



US008846100B2

(12) United States Patent
Shojaei et al.**(10) Patent No.: US 8,846,100 B2**
(45) Date of Patent: Sep. 30, 2014**(54) CONTROLLED DOSE DRUG DELIVERY SYSTEM****(75) Inventors:** Amir Shojaei, Phoenixville, PA (US);
Stephanie Read, Philadelphia, PA (US);
Richard A. Couch, Bryn Mawr, PA
(US); Paul Hodgkins, Exton, PA (US)**(73) Assignee:** Shire LLC, Florence, KY (US)**(*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1200 days.**(21) Appl. No.: 11/383,066****(22) Filed: May 12, 2006****(65) Prior Publication Data**

US 2007/0264323 A1 Nov. 15, 2007

(51) Int. Cl.
A61K 9/16 (2006.01)
A61K 9/48 (2006.01)
A61K 31/137 (2006.01)
A61K 9/50 (2006.01)**(52) U.S. Cl.**
CPC **A61K 9/4808** (2013.01); **A61K 31/137**
(2013.01); **A61K 9/5078** (2013.01);
A61K 9/1676 (2013.01)USPC **424/490**; **424/463**; **424/493****(58) Field of Classification Search**
USPC **424/489-502, 464-483**
See application file for complete search history.**(56) References Cited****U.S. PATENT DOCUMENTS**

2,099,402 A	11/1937	Keller	
2,738,303 A	3/1956	Blythe	
2,881,113 A	4/1959	Millman	
3,048,526 A	8/1962	Boswell	
3,066,075 A	11/1962	Deutsch	
3,365,365 A	1/1968	Butler et al.	
3,979,349 A	9/1976	Fink et al.	
4,794,001 A	12/1988	Mehta et al.	
5,137,733 A	8/1992	Noda et al.	
5,202,159 A	4/1993	Chen et al.	
5,328,697 A	7/1994	Raman et al.	
5,411,745 A	5/1995	Oshlack et al.	
5,422,121 A	6/1995	Lehmann et al.	
5,496,561 A	3/1996	Okada et al.	
5,501,861 A	3/1996	Makino et al.	
5,618,559 A	4/1997	Desai et al.	
5,733,575 A	3/1998	Mehra et al.	
5,773,031 A	6/1998	Shah et al.	
5,846,568 A	12/1998	Olinger et al.	
6,005,027 A	12/1999	Guillet et al.	
6,228,398 B1	5/2001	Devane et al.	
6,322,819 B1	11/2001	Burnside et al.	
6,475,493 B1	11/2002	Mulye	
6,605,300 B1*	8/2003	Burnside et al.	424/452
6,749,867 B2	6/2004	Robinson et al.	
6,764,696 B2	7/2004	Pather et al.	
6,913,768 B2	7/2005	Couch et al.	
RE41,148 E	2/2010	Burnside et al.	
2003/0050620 A1*	3/2003	Odidi et al.	604/890.1
2003/0157173 A1*	8/2003	Percel et al.	424/473

FOREIGN PATENT DOCUMENTS

AU	109438	1/1940
EP	0 640 337	3/1995
JP	59-082311	5/1984
JP	03-148215	6/1991
JP	07-061922	3/1995
JP	09-249557	9/1997
JP	09-267035	10/1997
JP	10-081634	3/1998
WO	WO87/00441	1/1987
WO	97/03673	2/1997
WO	98/14168	4/1998
WO	WO99/03471	1/1999
WO	WO00/25752	5/2000
WO	WO00/35450	6/2000
WO	2004028509 A1	4/2004

OTHER PUBLICATIONS

Adderall XR Package Inset, Sep. (2004).

Agyilrah GA and Banker SB, Polymers for Enteric Coating applications, Polymers for Controlled Drug Delivery (Peter J. Tarcha ed. 1991) 39-66.

American Chemical Society, Polymer Preprints, pp. 633-634, vol. 34, No. 1, Mar. 1993.

Ansel, et al., Rate Controlled Dosage Forms and Drug Delivery Systems, Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed. (1995), 213-222.

Answering Expert Report of Dr. Alexander M. Klibanov, expert for Shire Laboratories, Inc., Apr. 25, 2005.

Answering Expert Report of Robert Langer, Sc. D. Regarding United States Patent Nos. 6,322,819 and 6,605,300, expert for Shire Laboratories Inc., dated Apr. 25, 2005.

