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

HELSINN 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. and Roche Palo Alto LLC (collectively, "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Reddy" or "Defendants"), hereby allege as follows:

THE PARTIES

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

2. Plaintiff Roche Palo Alto LLC 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 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., a New Jersey corporation, manufactures generic drugs for sale and use throughout the United States, including in this judicial district. 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), *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-5579 (MLC)(DEA), and *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 13-5815 (MLC)(DEA), the latter two of which were consolidated with Civil Action No. 11-3962, and *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 12-2867 (MLC)(DEA).

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 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. 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), *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-5579 (MLC)(DEA), and *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 13-5815 (MLC)(DEA), the latter two of which were consolidated with Civil Action No. 11-3962, and *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 12-2867 (MLC)(DEA).

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) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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 Defendants for the additional reasons set forth 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 Reddy Ltd.

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

THE PATENT

12. 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 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

COUNT I – INFRINGEMENT OF THE '094 PATENT BY REDDY'S ANDA

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

15. Upon information and belief, Reddy submitted ANDA No. 201533 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 201533 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent. ANDA No. 201533 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi[®] brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

16. The '094 patent had not been issued at the time Reddy made its § 505(j)(2)(A)(vii)(IV) certification regarding Plaintiffs' other Orange Book-listed patents.

17. The '094 patent shares the same expiration date as Plaintiffs' other Orange Book-listed patents. By seeking FDA approval of its ANDA No. 201533 prior to expiration of

Plaintiffs' other Orange Book-listed patents, Reddy necessarily seeks approval of that ANDA prior to expiration of the '094 patent.

18. Upon information and belief, Reddy is required by law to either amend its ANDA to contain a § 505(j)(2)(A)(vii)(IV) certification with respect to the '094 patent, or must relinquish its request that the FDA approve ANDA No. 201533 prior to the expiration of Plaintiffs' Orange Book-listed patents.

19. Reddy continues to seek approval of ANDA No. 201533 from the FDA and intends to continue in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

20. By seeking approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent, Reddy has infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

21. Reddy Ltd. and Reddy Inc. are jointly and severally liable for any infringement of the '094 patent. This is because, upon information and belief, Reddy Ltd. and Reddy Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 201533 to the FDA.

22. Reddy's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 201533 constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

23. Plaintiffs are entitled to a declaration that, if Reddy 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, Reddy would infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

**COUNT II – INFRINGEMENT OF THE '094 PATENT
BY REDDY'S 505(b)(2) APPLICATION**

25. Plaintiffs reallege paragraphs 1-24 as fully set forth herein.

26. Upon information and belief, Reddy submitted NDA No. 203050 to the 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 palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent. NDA No. 203050 specifically seeks FDA approval to market and sell generic versions of Helsinn's Aloxi[®] brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

27. The '094 patent had not issued at the time Reddy made its § 505(b)(2)(A)(iv) certification regarding Plaintiffs' other Orange Book-listed patents.

28. The '094 patent shares the same expiration date as Plaintiffs' other Orange Book-listed patents. By seeking FDA approval of its NDA No. 203050 prior to expiration of Plaintiffs' other Orange Book-listed patents, Reddy necessarily seeks approval of that NDA prior to expiration of the '094 patent.

29. Upon information and belief, Reddy is required by law to either amend its NDA to contain a § 505(b)(2)(A)(iv) certification with respect to the '094 patent, or must relinquish its request that the FDA approve NDA No. 203050 prior to the expiration of Plaintiffs' Orange Book-listed patents.

30. Reddy continues to seek approval of NDA No. 203050 from the FDA and intends to continue in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent.

31. By seeking approval of its NDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '094 patent, Reddy has infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

32. Reddy Ltd. and Reddy Inc. are jointly and severally liable for any infringement of the '094 patent. This is because, upon information and belief, Reddy Ltd. and Reddy Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of NDA No. 203050 to the FDA.

33. Reddy's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 203050 constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

34. Plaintiffs are entitled to a declaration that, if Reddy 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, Reddy would infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

35. Plaintiffs will be irreparably harmed by Reddy'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 Reddy Ltd. and Reddy Inc. have infringed the '094 patent by submitting the aforesaid ANDA;
- B. A Judgment be entered declaring that Defendants Reddy Ltd. and Reddy Inc. have infringed the '094 patent by submitting the aforesaid NDA;
- C. 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 dates of the '094 patent, or any later expiration of exclusivity for the '094 patent to which Plaintiffs are or become entitled;
- D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendants' NDA 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;
- E. An Order be issued that Defendants Reddy Ltd. and Reddy Inc., their officers, agents, servants, and employees, and those persons in active concert or participation with either 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
- F. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: July 7, 2014

Respectfully submitted,

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