IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
FRESENIUS KABI USA, LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendant Fresenius Kabi USA, LLC ("Fresenius" or "Defendant") hereby allege as follows:

THE PARTIES

1. Helsinn is a Swiss corporation having a 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 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 the State of Delaware, having a 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 Delaware.

NATURE OF THE ACTION

5. This is a civil action concerning the infringement of United States Patent No. 7,947,724 ("the '724 patent"), United States Patent No. 8,518,981 ("the '981 patent"), United States Patent No. 8,598,218 ("the '218 patent"), United States Patent No. 9,066,980 ("the '980 patent"), and United States Patent No. 9,125,905 ("the '905 patent") (collectively, the "patents-in-suit"). 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

6. 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.

7. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case presents an actual controversy within the Court's jurisdiction.

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

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

10. Fresenius sent a Notice Letter to Plaintiffs dated August 28, 2015 ("Fresenius's Notice Letter"). Fresenius's Notice Letter states that it filed New Drug Application ("NDA") No. 208109 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 solution in the United States (including, upon information and belief, in the State of Delaware), prior to the expiration of the patents-in-suit.

11. This Court also has personal jurisdiction over Defendant Fresenius because, upon information and belief, *inter alia*, Fresenius: (1) is a limited liability company organized and existing under the laws of the State of Delaware, and has a registered agent for service in Delaware; (2) engages in persistent conduct within Delaware, including, upon information and belief, the preparation and submission of NDA No. 208109; (3) has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having consented to jurisdiction in this Court, *see, e.g.*, *Astellas Pharma Inc. et al. v. Fresenius Kabi USA LLC*, 1:15-cv-00080-LPS (D. Del. Jan. 23, 2015); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA LLC*, 1:14-cv-01533-LPS (D. Del. Dec. 30, 2014); *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA LLC*, 1:14-cv-01018-RGA (D. Del. Aug. 7, 2014); *Cubist Pharmaceuticals Inc. v. Fresenius Kabi USA LLC*, 1:14-cv-00914-GMS (D. Del. July 11, 2014); *Allos Therapeutics Inc. et al. v. Teva Pharmaceuticals USA Inc. et al.*, 1:14-cv-00778-RGA (D. Del. June 19, 2014); *Celgene Corporation et al. v. Fresenius Kabi USA LLC et al.*, 1:14-cv-00571-RGA (D. Del. Apr. 30, 2014); *Pfizer Inc. et al. v. Fresenius Kabi USA LLC*, 1:13-cv-01893-SLR (D. Del. Nov. 13, 2013); *Millennium Pharmaceuticals Inc. v. Fresenius Kabi USA LLC et al.*, 1:13-cv-00467-GMS (D. Del. Mar. 22, 2013); *Fresenius Kabi USA LLC v.*

Claris Lifesciences Ltd. et al., 1:14-cv-01498-RGA (D. Del. Dec. 19, 2014); *Fresenius Kabi USA LLC v. Mylan Laboratories Limited et al.*, 1:14-cv-01438-RGA (D. Del. Nov. 26, 2014); *Fresenius Kabi USA LLC v. Dr Reddy's Laboratories Ltd et al.*, 1:14-cv-00160-RGA (D. Del. Feb. 6, 2014); *Fresenius Kabi USA LLC v. Watson Laboratories Inc. et al.*, 1:14-cv-00161-RGA (D. Del. Feb. 6, 2014); and (4) maintains extensive systematic contacts within the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

THE PATENTS-IN-SUIT

12. 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.

13. On August 27, 2013, the '981 patent, titled, "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '981 patent is attached as Exhibit B.

14. On December 3, 2013, the '218 patent, titled, "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '218 patent is attached as Exhibit C.

15. On June 30, 2015, the '980 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '980 patent is attached as Exhibit D.

16. On September 8, 2015, the '905 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '905 patent is attached as Exhibit E.

17. Pursuant to 21 U.S.C. § 355(b)(l), the '724 patent, the '981 patent, the '218 patent, the '980 patent, and the '905 patent are listed in the 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

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

19. Upon information and belief, Defendant Fresenius submitted NDA No. 208109 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208109 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. NDA No. 208109 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.

20. Upon information and belief, NDA No. 208109 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid and/or not infringed. Defendant Fresenius notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

21. Defendant Fresenius's submission to the FDA of NDA No. 208109, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

22. 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).

23. 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 '981 PATENT

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

25. Upon information and belief, Defendant Fresenius submitted NDA No. 208109 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208109 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 '981 patent. NDA No. 208109 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 '981 patent.

