Anthony J. Viola
Andre K. Cizmarik
Zachary W. Silverman
EDWARDS WILDMAN PALMER LLP
Attorneys for Plaintiffs
Takeda Pharmaceutical Company Limited,
Takeda Pharmaceuticals U.S.A., Inc.
(formerly known as Takeda Pharmaceuticals
North America, Inc.), and Takeda
Development Center Americas, Inc.
(formerly known as Takeda Global
Research and Development Center, Inc.)
750 Lexington Ave.
New York, NY 10022
(212) 308-4411

Jason A. Nagi
POLSINELLI PC
Attorneys for Plaintiffs
Actavis, Inc. (formerly known as Watson
Pharmaceuticals, Inc.) and Andrx Labs, LLC
900 Third Avenue, Suite 2100
New York, NY 10022
(212) 684-0199

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc. Takeda Global Research and Development Center, Inc., Watson Pharmaceuticals, Inc. and Andrx Labs, LLC

Plaintiffs.

Mylan, Inc. and Mylan Pharmaceuticals, Inc.,

Defendants.

Civil Action No. 12-CIV-0024 (DLC)

Hon. Denise L. Cote

D S DISTRICT COURT SONY

FIRST AMENDED COMPLAINT

Plaintiffs, Takeda Pharmaceutical Company Limited (formerly known as Takeda Chemical Industries, Ltd.) ("TPC"), Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA") (formerly known as Takeda Pharmaceuticals North America, Inc. ("TPNA")) and Takeda Development Center Americas, Inc. (formerly known as Takeda Global Research & Development Center, Inc. ("Takeda Global")) (collectively, "Takeda"); and Actavis, Inc. ("Actavis, Inc.") (formerly known as Watson Pharmaceuticals, Inc.) and Andrx Labs, LLC ("Andrx") (collectively, "Actavis"), by

their undersigned counsel, for their First Amended Complaint against defendants Mylan Pharmaceuticals, Inc. ("MPI") and Mylan, Inc. ("Mylan, Inc.") (collectively, "Mylan"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(a), 271(b), 271(c), and/or 271(e)(2), and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over the defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because defendants are doing business in this jurisdiction.

Parties

- 2. TPC is a Japanese corporation having its corporate headquarters in Osaka, Japan and principal place of business in Osaka, Japan. TPUSA is a wholly owned U.S. subsidiary of Takeda American Holdings, Inc., which is a wholly owned U.S. subsidiary of TPC. TPUSA has its corporate headquarters and principal place of business in Deerfield, Illinois and is organized under the laws of Delaware. Takeda Global is a wholly owned subsidiary of TPC. Takeda Global has its corporate headquarters and principal place of business in Deerfield, Illinois and is organized under the laws of Delaware.
- 3. Takeda is engaged in the business of researching, developing, manufacturing, and/or marketing of a broad spectrum of innovative pharmaceutical products, including ACTOPLUS MET® XR, which comprises an extended release dosage form of the combination of the active ingredients pioglitazone hydrochloride and metformin hydrochloride.
 - 4. Actavis, Inc. is a Nevada corporation having corporate offices and a place of

business in Parsippany, New Jersey.

- 5. Andrx is a Delaware limited liability company having a place of business in Davie, Florida, and is a subsidiary of Andrx Corporation, which is a subsidiary of Actavis, Inc.
- 6. Andrx is engaged in the business of researching, developing, manufacturing, and/or selling pharmaceutical products including ACTOPLUS MET® XR and/or components thereof.
- 7. Upon information and belief, MPI is incorporated in West Virginia having a place of business in Morgantown, West Virginia, and is a wholly owned subsidiary of Mylan, Inc. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 203488 was filed under the name of MPI.
- 8. Upon information and belief, Mylan, Inc. is a Pennsylvania corporation having its corporate headquarters in Canonsburg, Pennsylvania. Upon information and belief, Mylan, Inc. has actual control over the activities of MPI including MPI's filing of ANDA No. 203488.
- 9. Upon information and belief, Mylan is currently transacting business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Upon information and belief, Mylan derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and the Southern District of New York. MPI is registered with the N.Y. State Department of State, Division of Corporations, to do business as a foreign corporation in New York. Additionally, Mylan, Inc. common stock is listed on the NASDAQ Market, and Mylan, Inc. has had contractual dealings with at least the American Stock Transfer & Trust Company located at 59 Maiden Lane, Plaza Level, New York, NY 10038. By

filing its ANDA, Mylan has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, that Mylan expects or should reasonably expect to have consequences in the State of New York including in this Judicial District.

