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PAR PHARMACEUTICAL, INC. AND
HANDA PHARMACEUTICALS, LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PAR PHARMACEUTICAL, INC. AND HANDA PHARMACEUTICALS, LLC,

Plaintiffs,

v.

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

Defendants.

MEJ

Case No. 13 1927

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Par Pharmaceutical, Inc. ("Par") and Handa Pharmaceuticals, LLC ("Handa") (collectively, "Plaintiffs"), by and through their attorneys, bring the following Complaint against Defendants Takeda Pharmaceutical Co., Ltd.; Takeda Pharmaceuticals North America, Inc.; Takeda Pharmaceuticals America, Inc.; and Takeda Pharmaceuticals U.S.A., Inc. (collectively, "Defendants") for a declaratory judgment of patent non-infringement and invalidity as follows:

NATURE OF THE ACTION

1. Plaintiffs seek a declaratory judgment of invalidity and/or non-infringement of U.S. Patent Nos. 8,105,626 ("the '626 Patent") and 8,173,158 ("the '158 Patent") pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

PARTIES

2. Plaintiff Par is a corporation organized under the laws of Delaware with its principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

3. Plaintiff Handa is a limited liability company organized under the laws of California with its principal place of business in this district at 39465 Paseo Padre Parkway, Suite 2600, Fremont, California 94538.

4. On information and belief, Defendant 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, and doing business in the state of California and in this district on a permanent and continuous basis.

5. On information and belief, Defendant Takeda Pharmaceuticals North America, Inc. ("TPNA") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015, and doing business in the state of California and in this district on a permanent and continuous basis.

6. On information and belief, Defendant Takeda Pharmaceuticals America, Inc. ("TPA") is a Delaware corporation, with its principal place of business at One Takeda Parkway, Deerfield, IL 60015, and doing business in the state of California and in this district on a permanent and continuous basis.

7. On information and belief, Defendant Takeda Pharmaceuticals U.S.A., Inc. ("TP U.S.A.") is a Delaware corporation, with its principal place of business at One Takeda Parkway, Deerfield, IL 60015, and doing business in the state of California and in this district on a permanent and continuous basis.

8. On information and belief, as of January 18, 2012, the name of the entity Takeda Pharmaceuticals, North America, Inc. has been changed to Takeda Pharmaceuticals U.S.A., Inc.

JURISDICTION AND VENUE

9. This Court has jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 21 U.S.C. § 355(j)(5)(C)(i)(II) and/or 35 U.S.C. § 271(e)(5).

10. The Court has personal jurisdiction over Defendants, as they engage in significant business activities in this judicial district, including selling products in this district, soliciting business in this district, and deriving substantial revenue from this district. The Court also has personal jurisdiction over these Defendants as they have purposefully availed themselves of the courts of this state and this district, in particular by filing and prosecuting patent infringement actions in this district against Par and Handa relating to Plaintiffs' Abbreviated New Drug Application ("ANDA"), and intent to manufacture and market a generic version of Defendants' DEXILANT® pharmaceutical product.

11. Venue is proper under 28 U.S.C. §§ 1391.

INTRADISTRICT ASSIGNMENT AND NOTICE OF RELATED PENDING CASE

12. This is an Intellectual Property Action to be assigned on a district-wide basis pursuant to Civil Local Rule 3-2(c).

13. Plaintiffs believe this case to be Related—within the meaning of Civil Local Rule 3-12—to Case No. 3:11-cv-00840-JCS, currently pending before the Honorable Joseph C. Spero of the San Francisco Division.

FACTUAL BACKGROUND

14. The '626 Patent, entitled "Granules Containing Acid-Unstable Chemicals in Large Amount," issued on January 31, 2012.

15. On information and belief, the '626 Patent is currently scheduled to expire on

September 27, 2026, with pediatric exclusivity currently scheduled to expire on March 27, 2027.

16. According to the U.S. Patent and Trademark Office ("USPTO") assignment database, TPC is the named assignee of the '626 Patent.

17. The '158 Patent, entitled "Methods of Treating Gastrointestinal Disorders Independent of the Intake of Food," issued on May 8, 2012.

18. On information and belief, the '158 Patent is currently scheduled to expire on March 17, 2030, with pediatric exclusivity currently scheduled to expire on September 17, 2030.

19. According to the USPTO assignment database, TP U.S.A. is the named assignee of the '158 Patent.

20. TPNA is the registered holder of approved New Drug Application No. 22-287 for DEXILANT® brand dexlansoprazole capsules.

21. TPA sells DEXILANT® brand dexlansoprazole capsules in the United States in 30 mg and 60 mg dosage forms.

22. On information and belief, TPNA caused the U.S. Food and Drug Administration ("FDA") to list the '158 Patent and the '626 Patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* s "Orange Book") in connection with DEXILANT®. By doing so, TPNA represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use, or sale of DEXILANT®.