26. Upon information and belief, NDA No. 208109 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the '981

patent are invalid and/or not infringed. Defendant Fresenius notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

27. Defendant Fresenius's submission to the FDA of NDA No. 208109, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

28. 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 '981 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. 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 III – INFRINGEMENT OF THE '218 PATENT

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

31. Upon information and belief, Defendant Fresenius submitted NDA No. 208109 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208109 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 '218 patent. NDA No. 208109 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 ’218 patent.

32. Upon information and belief, NDA No. 208109 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the ’218 patent are invalid and/or not infringed. Defendant Fresenius notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

33. Defendant Fresenius’s submission to the FDA of NDA No. 208109, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the ’218 patent under 35 U.S.C. § 271(e)(2)(A).

34. 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 ’218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

35. 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 ’980 PATENT

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

37. Upon information and belief, Defendant Fresenius submitted NDA No. 208109 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208109 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 '980 patent. NDA No. 208109 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 '980 patent.

38. The '980 patent shares the same expiration date as Plaintiffs' other Orange Book-listed patents. By seeking FDA approval of its NDA No. 208109 prior to the expiration of Plaintiffs' other Orange Book-listed patents, Fresenius necessarily seeks approval of that NDA prior to the expiration of the '980 patent.

39. Upon information and belief, Fresenius is required by law to either amend its NDA to contain a § 505(b)(2)(A)(iv) certification with respect to the '980 patent, or must relinquish its request that the FDA approve NDA No. 208109 prior to the expiration of Plaintiffs' Orange Book-listed patents.

40. Fresenius continues to seek approval of NDA No. 208109 from the FDA and intends to continue in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the '980 patent.

41. By seeking approval of its NDA 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 the '980 patent, Fresenius infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

42. 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 '980 patent under 35 U.S.C. § 271(a), (b), and/or (c).

43. 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 V - INFRINGEMENT OF THE '905 PATENT

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

45. Upon information and belief, Defendant Fresenius submitted NDA No. 208109 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208109 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 '905 patent. NDA No. 208109 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 '905 patent.

46. The '905 patent had not issued at the time Fresenius made its § 505(b)(2)(A)(iv) certification regarding Plaintiffs' other Orange Book-listed patents.

47. The ’905 patent shares the same expiration date as Plaintiffs’ other Orange Book-listed patents. By seeking FDA approval of its NDA No. 208109 prior to the expiration of Plaintiffs’ other Orange Book-listed patents, Fresenius necessarily seeks approval of that NDA prior to the expiration of the ’905 patent.

48. Upon information and belief, Fresenius is required by law to either amend its NDA to contain a § 505(b)(2)(A)(iv) certification with respect to the ’905 patent, or must relinquish its request that the FDA approve NDA No. 208109 prior to the expiration of Plaintiffs’ Orange Book-listed patents.

49. Fresenius continues to seek approval of NDA No. 208109 from the FDA and intends to continue in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of the ’905 patent.

50. By seeking approval of its NDA 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 the ’905 patent, Fresenius infringed that patent pursuant to 35 U.S.C. § 271(e)(2)(A).

51. 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 ’905 patent under 35 U.S.C. § 271(a), (b), and/or (c).

52. 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.

STATEMENT REGARDING PRIOR-FILED SUIT

53. Plaintiffs previously filed, on October 8, 2015, an action in the District of New Jersey seeking to enjoin Defendant Fresenius, along with Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc., from infringing the '724, '981, '218, '980 and '905 patents. That action has been assigned Civil Action No. 15-7378 ("the D.N.J. Action"). The D.N.J. Action is assigned to Judge Mary L. Cooper.

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

55. Judicial economy would be promoted, and Plaintiffs' choice of forum respected, if the claims related to Plaintiffs' action for infringement of the '724, '981, '218, '980, and '905 patents are addressed by Judge Cooper in the District of New Jersey.

56. Pursuant to 21 U.S.C. § 355(c)(3)(C), a patent owner has 45 days from receipt of an NDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an NDA pending resolution of litigation regarding the submission of such NDA. Plaintiffs filed this action as a further protective measure with regard to this statutory right.

57. 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(c)(3)(C).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that:

A. A Judgment be entered declaring that Defendant Fresenius has infringed the '724, '981, '218, '980, and '905 patents by submitting NDA No. 208109;

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 Fresenius's NDA No. 208109 be a date that is not earlier than the expiration dates of the '724, '981, '218, '980, and '905 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, 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, selling, offering to sell, and/or importing the proposed generic versions of Helsinn's Aloxi® brand products identified in this Complaint or NDA No. 208109 and any other product that infringes or induces or contributes to the infringement of the '724, '981, '218, '980, and '905 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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