The New Drug Application

- 10. TPUSA sells drug products including an extended release drug product containing a combination of pioglitazone hydrochloride and metformin hydrochloride, under the trade name ACTOPLUS MET® XR in the United States pursuant to the United States Food and Drug Administration's ("FDA") approval of a New Drug Application ("NDA") held by TPUSA (NDA No. 022024).
- 11. ACTOPLUS MET® XR is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes (non-insulin-dependent diabetes mellitus).
 - 12. The FDA approval letter for ACTOPLUS MET® XR is dated May 12, 2009.

The Patents-in-Suit

- 13. United States Patent No. 5,965,584 ("the '584 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 12, 1999, to inventors Hitoshi Ikeda, Takashi Sohda, and Hiroyuki Odaka.
- 14. TPC has been and still is the owner through assignment of the '584 patent, which expires on June 19, 2016.
- 15. United States Patent No. 6,166,043 ("the '043 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on December 26, 2000, to inventors Hitoshi Ikeda, Takashi Sohda, and Hiroyuki Odaka.
 - 16. TPC has been and still is the owner through assignment of the '043 patent, which

expires on June 19, 2016.

- 17. United States Patent No. 6,172,090 ("the '090 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit C**, was duly issued on January 9, 2001, to inventors Hitoshi Ikeda, Takashi Sohda, and Hiroyuki Odaka.
- 18. TPC has been and still is the owner through assignment of the '090 patent, which expires on June 19, 2016.
- 19. TPC has granted an exclusive license to TPUSA under the '584 patent, the '043 patent, and the '090 patent (collectively, "Takeda Patents").
- 20. United States Patent No. 6,099,859 ("the '859 patent"), entitled "Controlled Release Oral Tablet Having a Unitary Core," a true and correct copy of which is appended hereto as **Exhibit D**, was duly issued on August 8, 2000, to inventors Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan, and Joseph Chou.
- 21. Andrx has been and still is the owner through assignment of the '859 patent, which expires on March 20, 2018.
- 22. United States Patent No. 6,495,162 ("the '162 patent"), entitled "Controlled Release Oral Tablet Having a Unitary Core," a true and correct copy of which is appended hereto as **Exhibit E**, was duly issued on December 17, 2002, to inventors Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan, and Joseph Chou.
- 23. Andrx has been and still is the owner through assignment of the '162 patent, which expires on March 20, 2018.
- 24. United States Patent No. 6,790,459 ("the '459 patent"), entitled "Methods for Treating Diabetes via Administration of Controlled Release Metformin," a true and correct copy of which is appended hereto as **Exhibit F**, was duly issued on September 14, 2004, to inventors

Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan, and Joseph Chou.

- 25. Andrx has been and still is the owner through assignment of the '459 patent, which expires on March 17, 2021.
- 26. United States Patent No. 7,919,116 ("the '116 patent"), entitled "Controlled Release Metformin Compositions," a true and correct copy of which is appended hereto as **Exhibit G**, was duly issued on April 5, 2011, to inventors Chih-Ming Chen, Xiu Xiu Cheng, Steve Jan, and Joseph Chou.
- 27. Andrx has been and still is the owner through assignment of the '116 patent, which expires on March 20, 2018.
- 28. United States Patent No. 7,959,946 ("the '946 patent"), entitled "Pharmaceutical Formulation Containing a Biguanide and a Thiazolidinedione Derivative," a true and correct copy of which is appended hereto as **Exhibit H**, was duly issued on June 14, 2011, to inventors Unchalee Kositprapa, Robert Goldfarb, John Cardinal, and Avinash Nangia.
- 29. Actavis, Inc. has been and still is the owner through assignment of the '946 patent, which expires on July 31, 2026.
- 30. United States Patent No. 8,470,368 ("the '368 patent"), entitled "Pharmaceutical Formulation Containing a Biguanide and a Thiazolidinedione Derivative," a true and correct copy of which is appended hereto as **Exhibit I**, was duly issued on June 25, 2013, to inventors Unchalee Kositprapa, Robert I. Goldfarb, John R. Cardinal, and Avinash Nangia.
- 31. Actavis, Inc. has been and still is the owner through assignment of the '368 patent, which expires on July 31, 2026.
- 32. United States Patent No. 8,475,841 ("the '841 patent"), entitled "Controlled Release Metformin Formulations," a true and correct copy of which is appended hereto as

Exhibit J, was duly issued on July 2, 2013, to inventors Xiu Xiu Cheng, Steve Jan, Joseph Chou, and Chih-Ming Chen.

- 33. Andrx has been and still is the owner through assignment of the '841 patent, which expires on March 20, 2018.
- 34. Takeda is licensed under the '859, '162, '459, '116, '946, '368, and '841 patents (collectively, "Actavis Patents") in connection with ACTOPLUS MET® XR.
- 35. Actavis is licensed under the Takeda Patents in connection with ACTOPLUS MET® XR.
- 36. In accordance with its licenses, TPUSA sells extended release drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS MET® XR in the United States. Sales of TPUSA's extended release drug products containing a combination of pioglitazone and metformin are made pursuant to approval by the FDA of NDA No. 022024.
- 37. TPUSA is the holder of NDA No. 022024, under which TPUSA sells ACTOPLUS MET® XR.

