IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Brian Ault, *et al*.	Filed: September 3, 2009
Application No: 12/553,107	Attorney Docket No: 103526-US
Examiner: Gina Chieun Yu Justice	Confirmation No. 5949
Art Unit: 1617	
Title: Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof	

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

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AMENDMENT C AND RESPONSE TO FINAL OFFICE ACTION

This amendment is being filed with an RCE in response to the July 30, 2012 final Office action in the above-referenced patent application.

Claim amendments begin on page **2**.

Remarks begin on page **5**.

Claim Amendments

Please amend the claims as follows:

Claims 1-18 (cancelled).

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%.

Claims 20-28 (cancelled).

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%.

Claims 30-32 (cancelled).

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.

Claims 35-39 (cancelled).

40. (**currently amended**) 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.

Claim 41 (cancelled).

42. (**currently amended**) 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.

Claims 43 and 44 (cancelled).

45. (**previously presented**) The method according to claim 40, wherein said multi-layer tablet is substantially free of sodium bicarbonate.

Claims 46 and 47 (cancelled).

Remarks/Arguments

Applicants request reconsideration of this application on the merits.

I. Claim amendments

Claims 19, 29, 33, 34, 40, 42, and 45 are pending. Applicants have amended claims 40 and 42 to characterize the recited salt as "pharmaceutically acceptable." This makes claims 40 and 42 more consistent with claim 19, *i.e.*, the claim from which claims 40 and 42 ultimately depend.

Applicants continue to reserve their right to pursue any subject matter cancelled or otherwise disclosed in this application in or more later-filed continuations and/or divisionals.

II. Response to obviousness-type double-patenting rejection

Claims 19, 29, 33, 34, 40, 42, and 45 have been rejected as obviousness-type double-patenting over claims 1-55 of Plachetka (U.S. Patent No. 6,926,907). Applicants request withdrawal of this rejection.

Applicants respectfully submit that claims 19, 29, 33, 34, 40, 42, and 45 are patentably distinct over Plachetka's claims 1-55 for reasons analogous to those discussed below regarding the non-obviousness of claims 19, 29, 33, 34, 40, 42, and 45 over Plachetka generally. On this ground alone, Applicants submit this rejection should be withdrawn on the merits.

In addition, Applicants respectfully submit that this rejection is not ripe until at least one of the rejected claims has been found to be otherwise patentable. Accordingly, to the extent this rejection is not withdrawn on the merits, Applicants request that it be held in abeyance until there is at least one claim in this application found to be otherwise allowable.

III. Response to rejection under 35 U.S.C. §103(a)

Claims 19, 29, 33, 34, 30, 42, and 45 have been rejected as being obvious over Plachetka. Applicants request withdrawal of this rejection.

A. Claim 19

Applicants respectfully submit that claim 19 represents a non-obvious selection over Plachetka. This selection is characterized by unexpected results. Nothing in Plachetka would have suggested such unexpected results at the time of Applicants' filing.

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