b) for the PM dose of naproxen, the mean  $C_{\max}$  is 76.8  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{\max}$  is 10 hours ( $\pm 20\%$ ); and
- ii) a pharmacokinetic (pk) profile for esomeprazole where:
  - a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10



hours ( $\pm 20\%$ ) after the AM dose is administered (AUC<sub>0-10,am</sub>) is 1216 hr\*ng/mL ( $\pm 20\%$ ),

b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours ( $\pm 20\%$ ) after the PM dose is administered (AUC<sub>0-14,pm</sub>) is 919 hr\*ng/mL ( $\pm 20\%$ ), and

c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours ( $\pm 20\%$ ) after the AM dose is administered (AUC<sub>0-24</sub>) is 2000 hr\*ng/mL ( $\pm 20\%$ ); and

the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

20-28. (Canceled)

29. (Previously presented) The method according to claim 19, wherein the mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period is at least about 71%.

30-32. (Canceled)

33. (Previously presented) The method according to claim 19, wherein said unit dose form is administered for a period of at least about 6 days.

34. (Previously presented) The method according to claim 29, wherein said unit dose form is administered for a period of at least about 9 days.

35-39. (Canceled)

40. (Previously presented) The method according to claim 19, wherein said AM and PM unit dose forms are each a multilayer tablet comprising at least one core and at least a first layer and a second layer, wherein:
- i) said core comprises naproxen, or pharmaceutically acceptable salt thereof;
  - ii) said first layer is a coating that at least begins to release the naproxen, or pharmaceutically acceptable salt thereof, when the pH of the surrounding medium is about 3.5 or greater; and
  - iii) said second layer comprises esomeprazole or a pharmaceutically acceptable salt thereof, wherein said esomeprazole or pharmaceutically acceptable salt thereof is released at a pH of from about 0 or greater.
41. (Canceled)
42. (Original) The method according to claim 40, wherein said esomeprazole is released at a pH of from about 0 to about 2.
- 43-44. (Canceled)
45. (Previously presented) The method according to claim 40, wherein said multi-layer tablet is substantially free of sodium bicarbonate.
- 46-47. (Canceled)

## REMARKS

### **I. Status of the Claims**

Claims 19, 29, 33, 34, 40, 42 and 45 are pending and stand rejected for obviousness-type double-patenting. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

### **II. Rejection for Obviousness-Type Double-Patenting**

Claims 19, 29, 33, 34, 40, 42 and 45 stand rejected as obvious over the claims of U.S. Patent 9,220,698. Without in any way acquiescing to the rejection, applicants are submitting herewith a terminal disclaimer over the '698 patent. Therefore, it is believed that the rejection is overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

### **III. Conclusion**

In light of the foregoing response, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Steven L. Highlander/

Date: April 22, 2016

Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

PARKER HIGHLANDER PLLC  
1120 S. Capital of Texas Highway  
Building One, Suite 200  
Austin, Texas 78746  
512-334-2901 (Direct)