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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES,
LTD.,

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 Teva Pharmaceuticals USA, Inc. (“Teva USA”), and Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) (collectively, “Teva” or “Defendants”), hereby allege as follows:

THE PARTIES

1. Plaintiff Helsinn is a Swiss corporation having its 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 Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Teva USA is a wholly owned subsidiary and agent of Defendant Teva Ltd. Upon information and belief, Teva USA has facilities in New Jersey, is registered to do business in New Jersey, and does business in this judicial district. Teva USA has previously consented to personal jurisdiction in this Court, including in the related action *Helsinn Healthcare S.A., et al. v. Dr. Reddy’s Laboratories, Ltd., et al.*, No. 11-3962 (MLC)(DEA) (Consolidated).
4. Upon information and belief, Defendant Teva Ltd. is an Israeli corporation having a place of business at 5 Basel Street, Petah Tikva 49131, Israel. Upon information and belief, Teva Ltd., itself and through its wholly owned subsidiary and agent Defendant Teva USA, manufactures generic drugs for sale and use throughout the United States, including in this judicial district. Teva Ltd. has previously consented to personal jurisdiction in this Court,

including in the related action *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 11-3962 (MLC)(DEA) (Consolidated).

NATURE OF THE ACTION

5. This is a civil action concerning the infringement of 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.*, 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. 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.

8. 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).

9. 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.

10. This Court has personal jurisdiction over Defendant Teva USA.

11. This Court has personal jurisdiction over Defendant Teva Ltd.

THE PATENT

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

13. Pursuant to 21 U.S.C. § 355(b)(1), the '094 patent has been 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

INFRINGEMENT OF THE '094 PATENT BY TEVA

14. Plaintiffs reallege paragraphs 1-13 as if fully set forth herein.

15. Upon information and belief, Defendant Teva submitted ANDA No. 090713 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 090713 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 '094 patent. ANDA No. 090713 specifically seeks FDA approval to market 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 '094 patent.

16. Upon information and belief, ANDA No. 090713 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '094 patent are invalid. Defendants notified Plaintiffs of their certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of

any claim of the '094 patent, separate and apart from their assertions that those claims are allegedly invalid.

17. Teva's submission to the FDA of ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

18. Teva Ltd. and Teva USA are jointly and severally liable for any infringement of the '094 patent. This is because, upon information and belief, Teva Ltd. and Teva USA actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of the ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

19. Teva's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 090713 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

20. Plaintiffs are entitled to a declaration that, if Teva commercially manufactures, uses, offers for sale, or sells its 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, Teva would infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. Plaintiffs will be irreparably harmed by Teva's 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 Teva USA and Teva Ltd. have infringed the '094 patent by submitting the aforesaid ANDA;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendants' ANDA identified in this Complaint be a date that is not earlier than the expiration date of the '094 patent, or any later expiration of exclusivity for the '094 patent to which Plaintiffs are or become entitled;

C. An Order be issued that Defendants Teva USA and Teva Ltd., their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, importing, or selling the proposed generic versions of Helsinn's Aloxi[®] brand products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '094 patent, prior to the expiration of the '094 patent, including any extensions to which Plaintiffs are or become entitled; and

D. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: October 13, 2014

Respectfully submitted,

By: s/ Charles M. Lizza
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