

Charles M. Lizza  
William C. Baton  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102-5426  
(973) 286-6700

*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*

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

HELSINN HEALTHCARE S.A. and  
ROCHE PALO ALTO LLC,  
  
Plaintiffs,  
  
v.  
  
GAVIS PHARMA LLC,  
  
Defendant.

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 Defendant GAVIS Pharma LLC (“Gavis”) 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, Defendant Gavis is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Campus Drive, Somerset, NJ 08873. Upon information and belief, Defendant Gavis manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States.

**NATURE OF THE ACTION**

4. 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”), United States Patent No. 7,960,424 (“the ’424 patent”), United States Patent No. 8,598,219 (“the ’219 patent”), and 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.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

**JURISDICTION AND VENUE**

5. 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.

6. 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.

7. Venue is proper in this Court as to Defendant Gavis pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

8. This Court has personal jurisdiction over Defendant Gavis by virtue of the fact that, *inter alia*, Defendant Gavis 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 Defendant Gavis for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Gavis by virtue of the fact that, *inter alia*, it: (1) has its principal place of business in New Jersey; (2) engages in persistent conduct within New Jersey, including, upon information and belief, the preparation and submission of ANDA No. 207364; (3) has purposely availed itself of the privilege of doing business in this Judicial District; and (4) maintains extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents.

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

10. 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.

11. 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.

12. 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.

13. 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 D.

14. 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 E.

15. Pursuant to 21 U.S.C. § 355(b)(1), the '724 patent, the '725 patent, the '424 patent, the '219 patent, and the '094 patent are 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 '724 PATENT**

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

17. Upon information and belief, Defendant Gavis submitted ANDA No. 207364 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207364 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 certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '724 patent. ANDA No. 207364 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 '724 patent.

18. Upon information and belief, ANDA No. 207364 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid. Defendant Gavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '724 patent, separate and apart from its assertions that those claims are allegedly invalid.

19. Defendant Gavis's submission to the FDA of ANDA No. 207364, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

20. Defendant Gavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207364 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '724 patent under 35 U.S.C. § 271 (e)(2)(A).

21. Plaintiffs are entitled to a declaration that, if Defendant Gavis 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, Defendant Gavis will infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

22. Plaintiffs will be irreparably harmed by Defendant Gavis'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**

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

24. Upon information and belief, Defendant Gavis submitted ANDA No. 207364 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207364 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 certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '725 patent. ANDA No. 207364 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 '725 patent.

25. Upon information and belief, ANDA No. 207364 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '725 patent are invalid. Defendant Gavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '725 patent, separate and apart from its assertions that those claims are allegedly invalid.

26. Defendant Gavis's submission to the FDA of ANDA No. 207364, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

27. Defendant Gavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207364 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271 (e)(2)(A).

28. Plaintiffs are entitled to a declaration that, if Defendant Gavis 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, Defendant Gavis will infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Plaintiffs will be irreparably harmed by Defendant Gavis'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, Defendant Gavis submitted ANDA No. 207364 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207364 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 certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '424 patent. ANDA No. 207364 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 '424 patent.

32. Upon information and belief, ANDA No. 207364 includes a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '424 patent are invalid. Defendant Gavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of

any claim of the '424 patent, separate and apart from its assertions that those claims are allegedly invalid.

33. Defendant Gavis's submission to the FDA of ANDA No. 207364, 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. Defendant Gavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207364 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271 (e)(2)(A).

35. Plaintiffs are entitled to a declaration that, if Defendant Gavis 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, Defendant Gavis will infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

#### **COUNT IV - INFRINGEMENT OF THE '219 PATENT**

37. Plaintiffs reallege paragraphs 1-36 as if fully set forth herein.

38. Upon information and belief, Defendant Gavis submitted ANDA No. 207364 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207364 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 certain of Plaintiffs' Orange Book



listed patents that have the same expiration date as the '219 patent. ANDA No. 207364 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.

39. Upon information and belief, ANDA No. 207364 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. Defendant Gavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification, but did not allege noninfringement of any claim of the '219 patent, separate and apart from its assertions that those claims are allegedly invalid.

40. Defendant Gavis's submission to the FDA of ANDA No. 207364, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

41. Defendant Gavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207364 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271 (e)(2)(A).

42. Plaintiffs are entitled to a declaration that, if Defendant Gavis 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, Defendant Gavis will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

**COUNT V – INFRINGEMENT OF THE '094 PATENT**

44. Plaintiffs reallege paragraphs 1-43 as if fully set forth herein.

45. Upon information and belief, Defendant Gavis submitted ANDA No. 207364 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207364 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 certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '094 patent. ANDA No. 207364 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 '094 patent.

46. Upon information and belief, ANDA No. 207364 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. Defendant Gavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

47. Defendant Gavis's submission to the FDA of ANDA No. 207364, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

48. Defendant Gavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207364 and the

§ 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271 (e)(2)(A).

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

50. Plaintiffs will be irreparably harmed by Defendant Gavis'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 Defendant Gavis has infringed the '724, '725, '424, '219, and '094 patents by submitting ANDA No. 207364;

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. 207364 be a date that is not earlier than the expiration dates of the '724, '725, '424, '219, and '094 patents, or any later expiration of exclusivity for any of those patents to which Plaintiffs are or become entitled;

C. An Order be issued that Defendant Gavis, its 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 '724, '725, '424, '219, and '094 patents, prior to the expiration of any 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.

Dated: February 13, 2015

Respectfully submitted,

By: s/ Charles M. Lizza  
Charles M. Lizza  
William C. Baton  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102-5426  
(973) 286-6700  
clizza@saul.com  
wbaton@saul.com

*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  
josephomalley@paulhastings.com  
brucewexler@paulhastings.com  
ericdittmann@paulhastings.com  
davidconca@paulhastings.com  
garyji@paulhastings.com  
angelani@paulhastings.com

*Attorneys for Plaintiff  
Helsinn Healthcare S.A.*

Mark E. Waddell  
LOEB & LOEB LLP  
345 Park Avenue  
New York, NY 10154  
(212) 407-4127  
mwaddell@loeb.com

*Attorneys for Plaintiff  
Roche Palo Alto LLC*

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