UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. AND MYLAN INC., Defendants.	Civil Action No. 1:13-cv-197 (Keeley) Electronically Filed August 29, 2013

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), state the following as their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. and (collectively, "Defendants"):

I.

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation with a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. TPC's business includes the research, development, and marketing of pharmaceutical products. TPC manufactures dexlansoprazole delayed release capsules.

2. TPC is the owner of record and assignee of U.S. Patent No. 6,462,058 (the "'058 Patent"), U.S. Patent No. 6,664,276 (the "'276 Patent"), U.S. Patent No. 6,939,971 (the "'971 Patent"), U.S. Patent No. 7,285,668 (the "'668 Patent"), U.S. Patent No. 7,790,755 (the "'755 Patent).

3. Plaintiff Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc. ("TPNA"), is a Delaware corporation with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPUSA's business includes the research, development, and marketing of pharmaceutical products. TPUSA is the registered holder of approved New Drug Application No. 22-287. In addition, TPUSA has the exclusive right to import dexlansoprazole delayed release capsules into the United States. TPUSA purchases dexlansoprazole delayed release capsules manufactured by TPC from TPC and imports them into the United States.

4. TPUSA is the owner of record and assignee of U.S. Patent No. 8,173,158 (the "'158 Patent") and U.S. Patent No. 8,461,187 (the "'187 Patent") (collectively with the '058, '276, '971, '668, and '755 patents, the "Asserted Patents").

5. Plaintiff Takeda Pharmaceuticals America, Inc. ("TPA"), is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPA's business includes the purchase, sale, and marketing of pharmaceutical products. TPA has the exclusive right to purchase dexlansoprazole delayed release capsules from TPUSA and sell those capsules to the public in the United States. TPA sells dexlansoprazole delayed release capsules manufactured by TPC that it purchases from TPUSA to the public in the United States.

6. Plaintiffs are informed and believe, and thereupon allege, that Defendant Mylan Inc. is a Pennsylvania corporation with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Plaintiffs are further informed and believe, and thereupon allege, that Defendant Mylan Inc. was formerly known as Mylan Laboratories Inc.

7. Plaintiffs are informed and believe, and thereupon allege, that Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with a principal place of business at 781 Chestnut Ridge Rd. Morgantown, West Virginia 26505 and is a wholly owned subsidiary of Defendant Mylan Inc. On the basis of Defendant Mylan Inc.'s Form 10-K filed with the United States Securities and Exchange Commission for the fiscal Year ended December 31, 2012,

Plaintiffs are informed and believe, and thereupon allege that "[Defendant Mylan Inc.'s] sales in the U.S. are derived principally through [its] wholly owned subsidiary [Defendant] Mylan Pharmaceuticals Inc." Plaintiffs are informed and believe, and thereupon allege, that the acts of Defendant Mylan Pharmaceuticals, Inc. complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of Defendant Mylan Inc. Plaintiffs are further informed and believe, and thereupon allege, that Defendant Mylan Pharmaceuticals Inc. and Defendant Mylan Inc. have officers and/or directors in common.

8. Upon information and belief, Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. are both in the business of, among other things, manufacturing, marketing, and selling generic copies of branded pharmaceuticals throughout the United States.

9. Unless specifically stated otherwise, the acts complained of herein were committed by, on behalf of, and/or for the benefit of Defendants.

II.

NATURE OF THE ACTION

10. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA"), ANDA No. 205-205, filed by Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' DEXILANT products.

11. Plaintiffs are informed and believe, and thereupon allege, that Defendants have been infringing, are infringing, or will infringe one or more claims of each of the Asserted Patents.

III.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. because Defendant Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia and maintains a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505.

14. This Court also has personal jurisdiction over Defendant Mylan Inc. because: (1) Defendant Mylan Inc. is registered to do business in the State of West Virginia and its agent for service of process in West Virginia is Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302; (2) Defendant Mylan Inc. has submitted to jurisdiction in this District in numerous patent cases; and (3) Defendant Mylan Inc. has purposefully availed itself of the privilege of doing business in the State of West Virginia and the Northern District of West Virginia by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of West Virginia and Northern District of West Virginia, and/or by selling, directly or through its agents, pharmaceutical products in the State of West Virginia and the Northern District of West Virginia.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d), and/or 1400(b).

