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.
Eric W. Dittmann
Young J. Park
Isaac S. Ashkenazi
Gary Ji
Angela C. Ni
Dana Weir
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. SAGENT PHARMACEUTICALS, INC., 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 Sagent Pharmaceuticals, Inc. ("Sagent"), 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 Sagent is an entity organized and existing under the laws of the State of Delaware, having a principal place of business at 1901 N. Roselle Road, Suite 700, Schaumburg, Illinois 60195. Upon information and belief, Defendant Sagent 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 Sagent pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

8. This Court has personal jurisdiction over Sagent because, *inter alia*, Sagent has committed, aided, abetted, contributed to, and/or participated in an act of patent infringement that has led to foreseeable harm and injury to Plaintiffs. This Court has personal jurisdiction over Sagent 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 Sagent because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in this Judicial District, including, *inter alia*, registering with the New Jersey Department of Health as a wholesale drug manufacturer (Registration No. 5004419); (2) 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; (3) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court; and (4) has sent a Paragraph IV Notice, including a detailed statement of the factual and legal bases for its belief that the challenged patents are invalid or not infringed by Sagent's proposed generic product, into New Jersey.

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)(l), 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.

16. Pursuant to 21 C.F.R. § 314.95(a), Sagent is required to give notice of its certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act to “each owner of the patent which is the subject of the certification” listed in the Orange Book as covering Helsinn’s Aloxi® brand palonosetron hydrochloride intravenous solutions.

17. Roche is an owner of the ’724 patent, the ’725 patent, the ’424 patent, the ’219 patent, and the ’094 patent, and is listed as an assignee on each of the patents. Sagent did not provide notice to at least Roche of its certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act until February 4, 2016. Pursuant to 21 C.F.R. § 314.95(f), the 45-day period provided for in section § 505(j) of the Federal Food, Drug and Cosmetic Act did not begin until Roche received notice of Sagent’s certification under § 505(j)(2)(A)(vii)(IV).

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '724 PATENT BY SAGENT'S ANDA

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

19. Upon information and belief, Defendant Sagent submitted ANDA No. 204289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204289 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 certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '724 patent. ANDA No. 204289 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '724 patent.

20. Upon information and belief, ANDA No. 204289 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 Sagent 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.

21. Defendant Sagent's submission to the FDA of ANDA No. 204289, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

22. Defendant Sagent's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204289 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

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

24. Plaintiffs will be irreparably harmed by Defendant Sagent'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 BY SAGENT'S ANDA

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

26. Upon information and belief, Defendant Sagent submitted ANDA No. 204289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204289 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 certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '725 patent. ANDA No. 204289 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '725 patent.

27. Upon information and belief, ANDA No. 204289 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 Sagent 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.

28. Defendant Sagent's submission to the FDA of ANDA No. 204289, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

29. Defendant Sagent's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204289 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

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

31. Plaintiffs will be irreparably harmed by Defendant Sagent'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 BY SAGENT'S ANDA

32. Plaintiffs reallege paragraphs 1-31 as if fully set forth herein.

33. Upon information and belief, Defendant Sagent submitted ANDA No. 204289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204289 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 certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '424 patent. ANDA No. 204289 specifically seeks

FDA approval to market a generic version of Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '424 patent.

34. Upon information and belief, ANDA No. 204289 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 Sagent 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.

35. Defendant Sagent's submission to the FDA of ANDA No. 204289, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

36. Defendant Sagent's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204289 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

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

38. Plaintiffs will be irreparably harmed by Defendant Sagent'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 BY SAGENT'S ANDA

39. Plaintiffs reallege paragraphs 1-38 as if fully set forth herein.

40. Upon information and belief, Defendant Sagent submitted ANDA No. 204289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204289 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 certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '219 patent. ANDA No. 204289 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '219 patent.

41. Upon information and belief, ANDA No. 204289 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 Sagent 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.

42. Defendant Sagent's submission to the FDA of ANDA No. 204289, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

43. Defendant Sagent's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204289 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

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

45. Plaintiffs will be irreparably harmed by Defendant Sagent'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 BY SAGENT'S ANDA

46. Plaintiffs reallege paragraphs 1-45 as if fully set forth herein.

47. Upon information and belief, Defendant Sagent submitted ANDA No. 204289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 204289 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 certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '094 patent. ANDA No. 204289 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.

48. Upon information and belief, ANDA No. 204289 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 Sagent 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 '094 patent, separate and apart from its assertions that those claims are allegedly invalid.

49. Defendant Sagent's submission to the FDA of ANDA No. 204289, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

50. Defendant Sagent's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 204289 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

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

52. Plaintiffs will be irreparably harmed by Defendant Sagent'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 Sagent has infringed the '724, '725, '424, '219, and '094 patents by submitting ANDA No. 204289;

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. 204289 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 Sagent, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing 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 8, 2016

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

Attorneys for Plaintiffs
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ericdittmann@paulhastings.com
youngpark@paulhastings.com
isaacashkenazi@paulhastings.com
garyji@paulhastings.com
angelani@paulhastings.com
danaweir@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

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Helsinn Healthcare S.A., et al. v. Dr. Reddy Laboratories, Ltd., et al.*, Civil Action No. 11-3962 (MLC)(DEA) (D.N.J. July 8, 2011) (Consolidated), *Helsinn Healthcare, S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 12-2867 (MLC)(DEA) (D.N.J. May 11, 2012), *Helsinn Healthcare, S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 14-4274 (MLC)(DEA) (D.N.J. July 7, 2014), *Helsinn Healthcare, S.A., et al. v. Hospira, Inc., et al.*, Civil Action No. 15-2077 (MLC)(DEA) (D.N.J. Mar. 23, 2015), *Helsinn Healthcare, S.A., et al. v. Fresenius Kabi USA, LLC, et al.*, Civil Action No. 15-7015 (MLC)(DEA) (D.N.J. Sept. 22, 2015); *Helsinn Healthcare, S.A., et al. v. Fresenius Kabi USA, LLC, et al.*, Civil Action No. 15-7378 (MLC)(DEA) (D.N.J. Oct. 8, 2015), *Helsinn Healthcare S.A., et al. v. Qilu Pharmaceutical Co., Ltd., et al.*, Civil Action No. 15-8132 (MLC)(DEA) (D.N.J. Oct. 17, 2015), *Helsinn Healthcare S.A., et al. v. Dr. Reddy Laboratories, Ltd., et al.*, Civil Action No. 15-8662 (MLC)(DEA) (D.N.J. Dec. 15, 2015), *Helsinn Healthcare, S.A., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 15-8663 (MLC)(DEA) (D.N.J. Dec. 15, 2015), *Helsinn Healthcare, S.A., et al. v. Sagent Pharmaceuticals, Inc., et al.*, Civil Action No. 16-173 (MLC)(DEA), *Helsinn Healthcare, S.A., et al. v. Hospira, Inc.*, Civil Action No. 15-264 (GMS) (D. Del. Mar. 25, 2015), and *Helsinn Healthcare, S.A., et al. v. Exela Pharma Sciences LLC, et al.*, Civil Action No. 14-1444 (GMS) (D. Del. Dec. 1, 2014) (currently stayed) are related to the matter in controversy because the matter in controversy involves the same plaintiffs and the same or related patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical products.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: February 8, 2016

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
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Joseph M. O'Malley, Jr.
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Dana Weir
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000
josephomalley@paulhastings.com
ericdittmann@paulhastings.com
youngpark@paulhastings.com
isaacashkenazi@paulhastings.com
garyji@paulhastings.com
angelani@paulhastings.com
danaweir@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