Barr Laboratories' Objections and Responses to Plaintiff Shire Laboratories Inc.'s Fifth Set of Interrogatories (No. 17), dated Sep. 3, 2004.

Barr Laboratories' Amended Answer, Affirmative Defenses and Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC.

Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, dated Sep. 25, 2003.

Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Second Set of Interrogatories (Nos. 8-11), dated Feb. 18, 2004.

Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Fourth Set of Interrogatories (Nos. 15-16), dated Jul. 9, 2004.

(Continued)

Primary Examiner — Nissa Westerberg*Assistant Examiner* — Micah-Paul Young**(74) Attorney, Agent, or Firm** — McDermott Will & Emery LLP**(57) ABSTRACT**

A multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising a pharmaceutically active amphetamine salt covered with an immediate-release coating and a pharmaceutically active amphetamine salt covered with an enteric coating wherein the immediate release coating and the enteric coating provide for multiple pulsed dose delivery of the pharmaceutically active amphetamine salt. 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.

31 Claims, 10 Drawing SheetsSHIRE EX. 2085
KVK V. SHIRE
IPR2018-00290

(56)

References Cited

OTHER PUBLICATIONS

- Barr Laboratories' Memorandum in Support of Its Motion to Amend Its Pleadings and exhibits thereto, dated Sep. 10, 2004.
- Barr Laboratories' Memorandum in Support of Its Motion to Compel Production, dated Sep. 13, 2004.
- Barr Laboratories' Supplemental Objections and Responses to Plaintiff Shire Laboratories Inc.'s Third Set of Interrogatories (Nos. 12-14)(Redacted), dated Aug. 27, 2004.
- 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).
- Barr Laboratories, Inc.'s '819 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).
- Bauer, et al., Cellulose Acetate Phthalate (CAP) and Trimellitate (CAT), Coated Pharmaceutical Dosage Forms (1998), 102-104.
- Bodmeier et al., The Influence of Buffer Species and Strength on Diltiazem HCl Release from Beads Coated with the Aqueous Catinoc Polymer Dispersions, *Eudragit RS, RL 30D*, Pharmaceutical Research vol. 13, No. 1, 1996, 52-56.
- Brown et al., Behavior and Motor Activity Response in Hyperactive Children and Plasma Amphetamine Levels Following a Sustained Release Preparation, *Journal of the American Academy of Child Psychiatry*, 19:225-239, 1980.
- Brown et al., Plasma Levels of d-Amphetamine in Hyperactive Children, *Psychopharmacology* 62, 133-140, 1979.
- Burns et al., A study of Enteric-coated Liquid-filled Hard Gelatin Capsules with Biphasic Release Characteristics, *International Journal of Pharmaceutics* 110 (1994) 291-296.
- C. Lin et al., Bioavailability of d-pseudoephedrine and Azatadine from a Repeat Action Tablet Formulation, *J Int Med Res* (1982), 122-125.
- C. Lin et al., Comparative Bioavailability of d-Pseudoephedrine from a Conventional d-Pseudoephedrine Sulfate Tablet and from a Repeat Action Tablet, *J Int Med Res* (1982) 10, 126-128.
- Chan, Materials Used for Effective Sustained-Release Products, Proceedings of the International Symposium held on 29th to 31st of Jan. 1987 (The Bombay College of Pharmacy 1988), 69-84.
- Chan, New Polymers for Controlled Products, Controlled Release Dosage Forms Proceedings of the International Symposium held on 29th to 31st of Jan. 1987 (The Bombay College of Pharmacy 1988) 59-67.
- Chang et al., Preparation and Evaluation of Shellac Pseudolatex as an Aqueous Enteric Coating Systems for Pellets, *International Journal of Pharmaceutics*, 60 (1990) 171-173.
- Charles S. L. Chiao and Joseph R. Robinson, Sustained-Release Drug Delivery Systems, Remington: The Science and Practice of Pharmacy, Tenth Edition (1995) 1660-1675.
- Civil Docket for Case #: 1:03-cv-01164-GMS *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-CV-01164-GMS.
- Civil Docket for Case #: 1:03-cv-01219-PKC-DFE *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC.
- Civil Docket for Case #: 1:03-cv-06632-VM-DFE *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC.
- Civil Docket for Case #: 1:05-cv-00020-GMS *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 05-20-GMS.