16. The following actions have been brought and are pending in the United States District Court for the Northern District of California: *Takeda Pharmaceutical Co., Ltd.et al. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, No. 3:11-cv-840 JCS and *Par Pharmaceutical, Inc. and Handa Pharmaceuticals LLC v. Takeda Pharmaceutical Co., Ltd. et al.*, No. 5:13-cv-1927 LHK (the "Handa Actions"); *Takeda Pharmaceutical Co., Ltd. et al. v. TWi Pharmaceuticals, Inc.*, Nos. 3:11-cv-1609 JCS and 5:13-cv-2420 LHK (the "TWi Actions"); *Takeda Pharmaceutical Co., Ltd. et al. v. Impax Laboratories, Inc.*, Nos. 3:11-cv-1610 JCS and 5:13-cv-2416 LHK (the "Impax Actions"); *Takeda Pharmaceutical Co., Ltd. et al. v. Sandoz Inc.*, Nos. 3:12-cv-446 JCS and 5:13-cv-2418 LHK (the "Sandoz Actions"); and *Takeda Pharmaceutical Co., Ltd. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, Nos.

3:13-cv-4001 NC and 3:13-cv-4002 NC (the "California Mylan Actions") (collectively, the "Pending Actions"). The Pending Actions involve claims by Plaintiffs of infringement of the same patents that are involved in the present action.

17. Plaintiffs believe that this action would be best adjudicated in the Northern District of California and should be coordinated and proceed concurrently with one or more of these related, pending actions. However, Counsel for Defendants may assert in the California Mylan Actions that Defendants are not subject to jurisdiction in the Northern District of California.

18. Plaintiffs are therefore filing the instant complaint, which contains essentially identical infringement claims against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. as the California Mylan Actions, as a so-called Hatch-Waxman "protective suit" to preserve their rights for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). If Defendant Mylan Inc. or Defendant Mylan Pharmaceuticals Inc. challenges jurisdiction in the California Mylan Actions, Plaintiffs intend to move this Court to stay or transfer the instant action pending resolution of any jurisdictional challenge in the California Mylan Actions.

IV.

FACTUAL BACKGROUND

A. Asserted Patents

1. The '058 Patent

19. On October 8, 2002, U.S. Patent No. 6,462,058, titled "Benzimidazole Compound Crystal," was duly and legally issued to Takeda Chemical Industries, Ltd., as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. On June 29, 2004, Takeda Chemical Industries, Ltd., changed its name to Takeda Pharmaceutical Company Limited (i.e., TPC). The change of the name of the assignee of the '058 Patent to TPC was recorded in the United States Patent and Trademark Office ("PTO") on January 19, 2005. A true and correct copy of the '058 Patent is attached as Exhibit A to this Complaint.

20. The expiration date of the ’058 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the Orange Book) is June 15, 2020, with an extension for pediatric exclusivity until December 15, 2020.

2. The ’276 Patent

21. On December 16, 2003, U.S. Patent No. 6,664,276, titled “Benzimidazole Compound Crystal,” was duly and legally issued to Takeda Chemical Industries, Ltd., as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. On June 29, 2004, Takeda Chemical Industries, Ltd., changed its name to Takeda Pharmaceutical Company Limited (i.e., TPC). The change of the name of the assignee of the ’276 Patent to TPC was recorded in the PTO on January 19, 2005. A true and correct copy of the ’276 Patent is attached as Exhibit B to this Complaint.

22. The expiration date of the ’276 Patent listed in the Orange Book is June 15, 2020, with an extension for pediatric exclusivity until December 15, 2020.

3. The ’971 Patent

23. On September 6, 2005, U.S. Patent No. 6,939,971, titled “Benzimidazole Compound Crystal,” was duly and legally issued to TPC, as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. A true and correct copy of the ’971 Patent is attached as Exhibit C to this Complaint.

24. The expiration date of the ’971 Patent listed in the Orange Book is June 15, 2020, with an extension for pediatric exclusivity until December 15, 2020.

