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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. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's

Dr. Reddy's Laboratories, Ltd., et al.
v.

Laboratories, Ltd. ("Reddy Ltd.") and Dr. Reddy's Laboratories, Inc. ("Reddy Inc.") (collectively, "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 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 action *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 action *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. 9,173,942 ("the '942 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 because, *inter alia*, each Defendant has committed, aided, abetted, contributed to, and/or participated in the commission of an 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 November 3, 2015, the '942 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '942 patent is attached as Exhibit A.

13. Pursuant to 21 U.S.C. § 355(b)(1), the '942 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 '942 PATENT BY REDDY'S 505(b)(2) APPLICATION

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

15. Upon information and belief, Defendants 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 '942 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 '942 patent.

16. The '942 patent had not issued at the time Defendants made their § 505(b)(2)(A)(iv) certification regarding Plaintiffs' other Orange Book-listed patents.

17. The '942 patent shares the same expiration date as Plaintiffs' other Orange Book-listed patents. By seeking FDA approval of their NDA No. 203050 prior to expiration of Plaintiffs' other Orange Book-listed patents, Defendants necessarily seek approval of that NDA prior to expiration of the '942 patent.

18. Upon information and belief, Defendants are required by law to either amend their NDA to contain a § 505(b)(2)(A)(iv) certification with respect to the '942 patent, or must relinquish their request that the FDA approve NDA No. 203050 prior to the expiration of Plaintiffs' Orange Book-listed patents.

19. Upon information and belief, Defendants continue to seek approval of NDA No. 203050 from the FDA and intend 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 '942 patent.

20. By seeking approval of their 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 '942 patent, Defendants have infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

21. Defendants Reddy Ltd. and Reddy Inc. are jointly and severally liable for any infringement of the '942 patent. This is because, upon information and belief, Defendants 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.

22. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 203050 for the purpose of seeking FDA approval 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 '942 patent constitutes infringement of the '942 patent under 35 U.S.C. § 271(e)(2)(A).

23. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer to sell, or sell their proposed generic versions of Helsinn's Aloxi® brand products within the United States, import their proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendants would infringe the '942 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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