- Cody et al., Amphetamine Enantiomer Excretion Profile Following Administration of Adderall, *Journal of Analytical Toxicology*, vol. 2, Oct. 2003, 485-492.
- Complaint for Declaratory Judgment, *Impax Laboratories, Inc. v. Shire International Laboratories, Inc.* (Civ. Action No. 05772) and Exhibits attached thereto.
- Daynes, Treatment of Nocturnal Enuresis with Enteric-Coated Amphetamine, *The Practitioner*, No. 1037, vol. 173, Nov. 1954.
- Deposition of Transcript of Beth Burnside, dated Feb. 2, 2005.
- Deposition of Transcript of Charlotte M. McGuinness, dated Aug. 6, 2004.
- Deposition of Transcript of Donald John Treacy, Jr., dated Aug. 30, 2004.
- Deposition of Transcript of Edward Rudnic, dated Jul. 28, 2004.
- Deposition of Transcript of James J. Harrington, dated Jul. 27, 2005.
- Deposition of Transcript of Kimberly Fiske, dated Sep. 17, 2004.
- Deposition of Transcript of Richard Rong-Kun Chang, dated Jan. 20, 2005.
- Deposition of Transcript of Richard A. Couch, dated Sep. 14, 2004.
- Deposition of Transcript of Robert Schaffer, dated Aug. 17, 2005.
- Deposition of Transcript of Xiaodi Guo, dated Jan. 24, 2005.
- Deposition of Transcript of Xiaodi Guo, dated Jul. 26, 2004.
- Deposition transcript of Honorable Gerald J. Mossinghoff and exhibits thereto, dated Jun. 8, 2005.
- Deposition Transcript of Richard Chang, dated Sep. 8, 2004.
- Edward Stempel, Prolonged Drug Action, *HUSA's Pharmaceutical Dispensing*, Sixth Edition, 1996, 464, 481-485.
- Expert Report of Dr. Joseph R. Robinson, expert for Barr Laboratories and exhibits thereto, Feb. 28, 2005.
- Expert Report of the Honorable Gerald J. Mossinghoff, expert for Barr Laboratories, Inc. and exhibits thereto, Mar. 16, 2005.
- Freedom of Information Request Results for—Dexadrine (SmithKline Beecham): May 20, 1976 Disclosable Approval Information.
- Fukumori, Coating of Multiparticulates Using Polymeric Dispersions, *Multiparticulate Oral Drug Delivery* (Swarbrick and Selassie eds. 1994), 79-110.
- Garnett et al., Pharmacokinetic Evaluation of Twice-Daily Extended-Release Carbamazepine (CBZ) and Four-Times-Daily Immediate-Release CBZ in Patients with Epilepsy, *Epilepsia* 39(3): 274-279, 1998.
- Glatt, The World of the Fluid Bed, *Fluid Bed Systems*, 1-19.
- Goodhart et al., An evaluation of Aqueous Film-forming Dispersions for Controlled Release, *Pharmaceutical Technology*, Apr. 1984, 64-71.
- Greenhill et al., A Pharmacokinetic/Pharmacodynamic Study Comparing a Single Morning Dose of Adderall to Twice-Daily Dosing in Children with ADHD, *J. Am. Acad. Adolesc. Psychiatry*, 42:10, Oct. 2003.
- Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (1997).
- Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies (2002).
- Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms (1997).
- Hall HS and Pondell RE, Controlled Release Technologies: Methods, Theory, and Applications, pp. 133-154 (Agis F. Kydonieus ed. 1980).
- Handbook of Pharmaceutical Excipients: Ethycellulose, Polymethacrylates, 4th ed. (2003), 237-240, 462-468.
- Handbook of Pharmaceutical Excipients: Polymethacrylates, 2nd Ed. (1994), 361-366.
- Hans-Martin Klein & Rolf W. Gunther, Double Contrast Small Bow Follow-Through with an Acid-Resistant Effervescent Agent, *Investigative Radiology* vol. 28, No. 7, Jul. 1993, 581-585.
- Harris, et al., Aqueous Polymeric Coating for Modified-Release Pellets, *Aqueous Polymeric Coating for Pharmaceutical Dosage Forms* (McGinity ed., 1989), 63-79.
- Hawley's Condensed Chemical Dictionary 13th Ed. 1997, 584, 981.
- Holt, Bioequivalence Studies of Ketoprofen: Product formulation, Pharmacokinetics, Deconvolution, and In Vitro-In Vivo correlations, Thesis submitted to Oregon State University, Aug. 20, 1997 (1997).
- Husson et al., Influence of Size Polydispersity on Drug Release from Coated Pellets, *International Journal of Pharmaceutics*, 86 (1992) 113-121, 1992.
- Impax Laboratories Answer and Affirmative Defenses *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-CV-01164-GMS.
- Impax Laboratories, Inc.'s First Supplemental Responses to Shire Laboratories Inc.'s First Set of Interrogatories (Nos. 11-12) dated