Mylan's ANDA

- 38. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 39. Upon information and belief, MPI, under the control of Mylan, Inc., filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 203488) seeking approval to market (i) extended release tablets comprising a combination of 15 mg/1000 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) extended release tablets comprising a combination of 30 mg/1000 mg of pioglitazone hydrochloride/metformin hydrochloride (the

"Mylan Products").

- 40. By the filing of ANDA No. 203488, Mylan has indicated that its extended release combination pioglitazone and metformin drug products are bioequivalent to Plaintiffs' extended release combination pioglitazone and metformin drug products.
- 41. By its filing of ANDA No. 203488 with a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Mylan seeks to obtain approval to commercially manufacture, use, offer for sale, and/or sell alleged generic equivalents of Plaintiffs' ACTOPLUS MET® XR pioglitazone and metformin extended release combination drug products prior to the expiration date of the Takeda and Actavis Patents.
- 42. By a letter (the "Notice Letter") dated November 21, 2011, MPI informed Plaintiffs FDA that **MPI** had filed a certification to the pursuant 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about November 22, 2011, NDA holder, Takeda Global, received the Notice Letter. On or about November 25, 2011, patent owner, TPC, received a copy of the Notice Letter. On or about November 22, 2011, patent owner, Actavis, received a copy of the Notice Letter.
- 43. The Notice Letter, purporting to be MPI's Notification of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that Mylan believes that the '584, '043, '090, '859, '162, '459, '116, and '946 patents are "not valid, unenforceable, or will not be infringed."
- 44. Mylan's filing of ANDA No. 203488 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of extended release drug products containing pioglitazone and metformin or salts thereof before the expiration of the Takeda Patents and/or Actavis Patents is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

- 45. Upon information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of Type 2 Diabetes.
- 46. Additionally, upon information and belief, Mylan's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Mylan and to customers of Mylan.
- 47. Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone and metformin extended release combination drug product, namely Mylan intends to list its generic product and refer customers to Plaintiffs' product, ACTOPLUS MET® XR. Upon information and belief, such marketing practices are substantially likely to lead to a customer of a generic combination pioglitazone and metformin extended release drug product to infer that prescribing information for ACTOPLUS MET® XR, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Mylan's generic combination pioglitazone and metformin extended release drug products. Upon information and belief, in the event that the FDA approves ANDA No. 203488, Mylan intends to offer to sell and/or sell the approved generic version of ACTOPLUS MET® XR throughout the United States, including in New York.
- 48. Upon information and belief, the acts alleged above are, have been, and will be deliberate and willful.
 - 49. Mylan's filing of ANDA No. 203488, and/or Mylan's manufacture, use, offer for

sale, and/or sale of its proposed combination of pioglitazone and metformin extended release drug products constitute infringement of at least one of the claims of the Takeda Patents and/or Actavis Patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

50. Unless Mylan is enjoined from infringing, contributing to and/or inducing the infringement of the Takeda Patents and/or Actavis Patents, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT I

(THE '584 PATENT)

- 51. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 52. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 53. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes.
- 54. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '584 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT II

(THE '043 PATENT)

55. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

- 56. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 57. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly the use of such combinations to reduce the amount of active components administered to the diabetic patient.
- 58. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '043 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT III

(THE '090 PATENT)

- 59. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 60. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 61. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly the use of such combinations for reducing the side effects of active components administered to a diabetic patient.
 - 62. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for

sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '090 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT IV

(THE '859 PATENT)

- 63. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 64. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 65. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '859 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT V

(THE '162 PATENT)

- 66. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 67. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 68. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug

products constitute infringement of the '162 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT VI

(THE '459 PATENT)

- 69. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 70. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 71. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '459 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT VII

(THE '116 PATENT)

- 72. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 73. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 74. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '116 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or

(e)(2)(A).

