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

HEL SINN HEALTHCARE S.A. and
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiffs Helsinn Healthcare S.A. (“Helsinn”) and Roche Palo Alto LLC (“Roche”), for their Complaint against Defendants Dr. Reddy’s Laboratories, Ltd. (“Reddy Ltd.”) and Dr. Reddy’s Laboratories, Inc. (“Reddy Inc.”), hereby allege as follows:

THE PARTIES

1. Plaintiff Helsinn is a Swiss corporation having a principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.
2. Plaintiff 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, Defendant Reddy Ltd. is an Indian corporation having a principal place of business at 7-1-27, Ameerpet, Hyderabad, Andhra Pradesh, India. Upon information and belief, Reddy Ltd., itself and through its wholly owned subsidiary and agent Defendant Reddy Inc. (referred to collectively as “Reddy”), manufactures generic drugs for sale and use throughout the United States, including in this Judicial District. In its March 30, 2012 notice letter addressed to Helsinn and Roche, Reddy Ltd. appointed Lee Banks, Esq. of Reddy Inc., 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, as its agent in New Jersey authorized to accept service of process for purposes of the subject matter at issue in this action. Reddy Ltd. has previously consented to personal jurisdiction in this Court, including in the related actions *Helsinn Healthcare S.A., et al. v. Dr. Reddy’s Laboratories, Ltd., et al.*, Civil Action No. 11-3962 (MLC)(DEA), and *Helsinn Healthcare S.A., et al. v. Dr. Reddy’s Laboratories, Ltd., et al.*, Civil Action No. 11-5579 (MLC)(DEA), the latter of which was consolidated with Civil Action No. 11-3962.
4. Upon information and belief, Defendant Reddy Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of

business at 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary and agent of Defendant Reddy Ltd. Upon information and belief, Reddy Inc. is registered to do business in New Jersey and does business in this Judicial District. In its March 30, 2012 notice letter addressed to Helsinn and Roche, Reddy Inc. appointed Lee Banks, Esq. of Reddy Inc., 200 Somerset Corporate Boulevard, Floor 7, Bridgewater, New Jersey 08807, as its agent in New Jersey authorized to accept service of process for purposes of the subject matter at issue in this action. Reddy Inc. has previously consented to personal jurisdiction in this Court, including in the related actions *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-3962 (MLC)(DEA), and *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-5579 (MLC)(DEA), the latter of which was consolidated with Civil Action No. 11-3962.

NATURE OF THE ACTION

5. This is a civil action concerning the infringement of United States Patent No. 7,947,724 (“the ’724 patent”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. 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).

8. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has 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 each of the Defendants

for the additional reasons set forth above and below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Reddy Ltd.

10. This Court has personal jurisdiction over Defendant Reddy Inc.

THE PATENT

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

ACTS GIVING RISE TO THIS ACTION

INFRINGEMENT OF THE '724 PATENT BY REDDY

12. Plaintiffs reallege paragraphs 1-11 as if fully set forth herein.

13. Upon information and belief, Defendants submitted NDA No. 203050 to the United States Food and Drug Administration ("FDA") under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 203050 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 and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent. NDA No. 203050 specifically seeks FDA approval to market and sell generic versions of Helsinn's Aloxi[®] brand 0.25 mg / 5 mL and 0.075 mg / 1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

14. NDA No. 203050 alleges under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are not infringed.

15. Defendants' submission to the FDA of NDA No. 203050, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

16. Defendants are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of NDA No. 203050 and the § 505(b)(2)(A)(iv) allegations to the FDA.

17. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 203050 and the § 505(b)(2)(A)(iv) allegations constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

18. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell their proposed generic versions of Helsinn's Aloxi[®] brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi[®] brand products into the United States, and/or induces or contributes to such conduct, Defendants would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

19. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that:

A. A Judgment be entered declaring that Defendants have infringed the '724 patent by submitting the aforesaid NDA;

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