IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| CIPLA LTD. and CIPLA USA, INC., | ) | |
| Defendants. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendants Cipla Ltd. and Cipla USA, Inc. (collectively, "Defendants"), 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, Cipla Ltd. is a corporation organized under the laws of India, with its principal place of business at Mumbai Central, Mumbai – 400 008 India. Upon information and belief, Cipla Ltd., directly and/or through Cipla USA, Inc., markets, manufactures, distributes, and sells generic drugs for use in the State of Delaware and throughout the United States.

4. Upon information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 9100

S. Dadeland Blvd., Suite 1500, Miami, FL 33156. Upon information and belief, Cipla USA, Inc. manufactures, markets, and/or sells various generic drug products for sale and use in the State of Delaware and throughout the United States, including generic pharmaceutical drugs manufactured by Cipla Ltd. Upon information and belief, Cipla USA, Inc. is a wholly owned subsidiary of, and the United States agent, affiliate, and/or representative of, Cipla Ltd., and has submitted regulatory filings to the FDA on behalf of Cipla Ltd.

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

## NATURE OF THE ACTION

6. This is a civil action concerning the infringement of United States Patent No. 8,598,218 ("the '218 patent") and United States Patent No. 8,598,219 ("the '219 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

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

11. This Court has personal jurisdiction over Cipla Ltd. by virtue of the fact that, *inter alia*, it: (1) engages in persistent conduct within Delaware, with and through its agent Cipla USA, Inc., a Delaware Corporation, including, upon information and belief, the preparation and submission of ANDA No. 206396; (2) has purposely availed itself of the privilege of doing business in this Judicial District including through, *inter alia*, Cipla USA, Inc., a Delaware Corporation; (3) maintains systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents including through, *inter alia*, Cipla USA, Inc.; (4) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction.

12. This Court has personal jurisdiction over Cipla USA, Inc. by virtue of the fact that, *inter alia*, it: (1) is incorporated in Delaware; (2) engages in persistent conduct within Delaware, including, upon information and belief, the preparation and submission of ANDA No. 206396; (3) has purposely availed itself of the privilege of doing business in this Judicial District; and (4) maintains systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

## THE PATENTS-IN-SUIT

13. On December 3, 2013, the '218 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '218 patent is attached as Exhibit A.

14. 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 B.

15. Pursuant to 21 U.S.C. § 355(b)(1), the ’218 and ’219 patents have 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 ’218 PATENT

16. Plaintiffs reallege paragraphs 1-15 as if fully set forth herein.

17. Upon information and belief, Defendants submitted ANDA No. 206396 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206396 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 the ’218 patent. ANDA No. 206396 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 ’218 patent.

18. Upon information and belief, ANDA No. 206396 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ’218 patent are invalid, and that certain (but not all) of the claims are not infringed by ANDA No. 206396.

19. Defendants' submission to the FDA of ANDA No. 206396, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A).

20. Cipla Ltd. and Cipla USA, Inc. are jointly and severally liable for any infringement of the '218 patent. This is because, upon information and belief, Cipla Ltd. and Cipla USA, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206396 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

21. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206396 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A).

22. 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, import their proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

23. 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.

**COUNT II – INFRINGEMENT OF THE '219 PATENT**

24. Plaintiffs reallege paragraphs 1-23 as if fully set forth herein.

25. Upon information and belief, Defendants submitted ANDA No. 206396 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANDA No. 206396 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 the '219 patent. ANDA No. 206396 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 '219 patent.

26. Upon information and belief, ANDA No. 206396 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '219 patent are invalid, and that certain (but not all) of the claims are not infringed by ANDA No. 206396.

27. Defendants' submission to the FDA of ANDA No. 206396, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

28. Cipla Ltd. and Cipla USA, Inc. are jointly and severally liable for any infringement of the '219 patent. This is because, upon information and belief, Cipla Ltd. and Cipla USA, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206396 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

29. Defendants' active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 206396 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

30. 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, import their proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

31. 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 '218 and '219 patents by submitting ANDA No. 206396;

B. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206396 be a date that is not earlier than the expiration dates of the '218 and '219 patents, or any later expiration of exclusivity for either of these patents to which Plaintiffs are or become entitled;

C. An order be issued that Defendants, 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 '218 or '219 patents, prior to the expiration of those patents, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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