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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, EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC.,

Defendants.

Civil Action No._____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs"), for their Complaint against Defendant Fresenius Kabi USA, LLC (hereinafter, "Fresenius"), Exela Pharma Sciences, LLC (hereinafter, "Exela Pharma"), Exela PharmSci, Inc. (hereinafter, "Exela PharmSci"), and Exela Holdings, Inc. (hereinafter, "Exela Holdings") (together with Exela Pharma and Exela PharmSci, "Exela") (collectively, "Defendants"), 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 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 New Jersey.

5. Upon information and belief, Defendant Exela Pharma is an entity organized and existing under the laws of the State of Delaware, having a place of business at 1325 William White Place NE, Lenoir, North Carolina 28645.

6. Upon information and belief, Defendant Exela Pharma 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.

7. Upon information and belief, Defendant Exela Pharma is a wholly owned subsidiary of Exela PharmSci.

8. Upon information and belief, Defendant Exela PharmSci is an entity organized and existing under the laws of the Commonwealth of Virginia, having a place of business at 19978 Palmer Classic Parkway, Ashburn, Virginia 20147.

9. Upon information and belief, Defendant Exela PharmSci 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.

10. Upon information and belief, Defendant Exela Holdings is an entity organized and existing under the laws of the State of Delaware, having a place of business at 19978 Palmer Classic Parkway, Ashburn, Virginia 20147.

11. Upon information and belief, Defendant Exela Holdings is the parent company of Defendant Exela PharmSci.

12. Upon information and belief, Defendant Exela Holdings 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.

13. Upon information and belief, the acts of Defendant Exela Pharma complained of herein were done at the direction of, with the authorization of, and with the cooperation, assistance, and/or participation of Defendants Exela PharmSci and/or Exela Holdings.

NATURE OF THE ACTION

14. 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"). 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

15. 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.

16. 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.

17. 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).

18. 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.

19. 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 New Jersey) prior to the expiration of the patents-in-suit.

20. This Court also has personal jurisdiction over Fresenius because, upon information and belief, *inter alia*, it: (1) 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) holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5003710; (3) 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) has sent its Notice Letter into the State of New Jersey.

21. Exela sent a Notice Letter to Plaintiffs dated October 6, 2015 ("Exela's Notice Letter"). Exela's Notice Letter states that it filed NDA No. 207963 seeking approval from the 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 New Jersey), prior to the expiration of the '905 patent.

22. This Court also has personal jurisdiction over Exela because, upon information and belief, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in this Judicial District, including obtaining Drug and Medical Device Certificate of Registration Number 5004678 in this Judicial District; (2) maintains extensive contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical

drugs to New Jersey residents; (3) on information and belief, has entered into agreements and/or coordinated with New Jersey companies relating to its proposed generic palonosetron products; and (4) has sent Exela's Notice Letter into the State of New Jersey.

THE PATENTS-IN-SUIT

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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 BY FRESENIUS

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

30. 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.

31. 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.

32. 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).

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 '981 PATENT BY FRESENIUS

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

36. 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.

37. 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.

38. 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).

39. 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).

40. 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 BY FRESENIUS

41. Plaintiffs reallege paragraphs 1-40 as if fully set forth herein.

42. 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.

43. 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.

44. 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).

45. 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).

46. 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 BY FRESENIUS

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

48. 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.

49. 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.

50. 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.

51. 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.

52. 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).

53. 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).

54. 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 BY FRESENIUS

55. Plaintiffs reallege paragraphs 1-54 as if fully set forth herein.

56. 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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).

62. 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).

63. 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 '905 PATENT BY EXELA

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

65. Upon information and belief, Exela submitted NDA No. 207963 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 207963 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 the '905 patent. NDA No. 207963 specifically seeks FDA

approval to market a generic version of Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '905 patent.

66. Upon information and belief, NDA No. 207963 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the '905 patent are invalid and/or not infringed. Exela notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

67. Exela's submission to the FDA of NDA No. 207963, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '905 patent under 35 U.S.C. § 271(e)(2)(A).

68. Exela's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 207963 and the § 505(b)(2)(A)(iv) certification constitutes infringement of the '905 patent under 35 U.S.C. § 271(e)(2)(A).

69. Plaintiffs are entitled to a declaration that, if Exela commercially manufactures, uses, offer for sales, 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, Exela will infringe the '905 patent under 35 U.S.C. § 271(a), (b), and/or (c).

70. Plaintiffs will be irreparably harmed by Exela'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 Fresenius has infringed the '724, '981, '218, '980, and '905 patents by submitting NDA No. 208109;

B. A Judgment be entered declaring that Exela has infringed the '905 patent by submitting NDA No. 207963;

C. 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 identified in this Complaint 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;

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of any of Exela's NDA identified in this Complaint be a date that is not earlier than the expiration dates of the '905 patent, or any later expiration of exclusivity for this patent to which Plaintiffs are or become entitled;

E. 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 the aforesaid NDA 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;

F. An Order be issued that Exela, 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 the aforesaid NDA and any other product that infringes

or induces or contributes to the infringement of the '905 patent, prior to the expiration of this patent, including any extensions to which Plaintiffs are or become entitled; and

G. 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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