

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700

*Attorneys for Plaintiffs
Helsinn Healthcare S.A. and
Roche Palo Alto LLC*

Of Counsel:

Joseph M. O'Malley, Jr.
Bruce M. Wexler
Eric W. Dittmann
David M. Conca
Gary Ji
Angela C. Ni
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

*Attorneys for Plaintiff
Helsinn Healthcare S.A.*

Mark E. Waddell
LOEB & LOEB LLP
345 Park Avenue
New York, NY 10154
(212) 407-4127

*Attorneys for Plaintiff
Roche Palo Alto LLC*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A. and
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES,
INC. and PAR PHARMACEUTICAL, INC.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC

("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendants Par Pharmaceutical

Companies, Inc. (“Par Companies”) and Par Pharmaceutical, Inc., (“Par Inc.”) (collectively, “Defendants” or “Par”) hereby allege as follows:

THE PARTIES

1. Helsinn is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

2. Roche is a company, organized and existing under the laws of the State of Delaware, having a principal place of business at One DNA Way, South San Francisco, California 94080-4990.

3. Upon information and belief, Par Companies is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Upon information and belief, Par Companies manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States.

4. Upon information and belief, Par Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Upon information and belief, Par Inc. manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States. Upon information and belief, Par Inc. is a wholly-owned subsidiary of Par Companies.

5. Upon information and belief, the acts of Par Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, assistance, and/or participation of Par Companies.

NATURE OF THE ACTION

6. This is a civil action concerning the infringement of United States Patent No. 7,947,724 (“the ’724 patent”), United States Patent No. 7,947,725 (“the ’725 patent”), United States Patent No. 7,960,424 (“the ’424 patent”), United States Patent No. 8,598,219 (“the ’219 patent”), and United States Patent No. 8,729,094 (“the ’094 patent”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

8. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court’s jurisdiction.

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

10. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, both defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs. This Court has personal jurisdiction over Defendants for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. This Court has personal jurisdiction over Par Companies by virtue of the fact that, *inter alia*, it: (1) has a principal place of business in this Judicial District; (2) has purposely availed itself of the privilege of doing business in this Judicial District; (3) maintains

extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents; (4) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court; and (5) is registered to do business in New Jersey under Business I.D. No. 0100946477.

12. This Court has personal jurisdiction over Par Inc. by virtue of the fact that, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in this Judicial District; (2) maintains extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents; (3) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court; (4) is registered to do business in New Jersey under Business I.D. No. 0100071541; and (5) is a registered manufacturer and wholesaler of drugs in the State of New Jersey under Registration Nos. 5001143 and 5004032, respectively.

THE PATENTS-IN-SUIT

13. On May 24, 2011, the '724 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '724 patent is attached as Exhibit A.

14. On May 24, 2011, the '725 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '725 patent is attached as Exhibit B.

15. On June 14, 2011, the '424 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '424 patent is attached as Exhibit C.

16. On December 3, 2013, the '219 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '219 patent is attached as Exhibit D.

17. On May 20, 2014, the '094 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '094 patent is attached as Exhibit E.

18. Pursuant to 21 U.S.C. § 355(b)(1), the '724 patent, the '725 patent, the '424 patent, the '219 patent, and the '094 patent are listed in the United States Food and Drug Administration ("FDA") publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '724 PATENT

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. Upon information and belief, Defendants submitted ANDA No. 207330 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207330 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '724 patent. ANDA No. 207330 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

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