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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,

Plaintiffs,

v.

FRESENIUS KABI USA, LLC, EMCURE PHARMACEUTICALS LIMITED, and EMCURE PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. 15-7015 (MLC)(DEA)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Amended Complaint against Defendant Fresenius Kabi USA, LLC (hereinafter, "Fresenius"), Emcure Pharmaceuticals Limited (hereinafter, "Emcure Ltd."), and Emcure Pharmaceuticals USA, Inc. (hereinafter, "Emcure Inc.") (together with Emcure Ltd., "Emcure") (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Helsinn is a Swiss corporation having a 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 Fresenius is a corporation organized and existing under the laws of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

4. Upon information and belief, Defendant Fresenius develops, manufactures, imports, markets, distributes, and/or sells generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey.

5. Upon information and belief, Defendant Emcure Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at T-184, M.I.D.C. Bhosari, Pune, Maharashtra 411026, Pune, India.

6. Upon information and belief, Defendant Emcure Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 21-B Cotters Lane, East Brunswick, New Jersey 08816.

7. Upon information and belief, Defendant Emcure Inc. is a wholly owned subsidiary and agent of Defendant Emcure Ltd.

8. Upon information and belief, in August 2014, Emcure Inc. filed an Amended and Restated Certificate of Incorporation with the New Jersey Secretary of State, which effectively changed its name to "Heritage Pharma Labs, Inc."

9. Upon information and belief, Emcure Ltd. has appointed Dr. Pankaj Dave of Emcure Inc., 21-B Cotters Lane, East Brunswick, New Jersey 08816, as its agent in New Jersey authorized to accept service of process for this action.

10. Upon information and belief, Emcure Ltd. and Emcure Inc. have common officers and directors.

11. Upon information and belief, Emcure Ltd., by itself or through its wholly owned subsidiary and agent Emcure Inc., develops, manufactures, and imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Emcure Ltd., by itself or through its wholly owned subsidiary and agent Emcure Inc., markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in the State of New Jersey.

NATURE OF THE ACTION

12. 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

13. 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.

14. 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.

15. Venue is proper in this Court as to each of the Defendants pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

16. This Court has personal jurisdiction over each of the Defendants because, *inter alia*, each Defendant has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

17. Fresenius sent Notice Letters to Plaintiffs on August 10, 2015 and September 15, 2015 ("Fresenius's Notice Letters"). Fresenius's Notice Letters state that it filed Abbreviated New Drug Applications ("ANDAs") No. 206802 and No. 206801 seeking approval from the United States Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, importation, offer for sale and sale of 0.25 mg / 5 mL palonosetron hydrochloride intravenous solutions in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patents-in-suit.

18. This Court also has personal jurisdiction over Defendant Fresenius because, upon information and belief, *inter alia*, (1) Fresenius has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification

number 0600313148 and maintains a corporate agent for service of process at 830 Bear Tavern Road, West Trenton, New Jersey 08628; (2) Fresenius holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5003710; (3) Fresenius has affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution, or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey; and (4) Fresenius has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having consented to jurisdiction in this Court, *see, e.g.*, *Fresenius Kabi USA, LLC v. Emcure Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-5584 (NLW)(JS) (D.N.J. Sept. 8, 2014); *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC*, Civil Action No. 14-4989 (SRC)(CLW), D.I. 5, at 2-3, 7-13 (D.N.J. Aug. 12, 2014); *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC*, Civil Action No. 14-3917 (PGS)(LHG), D.I. 12, at 4-5, 45-55 (D.N.J. Aug. 4, 2014); *Novartis Pharm. Corp. v. Fresenius Kabi USA, LLC*, Civil Action No. 13-7914 (SDW)(MCA), D.I. 10, at 3, 7-11 (D.N.J. Feb. 13, 2014); *Novartis Pharm. Corp., et al. v. Wockhardt USA LLC, et al.*, Civil Action No. 12-3967 (SDW)(SCM), D.I. 125, at 3-4, 7-9 (D.N.J. June 19, 2013); *Sanofi-Aventis U.S. LLC, et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 14-8082 (MAS)(LHG), D.I. 11 at 3, 11-14 (D.N.J. Mar. 17, 2015); *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC, et al.*, Civil Action No. 15-2631(MAS)(LHG), D.I. 12 at 3 (D.N.J. June 1, 2015).

