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(54) **ORAL PULSED DOSE DRUG DELIVERY SYSTEM**

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See application file for complete search history.

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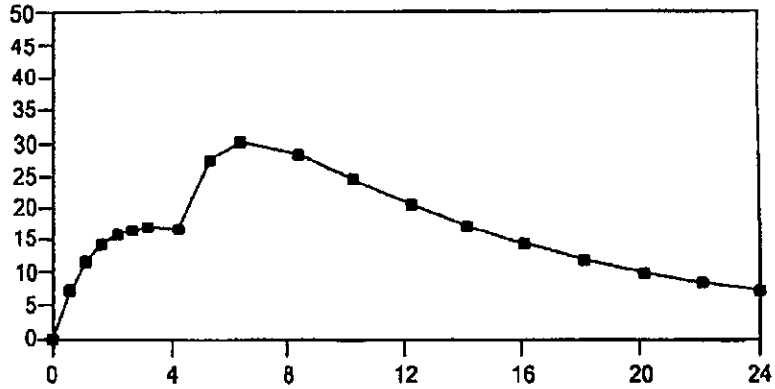
(57) **ABSTRACT**

A multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising an immediate-release component and an enteric delayed-release component wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating. The product can be composed of either one or a number of beads in a dosage form, including either capsule, tablet, or sachet method for administering the beads.

20 Claims, 7 Drawing Sheets



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Exh. 3, Excerpts from the Deposition Transcript of Richard Chang, dated Sep. 8, 2004.
Exh. 4, Excerpts from the Deposition Transcript of Richard A. Couch, dated Sep. 14, 2004.
Exh. 5, Excerpts from the Deposition Transcript of Kimberly Fiske, dated Sep. 17, 2004.
Exh. 7, Excerpts from the Deposition Transcript of Beth Burnside, dated Feb. 2, 2005.
Exh. 8, Excerpts from the Deposition Transcript of Donald John Treacy, Jr., dated Aug. 31, 2004.
Exh. 9, Excerpts from the Deposition Transcript of Beth Burnside, dated Feb. 3, 2005.
Exh. 10, Excerpts from the Deposition Transcript of Xiaodi Guo, dated Jan. 24, 2005.
Exh. 11, Excerpts from the Deposition Transcript of Xiaodi Guo, dated Jul. 26, 2004.
Exh. 12, Excerpts from the Deposition Transcript of Edward Rudnic, dated Jul. 28, 2004.
Exh. 13, Excerpts from the Deposition Transcript of Richard Rong–Kun Chang, dated Jan. 20, 2005.
Exh. 14, Impax Laboratories Answer And Affirmative Defenses *Shire Laboratories, Inc.* v. *Impax Laboratories, Inc.*, Civil Action No. 03–CV–01164–GMS.
Exh. 15, Barr Laboratories' Amended Answer, Affirmative Defenses, And Counterclaims, *Shire Laboratories, Inc.* v. *Barr Laboratories, Inc.*, Civil Action No. 03–CV–6632–PKC.
Exh. 16, Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims, *Shire Laboratories, Inc.* v. *Barr Laboratories, Inc.*, Civil Action No. 03–CV–1219–PKC.
Exh. 17, Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses And Counterclaims, *Shire Laboratories, Inc.* v. *Barr Laboratories, Inc.*, Civil Action No. 03–CV–6632–PKC.
Exh. 18, Civil Docket For Case #: 1:03–cv–01164–GMS, *Shire Laboratories, Inc.* v. *Impax Laboratories, Inc.*, Civil Action No. 03–CV–01164–GMS.
Exh. 19, Civil Docket For Case #: 1:05–cv–00020–GMS, *Shire Laboratories, Inc.* v. *Impax Laboratories, Inc.*, Civil Action No. 05–20–GMS.
Exh. 20, Civil Docket For Case #: 1:03–cv–06632–VM–DFE, *Shire Laboratories, Inc.* v. *Barr Laboratories, Inc.*, Civil Action No. 03–CV–6632–PKC.
Exh. 21, Civil Docket For Case #: 1:03–cv–01219–PKC–DFE, *Shire Laboratories, Inc.* v. *Barr Laboratories, Inc.*, Civil Action No. 03–CV–1219–PKC.
Exh. 25, Barr Laboratories, Inc.'s '819 Notification Pursuant to § 505(j)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.
Exh. 26, Barr Laboratories, Inc.'s '300 Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95).
Exh. 27, Order Construing The Terms Of U.S. Patent Nos. 6,322,819 and 6,605,300, *Shire Laboratories, Inc.* v. *Impax Laboratories, Inc.*, Civil Action No. 03–CV–01164–GMS.
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