Paper 1
Date: August 7, 2015

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

PETITION FOR *INTER PARTES* REVIEW

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A. A POSA Would Have Combined Goldman, Remington, and Lindberg....10

B. Claim 1: 12

1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising: 13

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; 13

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: 14

4. i) said unit dosage form is a tablet in which said naproxen is present in a core; 14

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 15

6. iii) said esomeprazole is in one or more layers outside said core, wherein said one or more layers: 16

7. A) do not include an naproxen; 16

8. B) are not surrounded by an enteric coating; and 17

9. C) upon ingestion of said tablet by a patient, release said esomeprazole into said patient's stomach. 17

C. Claim 2: The pharmaceutical composition of claim 1, wherein there is a single core comprising said naproxen. 18

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. 18

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.....19

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.....20

G. Claim 6: The method of claim 5, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.....20

H. Claim 7:.....21

1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:.....21

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;.....21

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:.....22

4. i) said unit dosage form is a capsule in which said naproxen is present in a core;.....23

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; and.....24

6. iii) said esomeprazole is in one or more layers outside said core, wherein said one or more layers:.....25

7. A) do not include an naproxen;.....26

8. B) are not surrounded by an enteric coating; and.....26

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

said esomeprazole into said patient's stomach. 27

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. 27

J. Claim 9: The pharmaceutical composition of claim 8, wherein said esomeprazole is present in said unit dosage form in an amount of between 5 mg and 100 mg. 29

K. Claim 10: The pharmaceutical composition of claim 8, wherein naproxen is present in said unit dosage form in an amount of 200-600 mg. 30

L. Claim 11: 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 7. 30

M. Claim 12: The method of claim 11, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis. 31

N. Claim 13: The pharmaceutical composition of claim 1, further comprising at least one carrier. 31

O. Claim 14: The pharmaceutical composition of claim 1, further comprising at least one auxiliary agent chosen from the group consisting of lubricants, preservatives, disintegrants, stabilizers, wetting agents, emulsifiers, salts, buffers, coloring agents, flavoring agents, and aromatic substances. 32

P. Claim 15: The pharmaceutical composition of claim 1, further comprising at least one ingredient to adjust pH. 32

Q. Claim 16: The pharmaceutical composition of claim 7, further comprising at least one carrier. 33

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