

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.

IPR2015-01680
Patent 8,852,636

DECLARATION OF LEON SHARGEL, PH.D., R.PH.

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B.	Claim 1:	37
1.	A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:	37
2.	(a) esomeprazole 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;	37
3.	(b) naproxen present 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:	40
4.	i) said unit dosage form is a tablet in which said naproxen is present in a core;.....	41
5.	ii) said tablet comprises a coating, wherein said coating surrounds said core and does not release said naproxen until the pH of the surrounding medium is 3.5 or higher; and	41
6.	iii) said esomeprazole is in one or more layers outside said core, wherein said one or more layers:.....	42
7.	A) do not include an naproxen;.....	43
8.	B) are not surrounded by an enteric coating; and	44
9.	C) upon ingestion of said tablet by a patient, release said esomeprazole into said patient's stomach.....	44
C.	Claim 2: The pharmaceutical composition of claim 1, wherein there is a single core comprising said naproxen.	45
D.	Claim 3: The pharmaceutical composition of claim 2, wherein said esomeprazole is present in said unit dosage form in an amount of between 5 mg and 100 mg.	46
E.	Claim 4: The pharmaceutical composition of claim 2, wherein naproxen is present in said unit dosage form in an amount of	

200-600 mg.....47

F. Claim 5: A method of treating a patient for pain or inflammation, comprising administering to said patient a therapeutically effective amount of the pharmaceutical composition of claim 1.....47

G. Claim 6: The method of claim 5, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.....48

H. Claim 7:48

1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:48

2. (a) esomeprazole 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;49

3. (b) naproxen present 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:52

4. i) said unit dosage form is a capsule in which said naproxen is present in a core;.....52

5. ii) said capsule comprises a coating, wherein said coating surrounds said core containing said naproxen and does not release said naproxen until the pH of the surrounding medium is 3.5 or higher; and53

6. iii) said esomeprazole is in one or more layers outside said core, wherein said one or more layers:.....54

7. A) do not include an naproxen;.....55

8. B) are not surrounded by an enteric coating; and56

9. C) upon ingestion of said capsule by a patient, release

	said esomeprazole into said patient's stomach.	56
I.	Claim 8: The pharmaceutical composition of claim 7, wherein there are multiple particles of said naproxen each constituting a core surrounded by said coating that does not release said naproxen until the pH of the surrounding medium is 3.5 or higher.	57
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