

CLAIM CHART – GROUND 3

8,945,636	’118 patent and ’225 patent
Claim 1	
A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:	“Examples 1-10 disclose various formulations for preparing tablets or caplets in accordance with the invention.” (’118 patent, 6:24-26.)
(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;	<p>“[T]he invention comprises pharmaceutical compositions and methods [. . .] comprising [. . .] a gastric acid inhibiting effective amount of [. . .] a proton pump inhibitor.” (’118 patent, 3:10-16.)</p> <p>“Omeprazole, a proton pump inhibitor, irreversibly inhibits the enzyme responsible for acid production.” (’118 patent, 4:64-66.)</p> <p>“The composition of the present invention shall preferably contain a combination of the following compositions or their pharmaceutically acceptable salts [. . .] proton pump inhibitor drugs including omeprazole from 60 to 500mg per dose”. (’118 patent, 5:9-11, 30-31.)</p>
(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:	<p>“[T]he invention comprises pharmaceutical compositions and methods [. . .] comprising an analgesic effective amount of an NSAID” (’118 patent, 3:10-14.)</p> <p>“NSAIDs are commonly used for the treatment of pain and inflammation of a variety of etiologies.” (’118 patent, 3:10-14.)</p> <p>“The composition of the present invention shall preferably contain [. . .] one of several NSAIDs form the group of: [. . .] naproxen from 200 to 500mg per dose”. (’118 patent, 5:09-19.)</p>
i) said unit dosage form is a tablet in which said naproxen is present in a	“The invention herein is directed to a pharmaceutical composition which is a core/mantle tablet consisting of a core of a nonsteroidal anti-inflammatory drug

<p>core;</p>	<p>(NSAID).” (’225 patent, 3:9-11)</p> <p>“We claim: 1. A pharmaceutical composition comprising: a. a core consisting of a therapeutically-effective amount of a nonsteroidal anti-inflammatory agent; and b. a mantle coating surrounding the core comprising a therapeutically-effective amount of misoprostol.” (’225 patent, 12:34-40.)</p> <p>“The composition of the present invention shall preferably contain [. . .] one of several NSAIDs from the group of: [. . .] naproxen from 200 to 500mg per dose”. (’118 patent, 5:09-19.)</p>
<p>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</p>	<p>“Surrounding the [NSAID] core is an enteric coating.” (’225 patent, 6:28-29.) “The coating aids in segregating the NSAID [. . .] and in directing the dissolution of the NSAID core in the lower G.I. tract as opposed to the stomach.” (’225 patent, 6:33-36.)</p> <p>Examples 3-6 include “methacrylic acid copolymer type C” within the enteric coating, which is known to prevent release of contents until pH is above 3.5. (’225 patent, 8:30-32, 9:5-7, 42-43; 10:12-13.)</p>
<p>iii) said esomeprazole is in one or more layers outside said core, wherein said one “or more layers:</p>	<p>“Surrounding the coated inner core is a mantle consisting of [an acid inhibitor]” (’225 patent, 6:41-43.)</p> <p>“We claim: 1. A pharmaceutical composition comprising: a. a core consisting of a therapeutically-effective amount of a nonsteroidal anti-inflammatory agent; and b. a mantle coating surrounding the core comprising a therapeutically-effective amount of [acid inhibitor].” (’225 patent, 12:34-40.)“</p> <p>“The composition of the present invention shall preferably contain a combination of the following compositions or their pharmaceutically acceptable salts [. . .] proton pump inhibitor drugs including omeprazole from 60 to 500mg per dose”. (’118 patent, 5:9-11, 30-31.)</p>
<p>A) do not include an</p>	<p>“Surrounding the coated inner core is a mantle</p>

