

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII LLC,
Petitioner,

v.

POZEN INC.,
Patent Owner.

IPR2015-01241
Patent 6,926,907

PETITION FOR *INTER PARTES* REVIEW

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B. Claim 1:12

1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:12

2. (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;13

3. (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;14

4. and wherein said unit dosage form provides for coordinated release such that: 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;14

5. 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 3.5.15

C. Claim 7: The pharmaceutical composition of claim 1, wherein said NSAID is a cyclooxygenase-2 (COX-2) inhibitor.17

D. Claim 8: 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 NS398.17

E. Claim 12:17

1. The pharmaceutical composition of claim 1 wherein said unit dosage form is a multilayer tablet comprising17

2.	a single core and one or more layers outside of said single core, wherein:	18
3.	i) said NSAID is present in said core;.....	18
4.	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.....	18
5.	iii) said acid inhibitor is in said one more layers outside said core.	19
F.	Claim 13: The pharmaceutical composition of claim 12, wherein said one or more layers outside of said core do not contain NSAID and are not surrounded by an enteric coating.	19
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1.	A method of treating a patient for pain or inflammation, comprising.....	20
2.	administering to said patient the pharmaceutical composition of any one of claims 1-14.....	20
H.	Claim 23: The method of claim 22, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.....	20
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B.	Claim 1:	22
1.	A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:	22
2.	(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;22

3. (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;23

4. and wherein said unit dosage form provides for coordinated release such that: 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;23

5. 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 3.5.24

C. Claim 2: The pharmaceutical composition of claim 1, wherein said acid inhibitor is an H2 blocker.....24

D. Claim 3: The pharmaceutical composition of claim 2, wherein said H2 blocker is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxidine and famotidine.....24

E. Claim 4: 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.25

F. Claim 5: 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.....26

G. Claim 7: The pharmaceutical composition of claim 1, wherein said NSAID is a cyclooxygenase-2 (COX-2) inhibitor.26

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