19. Emcure sent a Notice Letter to Plaintiffs on August 11, 2015 ("Emcure's Notice Letter"). Emcure's Notice Letter states that Emcure filed Abbreviated New Drug Application ("ANDA") No. 202951 seeking approval from the United States Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, importation, offer for sale and sale of 0.25 mg / 5 mL (free base) and 0.075 mg / 1.5 mL (free base) palonosetron

single-use vials for intravenous administration in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patents-in-suit.

20. Emcure's Notice Letter authorized Dr. Pankaj Dave of Emcure Inc. to accept service of process for Emcure Ltd.

21. This Court also has personal jurisdiction over Emcure, because, upon information and belief, *inter alia*: (1) Emcure Inc. is a corporation organized and existing under the laws of the State of New Jersey; (2) Emcure Inc. has a principal place of business in the State of New Jersey; (3) Emcure Inc. is registered to do business in the State of New Jersey under Business I.D. No. 0400060460; (4) Emcure has purposely availed itself of the privilege of doing business in the State of New Jersey; (5) Emcure has affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution, or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey by Emcure Ltd. itself or through its wholly owned subsidiary and agent Emcure Inc.; and (6) Emcure has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court. *See, e.g.*, *Genzyme Corporation, et al. v. Emcure Pharmaceuticals USA Inc., et al.*, Civil Action No. 14-5975 (JEI)(KMW) (D.N.J. Dec. 2, 2014); *Sumitomo Dainippon Pharma Co., Ltd., et al. v. Emcure Pharmaceuticals Limited, et al.*, Civil Action No. 15-280 (SRC)(CLW) (D.N.J. Feb. 23, 2015)

THE PATENTS-IN-SUIT

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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 BY FRESENIUS

28. Plaintiffs reallege paragraphs 1-27 as if fully set forth herein.

29. Upon information and belief, Defendant Fresenius submitted ANDA Nos. 206802 and 206801 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 206802 and 206801 seek 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 Nos. 206802 and 206801 specifically seek 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.

30. Upon information and belief, ANDA Nos. 206802 and 206801 include 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 Fresenius 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.

31. Defendant Fresenius's submission to the FDA of ANDA Nos. 206802 and 206801, including the § 505(j)(2)(A)(vii)(IV) allegations, constitute infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

32. Defendant Fresenius's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA Nos. 206802 and 206801 and the § 505(j)(2)(A)(vii)(IV) certifications constitute infringement of the '724 patent under 35 U.S.C. § 271 (e)(2)(A).

33. Plaintiffs are entitled to a declaration that, if Defendant Fresenius commercially manufactures, uses, sells, or offers to sell 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 Fresenius will infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Plaintiffs will be irreparably harmed by Defendant Fresenius'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 '724 PATENT BY EMCURE

35. Plaintiffs reallege paragraphs 1-34 as if fully set forth herein.

36. Upon information and belief, Defendant Emcure submitted ANDA No. 202951 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202951 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 (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '724 patent. ANDA No. 202951 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of the '724 patent.

37. Upon information and belief, ANDA No. 202951 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 Emcure 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.

38. Defendant Emcure's submission to the FDA of ANDA No. 202951, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

39. Defendant Emcure's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 202951 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '724 patent under 35 U.S.C. § 271 (e)(2)(A).

40. Plaintiffs are entitled to a declaration that, if Defendant Emcure commercially manufactures, uses, sells, or offers to sell its proposed generic versions of Helsinn's Aloxi® brand products within the United States, import its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendant Emcure will infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

41. Plaintiffs will be irreparably harmed by Defendant Emcure'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 '725 PATENT BY FRESENIUS

42. Plaintiffs reallege paragraphs 1-41 as if fully set forth herein.

43. Upon information and belief, Defendant Fresenius submitted ANDA Nos. 206802 and 206801 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 206802 and 206801 seek 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 Nos. 206802 and 206801 specifically seek 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.