naproxen;	consisting of [an acid inhibitor]" ('225 patent, 6:41-43.)
B) are not surrounded by an enteric coating; and	<p>"EXAMPLE 11 A tablet consisting of: 500 mg acetaminophen; 60 mg of omeprazole; and other auxiliary agents and coloring agents." ('118 patent, 7:29-35.)</p> <p>"EXAMPLE 12 A tablet consisting of: 200 mg ibuprofen; 60 mg of omeprazole; and other auxiliary agents and coloring agents." ('118 patent, 7:36-42.)</p>
C) upon ingestion of said tablet by a patient, release said esomeprazole into said patient's stomach.	<p>"Surrounding the [NSAID] core is an enteric coating." ('225 patent, 6:28-29.) "The coating aids in [. . .] directing the dissolution of the NSAID core in the lower G.I. tract as opposed to the stomach [where the acid inhibitor is released]." ('225 patent, 6:33-36.)</p> <p>"The composition of the present invention shall preferably contain a combination of the following compositions or their pharmaceutically acceptable salts [. . .] proton pump inhibitor drugs including omeprazole from 60 to 500mg per dose". ('118 patent, 5:9-11, 30-31.)</p>
Claim 2	
The pharmaceutical composition of claim 1, wherein there is a single core comprising said naproxen.	<p>"The invention herein is directed to a pharmaceutical composition which is a core/mantle tablet consisting of a core of a nonsteroidal anti-inflammatory drug (NSAID)." ('225 patent, 3:9-11.)</p> <p>"We claim: 1. A pharmaceutical composition comprising: a. a core consisting of a therapeutically-effective amount of a nonsteroidal anti-inflammatory agent; and b. a mantle coating surrounding the core comprising a therapeutically-effective amount of [acid inhibitor]." ('225 patent, 12:34-40.)</p> <p>"The composition of the present invention shall preferably contain [. . .] one of several NSAIDs from the group of: [. . .] naproxen from 200 to 500mg per dose". ('118 patent, 5:09-19.)</p>
Claim 3	
The pharmaceutical composition of claim 2,	"The composition of the present invention shall preferably contain a combination of the following

wherein said esomeprazole is present in said unit dosage form in an amount of between 5 mg and 100 mg.	compositions or their pharmaceutically acceptable salts [. . .] proton pump inhibitor drugs including omeprazole from 60 to 500mg per dose”. (’118 patent, 5:9-11, 30-31.)
Claim 4	
The pharmaceutical composition of claim 2, wherein naproxen is present in said unit dosage form in an amount of 200-600 mg.	“The composition of the present invention shall preferably contain [. . .] one of several NSAIDs form the group of: [. . .] naproxen from 200 to 500mg per dose”. (’118 patent, 5:09-19.)
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.	“A method of treating inflammation comprising orally administering to a patient in need of such treatment, a therapeutically effective amount to treat inflammation of a composition comprising a. a core consisting of a therapeutically effective amount of a nonsteroidal anti-inflammatory agent [. . .]; and b. a mantle coating surrounding the core comprising a therapeutically-effective amount of [acid inhibitor].” (’225 patent, 12:42-44.)
Claim 6	
The method of claim 5, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.	“[NSAIDs] comprise a class of drugs which have long been recognized as having high therapeutic value especially for the treatment of inflammatory conditions such as exhibited in inflammatory diseases like osteoarthritis (OA) and rheumatoid arthritis (RA).” (’225 patent, 1:18-22.) “It would be desirable to provide a pharmaceutical composition which would exhibit the beneficial properties of an NSAID and which composition would exhibit the beneficial properties of [an acid inhibitor] for countering [. . .] the ulcerogenic side effects attendant to NSAID administration.” (’225 patent, 1:57-62.)
Claim 13	
The pharmaceutical composition of claim 1, further comprising at least	“Other ingredients both active and inactive can be added to the combination pharmaceutical compositions of the invention.” (’118 patent, 6:1-3.)

one carrier.	“Various excipients such as binders, bulking agents, lubricants, fillers and the like, can be combined” (’225 patent, 4:28-29.)
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.	“Other ingredients both active and inactive can be added to the combination pharmaceutical compositions of the invention.” (’118 patent, 6:1-3.) “Various excipients such as binders, bulking agents, lubricants, fillers and the like, can be combined” (’225 patent, 4:28-29.)
Claim 15	
The pharmaceutical composition of claim 1, further comprising at least one ingredient to adjust pH.	“Other ingredients both active and inactive can be added to the combination pharmaceutical compositions of the invention.” (’118 patent, 6:1-3.) “Various excipients such as binders, bulking agents, lubricants, fillers and the like, can be combined” (’225 patent, 4:28-29.)

CLAIM CHART – GROUND 4

8,945,636	’118, ’225, and ’192 patents
Claim 1	
A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:	“Examples 1-10 disclose various formulations for preparing tablets or caplets in accordance with the invention.” (’118 patent, 6:24-26.)
(a) esomeprazole present in an amount effective to raise the gastric pH of said	“[T]he invention comprises pharmaceutical compositions and methods [. . .] comprising [. . .] a gastric acid inhibiting effective amount of [. . .] a

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