COUNT VIII

(THE '946 PATENT)

- 75. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 76. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 77. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '946 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT IX

(THE '368 PATENT)

- 78. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 79. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 80. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '368 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

COUNT X

(THE '841 PATENT)

- 81. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.
- 82. On information and belief, approval of ANDA No. 203488 is substantially likely to result in the immediate or imminent commercial use, manufacture, offer for sale, and/or sale, or inducement thereof, of the Mylan Products.
- 83. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '841 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

WHEREFORE, Plaintiffs request the following relief:

- a. A judgment that, through Mylan's submission of its ANDA No. 203488 with the FDA seeking to market Mylan's Products, Mylan infringed and/or will infringe the Takeda Patents and the Actavis Patents under 35 U.S.C. § 271(e)(2)(A);
- b. A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell, and/or importing Mylan's Products for which it seeks FDA approval or the active ingredients pioglitazone and metformin in combination in an extended release dosage form, and/or inducing or contributing to the same, will infringe at least one claim of the Takeda Patents and/or Actavis Patents;
- c. A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 203488 for Mylan to commercially make, use, sell, offer to sell, or import

Mylan's Products or an extended release dosage form of pioglitazone in combination with metformin or any drug product containing an extended release dosage form of pioglitazone in combination with metformin be no earlier than the date following the expiration date of the last to expire of any of the Takeda Patents and/or Actavis Patents that this Court determines would be infringed through the commercial manufacture, use, sale, offer for sale, or importation into the United States of said product(s);

- d. A permanent injunction restraining and enjoining against any infringement by defendants, their officers, agents, or employees, or those acting in privity or concert with them, of any of the Takeda Patents and/or Actavis Patents that this Court determines would be infringed through the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's Products, or pioglitazone or any drug product containing pioglitazone in combination with metformin in an extended release dosage form, and/or any inducement of and/or any contribution to the same;
- e. Attorneys' fees in this action under 35 U.S.C. § 285; and
- f. Such further and other relief as this Court may deem just and proper.

Dated: New York, New York July 12, 2013

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.), and Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research and Development, Inc.).

By their attorneys,

/s/David G. Conlin

Anthony J. Viola
Andre K. Cizmarik
Zachary W. Silverman
aviola@edwardswildman.com
acizmarik@edwardswildman.com
zsilverman@edwardswildman.Com
EDWARDS WILDMAN PALMER LLP
750 Lexington Avenue
New York, NY 10022
(212) 308-4411

David G. Conlin (pro hac vice)
Kathleen B. Carr (pro hac vice)
Adam P. Samansky
dconlin@edwardswildman.com
kcarr@edwardswildman.com
asamansky@edwardswildman.com
EDWARDS WILDMAN PALMER LLP
111 Huntington Avenue
Boston, MA 02199-7613
(617) 239-0100

Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.), and Andrx Labs, LLC,

By their attorneys,

/s/Gary E. Hood

Jason A Nagi (JN6891)

POLSINELLI PC

900 Third Avenue, Suite 2100

New York, NY 10022

jnagi@polsinelli.com

(212) 684-0199

Fax No. (212) 684-0197

Gary E. Hood (admitted *pro hac vice*)

Mark T. Deming (admitted *pro hac vice*)

POLSINELLI PC

161 North Clark, Suite 4200

Chicago, IL 60601

ghood@polsinelli.com

mdeming@polsinelli.com

(312) 819-1900

Fax No. (312) 819-1910

Keith J. Grady (admitted *pro hac vice*)

Robyn H. Ast (admitted pro hac vice)

Karen M. Zelle (admitted pro hac vice)

Richard Juang (admitted pro hac vice)

POLSINELLI PC

100 South Fourth Street, Suite 1000

St. Louis, MO 63102

kgrady@polsinelli.com

rast@polsinelli.com

kzelle@polsinelli.com

rjuang@polsinelli.com

(314) 889-8000

Fax No. (314) 231-1776

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2013, a true and correct copy of the foregoing was served

by electronical mail to the following individuals:

Matthew J. Bresnahan Elham Firouzi Steiner

Wilson Sonsini Goodrich & Rosati, P.C. 12235 El Camino Real, Suite 200

San Diego, CA 92130 Tel: (858) 350-2300 Fax: (858) 350-2399

Email: mbresnahan@wsgr.com
Email: esteiner@wsgr.com

Michael S. Sommer

Tonia Maria Ouellette Klausner

Wilson Sonsini Goodrich & Rosati, P.C.

1301 Avenue of the Americas

40th Floor

New York, NY 10019-6033

Tel: (212) 999-5800 Fax: (212) 99-5899

Email: msommer@wsgr.com
Email: tklausner@wsgr.com

T.O. Kong

Ariana Chung-Han

Wilson Sonsini Goodrich & Rosati, P.C. One Market Street, Spear Tower, Suite 3300

San Francisco, CA 94105

Tel: (415) 947-2000 Fax: (415) 947-2099 Email: tkong@wsgr.com Email: achung@wsgr.com

Matthew R. Reed Kirin K. Gill

Wilson Sonsini Goodrich & Rosati, P.C.

650 Page Mill Road Palo Alto, CA 94304 Tel: (650) 493-9300 Fax: (650) 493-6811

Email: mreed@wsgr.com
Email: kgill@wsgr.com

/s/Gary E. Hood