44. Upon information and belief, ANDA Nos. 206802 and 206801 include 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 Fresenius 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.

45. Defendant Fresenius's submission to the FDA of ANDA Nos. 206802 and 206801, including the § 505(j)(2)(A)(vii)(IV) allegations, constitute infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

46. Defendant Fresenius's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA Nos. 206802 and 206801 and the § 505(j)(2)(A)(vii)(IV) certification constitute infringement of the '725 patent under 35 U.S.C. § 271 (e)(2)(A).

47. Plaintiffs are entitled to a declaration that, if Defendant Fresenius commercially manufactures, uses, sells, or offers to sell 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 Fresenius will infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

48. Plaintiffs will be irreparably harmed by Defendant Fresenius'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 '725 PATENT BY EMCURE

49. Plaintiffs reallege paragraphs 1-48 as if fully set forth herein.

50. Upon information and belief, Defendant Emcure submitted ANDA No. 202951 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202951 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 (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '725 patent. ANDA No. 202951 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of the '725 patent.

51. Upon information and belief, ANDA No. 202951 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 Emcure 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.

52. Defendant Emcure's submission to the FDA of ANDA No. 202951, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

53. Defendant Emcure's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 202951 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

54. Plaintiffs are entitled to a declaration that, if Defendant Emcure commercially manufactures, uses, sells, or offers to sell its proposed generic versions of Helsinn's Aloxi® brand products within the United States, import its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendant Emcure will infringe the '725 patent under 35 U.S.C. § 271(a), (b), and/or (c).

55. Plaintiffs will be irreparably harmed by Defendant Emcure'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 '424 PATENT BY FRESENIUS

56. Plaintiffs reallege paragraphs 1-55 as if fully set forth herein.

57. Upon information and belief, Defendant Fresenius submitted ANDA Nos. 206802 and 206801 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 206802 and 206801 seek 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 Nos. 206802 and 206801 specifically seek 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.

58. Upon information and belief, ANDA Nos. 206802 and 206801 include 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 Fresenius 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.

59. Defendant Fresenius's submission to the FDA of ANDA Nos. 206802 and 206801, including the § 505(j)(2)(A)(vii)(IV) allegations, constitute infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

60. Defendant Fresenius's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA Nos. 206802 and 206801 and the § 505(j)(2)(A)(vii)(IV) certification constitute infringement of the '424 patent under 35 U.S.C. § 271 (e)(2)(A).

61. Plaintiffs are entitled to a declaration that, if Defendant Fresenius commercially manufactures, uses, sells, or offers to sell 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 Fresenius will infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT VI – INFRINGEMENT OF THE '424 PATENT BY EMCURE

63. Plaintiffs reallege paragraphs 1-62 as if fully set forth herein.

64. Upon information and belief, Defendant Emcure submitted ANDA No. 202951 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202951 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 (free base)

and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '424 patent. ANDA No. 202951 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of the '424 patent.

65. Upon information and belief, ANDA No. 202951 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 Emcure 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.

66. Defendant Emcure's submission to the FDA of ANDA No. 202951, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '424 patent under 35 U.S.C. § 271(e)(2)(A).

67. Defendant Emcure's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 202951 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '424 patent under 35 U.S.C. § 271 (e)(2)(A).

68. Plaintiffs are entitled to a declaration that, if Defendant Emcure commercially manufactures, uses, sells, or offers to sell its proposed generic versions of Helsinn's Aloxi® brand products within the United States, import its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such

conduct, Defendant Emcure will infringe the '424 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT VII - INFRINGEMENT OF THE '219 PATENT BY FRESENIUS

70. Plaintiffs reallege paragraphs 1-69 as if fully set forth herein.

71. Upon information and belief, Defendant Fresenius submitted ANDA Nos. 206802 and 206801 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 206802 and 206801 seek 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 Nos. 206802 and 206801 specifically seek 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.

72. Upon information and belief, ANDA Nos. 206802 and 206801 include 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 Fresenius notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

73. Defendant Fresenius's submission to the FDA of ANDA Nos. 206802 and 206801, including the § 505(j)(2)(A)(vii)(IV) allegations, constitute infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

74. Defendant Fresenius's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA Nos. 206802 and 206801 and the § 505(j)(2)(A)(vii)(IV) certification constitute infringement of the '219 patent under 35 U.S.C. § 271 (e)(2)(A).

