

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

HELINN HEALTHCARE S.A. and	)	
ROCHE PALO ALTO LLC,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
	)	
AUROBINDO PHARMA LTD. and	)	
AUROBINDO PHARMA 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 Aurobindo Pharma Ltd. (“Aurobindo Ltd.”) and Aurobindo Pharma USA Inc. (“Aurobindo Inc.”) (collectively, “Aurobindo” or “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, Aurobindo Ltd. is a corporation organized and existing under the laws of India, having a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad- 500038, Andhra Pradesh, India. Upon information and belief, Aurobindo Ltd., directly and/or through Aurobindo 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, Aurobindo Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Aurobindo Inc. markets, manufactures, distributes, and sells generic drugs for use in the State of Delaware and throughout the United States, including generic pharmaceutical drugs, manufactured by Aurobindo Ltd. Upon information and belief, Aurobindo Inc. is a wholly owned subsidiary of, and the United States agent, affiliate, representative, and/or alter ego of, Aurobindo Ltd.

#### **NATURE OF THE ACTION**

5. This is a civil action concerning the infringement of United States Patent No. 7,947,724 (“the ’724 patent”), United States Patent No. 7,947,725 (“the ’725 patent”), and United States Patent No. 7,960,424 (“the ’424 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 Aurobindo 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 Aurobindo for the additional reasons set forth below.

9. This Court has personal jurisdiction over Aurobindo Ltd. by virtue of the fact that, *inter alia*, it: (1) has previously consented to this Court's jurisdiction, and taken advantage of the rights and protections provided by this Court; (2) does substantial business, derives substantial revenue, and engages in persistent conduct within Delaware, with and through its agent Aurobindo Inc., including, upon information and belief, the preparation and submission of ANDA No. 204702; and (3) has such substantial control over Aurobindo Inc. to justify treating Aurobindo Inc. as a mere alter ego of Aurobindo Ltd., and imputing Aurobindo Inc.'s Delaware contacts to Aurobindo Ltd. *See In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949-JJF (D. Del. Feb. 19, 2010).

10. This Court has personal jurisdiction over Aurobindo Inc. by virtue of the fact that, *inter alia*, it: (1) is incorporated in Delaware; (2) has previously consented to this Court's jurisdiction, and taken advantage of the rights and protections provided by this Court; (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 sale of generic pharmaceutical drugs to Delaware residents.

#### **THE PATENTS-IN-SUIT**

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

12. On May 24, 2011, the '725 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '725 patent is attached as Exhibit B.

13. On June 14, 2011, the '424 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '424 patent is attached as Exhibit C.

**ACTS GIVING RISE TO THIS ACTION**

**COUNT I – INFRINGEMENT OF THE '724 PATENT**

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

15. Upon information and belief, Aurobindo submitted ANDA No. 204702 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204702 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 '724 patent. ANDA No. 204702 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi<sup>®</sup> brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

16. ANDA No. 204702 has asserted under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid. Aurobindo did not allege noninfringement of any claim of the '724 patent, separate and apart from its assertions that those claims are invalid.

17. Aurobindo's submission to the FDA of ANDA No. 204702, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

18. Aurobindo Ltd. and Aurobindo Inc. are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Aurobindo Ltd. and Aurobindo Inc. actively and knowingly caused to be submitted, assisted with, participated in,

contributed to, and/or directed the submission of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

19. Aurobindo's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

20. Plaintiffs are entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Aurobindo would infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. Plaintiffs will be irreparably harmed by Aurobindo'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 '725 PATENT**

22. Plaintiffs reallege paragraphs 1-21 as if fully set forth herein.

23. Upon information and belief, Aurobindo submitted ANDA No. 204702 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204702 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 '725 patent. ANDA No. 204702 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi<sup>®</sup> brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

24. ANDA No. 204702 has asserted under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid. Aurobindo did not allege noninfringement of any claim of the '725 patent, separate and apart from its assertions that those claims are invalid.

25. Aurobindo's submission to the FDA of ANDA No. 204702, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

26. Aurobindo Ltd. and Aurobindo Inc. are jointly and severally liable for any infringement of the '725 patent. This is because, upon information and belief, Aurobindo Ltd. and Aurobindo Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

27. Aurobindo's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

28. Plaintiffs are entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Aurobindo would infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

**COUNT III – INFRINGEMENT OF THE '424 PATENT**

30. Plaintiffs reallege paragraphs 1-29 as if fully set forth herein.

31. Upon information and belief, Aurobindo submitted ANDA No. 204702 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204702 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 '424 patent. ANDA No. 204702 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi<sup>®</sup> brand 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions prior to the expiration of the '424 patent.

32. ANDA No. 204702 has asserted under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '424 patent are invalid. Aurobindo did not allege noninfringement of any claim of the '424 patent, separate and apart from its assertions that those claims are invalid.

33. Aurobindo's submission to the FDA of ANDA No. 204702, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

34. Aurobindo Ltd. and Aurobindo Inc. are jointly and severally liable for any infringement of the '424 patent. This is because, upon information and belief, Aurobindo Ltd. and Aurobindo Inc. actively and knowingly caused to be submitted, assisted with, participated in,

contributed to, and/or directed the submission of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

35. Aurobindo's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204702 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

36. Plaintiffs are entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Aurobindo would infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

37. Plaintiffs will be irreparably harmed by Aurobindo'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. Judgment be entered declaring that Defendants have infringed the '724, '725, and '424 patents by submitting ANDA No. 204702;

B. Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 204702 be a date that is not earlier than the expiration dates of the '724, '725, and '424 patents, or any later expiration of exclusivity for any of these patents to which Plaintiffs are or become entitled;

C. 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<sup>®</sup> brand products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '724, '725, or '424 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



Jack B. Blumenfeld (#1014)

Maryellen Noreika (#3208)

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899-1347

(302) 658-9200

jblumenfeld@mnat.com

mnoreika@mnat.com

*Attorneys for Plaintiffs Helsinn Healthcare  
S.A. and Roche Palo Alto LLC*

OF COUNSEL:

Joseph M. O'Malley, Jr.

Bruce M. Wexler

Eric W. Dittmann

David M. Conca

Gary Ji

Angela C. Ni

PAUL HASTINGS LLP

75 East 55th Street

New York, NY 10022

(212) 318-6000

*Attorneys for Plaintiff Helsinn Healthcare S.A.*

Mark E. Waddell

LOEB & LOEB LLP

345 Park Avenue

New York, NY 10154

(212) 407-4127

*Attorneys for Plaintiff Roche Palo Alto LLC*

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