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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
SAN FRANCISCO DIVISION

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

Plaintiffs,

v.

ANCHEN PHARMACEUTICALS, INC., AND TWI PHARMACEUTICALS, INC.,

Defendants.

Case No. 3:11-cv-01609 CRB

FIRST 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 Complaint against Defendants Anchen Pharmaceuticals, Inc., and TWi Pharmaceuticals, 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 is a sublicensee of Takeda LLC with respect to the Asserted Patents and 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 is a sublicensee of Takeda LLC with respect to the Asserted Patents and 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 Anchen Pharmaceuticals, Inc. ("Anchen"), is a corporation organized under the laws of California with its principal place of business at 9601 Jeronimo Road, Irvine, CA 92618.

7. Plaintiffs are informed and believe, and thereupon allege, that Defendant TWi Pharmaceuticals, Inc. ("TWi"), formerly Anchen Pharmaceuticals (Taiwan), Inc., is a corporation organized under the laws of Taiwan with its principal place of business at 4Fl., No. 41, Lane 221, Kang Chien Rd., Nei Hu Dist., Tai Pei 114 Taiwan.

8. Plaintiffs are informed and believe, and thereupon allege, that Defendants Anchen and TWi are wholly-owned subsidiaries of non-party Anchen Inc., a corporation organized under the laws of Delaware and having its principal place of business at 9601 Jeronimo Road, Irvine, CA 92618.

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

II.

NATURE OF THE ACTION

10. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Anchen and maintained by TWi 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 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 Anchen because it is a corporation organized under the laws of California, 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 this Court has personal jurisdiction over TWi because it has purposefully availed itself of the privilege of doing business in the State of California by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of California.

15. Plaintiffs further are informed and believe, and thereupon allege, that TWi ships pharmaceutical products to Anchen from locations outside the United States for distribution by Anchen within the United States generally and California specifically, and/or by selling, directly or through its agents, pharmaceutical products in the State of California. For example, Plaintiffs are informed and believe, and thereupon allege, that TWi manufactures and ships to the United States divalproex sodium extended-release tablets 250 mg and 500 mg for sale in the State of California, including this judicial district. Furthermore, TWi's maintainence of ANDA No. 202-666, discussed below, indicates its intention to engage in the commercial manufacture, use, sale, or offer for sale of generic versions of Plaintiffs' DEXILANT products, of which a significant portion of sales occur in the State of California and this judicial district.

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

17. By letter dated March 25, 2011, Anchen's counsel informed Plaintiffs' counsel that Anchen will not object to personal jurisdiction and/or venue in the United States District Court for the Northern District of California.

IV.

FACTUAL BACKGROUND

A. Asserted Patents

1. The '058 Patent

18. 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.

19. 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

20. 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.

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

3. The ’971 Patent

22. 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.

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

4. The ’282 Patent

24. 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 Complaint.

25. The expiration date of the ’282 Patent is June 15, 2020.

5. The ’668 Patent

26. 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 Complaint.

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

6. The ’755 Patent

28. 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 Complaint.

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

B. <u>DEXILANT</u>

30. 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]

31. 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.

32. 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 Anchen and TWi

33. Plaintiffs are informed and believe, and thereupon allege, that Anchen submitted ANDA No. 202-666 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 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.

34. On February 25, 2011, TPC received by facsimile a letter dated February 24, 2011 (the "Notice Letter") from Anchen, addressed to TPC, TPNA, and Takeda Global Research &

[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.

Development Center, Inc. This was the first Notice Letter that any of the Plaintiffs received related to ANDA No. 202-666.

35. The Notice Letter stated that the ANDA includes a Paragraph IV Certification that, in Anchen's opinion, the '058, '276, '971, '668, and '755 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules.

36. 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 Proposed Capsules.

37. Plaintiffs commenced this action against Anchen on April 1, 2011, within 45 days of receiving the Notice Letter, as required by 21 U.S.C. § 355(j)(5)(B)(iii).

38. After Plaintiffs filed the Complaint, Anchen's counsel informed Plaintiffs' counsel that, effective May 10, 2011, ownership of ANDA No. 202-666 was transferred from Anchen to TWi. Anchen's counsel further stated that Anchen will continue to serve as the U.S. agent for ANDA No. 202-666, and that the ANDA had been amended to reflect this change in ownership.

39. Plaintiffs are informed and believe, and thereupon allege, that the submission and maintenance of the ANDA by Anchen and TWi 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 Proposed Capsules would infringe the Asserted Patents under 35 U.S.C. § 271(a)–(c).

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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '058 Patent.

42. Unless Anchen and TWi are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Anchen's and TWi's 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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '276 Patent.

45. Unless Anchen and TWi are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Anchen's and TWi's 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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '971 Patent.

48. Unless Anchen and TWi are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Anchen's and TWi's 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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '282 Patent.

51. Unless Anchen and TWi are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Anchen's and TWi's 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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '668 Patent.

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

COUNT VI

(Patent 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), by submitting and maintaining ANDA No. 202-666 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules, Anchen and TWi have been infringing, and continue to infringe, the '755 Patent.

57. Unless Anchen and TWi are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Anchen's and TWi's 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 Anchen and TWi 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 Anchen and TWi 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. 202-666.

61. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Anchen's and TWi's 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. Anchen's and TWi's 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. 202-666.

63. Plaintiffs are informed and believe, and thereupon allege, that Anchen and TWi 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, on the one hand, and Anchen and TWi, on the other, regarding whether Anchen's and TWi's commercial manufacture, use, sale, offer for sale, or

importation into the United States of the Proposed Capsules according to ANDA No. 202-666 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. 202-666 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 Anchen and TWi have infringed each of the Asserted Patents;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by Anchen and TWi 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 Anchen and TWi and each of 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.

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Respectfully Submitted,

DATED: May 18, 2011

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.