(56)

References Cited

OTHER PUBLICATIONS

- Impax Laboratories, Inc.'s Memorandum in Support of the Motion to Amend Its Answer dated Feb. 25, 2005 and exhibits thereto.
- Impax Laboratories, Inc.'s Reply Memorandum in Support of the Motion to Amend Its Answer dated Mar. 18, 2005 and exhibits thereto.
- Impax Laboratories, Inc.'s First Amended Answer and Affirmative Defenses, dated May 2, 2005.
- Ishibashi et al., Design and Evaluation of a New Capsule-type Dosage Form for Colon-targeted Delivery of Drugs, *International Journal of Pharmaceutics* 168, (1998) 31-40.
- J. Sjogren, Controlled Release Oral Formulation technology, *Rate Control in Drug Therapy*, (1985) 38-47.
- Jarowski, *The Pharmaceutical Pilot Plant, Pharmaceutical Dosage Forms: Tablets*, vol. 3, 2nd Ed. (1990), 303-367.
- Kao et al., Lag Time Method to Delay Drug release to Various Sites in the Gastrointestinal Tract, *Journal of Controlled Release* 44(1997) 263-270.
- Kiriya et al., The Bioavailability of Oral Dosage Forms of a New HIV-1 Protease Inhibitor, KNI-272, in Beagle Dogs, *Biopharmaceutics & Drug Disposition*, vol. 17 125-234 (1996).
- Klaus Lehmann, Coating of Multiparticulates Using Polymeric Solutions, *Multiparticulate Oral Drug Delivery* (Swarbrick and Sellasie ed., 1994) 51-78.
- Krowczynski & Brozyna, *Extended-Release Dosage Forms* pp. 123-131 (1987).
- Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, *The Theory and Practice of Industrial Pharmacy*, Second Edition (1976) 371-373.
- Leopold & Eikeler, Eudragit E as Coating Material for the pH-Controlled Drug Release in the Topical Treatment of Inflammatory Bowel Disease (IBD), *Journal of Drug Targeting*, 1998, vol. 6, No. 2, pp. 85-94.
- Lin & Cheng, In-vitro Dissolution Behaviour of Spansule-type Micropellets Prepared by Pan Coating Method, *Pharm. Ind.* 51 No. 5 (1989) 528-531.
- Liu et al., Comparative Release of Phenylprepanolamine HCl from Long-Acting Appetite Suppressant Product: Acutrim vs. Dexatrim, *Drug Development and Industrial Pharmacy*, 10(10), 1639-1661 (1984).
- Marcotte, et al., Kinetics of Protein Diffusion from a Poly(D, L-Lactide) Reservoir System, *Journal of Pharmaceutical Sciences* vol. 79, No. 5, May 1990.
- Mathir, et al., In vitro characterization of a controlled-release chlorpheniramine maleate delivery system prepared by the air-suspension technique, *J. microencapsulation*, vol. 14, No. 6, 743-751 (1997).
- McGough, et al., Pharmacokinetics of SL1381 (Adderall XR), an Extended-Release Formulation of Adderall, *Journal of the American Academy of Child & Adolescent Psychiatry*, vol. 42, No. 6, Jun. 2003, 684-691.
- McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Ed. (1994), 97,972.
- Mehta, et al., Evaluation of Fluid-bed Processes for Enteric Coating Systems, *Pharmaceutical Technology*, Apr. 1986, 46-56.
- Moller, Dissolution Testing of delayed Release Preparations, *Proceedings of the International Symposium held on 29th to 31st of Jan. 1987* (the Bombay College of Pharmacy 1988), 85-111.
- Response to Office Action filed May 2, 2006 in U.S. Appl. No. 11/091,010.
- Office Action in U.S. Appl. No. 11/091,010, mailed Feb. 3, 2006.
- Office Action in U.S. Appl. No. 11/091,010, mailed Jul. 13, 2006.
- Response to Office Action filed Jul. 18, 2006 in U.S. Appl. No. 11/091,010.
- Office Action in U.S. Appl. No. 11/091,010, mailed Oct. 10, 2006.
- Office Action mailed Mar. 2, 2005 in European Patent Application No. 99 970594.0-2123.
- Opening Expert Report of Dr. Michael Mayersohn, expert for Impax Laboratories Inc. and exhibits thereto, Mar. 12, 2005.
