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- (54) **METHOD FOR DELIVERING A PHARMACEUTICAL COMPOSITION TO PATIENT IN NEED THEREOF**
- (71) Applicants: **POZEN INC.**, Chapel Hill, NC (US); **HORIZON PHARMA USA, INC.**, Deerfield, IL (US)
- (72) Inventors: **Brian Ault**, Wilmington, DE (US); **Everardus Orlemans**, Chapel Hill, NC (US); **John R. Plachetka**, Chapel Hill, NC (US); **Mark Sostek**, Wilmington, DE (US)
- (73) Assignees: **Pozen Inc.**, Chapel Hill, NC (US); **Horizon Pharma USA, Inc.**, Deerfield, IL (US)
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CPC **A61K 9/209** (2013.01); **A61K 9/0053** (2013.01); **A61K 31/192** (2013.01); **A61K 31/4439** (2013.01)
- (58) **Field of Classification Search**
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(56) **References Cited**

U.S. PATENT DOCUMENTS

4,198,390 A	4/1980	Rider
4,255,431 A	3/1981	Junggren et al.
4,344,929 A	8/1982	Bonsen et al.
4,508,905 A	4/1985	Junggren et al.
4,554,276 A	11/1985	LaMatina
4,562,261 A	12/1985	Hirata et al.
4,619,934 A	10/1986	Sunshine et al.
4,676,984 A	6/1987	Wu et al.
4,704,278 A	11/1987	Wu et al.

4,726,951 A	2/1988	Panoz et al.
4,738,974 A	4/1988	Brandstrom
4,757,060 A	7/1988	Lukacsko et al.
4,758,579 A	7/1988	Kohl et al.
4,766,117 A	8/1988	Crawford et al.
4,786,505 A	11/1988	Lovgren et al.
4,853,230 A	8/1989	Lovgren et al.
4,865,847 A	9/1989	Gosswein
4,948,581 A	8/1990	Sawayanagi et al.
4,965,065 A	10/1990	Lukacsko et al.
5,026,560 A	6/1991	Makino et al.
5,035,899 A	7/1991	Saeki et al.
5,037,815 A	8/1991	Lukacsko et al.
5,043,358 A	8/1991	Lukacsko et al.
5,051,262 A	9/1991	Panoz et al.
5,093,132 A	3/1992	Makino et al.
5,204,118 A	4/1993	Goldman et al.
5,260,333 A	11/1993	Lukacsko et al.
5,364,616 A	11/1994	Singer et al.
5,373,022 A	12/1994	Fawzi et al.
5,409,709 A	4/1995	Ozawa et al.
5,417,980 A	5/1995	Goldman et al.
5,466,436 A	11/1995	Stables
5,514,663 A	5/1996	Mandel
5,601,843 A	2/1997	Gimet
5,631,022 A	5/1997	Mandel et al.
5,643,960 A	7/1997	Breitner et al.
5,667,802 A	9/1997	Grimberg
5,679,376 A	10/1997	Stevens et al.
5,686,105 A	11/1997	Kelm et al.
5,690,960 A	11/1997	Bengtsson et al.
5,702,723 A	12/1997	Griffin
5,714,504 A	2/1998	Lindberg et al.
5,716,648 A	2/1998	Halskov et al.
5,750,531 A	5/1998	Lee et al.
5,817,338 A	10/1998	Bergstrand et al.
5,817,340 A	10/1998	Roche et al.
5,840,737 A	11/1998	Phillips
5,872,145 A	2/1999	Plachetka
5,877,192 A	3/1999	Lindberg et al.
5,900,424 A	5/1999	Kallstrom et al.
5,955,451 A	9/1999	Lichtenberger et al.
6,013,281 A	1/2000	Lundberg et al.
6,025,395 A	2/2000	Breitner et al.

(Continued)

FOREIGN PATENT DOCUMENTS

AU	2006235929	11/2006
CA	2139653	7/2001

(Continued)

OTHER PUBLICATIONS

"A 12 month, phase 3, open-label, multi-center study to evaluate the long-term safety of PN 400," ClinicalTrials.gov, Sep. 11, 2007, accessed from <<http://clinicaltrials.gov/ct2/show/NCT00527904>> on Sep. 6, 2012.

(Continued)

Primary Examiner — Gina Justice

(74) *Attorney, Agent, or Firm* — Parker Highlander PLLC

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ABSTRACT

The present disclosure is directed to a method for delivering a pharmaceutical composition to a patient in need thereof, comprising: administering to said patient a pharmaceutical composition in unit dose form comprising naproxen, or pharmaceutically acceptable salt thereof, and esomeprazole, or pharmaceutically acceptable salt thereof.

7 Claims, 9 Drawing Sheets