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**Chen et al.**

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(54) **PHARMACEUTICAL FORMULATIONS  
CONTAINING A NON-STEROIDAL  
ANTIINFLAMMATORY DRUG AND A  
PROTON PUMP INHIBITOR**

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/659,222**

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Hawkey, Christopher J., et al., Omeprazole Compared with Misoprostol for Ulcers Associated with Nonsteroidal Anti-inflammatory Drugs, *New England Journal of Medicine* (Mar. 12, 1988), 338:727-734.

(51) **Int. Cl.**<sup>7</sup> ..... **A61K 9/20; A61K 9/22;**  
**A61K 9/24; A61K 9/26; A61K 9/54**

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**424/472**

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**481, 482, 489, 493, 494, 495, 496, 497,**  
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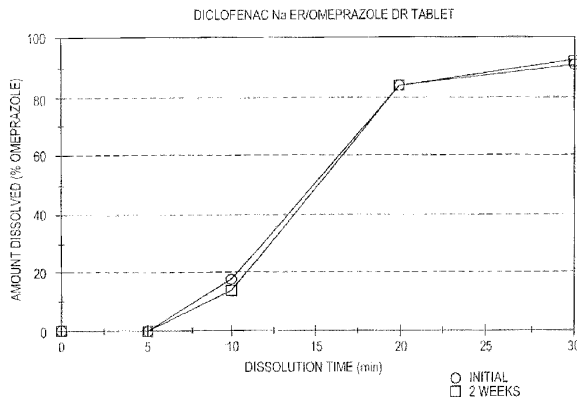
**ABSTRACT**

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An oral solid dosage form includes a therapeutically effective amount of an NSAID and a proton pump inhibitor in an amount effective to inhibit or prevent gastrointestinal side effects normally associated with the NSAID. 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. The invention is further related to a method of prophylactically treating a human patient who is on a therapy known to have significant gastrointestinal side effects or is about to begin such a therapy, via concurrent administration of an NSAID and a proton pump inhibitor in a combination (single) oral dosage form.