23. By listing the '158 Patent and the '626 Patent in the Orange Book, TPNA created a reasonable apprehension that it, or one of the patent assignees, which based on USPTO patent assignment database appear to be TPC or TP U.S.A., would file a patent infringement action against applicants seeking regulatory approval for dexlansoprazole capsules based on the '158 Patent and/or the '626 Patent, or against Par, Handa, or any other applicant for or manufacturer of a generic version of DEXILANT®. Accordingly, Plaintiffs have a reasonable apprehension that TPNA would file a patent infringement action against applicants seeking regulatory approval for dexlansoprazole capsules based on the '158 Patent and/or the '626 Patent, or that one or more of the Defendants will file a patent infringement action under the '158 Patent and/or the '626 Patent to prevent Par from marketing a generic version of DEXILANT®.

24. Handa submitted to FDA and Par is continuing to seek FDA approval of ANDA No. 202-294 directed to a drug product containing dexlansoprazole. As currently amended, ANDA No. 202-294 seeks approval for Plaintiffs to engage in the commercial manufacture, use, importation, offer for sale, or sale of dexlansoprazole capsules, 60 mg ("ANDA Product").

25. ANDA No. 202-294 contains bioavailability or bioequivalence data demonstrating that the ANDA Product is bioequivalent to DEXILANT®.

26. The ANDA Product has the same active ingredient, strength, dosage form, and route of administration as DEXILANT®, 60 mg.

27. Par submitted to FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '626 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product that is the subject of ANDA No. 202-294.

28. Par also submitted to FDA a Paragraph IV Certification that the '158 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product that is the subject of ANDA No. 202-294

29. Pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and § 314.95 of Title 21 of the U.S. Code of Federal Regulations, on September 10, 2012, Par provided notice to TPC, TPNA, and TP U.S.A. of the Paragraph IV Certifications for the '626 Patent and the '158 Patent ("Notice Letter").

30. Defendants could have but did not bring an action for patent infringement against Plaintiffs during the 45-day statutory period under 35 U.S.C. § 355(j)(5)(B)(iii) following receipt of the Notice Letter.

31. Since TPC, TPNA, Takeda Pharmaceuticals LLC, and TPA brought a patent infringement action against Handa before the expiration of 45 days after TPC and TPNA received a notice of Paragraph IV Certifications from Handa for U.S. Patent Nos. 6,462,058; 6,664,276; 6,939,971; 7,285,668; and 7,790,755—*Takeda Pharmaceutical Co., Ltd. et al. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, No. 11-840-JCS, currently pending in the U.S. District Court for the District of Northern California—pursuant to 21 U.S.C.

§ 355(j)(5)(B)(iii), Par expects to receive approval from FDA to engage in the commercial manufacture, use, or sale of the ANDA Product no earlier than the expiration of the thirty-month period beginning on January 14, 2011, thus allowing Par to manufacture and market its ANDA Product in the United States.

32. In view of the foregoing, an actual case and controversy exists between Plaintiffs and Defendants with respect to the '626 Patent and the '158 Patent that is within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201.

COUNT I

DECLARATION REGARDING INVALIDITY OF THE '626 PATENT

33. Plaintiffs incorporate by reference and re-allege Paragraphs 1-32 as if set forth specifically herein.

34. The claims of the '626 Patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

35. An actual and justiciable controversy exists between the parties with respect to the '626 Patent, and Plaintiffs are entitled to a declaratory judgment that the '626 Patent is invalid.

COUNT II

DECLARATION REGARDING INVALIDITY OF THE '158 PATENT

36. Plaintiffs incorporate by reference and re-allege Paragraphs 1-35 as if set forth specifically herein.

37. The claims of the '158 Patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

38. An actual and justiciable controversy exists between the parties with respect to the '158 Patent, and Plaintiffs are entitled to a declaratory judgment that the '158 Patent is invalid.

COUNT III

DECLARATION REGARDING NON-INFRINGEMENT OF THE '158 PATENT

39. Plaintiffs incorporate by reference and re-allege Paragraphs 1-38 as if set forth specifically herein.

40. The submission of ANDA No. 202-294 does not infringe any valid claim of the

'158 Patent.

41. The commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product that is the subject of ANDA No. 202-294 would not infringe any valid claim of the '158 Patent.

42. An actual and justiciable controversy exists between the parties with respect to the '158 Patent, and Plaintiffs are entitled to a declaratory judgment that the '158 Patent is not infringed.

PRAYER RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

A. That a judgment be entered declaring that the claims of the '626 Patent are invalid;

B. That a judgment be entered declaring that the claims of the '158 Patent are invalid;

C. That a judgment be entered declaring that the submission of ANDA No. 202-294 does not infringe any valid claim of the '158 Patent;

D. That a judgment be entered declaring that the manufacture, use, offer for sale, sale, or importation of the ANDA Product described in ANDA No. 202-294 would not infringe any valid claim of the '158 Patent;

E. That Defendants and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Plaintiffs or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Plaintiffs, or charging any of them either orally or in writing with infringement of the '626 Patent and the '158 Patent;

F. That Plaintiffs be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

G. That Plaintiffs be awarded such other and further relief as is the Court deems just and proper.

Respectfully Submitted,

Dated: April 26, 2013

PAR PHARMACEUTICAL, INC. AND
HANDA PHARMACEUTICALS, LLC

By: _____

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