IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HOSPIRA, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendant Hospira, Inc. ("Hospira") 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 Hospira is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 275 North Field Drive, Lake Forest, Illinois. Upon information and belief, Defendant Hospira manufactures, markets, and/or sells various generic drug products for sale and use in the State of Delaware 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 Hospira pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

8. This Court has personal jurisdiction over Defendant Hospira by virtue of the fact that, *inter alia*, Defendant Hospira 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 Hospira 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 Hospira 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. 207005; (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 Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware 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)(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.

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 Hospira submitted ANDA No. 207005 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207005 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. 207005 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. 207005 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 Hospira 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 Hospira's submission to the FDA of ANDA No. 207005, 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 Hospira's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207005 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 Hospira 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 Hospira will infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

22. Plaintiffs will be irreparably harmed by Defendant Hospira'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 Hospira submitted ANDA No. 207005 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207005 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. 207005 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. 207005 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 Hospira 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 Hospira's submission to the FDA of ANDA No. 207005, 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 Hospira's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207005 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 Hospira 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 Hospira will infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Plaintiffs will be irreparably harmed by Defendant Hospira'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 Hospira submitted ANDA No. 207005 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207005 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. 207005 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. 207005 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 Hospira 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 Hospira's submission to the FDA of ANDA No. 207005, 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 Hospira's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207005 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 Hospira 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 Hospira will infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

36. Plaintiffs will be irreparably harmed by Defendant Hospira'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 Hospira submitted ANDA No. 207005 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207005 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. 207005 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. 207005 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 Hospira notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

40. Defendant Hospira's submission to the FDA of ANDA No. 207005, 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 Hospira's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207005 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 Hospira 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 Hospira will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

43. Plaintiffs will be irreparably harmed by Defendant Hospira'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 Hospira submitted ANDA No. 207005 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207005 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. 207005

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. 207005 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 Hospira notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

47. Defendant Hospira's submission to the FDA of ANDA No. 207005, 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 Hospira's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 207005 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 Hospira 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 Hospira will infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

STATEMENT REGARDING PRIOR-FILED SUIT

51. Plaintiffs previously filed, on March 23, 2015, an action in the District of New Jersey seeking to enjoin Defendant Hospira from infringing the ’724, ’725, ’424, ’219, and ’094 patents. That action has been assigned Civil Action No. 15-2077 (“the D.N.J. Action”). The D.N.J. Action is assigned to Judge Mary L. Cooper.

52. In the D.N.J. Action, Plaintiffs alleged that the District Court for the District of New Jersey has personal jurisdiction over Defendant Hospira with regard to Plaintiffs’ claim of patent infringement.

53. Judicial economy would be promoted, and Plaintiffs’ choice of forum respected, if the claims related to Plaintiffs’ action for infringement of the ’724, ’725, ’424, ’219, and ’094 patents are addressed by Judge Cooper in the District of New Jersey.

54. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of an ANDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an ANDA pending resolution of litigation regarding the submission of such ANDA. Plaintiffs filed this action as a further protective measure with regard to this statutory right.

55. Plaintiffs expect that personal jurisdiction will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and will be voluntarily dismissed without prejudice in favor of continued prosecution of the D.N.J. Action, transferred to the District of New Jersey for consolidation with the D.N.J. Action, or subject to such other non-substantive disposition that would ensure maintenance of Plaintiffs’ rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that:

A. A Judgment be entered declaring that Defendant Hospira has infringed the '724, '725, '424, '219, and '094 patents by submitting ANDA No. 207005;

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. 207005 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 Hospira, 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.

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