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TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.,

Plaintiffs,

v.

HANDA PHARMACEUTICALS, LLC, AND PAR PHARMACEUTICAL, INC.

Defendants.

Case No. 3:11-cv-00840 JCS

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), state the following as their Second Amended Complaint against Defendants Handa Pharmaceuticals, LLC, and Par Pharmaceutical, Inc. (collectively, "Defendants"):

I.

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation with its 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.

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. 7,737,282 ("'282 Patent"), U.S. Patent No. 7,285,668 (the "'668 Patent"), and U.S. Patent No. 7,790,755 (the "'755 Patent") (collectively, the "Asserted Patents").

3. Plaintiff Takeda Pharmaceuticals North America, Inc. ("TPNA"), is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPNA's business includes the research, development, and marketing of pharmaceutical products. TPNA is the registered holder of approved New Drug Application No. 22-287. In addition, TPNA has the exclusive right to import dexlansoprazole delayed release capsules into the United States and sell those capsules to Takeda Pharmaceuticals LLC.

4. Plaintiff Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda LLC's business includes the purchase and sale of pharmaceutical products. Takeda LLC is an exclusive licensee of 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 Takeda LLC and sell those capsules to the public in the United States.

6. Plaintiffs are informed and believe, and thereupon allege, that defendant Handa Pharmaceuticals, LLC ("Handa"), is a limited liability company organized under the laws of California with its principal place of business at 39465 Paseo Padre Parkway, Suite 2600, Fremont, CA 94538.

7. Plaintiffs are informed and believe, and thereupon allege, that defendant Par Pharmaceutical, Inc. ("Par"), is a corporation organized under the laws of Delaware with its principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

8. 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

9. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Handa/Par with the United States Food and Drug Administration ('FDA") for approval to market generic versions of Plaintiffs' DEXILANT products.

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

III.

JURISDICTION AND VENUE

11. 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).

12. This Court has personal jurisdiction over Handa because Handa is a company organized under the laws of California, has its principal place of business within this district, conducts business in this district, purposefully avails itself of the rights and benefits of California

law, and has been infringing, contributing to the infringement of and/or actively inducing others to infringe claims of the Asserted Patents in California and elsewhere.

13. This Court has personal jurisdiction over Par because Par has voluntarily consented to be joined as a party in this action, conducts business in this district, purposefully avails itself of the rights and benefits of California law, and has been infringing, contributing to the infringement of and/or actively inducing others to infringe claims of the Asserted Patents in California and elsewhere.

14. Plaintiffs are informed and believe, and thereupon allege, that a substantial part of the events giving rise to Plaintiffs' claims occurred in the Northern District of California. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d) and/or 1400(b).

IV.

FACTUAL BACKGROUND

A. Asserted Patents

1. The '058 Patent

15. 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 First Amended Complaint.

16. 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.

2. The '276 Patent

17. 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 First Amended Complaint.

18. The expiration date of the '276 Patent listed in the Orange Book is June 15, 2020.

3. The '971 Patent

19. 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 First Amended Complaint.

20. The expiration date of the '971 Patent listed in the Orange Book is June 15, 2020.

4. The '282 Patent

21. On June 15, 2010, U.S. Patent No. 7,737,282, 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 '282 Patent is attached as Exhibit D to this First Amended Complaint.

22. The expiration date of the '282 Patent is June 15, 2020.

5. The '668 Patent

23. 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 E to this First Amended Complaint.

24. The expiration date of the '668 Patent listed in the Orange Book is June 15, 2020.

6. The '755 Patent

25. 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 F to this First Amended Complaint.

26. The expiration date of the '755 Patent listed in the Orange Book is August 2, 2026.

B. DEXILANT

27. Plaintiff TPNA 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]

28. 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 later, DEXILANT releases a second dose of medicine.

29. The '058, '276, '971, '668, and '755 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

30. Plaintiffs are informed and believe, and thereupon allege, that Handa has submitted ANDA No. 202-294 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

[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.

U.S.C. § 355(j)). The ANDA seeks approval to market dexlansoprazole delayed release capsules in 30 mg and 60 mg dosage forms (the "Proposed Capsules") as a generic version of DEXILANT, prior to the expiration dates of the Asserted Patents.