- 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.
- PDR Drug information for Ritalin LA Capsules, Apr. (2004).
- Pelham, et al., A Comparison of Morning-Only and Morning/Late Afternoon Adderall to Morning-Only, Twice-daily, and Three Times-Daily Methyphenidate in Children with Attention-Deficit/Hyperactivity Disorder, *Pediatrics*, vol. 104, No. 6, Dec. 1999.
- Physicians' Desk Reference: Adderall, 51st Ed. (1997).
- Physicians' Desk Reference: Adderall, 56th Ed. (2002).
- Physicians' Desk Reference: Dexedrine, 56th ed. (2002).
- Physicians' Desk Reference: Ritalin, 56th Ed. (2002).
- Porter and Bruno, Coating of Pharmaceutical Solid-Dosage Forms, 77-160.
- Prescribing Information: Dexedrine, brand of dextroamphetamine sulfate (2001).
- R. Bianchini & C. Vecchio, Oral Controlled Release Optimization of Pellets Prepared by Extrusion-Spheronization Processing, *II. Farmaco* 44(6), 645-654, 1989.
- Rambali, et al., Using experimental design to optimize the process parameters in fluidized bed granulation on a semi-full scale, *International Journal of Pharmaceutics* 220 (2001) 149-160.
- Remington: The Science and Practice of Pharmacy, Basic Pharmacokinetics, 16th Ed. (1980), 693.
- Remington: The Science and Practice of Pharmacy, Elutriation, 20th Ed. (2000), 690.
- Remington's Pharmaceutical Sciences, Fifteenth Edition (1975) 1624-1625.
- Remington's Pharmaceutical Sciences, RPS XIV, 1700-1714.
- Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses and Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC.
- 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.
- Rong-Kun Chang and Joseph R. Robinson, Sustained Drug Release from Tablets and Particles Through Coating, *Pharmaceutical Dosage Forms: Tablets* (Marcel Dekker, Inc. 1990), 199-302.
- Rong-Kun Chang et al., Formulation Approaches for Oral Pulsatile Drug Delivery, *American Pharmaceutical Review*.
- Rong-Kun Chang, A Comparison of Rheological and Enteric Properties among Organic Solutions, Ammonium Salt Aqueous Solutions, and Latex Systems of Some Enteric Polymers, *Pharmaceutical Technology*, Oct. 1990, vol. 14, No. 10, 62-70.
- Rosen, et al., Absorption and Excretion of Radioactively Tagged Dextroamphetamine Sulfate from a Sustained-Release Preparation, *Journal of the American Medical Association*, Dec. 13, 1965, vol. 194, No. 11, 1203-1205.
- Scheffele, et al., Studies Comparing Kollicoat MAE 30 D with Commercial Cellulose Derivatives for Enteric Coating on Caffeine Cores, *Drug Development and Industrial Pharmacy*, 24(9), 807-818 (1998), 807-818.
- Serajuddin, et al., Selection of Solid Dosage Form Composition through Drug-Excipient Compatibility Testing, *Journal of Pharmaceutical Sciences* vol. 88, No. 7, Jul. 1999, 696-704.
- Shargel; *Pharmacokinetics of Oral Absorption*, *Applied Biopharmaceutics & Pharmacokinetics*, 5th Ed. (225), 164-166.
- Sheen et al., Aqueous Film Coating Studies of Sustained Release Nicotinic Acid Pellets: An In-Vitro Evaluation, *Drug Development and Industrial Pharmacy*, 18(8), 851-860 (1992).
- Shire Laboratories Inc.'s Opposition to Barr Laboratories' Motion to Amend Its Answers and Counterclaims, Sep. 15, 2004.
- Slattum, et al., Comparison of Methods for the Assessment of Central Nervous System Stimulant Response after Dextroamphetamine Administration to Healthy Male Volunteers, *J. clin Pharmacol* (1996) 36,1039-1050.
- Sprohls' *American Pharmacy: An Introduction to Pharmaceutical Techniques and Dosage Forms*, 7th Ed. (1974), 387-388.
- Sriamornsak, et al., Development of Sustained Release Theophylline