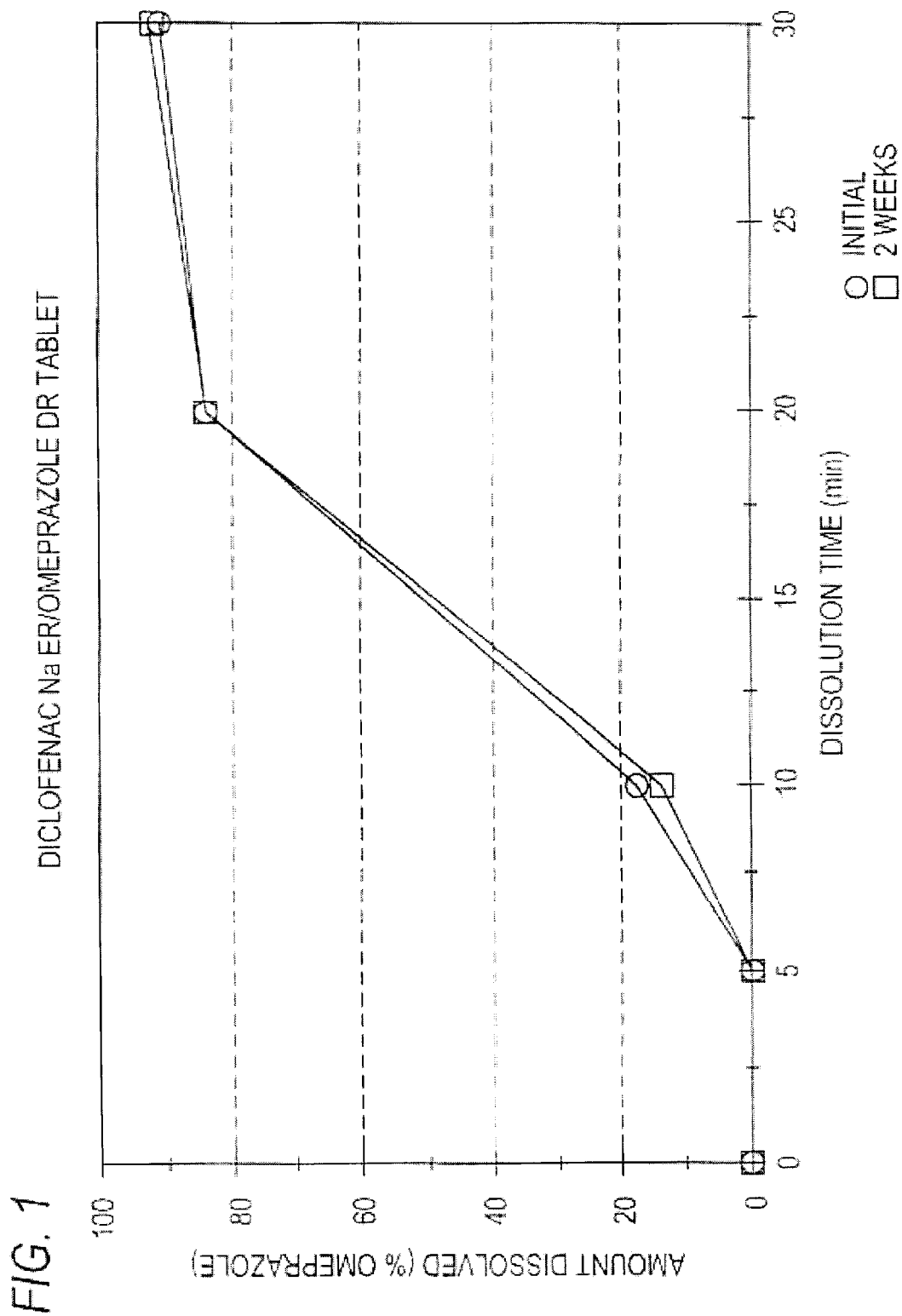
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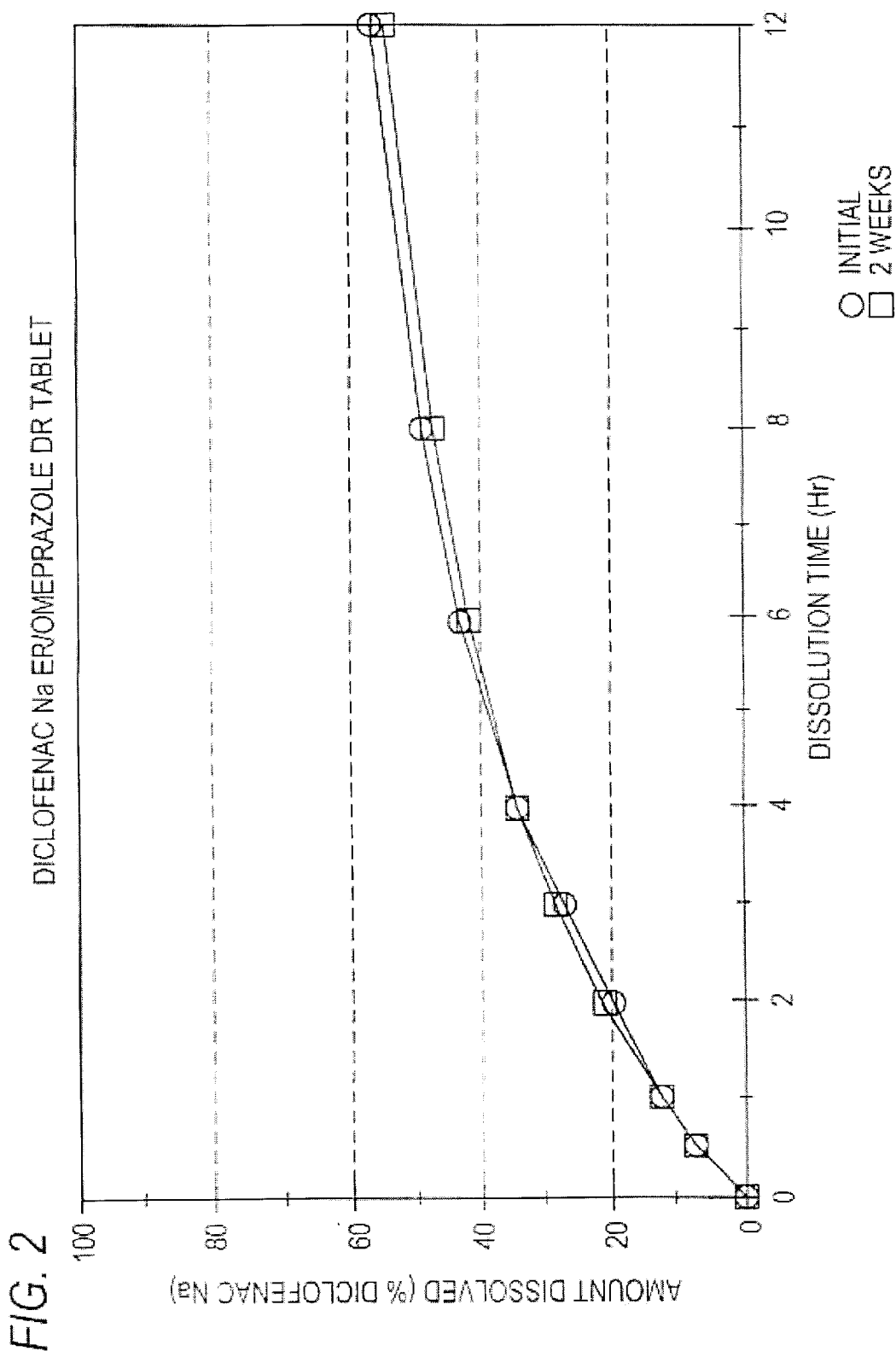
**34 Claims, 4 Drawing Sheets**