4. The ’668 Patent

25. On October 23, 2007, U.S. Patent No. 7,285,668, titled “Process for the Crystallization of (R)- or (S)-Lansoprazole,” was duly and legally issued to TPC, as assignee of named inventors Hideo Hashimoto and Tadashi Urai. A true and correct copy of the ’668 Patent is attached as Exhibit D to this Complaint.

26. The expiration date of the ’668 Patent listed in the Orange Book is June 15, 2020, with an extension for pediatric exclusivity until December 15, 2020.

5. The ’755 Patent

27. On September 7, 2010, U.S. Patent No. 7,790,755, titled “Controlled Release Preparation,” was duly and legally issued to TPC, as assignee of named inventors Yohko Akiyama, Takashi Kurasawa, Hiroto Bando, and Naoki Nagahara. A true and correct copy of the ’755 Patent is attached as Exhibit E to this Complaint.

28. The expiration date of the ’755 Patent listed in the Orange Book is August 2, 2026, with an extension for pediatric exclusivity until February 2, 2027.

6. The ’158 Patent

29. On May 8, 2012, the ’158 Patent, entitled “Methods of Treating Gastrointestinal Disorders Independent of the Intake of Food,” was duly and legally issued to TPUSA, as assignee of named inventors Ronald D. Lee, Majid Vakily, Darcy Mulford, Jing-Tao Wu, and Stuart Atkinson. A true and correct copy of the ’158 Patent is attached as Exhibit F to this Complaint.

30. The expiration date of the ’158 Patent listed in the Orange Book is March 17, 2030, with an extension for pediatric exclusivity until September 17, 2030.

7. The ’187 Patent

31. On June 11, 2013, the ’187 Patent, entitled “Multiple PPI Dosage Form,” was duly and legally issued to TPUSA, as assignee of named inventors Rajneesh Taneja and Majid Vakilynejad. A true and correct copy of the ’187 Patent is attached as Exhibit G to this Complaint.

32. The expiration date of the ’187 Patent listed in the Orange Book is January 17, 2026, with an extension for pediatric exclusivity until July 17, 2026.

B. DEXILANT

33. Plaintiff TPUSA is the registered holder of approved New Drug Application No. 22-287 for the manufacture and sale of the drug dexlansoprazole, a proton pump inhibitor, for the treatment of all grades of erosive esophagitis, maintaining healing of esophagitis, and treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease ("GERD"). Plaintiff TPA sells dexlansoprazole in the United States under the trade name DEXILANT, in 30 mg and 60 mg dosage forms. The 30 mg and 60 mg dosage forms of DEXILANT were approved by the FDA on January 30, 2009.[1]

34. Plaintiffs are informed and believe, and thereupon allege, that DEXILANT is the first and only acid reflux disease treatment specifically designed for the release of medicine in two stages over time. The key to this two-stage release is DEXILANT's Dual Delayed Release™ formulation ("DDR"). DDR combines two different types of granules in one pill. DEXILANT releases one dose of medicine within an hour of taking a pill. Then, around four to five hours after ingestion, DEXILANT releases a second dose of medicine.

35. The Asserted Patents are listed in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

C. Infringement by Defendants

36. Plaintiffs are informed and believe, and thereupon allege, that Defendants submitted ANDA No. 205-205 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market dexlansoprazole delayed release capsules in the 30 mg and 60 mg dosage forms (the "ANDA Products") as a generic version of DEXILANT, prior to the expiration dates of the Asserted Patents.

[1] Plaintiffs originally marketed the drug dexlansoprazole under the proprietary name KAPIDEX. On March 4, 2010, the FDA announced that TPNA would start marketing KAPIDEX under the new name DEXILANT to avoid potential confusion with two other medications, CASODEX and KADIAN.

37. Plaintiffs are informed and believe, and thereupon allege, that Abbreviated New Drug Application ("ANDA") No. 205-205 was filed under the name of Defendant Mylan Pharmaceuticals Inc. Plaintiffs are further informed and believe, and thereupon allege, that Defendant Mylan Inc. has and had at all times relevant to this action control over the activities of Defendant Mylan Pharmaceuticals Inc., including Defendant Mylan Pharmaceuticals Inc.'s filing of ANDA No. 205-205 and that Defendant Mylan Inc. was actively involved in the submission of ANDA No. 205-205.