(56)

References Cited

OTHER PUBLICATIONS

Stevens, et al., Controlled, Multidose, Pharmacokinetic Evaluation of Two Extended-Release Carbamazepine Formulations (carbatrol and Tegretol-XR), *Journal of Pharmaceutical Sciences* vol. 87, No. 12, Dec. 1998, 1531-1534.

Teva Notice letter dated Feb. 21, 2005.

Teva Notice letter dated Jun. 1, 2005.

The Merck Index: Amphetamine, 12th Ed., 620.

The Merck Index: Amphetamine, 13th Ed. (2001), 97, 1089.

The United States Pharmacopeia 23, National Formulary 18 (1995) pp. 1791-1799.

The United States Pharmacopeia 26, National Formulary 21 (2003) pp. 2157-2165.

The United States Pharmacopeia 27, National Formulary 22 (2004) pp. 2302-2312.

Treatise on Controlled Drug Delivery, pp. 185-199 (Agis Kydonieus ed. 1992).

Tulloch, et al., SL 1381 (Adderall XR), a Two-component, Extended-Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed, and Sprinkled Administration, *Pharmacotherapy* vol. 22, No. 11, (2002), 1405-1415.

Vasilevska, et al., Preparation and Dissolution Characteristics of Controlled Release Diltiazem Pellets, *Drug Development and Industrial Pharmacy*, 18(15), 1649-1661 (1992).

Watano, et al., Evaluation of aqueous Enteric Coated Granules Prepared by Moisture Control Method in Tumbling Fluidized Bed Process, *Chem. Pharm. Bull.* 42(3) 663-667 (1994).

Wesdyk, et al., Factors affecting differences in film thickness of beads coated in fluidized bed units, *International Journal of Pharmaceutics*, 93, 101-109, (1993).

Wouessidjewe, Aqueous polymethacrylate Dispersions as Coating Materials for Sustained and Enteric Release Systems, *S.T.P. Pharma Sciences* 7(6) 469-475 (1997).

Barr Laboratories' Amended Answer, Affirmative Defenses and Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC, dated Sep. 27, 2004.

Court Docket for *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Jan. 8, 2007.

Complaint in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, and exhibits thereto, Case No. 2:06-cv-00952-SD dated Mar. 2, 2006.

Answer and Counterclaims in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Jul. 24, 2006.

Reply to Counterclaims in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Aug. 16, 2006.

Defendants' Responses to Plaintiff Shire's First Set of Interrogatories (1-12) in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Sep. 20, 2006.

Defendants' Responses to Plaintiffs First Set of Request for the Production of Documents and Things (1-70) in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Oct. 4, 2006.

Plaintiff's Response to Defendants' First Set of Interrogatories in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Oct. 11, 2006.

Plaintiffs Response to Defendants' First Set of Production Requests in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Oct. 11, 2006.

Defendants' Responses to Plaintiffs Second Set of Requests for the Production of Documents and Things (71-80) in *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Nov. 8, 2006.

Defendants' Responses to Plaintiff Shire's Second Set of Interrogatories (No. 13) in *Shire Laboratories v. Teva Pharmaceuticals Industries Ltd.*, Case No. 2:06-cv-00952-SD dated Nov. 8, 2006.

Petition Under Section 8 and exhibits thereto, submitted to the Canadian Patent Office on Dec. 4, 2006.

Office Action in U.S. Appl. No. 11/091,011, mailed Dec. 1, 2006.

Response to Non-Final Office Action filed Jan. 10, 2007 in U.S. Appl. No. 11/091,011.

Response to Non-Final Office Action filed Jan. 10, 2007 in U.S. Appl. No. 11/091,010.

Neville et al., *Disintegration of Dextran Sulfate Tablet Products: Effect of Physicochemical Properties*, Drug Development and Industrial Pharmacy, New York, NY, vol. 18, No. 19, Jan. 1, 1992, pp. 2067-2079, XP009092848, ISSN: 0363-9045.