75. Plaintiffs are entitled to a declaration that, if Defendant Fresenius commercially manufactures, uses, sells, or offers to sell 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 Fresenius will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT VIII - INFRINGEMENT OF THE '219 PATENT BY EMCURE

77. Plaintiffs reallege paragraphs 1-76 as if fully set forth herein.

78. Upon information and belief, Defendant Emcure submitted ANDA Nos. 202951 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202951 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 (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '219 patent. ANDA No. 202951 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL (free base) and 0.075

mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of the '219 patent.

79. Upon information and belief, ANDA No. 202951 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 Emcure 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.

80. Defendant Emcure's submission to the FDA of ANDA No. 202951, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '219 patent under 35 U.S.C. § 271(e)(2)(A).

81. Defendant Emcure's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 202951 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '219 patent under 35 U.S.C. § 271 (e)(2)(A).

82. Plaintiffs are entitled to a declaration that, if Defendant Emcure commercially manufactures, uses, sells, or offers to sell its proposed generic versions of Helsinn's Aloxi® brand products within the United States, import its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendant Emcure will infringe the '219 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT IX – INFRINGEMENT OF THE '094 PATENT BY FRESENIUS

84. Plaintiffs reallege paragraphs 1-83 as if fully set forth herein.

85. Upon information and belief, Defendant Fresenius submitted ANDA Nos. 206802 and 206801 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 206802 and 206801 seek 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 Nos. 206802 and 206801 specifically seek 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.

86. Upon information and belief, ANDA Nos. 206802 and 206801 include 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 Fresenius notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

87. Defendant Fresenius's submission to the FDA of ANDA Nos. 206802 and 206801, including the § 505(j)(2)(A)(vii)(IV) allegations, constitute infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

88. Defendant Fresenius's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA Nos. 206802 and 206801 and the § 505(j)(2)(A)(vii)(IV) certification constitute infringement of the '094 patent under 35 U.S.C. § 271 (e)(2)(A).

89. Plaintiffs are entitled to a declaration that, if Defendant Fresenius commercially manufactures, uses, sells, or offers to sell 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 Fresenius will infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

COUNT X – INFRINGEMENT OF THE '094 PATENT BY EMCURE

91. Plaintiffs reallege paragraphs 1-90 as if fully set forth herein.

92. Upon information and belief, Defendant Emcure submitted ANDA No. 202951 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 202951 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 (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of certain of Plaintiffs' Orange Book listed patents that have the same expiration date as the '094 patent. ANDA No. 202951 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg / 5 mL (free base) and 0.075 mg / 1.5 mL (free base) palonosetron single-use vials for intravenous administration prior to the expiration of the '094 patent.

93. Upon information and belief, ANDA No. 202951 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 Emcure 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.

94. Defendant Emcure's submission to the FDA of ANDA No. 202951, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '094 patent under 35 U.S.C. § 271(e)(2)(A).

95. Defendant Emcure's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 202951 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '094 patent under 35 U.S.C. § 271 (e)(2)(A).

96. Plaintiffs are entitled to a declaration that, if Defendant Emcure commercially manufactures, uses, sells, or offers to sell its proposed generic versions of Helsinn's Aloxi® brand products within the United States, import its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induce or contribute to such conduct, Defendant Emcure will infringe the '094 patent under 35 U.S.C. § 271(a), (b), and/or (c).

97. Plaintiffs will be irreparably harmed by Defendant Emcure'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 Defendants Fresenius, Emcure Ltd., and Emcure Inc. have infringed the '724, '725, '424, '219, and '094 patents by submitting the aforesaid ANDAs;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of any of Defendants' ANDAs identified in this Amended Complaint 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 Fresenius, Emcure Ltd., and Emcure Inc., 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, selling, offering to sell, and/or importing the proposed generic versions of Helsinn's Aloxi® brand products identified in this Amended Complaint or the aforesaid ANDAs, 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: October 8, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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