38. On July 19, 2013, TPUSA received a letter dated July 17, 2013 and, on July 22, 2013, TPUSA received a materially identical letter dated July 18, 2013 (the "Notice Letters") via overnight delivery from Defendants addressed to TPC, TPUSA, and TPNA. These were the first Notice Letters that any of the Plaintiffs received related to ANDA No. 205-205.

39. On July 22, 2013, TPC received copies of both Notice Letters from Defendants.

40. The Notice Letters state that the ANDA included a Paragraph IV Certification that, in Defendant Mylan Pharmaceuticals Inc.'s opinion, the '058, '276, '971, '668, '755, and '158 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

41. On August 28, 2013, TPUSA received a letter dated August 26, 2013 via overnight delivery from Defendants addressed to TPC, TPUSA, and TPNA (the '187 Notice Letter).

42. The '187 Notice Letter states that ANDA No. 205-205 included a Paragraph IV Certification that, in Defendant Mylan Pharmaceuticals Inc.'s opinion, the '187 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

43. Plaintiffs are informed and believe, and thereupon allege, that the ANDA does not provide any valid basis for concluding that the Asserted Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

44. Plaintiffs are informed and believe, and thereupon allege, that the submission of the ANDA to the FDA constitutes infringement of the Asserted Patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, or import of the ANDA Products would infringe the Asserted Patents under 35 U.S.C. § 271(a)–(c).

45. Defendants' Notice Letters and '187 Notice Letter fail to comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II) because inter alia, they contain very limited information about the generic formulation for which Defendants submitted ANDA No. 205-205. For example, Defendants' Notice Letters and '187 Notice Letter do not list the amounts of the ingredients in the ANDA Products.

46. In Defendants' Notice Letters, Defendants purported to offer confidential access to portions of ANDA No. 205-205 to Plaintiffs on terms and conditions set forth in the Notice Letters (the "Mylan Offers"). Defendants requested that Plaintiffs accept the Mylan Offers before receiving access to Defendants' ANDA No. 205-205 and stated that by requesting ANDA No. 205-205, Plaintiffs necessarily accepted the Mylan Offers, including the terms and conditions expressed therein. The Mylan Offers contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the Mylan Offers unreasonably limited access to the ANDA to outside counsel for Plaintiffs at a single law firm, to the exclusion of outside experts and consultants retained by outside counsel, employees of outside counsel, and in-house counsel for Plaintiffs and also unreasonably limited the fields of practice and other activities of outside counsel who accepted access to the ANDA.

47. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

48. Since receiving Defendants' Notice Letters and the accompanying Mylan Offers, Plaintiffs have attempted to negotiate with Defendants to procure a copy of ANDA No. 205-

205 under restrictions "as would apply had a protective order been issued." To that end, on July 29, 2013, lead counsel for Plaintiffs, Jeffrey I. Weinberger, sent a letter proposing reasonable alternative terms that would apply had a protective order been issued. Despite repeated attempts by counsel for Plaintiffs to engage in negotiations with Defendants, counsel for Defendants did not engage in any negotiation with Plaintiffs or make a counterproposal prior to August 26, 2013, twenty-eight days after Plaintiffs' proposal was delivered to counsel for Defendants, when counsel for Defendants delivered a counterproposal to counsel for Plaintiffs by electronic mail. Defendants' counterproposal also contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, Defendants' counterproposal unreasonably precluded employees of outside counsel from access to the ANDA and also unreasonably limited the fields of practice and other activities of outside counsel who accepted access to the ANDA. On the same day, August 26, 2013, counsel for Plaintiffs delivered a reasonable counterproposal to counsel for Defendants, to which Defendants have not responded.

49. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter ("45-day window") in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

50. Plaintiffs are not aware of any other means of obtaining information regarding Defendants' ANDA Products within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegation of infringement and to present to the Court evidence that Defendants ANDA Products fall within the scope of one or more claims of the Asserted Patents.

51. Plaintiffs commenced this action within 45 days of receiving the first of the Notice Letters.

V.

CLAIMS FOR RELIEF

COUNT I

(Patent Infringement of U.S. Patent No. 6,462,058)

52. Plaintiffs incorporate by reference and reallege paragraphs 1 through 51 above as though fully restated herein.

53. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '058 Patent.

54. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '058 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT II

(Patent Infringement of U.S. Patent No. 6,664,276)

55. Plaintiffs incorporate by reference and reallege paragraphs 1 through 54 above as though fully restated herein.

56. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '276 Patent.

57. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '276 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT III

(Patent Infringement of U.S. Patent No. 6,939,971)

58. Plaintiffs incorporate by reference and reallege paragraphs 1 through 57 above as though fully restated herein.

59. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '971 Patent.

60. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '971 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(Patent Infringement of U.S. Patent No. 7,285,668)

61. Plaintiffs incorporate by reference and reallege paragraphs 1 through 60 above as though fully restated herein.

62. Plaintiffs are informed and believe, and thereon allege, that pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '668 Patent.

63. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '668 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT V

(Patent Infringement of U.S. Patent No. 7,790,755)

64. Plaintiffs incorporate by reference and reallege paragraphs 1 through 63 above as though fully restated herein.

65. Plaintiffs are informed and believe, and thereupon allege, that pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '755 Patent.

66. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '755 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(Patent Infringement of U.S. Patent No. 8,173,158)

67. Plaintiffs incorporate by reference and reallege paragraphs 1 through 66 above as though fully restated herein.

68. Plaintiffs are informed and believe, and thereon allege, that pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '158 Patent.

69. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '158 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VII

(Patent Infringement of U.S. Patent No. 8,461,187)

70. Plaintiffs incorporate by reference and reallege paragraphs 1 through 69 above as though fully restated herein.

71. Plaintiffs are informed and believe, and thereon allege, that pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '187 Patent.

72. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '187 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII

(Declaratory Judgment as to U.S. Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,285,668, 7,790,755, 8,173,158, and 8,461,187)

73. Plaintiffs incorporate by reference and reallege paragraphs 1 through 72 above as though fully restated herein.

74. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. Plaintiffs are informed and believe, and thereupon allege, that Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the ANDA Products prior to patent expiry.

76. Plaintiffs are informed and believe, and thereupon allege, that Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products upon receipt of final FDA approval of ANDA No. 205-205.

77. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Defendants' commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products would constitute infringement of the '058, '276, '971, '668, '755, '158, and '187 Patents.

78. Plaintiffs are informed and believe, and thereupon allege, that Defendants' infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products complained of herein will begin following FDA approval of ANDA No. 205-205.

79. Defendants maintain, and Plaintiffs deny, that the Asserted Patents are invalid or unenforceable. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products according to ANDA No. 205-205 will infringe one or more claims of the Asserted Patents. Plaintiffs thus are entitled to a declaration that the making, using, sale, offer for sale,

and importation into the United States of the ANDA Products according to ANDA No. 205-205 infringe one or more claims of the Asserted Patents.

VI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a declaration that Defendants have infringed each of the Asserted Patents;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by Defendants of the ANDA Products would infringe each of the Asserted Patents;

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of the ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be no earlier than the expiration date of the last of the Asserted Patents, including any extensions or adjustments;

D. For an order preliminarily and permanently enjoining Defendants and their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the Asserted Patents; and

E. For such other and further relief as this Court deems just and proper.

Respectfully Submitted,

DATED: August 29, 2013

By: */s/ James F. Companion*
JAMES F. COMPANION

James F. Companion
John Porco
SCHRADER, BYRD & COMPANION PLLC
The Maxwell Center
32-20th Street, Suite 500
Wheeling, West Virginia 26003
Telephone: (304) 233-3390
Facsimile: (304) 233-2769
jfc@schraderlaw.com
jp@schraderlaw.com

Of Counsel
Jeffrey I. Weinberger
Ted G. Dane
Ryan N. Hagglund (admitted to practice in New York)
MUNGER, TOLLES & OLSON LLP
355 South Grand Avenue
Thirty-Fifth Floor
Los Angeles, California 90071-1560
Telephone: (213) 683-9100
Facsimile: (213) 687-3702

Tina W. Arroyo
MUNGER, TOLLES & OLSON LLP
560 Mission Street
San Francisco, California 94105-2907
Telephone: (415) 512-4000
Facsimile: (415) 512-4077

Attorneys for Plaintiffs
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., AND TAKEDA PHARMACEUTICALS AMERICA, INC.