31. Plaintiffs are informed and believe, and thereupon allege, that Handa filed the original ANDA on August 24, 2010. The ANDA as originally filed related only to the 60 mg dosage form and included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), that the '058 Patent, the '276 Patent, the '971 Patent, and the '668 Patent are invalid or will not be infringed by the manufacture, use, or sale of the Proposed Capsules.

32. Plaintiffs are informed and believe, and thereupon allege, that Handa amended the ANDA on December 10, 2010, to add a Paragraph IV Certification with respect to the '755 Patent.

33. Plaintiffs are informed and believe, and thereupon allege, that Handa amended the ANDA on January 10, 2011, to add the 30 mg dosage form, and included Paragraph IV Certifications dated January 7, 2011, with respect to the '058, '276, '971,'668, and '755 Patents.

34. Plaintiffs thus are informed and believe, and thereupon allege, that the ANDA as presently amended relates to both 30 mg and 60 mg dosage forms and contains Paragraph IV Certifications with respect to the '058, '276, '971,'668, and '755 Patents.

35. On January 14, 2011, TPNA received a letter (the "Notice Letter") from Handa by Federal Express delivery dated January 13, 2011, notifying TPNA and TPC that the ANDA includes a Paragraph IV Certification that, in Handa's opinion, the '058, '276, '971,'668, and '755 Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules. This was the first Notice Letter that any of the Plaintiffs received related to ANDA No. 202-294.[2]

36. Plaintiffs are informed and believe, and thereupon allege, that Handa transferred ownership and all rights to ANDA No. 202-294 as presently amended to Par effective March 12, 2012.

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[2] On January 18, 2011, TPNA received a second, similar letter from Handa sent by certified mail and dated January 12, 2011.

37. The ANDA and its subsequent amendments do 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 Proposed Capsules.

38. Plaintiffs are informed and believe, and thereupon allege, that the submission of the ANDA and its subsequent amendments to the FDA constitute 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 Proposed Capsules would infringe the Asserted Patents under 35 U.S.C. § 271(a)–(c).

39. Plaintiffs commenced this action within 45 days of receiving the Notice Letter, as required by 21 U.S.C. § 355(j)(5)(B)(iii).

V.

CLAIMS FOR RELIEF

COUNT I

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

40. Plaintiffs incorporate by reference and reallege paragraphs 1 through 39 above as though fully restated herein.

41. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '058 Patent.

42. Unless Defendants are enjoined by the Court, 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)

43. Plaintiffs incorporate by reference and reallege paragraphs 1 through 42 above as though fully restated herein.

44. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '276 Patent.

45. Unless Defendants are enjoined by the Court, 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)

46. Plaintiffs incorporate by reference and reallege paragraphs 1 through 45 above as though fully restated herein.

47. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '971 Patent.

48. Unless Defendants are enjoined by the Court, 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. 7,737,282)

49. Plaintiffs incorporate by reference and reallege paragraphs 1 through 48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '282 Patent.

51. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '282 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT V

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

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. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '668 Patent.

54. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '668 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VI

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

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. 202-294 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '755 Patent.

57. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '755 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VII

(Declaratory Judgment as to U.S. Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,737,282, 7,285,668, and 7,790,755)

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

59. 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 Proposed Capsules prior to patent expiry.

60. 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 Proposed Capsules upon receipt of final FDA approval of ANDA No. 202-294.

61. 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 Proposed Capsules will constitute infringement of the '058, '276, '971, '282, '668, and '755 Patents.

62. Defendants' infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules complained of herein will begin following FDA approval of ANDA No. 202-294.

63. Plaintiffs are informed and believe, and thereupon allege, that Defendants maintain, and Plaintiffs deny, that the Asserted Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Proposed Capsules. 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 Proposed Capsules according to ANDA No. 202-294 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 Proposed Capsules according to ANDA No. 202-294 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 Proposed Capsules 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 22, 2012

MUNGER, TOLLES & OLSON LLP

By: */s/ Heather E. Takahashi*
HEATHER E. TAKAHASHI

Attorneys for Plaintiffs
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.