IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Brian Ault, *et al*.	Filed: September 3, 2009
Application No: 12/553,107	Attorney Docket No: POZN.P0026US
Examiner: Gina C. Yu Justice	Confirmation No. 5949
Title: Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof	

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September 25, 2015 /Steven L. Highlander/
Date Steven L. Highlander

RESPONSE TO FINAL OFFICE ACTION MAILED MARCH 26, 2015

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

This is in response to the Office Action ("Action") mailed on March 26, 2015, to which a response is due on September 26, 2015, by virtue of the accompanying Petition for Extension of Time (3 months) and payment of fees. No other fees are believed due in connection with this response; however, should applicants payment be missing, or any other fees due, the Commissioner is authorized to debit Parker Highlander PLLC Deposit Acct. No. 50-5902/POZN.P0026US/SLH.

A **Listing of Claims** begins 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 treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (±20%) later, a PM unit dose form, wherein:

the AM and PM unit dose forms each comprises:

naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and

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 µg/mL (±20%) and the median T_{max} is 3.0 hours (±20%); and

b) for the PM dose of naproxen, the mean C_{max} is 76.8 µg/mL (±20%) and the median T_{max} is 10 hours (±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 (±20%) after the AM dose is administered ($AUC_{0\text{-}10,am}$) is 1216 hr*µg/mL (±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 (±20%) after the PM dose is administered ($AUC_{0\text{-}14,pm}$) is 919 hr*µg/mL (±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

(±20%) after the AM dose is administered (AUC_{0-24}) is 2000 hr*µg/mL (±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 after reaching steady state is at least about 71%.

30-32. (Canceled).

33. (Previously presented) The method according to claim 19, wherein said AM and PM unit dose forms are administered for a period of at least about 6 days.

34. (Previously presented) The method according to claim 19, wherein said AM and PM unit dose forms are 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 0 or greater.

41. (Canceled)

42. (Previously presented) The method according to claim 40, wherein said esomeprazole or pharmaceutically acceptable salt thereof is released at a pH of from 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 in the application and stand rejected under 35 U.S.C. §103 and for obviousness-type double-patenting. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection under 35 U.S.C. §103

Claims 19, 29, 33, 34, 40, 42, and 45 are rejected over Hassan-Alin *et al.* in view of Plachetka (U.S. Patent 6,926,907). Applicants traverse.

Hassan-Alin is cited as teaching that there are no drug-drug interactions between esomeprazole and naproxen, as demonstrated by a study in human subjects. In addition, the reference indicates that esomeprazole is expected to be more effective than other PPI's against NSAID-associated ulcers and to provide GI protection. Plachetka is cited as teaching a coordinated delivery of NSAIDS, including naproxen, with an acid inhibitor. From this, the examiner argues that use of esomeprazole in combination with naproxen, using an AM-PM dosing regimen, would be obvious.

To establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Indeed, all words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Once again, the examiner has not addressed at least the following highlighted claim features:

> A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (±20%) later, a PM unit dose form, wherein:
>
> the AM and PM unit dose forms each comprises:
>
> naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and

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