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TAKEDA PHARMACEUTICAL CO., LTD.,
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.

SANDOZ INC.,

Defendant.

Case No. 5:13-cv-02418 LHK

FIRST 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 Sandoz 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.

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 imports dexlansoprazole delayed release capsules manufactured by TPC 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. 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 sells dexlansoprazole delayed release capsules manufactured by TPC to the public in the United States.

6. Plaintiffs are informed and believe, and thereupon allege, that Defendant Sandoz Inc. ("Sandoz") is a Colorado corporation with its principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540.

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

II.

NATURE OF THE ACTION

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

9. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has been infringing, is infringing, or will infringe one or more claims of the '158 and '187 Patents.

III.

JURISDICTION AND VENUE

10. 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).

11. This Court has personal jurisdiction over Sandoz because Sandoz 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, and/or by selling, directly or through its agents, pharmaceutical products in the State of California.

12. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in California and this district, including the sale of Sandoz's products in California and this district. Sandoz's website states, "We develop, produce and market a portfolio of approximately 1 000 high-quality and cost-effective generic compounds, including complex biosimilars, an emerging field in which we are the pioneer and global leader."

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

IV.

INTRADISTRICT ASSIGNMENT

14. 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

15. 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.

16. 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

17. On June 11, 2013, the '158 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.

18. The expiration date of the '187 Patent is January 17, 2026, with an extension for pediatric exclusivity until July 17, 2026.

C. DEXILANT

19. 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.

20. 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.

21. The '158 Patent is listed in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

22. Plaintiffs have requested that the FDA list the '187 Patent in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

D. Infringement by Sandoz

23. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has submitted ANDA No. 203-504 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.

24. Plaintiffs are informed and believe, and thereupon allege, that accordingly, Sandoz should have included a Paragraph IV Certification in its ANDA that, in Sandoz's opinion, the '158 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

25. Plaintiffs are informed and believe, and thereupon allege that the ANDA includes or will likely be amended to include a Paragraph IV Certification that, in Sandoz'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.

26. Plaintiffs have not received a letter ("Notice Letter") stating that the ANDA includes a Paragraph IV Certification that, in Sandoz's opinion, the '158 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

27. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has not sent submitted a certification to the FDA with respect to the '158 Patent, contrary to the requirements of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(vii).

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 of the ANDA to the FDA 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 Product 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), Sandoz' submission of ANDA No. 203-504 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.

32. Unless Sandoz is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Sandoz' 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 Sandoz 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 Sandoz 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. 203-504.

37. Plaintiffs are informed and believe, and thereupon allege, that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Sandoz'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 Sandoz'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. 203-504.

39. Plaintiffs are informed and believe, and thereupon allege, that Sandoz 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 Sandoz regarding whether Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products according to ANDA No. 203-504 will infringe one or more claims of the '158 Patent. Plaintiffs thus are entitled to a declaration that Sandoz's commercial manufacture, use, sale, offer for sale, and

importation into the United States of the ANDA Products according to ANDA No. 203-504 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), Sandoz' submission of ANDA No. 203-504 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.

42. Unless Sandoz is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Sandoz' 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 Sandoz 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 Sandoz 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. 203-504.

47. Plaintiffs are informed and believe, and thereupon allege, that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Sandoz'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 Sandoz'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. 203-504.

49. Plaintiffs are informed and believe, and thereupon allege, that Sandoz 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 Sandoz regarding whether Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products according to ANDA No. 203-504 will infringe one or more claims of the '187 Patent. Plaintiffs thus are entitled to a declaration that Sandoz's commercial manufacture, use, sale, offer for sale, and importation into the United States of the ANDA Products according to ANDA No. 203-504 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 Sandoz has infringed the '158 and '187 Patents;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by Sandoz 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 Sandoz 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: July 9, 2013

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