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TAKEDA PHARMACEUTICALS U.S.A., INC.,
AND TAKEDA PHARMACEUTICALS
AMERICA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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

Plaintiffs,

vs.

TWI PHARMACEUTICALS, INC.,

Defendant.

Case No. 5:13-cv-02420 LHK (PSG)

SECOND AMENDED 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 First Amended Complaint against Defendant TWi Pharmaceuticals, Inc.:

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. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA"), formerly known as Takeda Pharmaceuticals North America, Inc., 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. TPUSA purchases dexlansoprazole delayed release capsules manufactured by TPC from TPC and imports them into the United States.

3. TPUSA is the owner of record and assignee of U.S. Patent No. 8,173,158 (the "'158 Patent").

4. TPUSA is the owner of record and assignee of U.S. Patent No. 8,461,187 (the "'187 Patent").

5. TPC is an exclusive licensee of TPUSA with respect to the '158 and '187 Patents. TPUSA is in turn a sublicensee of TPC with respect to the '158 and '187 Patents and has the exclusive right to import dexlansoprazole delayed release capsules into the United States.

6. Plaintiff Takeda Pharmaceuticals America, Inc. ("TPA") is a Delaware corporation with its 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 TPUSA and has the exclusive right to sell dexlansoprazole delayed release capsules to the public in the United States. TPA purchases dexlansoprazole delayed release capsules manufactured by TPC from TPUSA and sells them to the public in the United States.

7. Plaintiffs are informed and believe, and thereupon allege, that Defendant TWi Pharmaceuticals, Inc. ("TWi") 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. Unless specifically stated otherwise, the acts complained of herein were committed by, on behalf of, and/or for the benefit of TWi.

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 TWi 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 TWi has been infringing, is infringing, or will infringe one or more claims of the '158 and '187 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. 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.

13. Plaintiffs are further informed and believe, and thereupon allege, that TWi ships pharmaceutical products from locations outside the United States for distribution within the United States generally and California specifically either directly or through its agents, 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 maintenance 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.

14. As further evidence of personal jurisdiction, TWi has been sued for patent infringement in this district and has not contested personal jurisdiction (No. 3:11-cv-1609 (N.D. Cal.)). TWi has further admitted to personal jurisdiction in this district (No. 3:11-cv-1609 (N.D. Cal.)).

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

IV.

INTRADISTRICT ASSIGNMENT

16. For purposes of intradistrict assignment pursuant to Civil Local Rules 3-2(c) and 3-5(b), this Intellectual Property Action is to be assigned on a district-wide basis.

V.

FACTUAL BACKGROUND

A. The '158 Patent

17. 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 A to this Complaint.

18. The '158 Patent, as listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the Orange Book), is scheduled to expire on March 17, 2030, with pediatric exclusivity scheduled to expire on September 17, 2030.

B. The '187 Patent

19. 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 B to this Complaint.

20. The '187 Patent, as listed in the Orange Book, is scheduled to expire on January 17, 2026, with pediatric exclusivity scheduled to expire on July 17, 2026.

C. DEXILANT

21. Plaintiff TPUSA is the registered holder of 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.

22. 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.

23. The '158 and '187 Patents are listed in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

D. Infringement by TWi

24. Plaintiffs are informed and believe, and thereupon allege, that Anchen Pharmaceuticals, Inc. ("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 form (the "ANDA Products") as a generic version of DEXILANT, prior to the expiration dates of the '158 and '187 Patents.

25. On the basis of representations provided to Plaintiffs by counsel for TWi and Anchen in another case relating to infringement of other patents owned by Plaintiffs by the ANDA Products, *Takeda Pharmaceutical Co., Ltd. et al. v. TWi Pharmaceuticals, Inc.*, No. 3:11-cv-1609 (N.D. Cal.), Plaintiffs are informed and believe, and thereupon allege, that, effective May 10, 2011, ownership of ANDA 202-666 was transferred from Anchen to TWi.

26. On June 16, 2012, TPUSA received by facsimile a letter dated June 15, 2012 (the "Notice Letter") from TWi.

27. The Notice Letter stated that the ANDA included a Paragraph IV Certification that, in TWi's opinion, the '158 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

28. Plaintiffs are informed and believe, and thereupon allege, that the ANDA does not provide any valid basis for concluding that the '158 Patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

29. Plaintiffs are informed and believe, and thereupon allege, that the submission and maintenance of the ANDA by TWi constitutes infringement of the '158 and '187 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 '158 and '187 Patents under 35 U.S.C. § 271(a)–(c).

VI.

CLAIMS FOR RELIEF

COUNT I

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

30. Plaintiffs incorporate by reference and reallege paragraphs 1 through 29 above as though fully restated herein.

31. 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 ANDA Products, TWi has been infringing, and will continue to infringe, the '158 Patent.

32. Unless TWi is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by TWi's infringement of the '158 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT II

(Declaratory Judgment as to U.S. Patent No. 8,173,158)

33. Plaintiffs incorporate by reference and reallege paragraphs 1 through 32 above as though fully restated herein.

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

35. Plaintiffs are informed and believe, and thereupon allege, that TWi has 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.

36. Plaintiffs are informed and believe, and thereupon allege, that TWi intends 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. 202-666.

37. Plaintiffs are informed and believe, and thereupon allege, that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), TWi's 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 '158 Patent.

38. Plaintiffs are informed and believe, and thereupon allege, that TWi's 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. 202-666.

39. Plaintiffs are informed and believe, and thereupon allege, that TWi maintains, and Plaintiffs deny, that the '158 Patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products. Accordingly, there is a real, substantial, and continuing justiciable case or

controversy between Plaintiffs and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products according to ANDA No. 202-666 will infringe one or more claims of the '158 Patent. Plaintiffs thus are entitled to a declaration that TWi's commercial manufacture, use, sale, offer for sale, and importation into the United States of the ANDA Products according to ANDA No. 202-666 will infringe one or more claims of the '158 Patent.

COUNT III

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

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 ANDA Products, TWi has been infringing, and will continue to infringe, the '187 Patent.

42. Unless TWi is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by TWi's infringement of the '187 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(Declaratory Judgment as to U.S. Patent No. 8,461,187)

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

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

45. Plaintiffs are informed and believe, and thereupon allege, that TWi has 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.

46. Plaintiffs are informed and believe, and thereupon allege, that TWi intends 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. 202-666.

47. Plaintiffs are informed and believe, and thereupon allege, that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), TWi's 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 '187 Patent.

48. Plaintiffs are informed and believe, and thereupon allege, that TWi's 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. 202-666.

49. Plaintiffs are informed and believe, and thereupon allege, that TWi maintains, and Plaintiffs deny, that the '187 Patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and TWi regarding whether TWi's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products according to ANDA No. 202-666 will infringe one or more claims of the '187 Patent. Plaintiffs thus are entitled to a declaration that TWi's commercial manufacture, use, sale, offer for sale, and importation into the United States of the ANDA Products according to ANDA No. 202-666 will infringe one or more claims of the '187 Patent.

VII.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a declaration that TWi has infringed the '158 and '187 Patents;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by TWi of the ANDA Products would infringe the '158 and '187 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 '158 and '187 Patents, including any extensions or adjustments;

D. For an order preliminarily and permanently enjoining TWi and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licenses, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the '158 and '187 Patents; and

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

DATED: October 29, 2013

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