CLAIM CHART – GROUND 1

8,945,636	’556 patent and Chandramouli
Claim 1	
A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:	“In preferred embodiments of the invention, the pharmaceutical compositions containing the proton pump inhibitors and NSAIDs set forth herein are administered orally.” (7:31-33.)
(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;	“The invention is further directed to a dosage form comprising a therapeutically effective amount of an NSAID and an amount of a proton pump inhibitor effective to substantially inhibit gastrointestinal side effects of the NSAID” (4:4-7.) “In certain preferred embodiments, the proton pump inhibitor is omeprazole, either in racemic mixture or only the (-)enantiomer of omeprazole (i.e. esomeprazole)” (6:53-56.) U.S. Patent No. 5,877,192, which is incorporated by reference, teaches esomeprazole may raise intragastric pH to 3.5 or higher. (*See* 6:53-58.)
(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:	“The invention is further directed to a dosage form comprising a therapeutically effective amount of an NSAID and an amount of a proton pump inhibitor effective to substantially inhibit gastrointestinal side effects of the NSAID” (4:4-7.) “For many years NSAIDs have been used for treating pain and/or inflammation.” (5:40-42.) “The term NSAID includes, but is not limited to, the group consisting of [. . .], naproxen, [. . .]” (5:60-63.)
i) said unit dosage form is a tablet in which said naproxen is present in a core;	“In certain preferred embodiments, the oral dosage form of the present invention comprises a compressed matrix comprising the NSAID or a salt thereof and a retardant material in an effective amount to provide a controlled release of the NSAID for at least about 24 hours; a proton pump inhibitor coated on the surface

	of the matrix" (12:54-59.)
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	"In certain preferred embodiments, the oral dosage form of the present invention comprises a compressed matrix comprising the NSAID or a salt thereof and a retardant material in an effective amount to provide a controlled release of the NSAID" (12:54-59.) "In one embodiment, coatings are provided to permit either pH-dependent or pH-independent release" (12:17-19.) "Coatings which are pH-dependent may be used in accordance with the present invention" (12:40-41.) "As enteric coating layer polymers one or more, separately or in combination, of the following can be used; e.g. solutions or dispersions of methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate trimellitate, carboxymethylethylcellulose, shellac or other suitable enteric coating layer polymer(s)." (13:13-22.)
iii) said esomeprazole is in one or more layers outside said core, wherein said one "or more layers:	"In certain preferred embodiments, the oral dosage form of the present invention comprises a compressed matrix comprising the NSAID [. . .]; a proton pump inhibitor coated on the surface of the matrix, wherein the proton pump inhibitor is in an amount effective to inhibit gastrointestinal side effects normally associated with oral administration of the NSAID" ('556 patent, 12:54-62.) "The proton pump inhibitor is coated onto the tablet. Preferably, a solution of the proton pump inhibitor is spray dried onto the surface of the tablet using any spray technique known to those skilled in the art." (14:8-11.) "In certain preferred embodiments, the proton pump

	inhibitor is omeprazole, either in racemic mixture or only the (—)enantiomer of omeprazole (i.e. esomeprazole)" (6:53-56.)
A) do not include an naproxen;	"In certain preferred embodiments, the oral dosage form of the present invention comprises a compressed matrix comprising the NSAID [. . .]; a proton pump inhibitor coated on the surface of the matrix" (12:54-59)
B) are not surrounded by an enteric coating; and	"Formulations according to the invention that utilize pH-dependent coatings to obtain formulations may also impart a repeat-action effect whereby unprotected drug [. . .] is coated over the enteric coat and is released in the stomach, while the remainder, [. . .] being protected by the enteric coating, is released further down the gastrointestinal tract." (12:33-40.)
C) upon ingestion of said tablet by a patient, release said esomeprazole into said patient's stomach.	"In one embodiment, coatings are provided to permit either pH-dependent or pH-independent release" (12:17-19.) "Formulations according to the invention that utilize pH-dependent coatings to obtain formulations may also impart a repeat-action effect whereby unprotected drug [. . .] is coated over the enteric coat and is released in the stomach, while the remainder, [. . .] being protected by the enteric coating, is released further down the gastrointestinal tract." (12:33-40.)
Claim 2	
The pharmaceutical composition of claim 1, wherein there is a single core comprising said naproxen.	"In certain preferred embodiments, the oral dosage form of the present invention comprises a compressed matrix comprising the NSAID or a salt thereof and a retardant material in an effective amount to provide a controlled release of the NSAID for at least about 24 hours; a proton pump inhibitor coated on the surface of the matrix" (12:54-59.) "The term NSAID includes, but is not limited to, the group consisting of [. . .], naproxen, [. . .]" (5:60-63.)
Claim 3	
The pharmaceutical	"In certain preferred embodiments, the proton pump

composition of claim 2, wherein said esomeprazole is present in said unit dosage form in an amount of between 5 mg and 100 mg.	inhibitor is omeprazole, either in racemic mixture or only the (—)enantiomer of omeprazole (i.e. esomeprazole)" (6:53-56.) "Thus, in certain embodiments of the invention, the amount of proton pump inhibitor which is included in the dosage form is an amount which is considered to be therapeutically effective, in accordance with the dosages set forth above for a variety of disease states." (7:1-5.) "For example, when the drug is omeprazole, the dosage form may contain from about 0.1mg to about 120 mg omeprazole. Lansoprazole is typically administered about 15-30 mg/day; rabeprazole is typically administered 20 mg/day and pantoprazole is typically administered 40 mg/day. However, any therapeutic or sub-therapeutic dose of these agents is considered within the scope of the present invention" (7:7-14.)
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 invention is further directed to a dosage form comprising a therapeutically effective amount of an NSAID and an amount of a proton pump inhibitor effective to substantially inhibit gastrointestinal side effects of the NSAID" (4:4-7.) Listing commonly prescribed naproxen dosage as 250-500mg, and 750-1000mg per day (Chandramouli, 34)
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.	"Also disclosed is a method of treating a human patient in need of antiinflammatory, analgesic and/or antipyretic therapy, comprising orally administering to the patient an oral pharmaceutical dosage form which includes a therapeutically effective amount of an NSAID and an amount of a proton pump inhibitor effective to substantially inhibit gastrointestinal side effects of the NSAID." (Abstract.)

	"For many years NSAIDs have been used for treating pain and/or inflammation." (5:40-42.)
Claim 6	
The method of claim 5, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.	"Pain includes, but is not limited to, chronic pains, such as arthritis pain (e.g. pain associated with osteoarthritis and rheumatoid arthritis)" (5:46-48.)
Claim 13	
The pharmaceutical composition of claim 1, further comprising at least one carrier.	"The combination of proton pump inhibitor and a NSAID can be employed in admixtures With conventional excipients, i.e., pharmaceutically acceptable organic or inorganic carrier substances suitable for oral, parenteral, nasal, intravenous, subcutaneous, enteral, or any other suitable mode of administration, known to the art. Suitable pharmaceutically acceptable carriers include but are not limited to [. . .]." (7:31-44.)
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.	"The pharmaceutical preparations can be sterilized and if desired mixed with auxiliary agents, e.g., lubricants, preservatives, stabilizers, wetting agents, emulsifiers, salts for influencing osmotic pressure buffers, coloring, flavoring and/or aromatic substances and the like." (7:44-48.)
Claim 15	
The pharmaceutical composition of claim 1, further comprising at least one ingredient to adjust pH.	"A further ingredient which can be added to the matrix is a pH modifying agent" (13:48-49.)

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