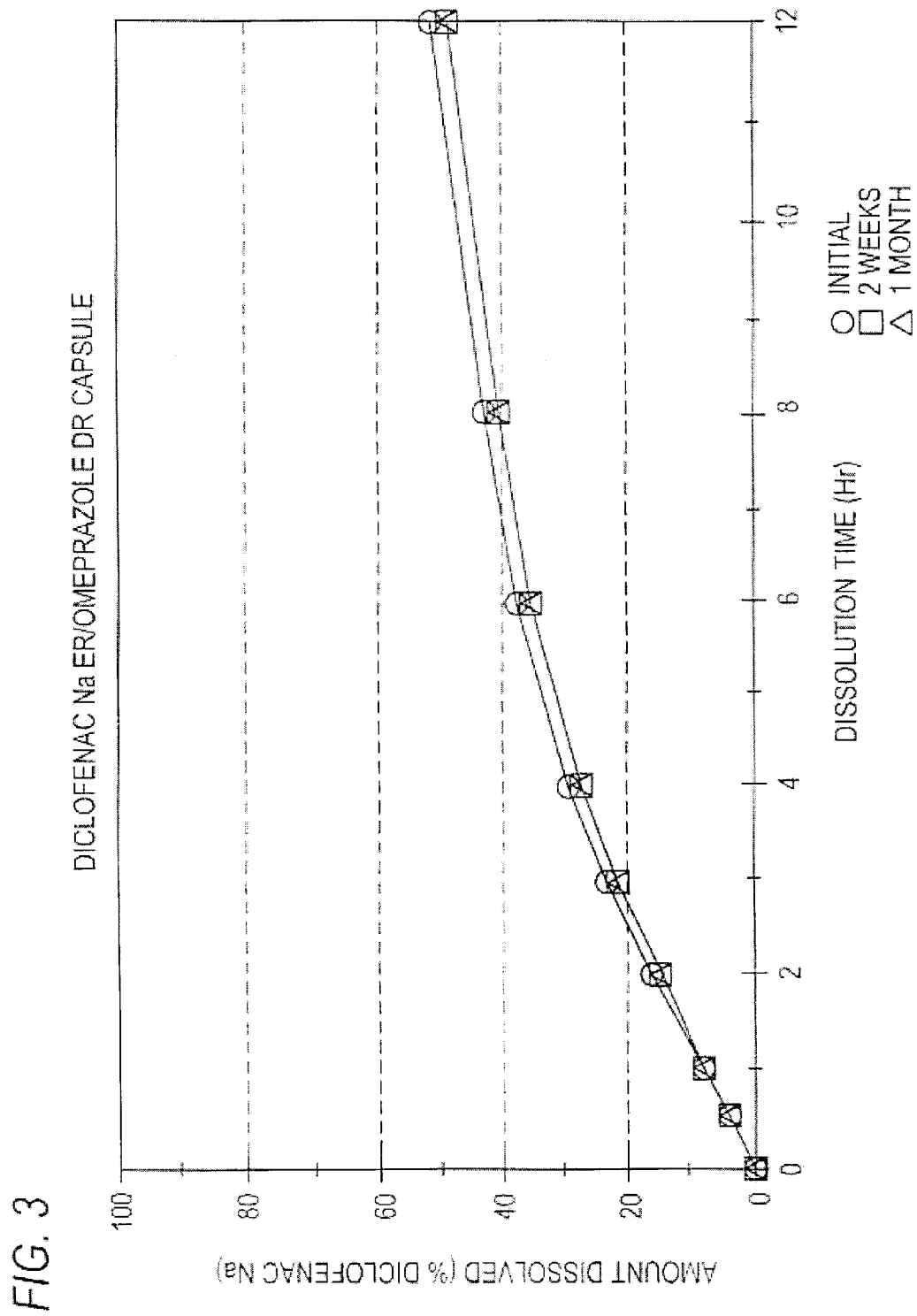


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