Patrick et al., *Pharmacology of Methylphenidate, Amphetamine Enantiomers and pemoline in Attention-Deficit Hyperactivity Disorder*, Human Psychopharmacology, vol. 12, pp. 527-546 (1997).

Chaumeil et al., *Enrobages gastro-resistants a l'acetophthalate de cellulose*, Annales Pharmaceutiques Francaises, 1973, No. 5, pp. 375-384.

Wigal, et al., Evaluation of Individual Subjects in the Analog Classroom Setting; II. Effects of Dose of Amphetamine (Adderall), Psychopharmacology Bulletin, vol. 34, No. 4, pp. 833-838, 1998.

Communication pursuant to Article 96(2) EPC dated Jun. 21, 2006 for corresponding E application No. EP99 970 594.0.

International Search Report dated Nov. 21, 2006 issued for corresponding International Application No. PCT/US06/18453.

U.S. Appl. No. 11/091,011: Final Office Action dated Nov. 13, 2009, including Form PTO-892 and the references cited therein (10 pages).

Office Action in Japanese Application No. 2008-159637 dated Sep. 11, 2012 (Original Japanese and English Translation attached).

Conte et al., "Press-coated tablets for time-programmed release of drugs," *Biomaterials*, vol. 14, No. 13, pp. 1017-1023 (1993).

Gazzaniga et al., "Oral Chronotropic Drug Delivery Systems: Achievement of Time and/or Site Specificity," *Eur J Pharm Biopharm*, vol. 40, No. 4, pp. 246-250 (1994).

Theeuwes, "Oros Osmotic System Development," *Drug Dev Ind Pharm*, vol. 9, No. 7, pp. 1331-1357 (1983).

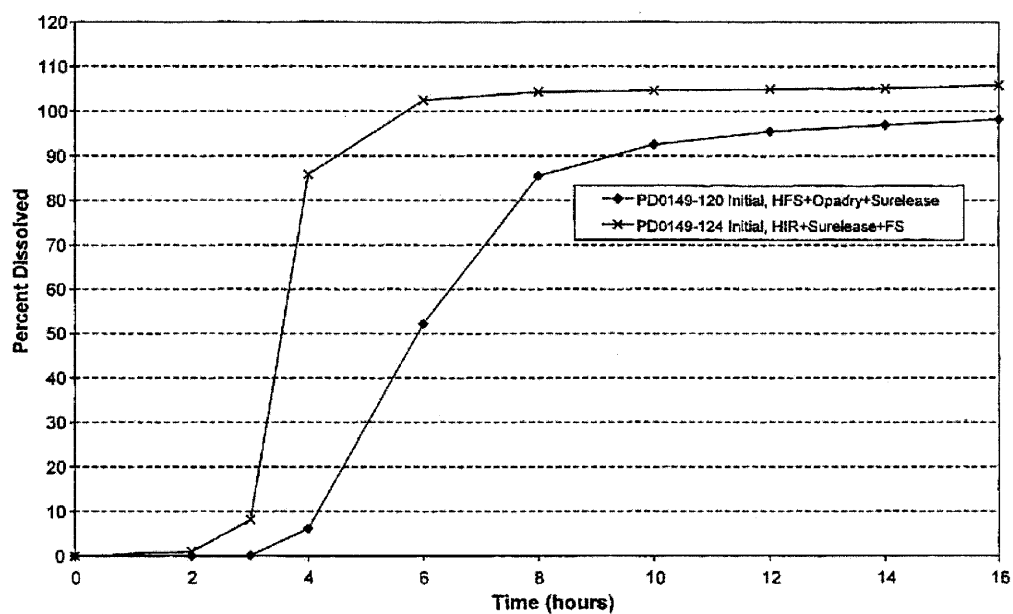
Walia et al., "Preliminary Evaluation of an Aqueous Wax Emulsion for Controlled-Release Coating," *Pharm Dev Tech*, vol. 3, No. 1, pp. 103-113 (1998).

Xu et al., "Programmable Drug Delivery from an Erodible Association Polymer System," *Pharm Res*, vol. 10, No. 8, pp. 1144-1152 (1993).

Office Action dated Feb. 18, 2014, which is issued during the prosecution of Mexican Patent Application No. MX/a/2008/014455, which is related to the present application together with a letter from a foreign agent re. the Office Action in English.

* cited by examiner

FIG. 1



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.