IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Plachetka, John R.

Appl. No.: 10/158,216

Filed: May 31, 2002

For: **Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs**

Group Art Unit: 1615

Examiner: Spear, J.

Atty. Dkt.: 7569/73281

Amendment and Response Under 37 C.F.R. § 1.116

Commissioner for Patents
U.S. Patent and Trademark Office
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Arlington, VA 22202

Sir:

In response to the Office Action dated October 20, 2004, Applicant respectfully requests reconsideration of the above-captioned application in view of the following amendments and remarks.

Amendments to the Claims begin on page 2 of the present document.

Remarks begin on page 10 of the present document.

Amendments to the Claims

Please cancel claims 51 and 52 without prejudice. Please add new claims 55-57 and amend the remaining claims as indicated below in the "List of Claims."

List of Claims

1. (Currently amended) A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:

(a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;

(b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;

and wherein said unit dosage form provides for coordinated release such that: ~~said acid inhibitor is released first and said NSAID is not released until the gastric pH of said patient is 3.5 or higher~~

i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;

ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

2. (Currently amended) The pharmaceutical composition of claim 1, wherein said acid inhibitor is ~~selected from: a proton pump inhibitor and~~ an H2 blocker.

3. (Currently amended) The pharmaceutical composition of claim 2, wherein said ~~acid inhibitor is an~~ H2 blocker is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxtidine and famotidine.

4. (Original) The pharmaceutical composition of claim 3, wherein said H2 blocker is famotidine, present in said unit dosage form in an amount of between 5 mg and 100 mg.

5. (Original) The pharmaceutical composition of claim 1, wherein said acid inhibitor is a proton pump inhibitor selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole.

6. (Original) The pharmaceutical composition of claim 5, wherein said proton pump inhibitor is pantoprazole, present in said unit dosage form in an amount of between 10 mg and 200 mg.

7. (Original) The pharmaceutical composition of claim 1, wherein said NSAID is a cyclooxygenese-2 (COX-2) inhibitor.

8. (Original) The pharmaceutical composition of claim 7, wherein said COX-2 inhibitor is selected from the group consisting of celecoxib; rofecoxib; meloxicam; piroxicam; valdecoxib, parecoxib, etoricoxib, CS-502, JTE-522; L-745,337; and NS398.

9. (Original) The pharmaceutical composition of claim 1, wherein said NSAID is selected from the group consisting of: aspirin; acetaminophen; ibuprofen; flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; and nabumetone.

10. (Original) The pharmaceutical composition of claim 9, wherein said NSAID is naproxen present in an amount of between 50 mg and 1500 mg.

11. (Original) The pharmaceutical composition of claim 10, wherein said naproxen is present in an amount of between 200 mg and 600 mg.

12. (Currently amended) The pharmaceutical composition of claim 1 wherein said unit dosage form is a multilayer tablet comprising a single core and one or more layers outside of said single core, wherein:

i) said NSAID is present in said core;

ii) said coating that does not release said NSAID unless the pH of the surrounding medium is 3.5 or higher surrounds said core; and

iii) said acid inhibitor is in said one more layers outside said core.

13. (Currently amended) The pharmaceutical composition of claim 12, wherein ~~said unit dosage form is a trilayer tablet having an outer layer of said acid inhibitor and an inner core of said NSAID~~ said one or more layers outside of said core do not contain NSAID and are not surrounded by an enteric coating.

14. (Currently amended) The pharmaceutical composition of claim ~~12~~ 13, wherein said unit dosage form is a bilayer tablet having an outer layer of said acid inhibitor and an inner core of said NSAID and wherein said outer layer of said tablet is surrounded by a non-enteric film coating that releases said acid inhibitor upon ingestion by a patient.

15. (Currently amended) The pharmaceutical composition of any one of claims ~~12-14~~ 1 or 7-14, wherein said ~~tablet has an inner core of said NSAID surrounded by a barrier coating that does not dissolve unless the pH of the surrounding medium is 3.5 or greater~~ acid inhibitor is a proton pump inhibitor.

16. (Currently amended) The pharmaceutical composition of ~~any one of claims 12-14~~ claim 15, wherein said ~~tablet has an inner core of said NSAID surrounded by a barrier~~ coating ~~that~~ surrounding said core does not dissolve unless the pH of the surrounding medium is 4 or greater.

17. (Currently amended) The pharmaceutical composition of ~~any one of claims 12-14~~ claim 15, wherein said ~~tablet has an inner core of said NSAID surrounded by a barrier~~ coating

~~that~~ surrounding said core does not dissolve unless the pH of the surrounding medium is 5 or greater.

18. (Currently amended) The pharmaceutical composition of any one of ~~claims 12-14~~ claims 7-14, wherein ~~said tablet has an inner core of said NSAID surrounded by a barrier coating that dissolves at a rate such that said NSAID is not released until the pH of the surrounding medium is 3.5 or greater~~ said acid inhibitor is an H2 blocker.

19. (Currently amended) The pharmaceutical composition of ~~any one of claims 12-14~~ claim 18, wherein said tablet has an inner core of said NSAID surrounded by a barrier coating that dissolves at a rate such that said NSAID is not released until the pH of the surrounding medium is 4 or greater.

20. (Currently amended) The pharmaceutical composition of ~~any one of claims 12-14~~ claim 18, wherein said tablet has an inner core of said NSAID surrounded by a barrier coating that dissolves at a rate such that said NSAID is not released until the pH of the surrounding medium is 5 or greater.

21. (Original) The pharmaceutical composition of claim 1, wherein said unit dosage form is a capsule.

22. (Original) A method of treating a patient for pain or inflammation, comprising administering to said patient the pharmaceutical composition of any one of claims 1-14.

23. (Previously presented) The method of claim 22, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

24. (Original) A method of treating a patient for pain or inflammation, comprising:

(a) orally administering to said patient an acid inhibitor at a dose effective to raise the gastric pH of said patient to at least 3.5; and

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