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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

cv11 0840

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. HANDA PHARMACEUTICALS, LLC, Defendant.	CASE NO. **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 Defendant Handa Pharmaceuticals, LLC:

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. As part of its business, TPC is involved in 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. 7,285,668 (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. As part of its business, TPNA is involved in 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. As part of its business, Takeda LLC is involved in 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. As part of its business, TPA is involved in 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. Unless specifically stated otherwise, the acts complained of herein were committed by, on behalf of, and/or for the benefit of Handa.

II.

NATURE OF THE ACTION

8. This is an action for patent infringement.

9. Plaintiffs are informed and believe, and thereupon allege, that Handa has been and/or is infringing one or more claims of each of the Asserted 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. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. 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.

12. 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

13. 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.

14. The expiration date of the '058 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the U.S. Food and Drug Administration ("FDA") and commonly known as the Orange Book) is June 15, 2020.

2. The '276 Patent

15. 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.

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

3. The '971 Patent

17. On September 6, 2005, U.S. Patent No. 6,939,971, titled "Benzimidazole Compound Crystal," was duly and legally issued to Takeda Pharmaceutical Company Limited, 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.

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

4. The '668 Patent

19. 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 Takeda Pharmaceutical Company Limited, 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.

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

5. The '755 Patent

21. On September 7, 2010, U.S. Patent No. 7,790,755, titled "Controlled Release Preparation," was duly and legally issued to Takeda Pharmaceutical Company Limited, 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.

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

B. DEXILANT

23. 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]

24. Upon information and belief, 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 the

[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.

second 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.

25. 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. The ANDA and Subsequent Amendments

26. On information and belief, Handa has submitted Abbreviated New Drug Application No. 202-294 (the "ANDA") 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.

27. 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.

28. 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.

29. 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 a Paragraph IV Certification with respect to all of the Asserted Patents dated January 7, 2011.

30. 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 all of the Asserted Patents.

31. 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 Asserted 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]

32. 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.

33. Plaintiffs are informed and believe, and thereupon allege, that the submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, 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).

34. 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 Under 35 U.S.C. § 271, *et seq.*)

35. Plaintiffs incorporate by reference and reallege paragraphs 1 through 34 above as though fully restated herein.

36. The submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, constitutes infringement of the '058 Patent 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 '058 Patent under 35 U.S.C. § 271(a)–(c).

37. Handa's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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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.

COUNT II

(Patent Infringement of U.S. Patent No. 6,664,276 Under 35 U.S.C. § 271, *et. seq.*)

38. Plaintiffs incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

39. The submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, constitutes infringement of the '276 Patent 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 '276 Patent under 35 U.S.C. § 271(a)–(c).

40. Handa's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III

(Patent Infringement of U.S. Patent No. 6,939,971 Under 35 U.S.C. § 271, *et. seq.*)

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

42. The submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, constitutes infringement of the '971 Patent 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 '971 Patent under 35 U.S.C. § 271(a)–(c).

43. Handa's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(Patent Infringement of U.S. Patent No. 7,285,668 Under 35 U.S.C. § 271, *et. seq.*)

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

45. The submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, constitutes infringement of the '668 Patent 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 '668 Patent under 35 U.S.C. § 271(a)–(c).

46. Handa's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT V

(Patent Infringement of U.S. Patent No. 7,790,755 Under 35 U.S.C. § 271, et. seq.)

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

48. The submission of the ANDA and its subsequent amendments to the FDA, including the Paragraph IV Certifications, constitutes infringement of the '755 Patent 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 '755 Patent under 35 U.S.C. § 271(a)–(c).

49. Handa's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

VI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a determination that Handa has infringed each of the Asserted Patents;

B. For a determination that the commercial use, sale, offer for sale, manufacture, and/or importation by Handa 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 Handa and its 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: February 23, 2010

MUNGER, TOLLES & OLSON LLP

By: _____
JEFFREY I. WEINBERGER

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